World Health Organization

TECHNICAL REPORT

AIDS MEDICINES AND DIAGNOSTICS SERVICE

SPECIFICATIONS AND QUANTITIES FOR EFFICIENT PROCUREMENT OF ESSENTIAL EQUIPMENT AND LABORATORY COMMODITIES FOR HIV

SECOND EDITION

JULY 2015

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CONTENTS

ABBREVIATIONS AND ACRONYMS

AIDS	acquired immunodeficiency syndrome
AMDS	AIDS Medicines and Diagnostics Service
ASLM	African Society for Laboratory Medicine
CDC	Centers for Disease Control and Prevention
CPS	Contracting and Procurement Service
CE-IVD	CE (European Commission) marked in vitro diagnostic device
CHAI	Clinton Health Access Initiative
CHEIA	chemiluminescence immunoassay
DIN	Deutsches Institut für Normung
DLT	Diagnostics and Laboratory Technology
EDTA	ethylene diamine tetra-acetic acid
EIA	enzyme immunosorbent assay
EMP	Essential Medicines and Health Products
ELISA	enzyme-linked immunosorbent assay (interchangeable with EIA)
EOS	eosinophils
FIND	Foundation for Innovative New Diagnostics
GLI	Global Laboratory Initiative
GPRM	Global Price Reporting Mechanism for HIV, tuberculosis and malaria
GSSHealth	Global Scientific Solutions for Health
HIV	human immunodeficiency virus
ISO	International Organization for Standardization
IVB/QSS	Immunization, Vaccines and Biologicals/Quality, Safety and Standards
IVDD	in-vitro diagnostic medical devices
JSI	John Snow, Inc.
LCD	liquid-crystal display
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
PCR	polymerase chain reaction
PfSCM	Partnership for Supply Chain Management
RCF	relative centrifugal force
RDT	rapid diagnostic test
rpm	revolutions per minute
SCMS	supply chain management system
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SI	Système international d'unités (international system of units)
STB	Stop TB
TB	tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UPS	uninterruptible power supply
UoM	unit of measurement
URL	uniform resource locator (website address)
USAID	United States Agency for International Development
USD	United States dollars
WHO	World Health Organization

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1. BACKGROUND

1.1 Rationale

Unlike the administration of treatment, which requires the availability of only one or a few drugs, laboratory testing typically requires many different consumables and pieces of equipment. This requirement, the limited standardization in the deployment of laboratory technology, and the inadequate attention given to logistics information systems, including laboratory items, make procurement of laboratory technology far more complicated than that of medicines. In addition, procurement managers often lack the expertise to assess whether, with the procurement of one or several laboratory items, they have provided all that is necessary for a laboratory result to be produced.

The effort to address these challenges began with a consensus meeting of major stakeholders and partners in Maputo on 22–24 January 2008. This meeting defined the tests required at each level of a tiered, integrated laboratory network; publicized key considerations for maintenance of equipment at each level of the laboratory network; and led to commitment from health care leaders to develop and adopt policies to standardize laboratory equipment and supplies (1).

Subsequently, at a World Health Organization (WHO) meeting in Geneva in October 2008, a working group was created to define generic specifications to assist in the procurement of laboratory products. With support from the US Centers for Disease Control and Prevention (CDC), WHO brought together inputs from the African Society for Laboratory Medicine (ASLM), the Clinton Health Access Initiative (CHAI), Contracting and Procurement Service (CPS), Crown Agents, the Foundation for Innovative New Diagnostics (FIND), Global Scientific Solutions for Health (GSSHealth), Médecins Sans Frontières (MSF), Management Sciences for Health (MSH), Stop TB (STB), the Supply Chain Management Systems (SCMS) of PEPFAR, the United Nations Development Programme (UNDP), the United Nations Children's Fund (UNICEF), and the United States Agency for International Development (USAID) DELIVER PROJECT. The output of this working group was the development of the present tool on specifications and quantities for efficient procurement of essential equipment and laboratory commodities for HIV. The tool has been regularly updated to take into account new developments in technology, changes to laboratory items prequalified by WHO, and alterations to procurement waiver lists.

1.2 HIV diagnostic eligibility criteria

The current 2015 edition covers HIV diagnostic laboratory equipment and commodities that have been found eligible for WHO procurement (2), including those which are WHO-prequalified (3), and products included on the USAID list of approved HIV/AIDS rapid test kits (4) and/or on the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF) waiver list for procurement by donor organizations (5). Important for the benchmarking of procurement prices, this tool also includes reference to the price of the commodities and equipment in the specification tables. Prices for branded products are procurement data for the period of 2011–2014 provided in the Global Price Reporting Mechanism for HIV, tuberculosis and malaria (GPRM, http://www.who.int/hiv/amds/gprm/en/). Prices for generic commodities are prices advertised for the USA market by manufacturers and distributors in the 1st quarter of 2015 (such as, by VWR International https://us.vwr.com/, Corning Life Sciences http://goo.gl/5nvD4P, and Fisher Scientific http://goo.gl/Gkqklv).

This document does not include TB diagnostics, as WHO has published the specifications for TB laboratory equipment and supplies in the Guidance for countries on the specifications for managing TB laboratory equipment and supplies (see Section 3 in http://www.who.int/tb/laboratory/tool_set/en/ (6)).

1.3 Intended audience and use

The tool is intended to be used by, but not limited to, the following personnel for the stated purposes:

Personnel	Use
Staff responsible for the procurement of HIV-related laboratory commodities, such as, ministry of health buyers, logisticians and national programme officers	• Development of correct specifications and catalogue numbers • Preparation of procurement bidding/tender documents • Listing of required accessories • Listing of optional accessories for review by laboratory technical staff • Guidance on installation and training • Identification of quality certificates • Identification of the source of products • Prequalification of vendors • Benchmarking of the price of commodities and equipment of interest
Staff responsible for laboratory logistics, supply chain management, service planning and scale-up	• Determination of appropriate laboratory network level for commonly used equipment • Identification of additional equipment required when establishing new testing services • Guidance on required quantities of items for bulk purchase • Shipping and storage conditions • Shelf-life • Benchmarking of the price of commodities and equipment of interest
Laboratory managers, supervisors and technical staff, haemophilia treatment centre providers	• Guidance on the suitability of equipment for the laboratory network level • Identification of the need for equipment installation, training, calibration and regular servicing • Equipment operating conditions • Expected quality standards • Identification of items required for assay (can assist in work flow planning)

2. MANAGEMENT OF LABORATORY COMMODITIES

2.1 Health systems and the role of laboratory services

Without diagnostics, medicine is blind. The medical laboratory plays a key role in quality health service delivery and, as part of the health system, it must respond in a balanced way to a population's needs (7). Laboratory services support health systems in a variety of ways, including:

- confirmation of disease/identification and drug susceptibility testing;
- identification and management of adverse effects (such as, the monitoring of pharmaceutical toxicity);
- screening of 'at-risk' patients;
- disease surveillance;
- confirmation of medical intervention efficacy;
- quality assurance (such as, quality control specimens, proficiency testing) (8);
- education and training of physicians, laboratory professionals and health care workers.

2.2 Laboratory service networks

In many countries, laboratories are organized as integrated, and often structured, systems within the country health delivery network. Such organization helps provide prompt diagnosis and treatment of the most common diseases and enables referral up the network to facilities capable of providing specialized services when more sophisticated diagnostic testing or treatment is required, or in the event of complications.

Generally, tiered laboratory networks have five main levels:

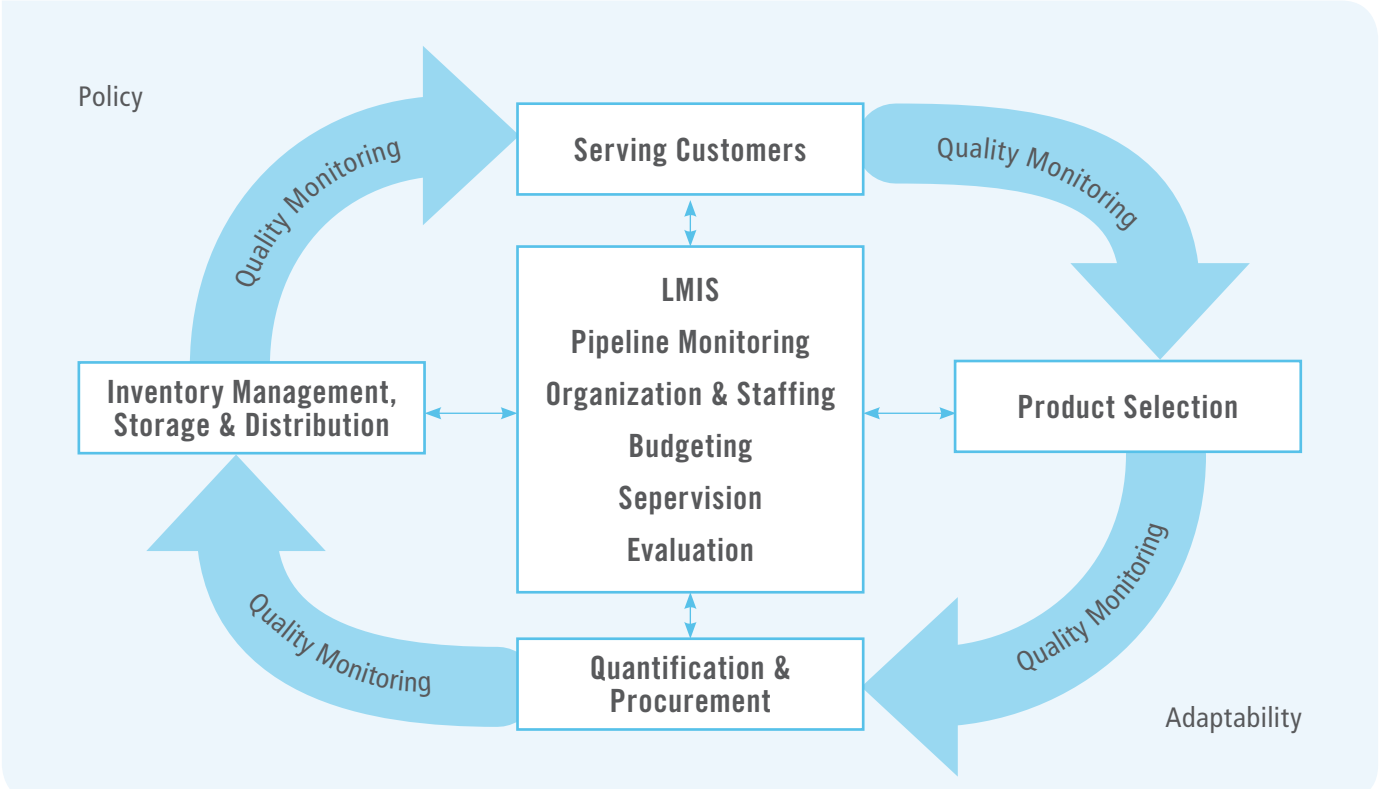
- *level I* – primary: health post and health centre laboratories that primarily serve outpatients;
- *level II* – district: laboratories in intermediate referral facilities (e.g. district hospitals);
- *level III* – regional/provincial: laboratories in a regional/provincial referral hospital that may be part of a regional or provincial health bureau;
- *level IV* – national/multicountry: reference laboratory (national/multicountry public health reference laboratory for one or more countries).

Standardized services are recommended at each level (1, 9), ranging from rapid diagnostic tests (RDTs) at level 0 to high throughput (that is, large numbers of specimens tested simultaneously) semi- and automated testing, where appropriate, at the higher levels.

2.3 The laboratory supply chain system

Supply chains are composed of numerous logistic processes to ensure efficient flow of commodities. Good management of supply chain processes ensures access to (10):

Figure 1. Task Order 1 (2011). LMIS, logistics management and information system. From USAID: DELIVER PROJECT (7)



- the RIGHT commodities
- in the RIGHT quantities
- in the RIGHT condition, delivered
- to the RIGHT place
- at the RIGHT time
- for the RIGHT cost.

The supply chain (or logistics) system is circular, with repetitive elements in each cycle (Fig. 1). Each cycle and each activity within it (customer service, product selection, quantification, procurement and inventory management) is affected by the others. As a result, a supply chain system can only be as strong as its weakest link.

Depending upon financial and human resources, local and regional need, and national infrastructure, health-related commodities may be procured and managed centrally, regionally, locally and by specific departments or various programmes and stakeholders.

In resource-limited settings, proper functioning of laboratory commodity supply chain systems is often impeded by limited resources for procurement; weak tracking and distribution; the existence of parallel systems (central, local and donor); and difficulties in forecasting future needs. Despite the complexities, the objectives of all laboratory commodity supply chains remain the same (10):

- to ensure laboratories are able to provide patients with the appropriate, high-quality diagnostic services;
- to permit laboratory staff to carry out a high-quality, reliable, effective and efficient diagnostic services;
- to guarantee that health care staff (such as physicians) have continuous access to the laboratory services required to manage patient care; and
- to safeguard epidemiological studies that are required for disease outbreak and case contact analysis.

2.4 Challenges in laboratory commodity supply chain management

Laboratory and logistics professionals face numerous challenges when managing laboratory commodities:

- Lack of standardization often leads to a variety of diagnostic systems in the laboratories, each requiring specific reagents and technical support.
- Placement of high throughput instruments in facilities with low patient volume may result in increased cost per test due to instrument underutilization (12).
- Availability of closed and open system instruments requires evaluation of the advantages and disadvantages to ensure optimal quality control, performance, after-sales service and cost per test.
- Rapid changes in technology may result in the need for prompt replacement of obsolete commodities.

Several defining reports are available that address laboratory commodity selection, including WHO/AMDS consultations on laboratory commodities (13, 14), the Maputo meeting on standardization (9), guides for developing laboratory commodity standardization plans (11, 15), and landscape reports on diagnostic products (16). Furthermore, there are a number of guidelines to assist in the development of quantification and forecasting plans (17-19). Therefore, in-depth descriptions of the issues surrounding quantification and forecasting will not be provided in this document.

2.5 Standardization of laboratory commodities

The timeliness and accuracy of diagnostic results are reliant on the availability of laboratory commodities that meet minimum quality standards. In an effort to enhance quality and maintain efficiency, laboratory commodities should be standardized wherever possible throughout the tiered laboratory network.

Standardizing the type of platform (or equipment) for chemistry, haematology and CD4 across different laboratory levels offers many benefits, including:

- cost reduction due to bulk procurement;
- ease of training and service due to a limited variety of platforms;
- higher manufacturer investment in regional/local service and distribution capability;
- minimal additional training needed when staff members move from laboratory to laboratory; and
- better standardization of reference ranges and test results, thus better continuity of care for patients.

As with all policies and practices, the benefits must be weighed against the disadvantages. In the case of platform standardization, to balance a situation in which a single or limited number of firms become the sole supplier of the majority of laboratory commodities, it is recommended to review laboratory commodities at least once every two years. The review should assess new technology on the market and evaluate performance of existing instruments, as well as performance and costs of vendors. Poorly performing instruments and vendors should be targeted for network removal. Only the most well-priced and well-performing instruments should constitute a laboratory network, which will help promote healthy market competition.

3. WHY DEVELOP A TOOL FOR SPECIFICATION AND QUANTIFICATION?

A tool for specification and quantification of laboratory commodities can help laboratory and logistics professionals in the following ways:

- Appropriate specifications are critical to ensuring that the supplier understands the end user's requirements, and that transparent procedures are enforced and legal obligations stated.
- Appropriate specifications do more than describe the required product, they provide information on:
- commodity requirements and functions;
- construction materials, dimensions and weight;
- environmental requirements;
- quality and regulatory requirements;
- electrical requirements;
  - required and optional accessories; and
  - the need for installation, training, refresher training, servicing and maintenance.
- Itemized lists of commonly used commodities allow laboratory and logistics professionals to determine commodity needs by test run and control.
- Details of inventory management requirements (such as shelf-life and storage conditions) can help laboratory and logistics professionals to plan orders and distribution.
- Approximate quantities of laboratory commodities required for a given test can assist in quantifications.
- Bundled items may aid in bulk purchasing and ease distribution.

4. HOW CAN THIS TOOL HELP?

Laboratory commodities present a unique challenge to laboratory staff, laboratory managers, store managers, logisticians and other individuals responsible for aspects of laboratory supply chain management. Laboratory commodities are composed of a vast array of items with varying operational characteristics, shelf-life, installation, training, servicing, shipping, transportation, handling and storage requirements.

To address the specific requirements for such a vast array of items, and for the purposes of this tool, laboratory commodities have been broken down into the following categories:

- Equipment: machines, analysers, and instruments used for or in testing.
- Kits: test kits (such as, HIV rapid diagnostic tests [HIV RDT], enzyme immunoassays [EIA]) that test for, or are used in testing for, the analyte of interest.
- Reagents and chemicals: chemicals (solid and liquid) and reagents that test for, or are used in testing for, the component of interest.
- Consumables: test-specific and general items that are used once and discarded.
- Durables: reusable items such as glassware and plastic ware.

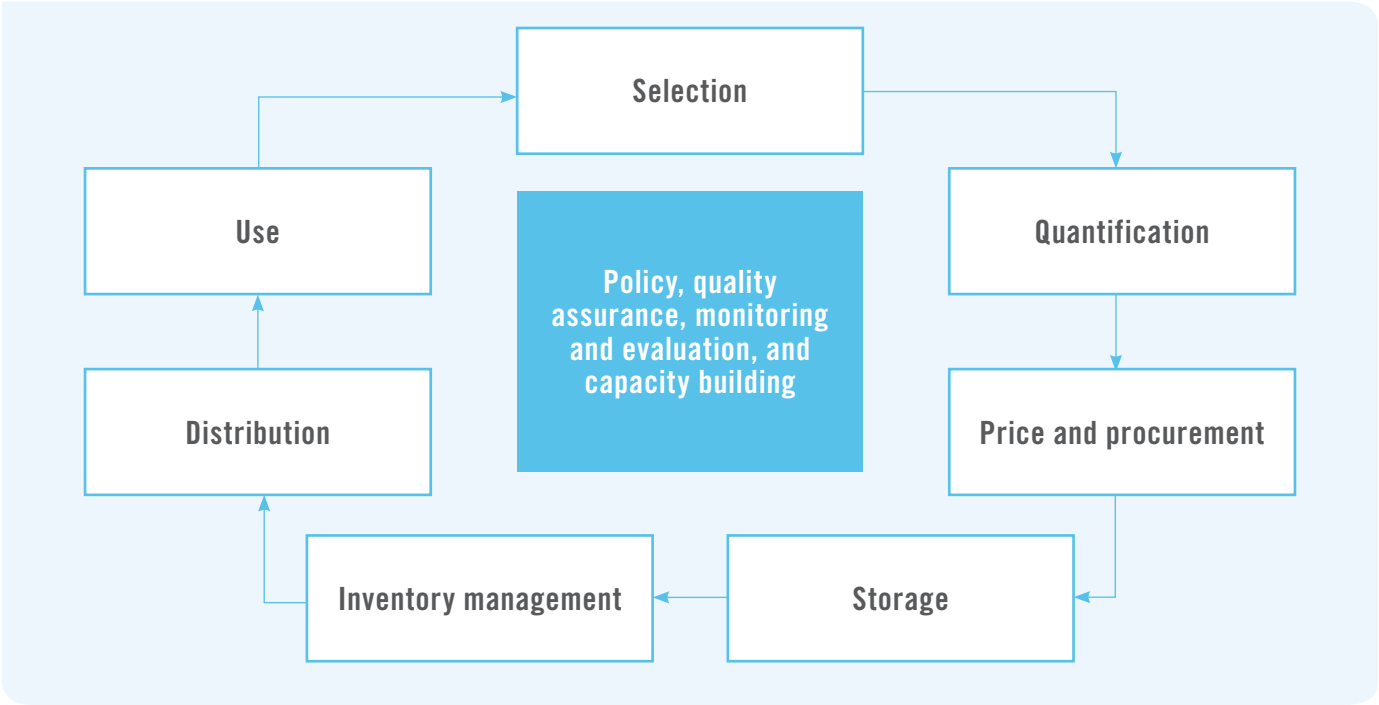
Commonly used tests for HIV diagnosis and monitoring are listed with the most commonly used or dedicated equipment, consumables, reagents, kits, chemicals and durables. This information can be particularly useful for quantification planning in new sites, for new tests, or for the arrangement of laboratory workflow.

Where possible (and based on particular assumptions, as described), laboratory commodities have been itemized and quantified on a per-test basis. Quantification information may help facilitate the development of quantification and forecasting plans. This information may also help in the preparation of procurement requests and contracts, and in distribution planning. In addition, items have been quantified in bulk to assist with larger procurements. Quantities in this tool are based upon assumptions and do not necessarily reflect the procedures used in all laboratories.

5. WHAT THIS TOOL CANNOT DO

- Commonly used commodities are based on manufacturers' package inserts. It is not possible to base commodities upon national standard operating procedures, which may vary widely. As a result, the commodities described herein are only used for guidance purposes. Managers should always quantify based on national/local standard operating procedures. This tool provides useful background information and a format for quantification but it must be tailored to the laboratory or country's specific need.
- This tool is not a substitute for guidelines used for supply chain management and inventory control. The following are key components of good supply chain management to ensure a constant supply of health products including laboratory commodities (Fig. 2):
- This tool is not a substitute for national policies and procedures. It should only be used to assist in the development of specifications and quantification plans.
- This tool cannot provide forecasting information, which must be based on quality information from the field.
- This tool cannot be used to determine order quantities for resupply to facilities.

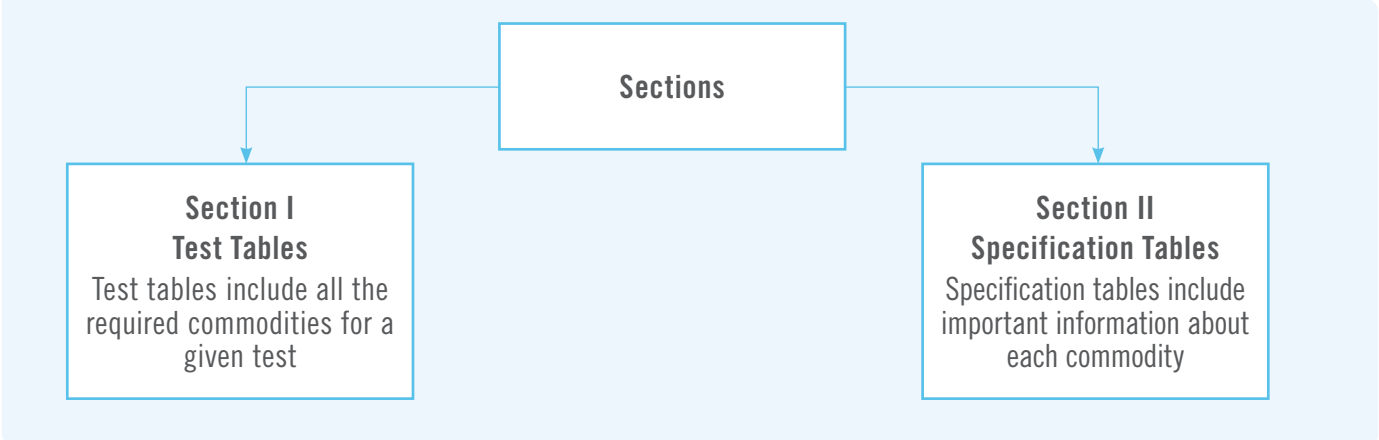
Figure 2. Key considerations in the procurement and supply chain management cycle. From World Health Organization (20)



6. CONTENT OVERVIEW

This tool is divided into two main sections with different tables in each:

- Test tables in Section I display all the required commodities by test and include some estimates to assist with deciding the quantities of items required for a given number of tests.
- Specification tables in Section II provide important information on each commodity.



6.1 Section I: Test Tables

Test tables are listed according to test type and in alphabetical order by test names and provide information on each laboratory commodity required for the test. Where possible, laboratory commodities are grouped into suggested scalable units. The number of items required for scaling up to 1000 tests varies, depending upon each laboratory's standard procedure and the unit of measure for a particular commodity.

Test tables are comprised of the following three sections:

- *1 – Required kit or equipment:* lists test kit(s) required to perform an assay.
- *2 – Test run:* lists commodities that are not provided with the kit but are required to perform the assay.
- *3 – Controls:* lists controls compatible with the assay. Dedicated test controls may be included in the kit or may be purchased from a manufacturer as an accessory.

- Manufactured controls often have particular shipping and storage requirements. When controls are not available with the kit, they must be obtained from a third party or made in-house.

Information on each commodity itemized in the test table includes:

- *Item no:* this unique number links the test table item to the specification table.
- *Item name:* includes the most commonly used name or names of the commodity.
- *Catalogue no:* 'generic' indicates that no manufacturer-specific product is required for that particular test or that multiple branded products exist; a number indicates the catalogue or part number for that commodity found on the manufacturer's website or partner commodities list.
- *Commodity code:* indicates the type of commodity and enables the user to select the corresponding specification table:
  - E = Equipment (includes equipment, in addition to the analyser, required to perform each test)
  - B = Kit
  - R = Reagent (includes chemicals)
  - C = Consumable
- *Unit of measure (UoM):* the smallest possible unit per pack (such as 20 tests per kit).
- *No. of tests per UoM:* details the number of tests a single UoM can perform.
- *No. of tests:* a standard figure of 1000 tests is included for every kit to show how many kits will be needed to perform 1000 tests.
- *No. of UoM units required:* number of units required to perform 1000 tests.
- *Specimen type:* type of human specimen required to perform a test.
- *Shelf-life:* where possible, the manufacturer's shelf-life has been stated. Note that this is the shelf-life from the point of manufacturing and NOT from receipt of delivery.
- *Temperature requirement:* indicates where special shipping and storage environmental conditions are required according to the manufacturer's product insert.
- *Document/package/link:* the URL for more information has been provided where possible.
- *Eligibility criteria:* indicates which organization supports procurement of the test.
- *Regulatory status:* shows WHO prequalification status, approval/clearance by regulatory bodies of founding members of the Global Harmonization Task Force on Medical Devices, and/or a rest of the world regulatory version.
- *Comment:* additional information deemed pertinent to the product such as availability of test controls within the kit.

Test tables are listed according to type as follows:

IA: Commodities by specimen collection
This section includes commonly used specimen collection methods, including dried blood spot (DBS), capillary whole blood, and venepuncture.

IB: HIV RDT
This section includes currently available HIV rapid diagnostic tests (RDTs). RDTs are commonly in use at every laboratory network level.

IC: HIV EIA
This section lists enzyme immunosorbent assays (EIAs). EIAs, including chemiluminescence EIA (CLIA) are most commonly used at the tertiary (that is, level III) and central levels.

ID |HIV Supplemental assays
Supplemental assays are used for confirmation of HIV diagnosis by testing specimens found to be repeatedly reactive by screening assays. Supplementary assays are not intended for use as a first-line assay. Some of these assays may discriminate between HIV-1 and HIV-2.

Test tables describing HIV RDT, HIV EIA, and HIV supplemental assays are preceded by a short description of assay intended use, time to result, sensitivity and specificity.

IE: Nucleic acid-based testing for viral load and early infant diagnosis
These tests include the commonly available, kit-based, quantitative and qualitative nucleic acid-based in vitro diagnostics (IVDs) for viral load and early infant diagnosis and are grouped together, as there is significant overlap between the technologies. These tests are almost exclusively used at the central level and occasionally used at tertiary levels, depending upon infrastructure. As all currently available viral load and early infant diagnostic tests are analyser-specific, the test table is preceded by an analyser table that provides the following information:

- name of the analyser
- description
- pre-installation requirements
- operating conditions
- items supplied with the analyser
- required accessories
- optional accessories
- turnaround time
- capacity
- throughput
- specimen needed and stability
- specimen preparation and protocol complexity
- reagent stability and storage requirements
- cost per test
- cost per instrument
- installation
- training
- maintenance/calibration
- internal QC
- external QA
- URL

IF: CD4 enumeration
A range of flow cytometers is included from very high throughput systems used at the tertiary and central levels through to medium throughput, point-of-care and dual-purpose CD4/haematology analysers. Similar to section ID, each CD4 enumerating technology is described in the analyser table followed by the test table.

6.2 Section II: Specification Tables

The specification section is divided according to commodity type: equipment, kits, reagents, consumables and durables. Each item is listed in the specification table according to the item number. Price range for a commodity has been included where possible. It serves as a reference point and may differ between regions and countries.

IIA: Equipment
Equipment specifications include information on the following:

- item number
- catalogue number
- manufacturer
- item description/specification
- required accessory
- optional accessory
- installation
- calibration
- service
- contract requirements
- price range

IIB: Kits
Kits are listed along with the following:

- item number
- item name
- catalogue number
- manufacturer
- description/specification
- pack type
- quantity per pack
- temperature requirement
- document/package insert
- shelf-life (months)
- price range
- comments

IIC: Reagents
Reagents and chemicals are listed along with the following:

- item number
- item name
- catalogue number
- manufacturer
- description/specification
- pack type
- quantity per pack
- temperature requirement
- shelf-life (months)
- price range

IID: Consumables
Information on consumables includes the following:

- item number
- item name
- catalogue number
- manufacturer
- description/specification
- pack type
- quantity per pack
- price range

IIE: Durables
Durables specifications include information on the following:

- item number
- item name
- catalogue number
- manufacturer
- description/specification
- pack type
- required accessory
- price range

7. HOW TO USE THIS TOOL

To facilitate ease-of-use of this document, this section will explain how to best find and derive benefit from the information contained herein.

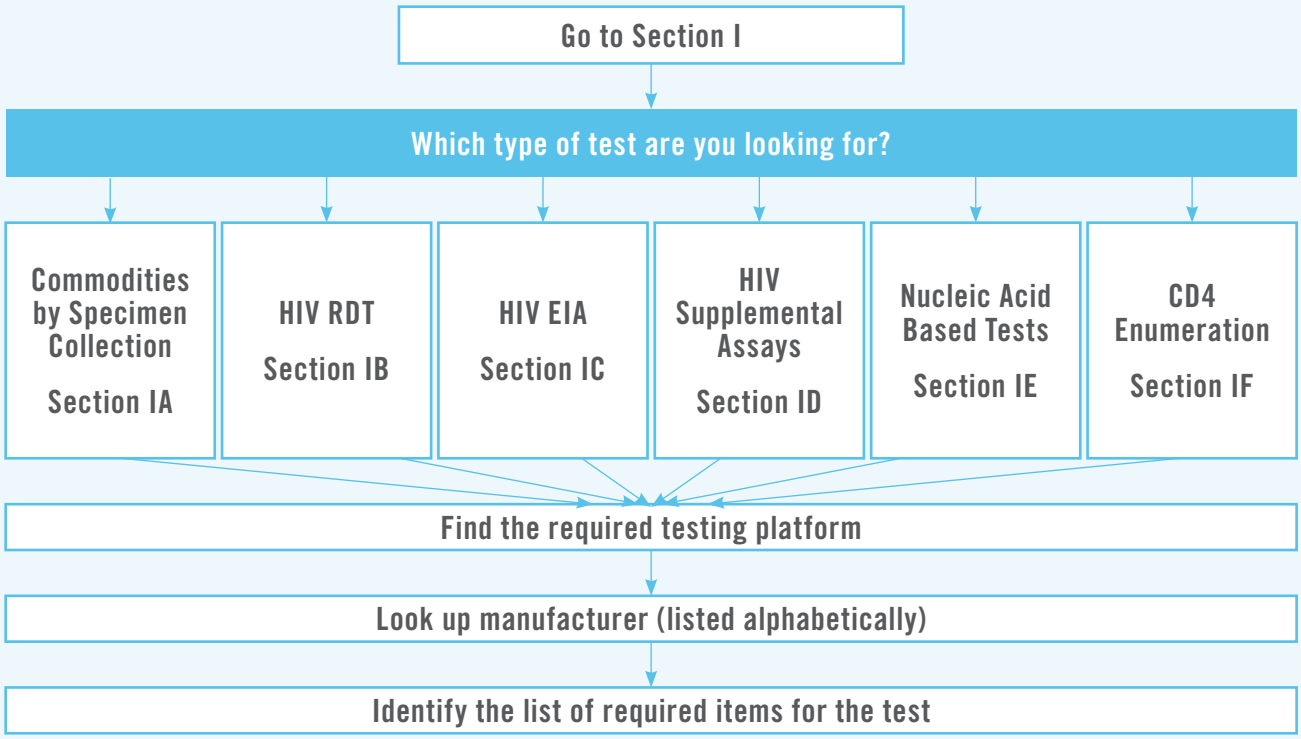
7.1 Flow chart for identifying the required types of commodity for a particular test using the test tables

Why do I need to know the types of commodities for each test?

This information is particularly useful if you want to create a list of standard commodities required for each test and/or at each level of service. You can also use it as the starting point for guidance on commodity quantities – remember that your standard operating procedures may differ from those of the manufacturers' package inserts so be prepared to create your own tables of commodities.

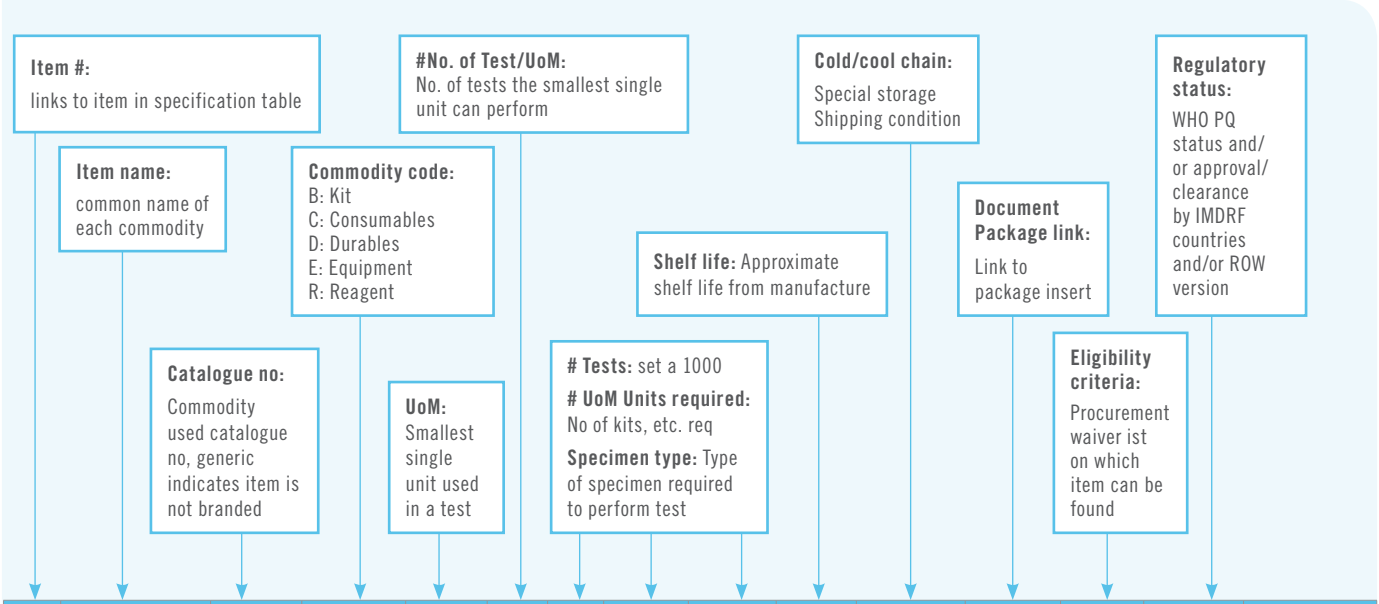
Finally, you may want to use this information to arrange workflow in your laboratory, i.e. to ensure all the required items are available close to the testing bench, within easy reach of the tester.

The following flow chart explains the best way to find the information you are looking for:



7.2 Information contained within the test tables

When you find the table displaying the commodities for the test you want, you will see the following information:



Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document Package Link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
546	ABON HIV 1/2/0 Tri-Line Human Immunodeficiency Virus Rapid Test Device	IHI-T402	B	40 tests/ kit	40	1000	25	Serum, plasma, capillary and venous whole blood	24 months	Store at 2-30°C	http://googl/7aCS1u	WHO, GF	WHO PQ, ROW	Kit includes 40x specimen droppers
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Venous blood, capillary blood, serum plasma						For plasma and venous whole blood, use EDTA-K2/sodium heparin; for capillary whole blood, use heparinized capillary tubes (50µl)
504	Gloves - multiple sizes, powder-free	Generic	C	100 gloves /box										
385, 386, 387	Biohazard waste container	Generic	D	1 Unit										
46	Timer, digital	Generic	E	1 Unit										
3 – Control														
460	Controls, HIV negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV positive		R			1000								

7.2a Will quantification data tell us exactly how much of each commodity to procure?

No, commodity data per test will not tell you how much of each commodity to procure. You will need to multiply the quantities of commodities by the average number of tests per facility and scale up based on the numbers of facilities. Once you have calculated the total quantities of commodities, you will need to make important adjustments to the numbers. To do this, follow the recommended quantity adjustment steps in Section 11.0.

7.2b Why are items arranged by item type?

Item types are commonly used groupings to distinguish between different kinds of laboratory commodity that may be used, handled and ordered in different ways. These include:

- E = Equipment: machines, analysers, instruments used for or in testing.
- B = Kits: test kits and devices that are used to test for the component of interest.
- R = Reagents and chemicals (solid and liquid), that accompany the test kit.
- C = Consumables: test-specific and general items that are often used once and discarded.
- D = Durables: reusable items such as glassware and plasticware.

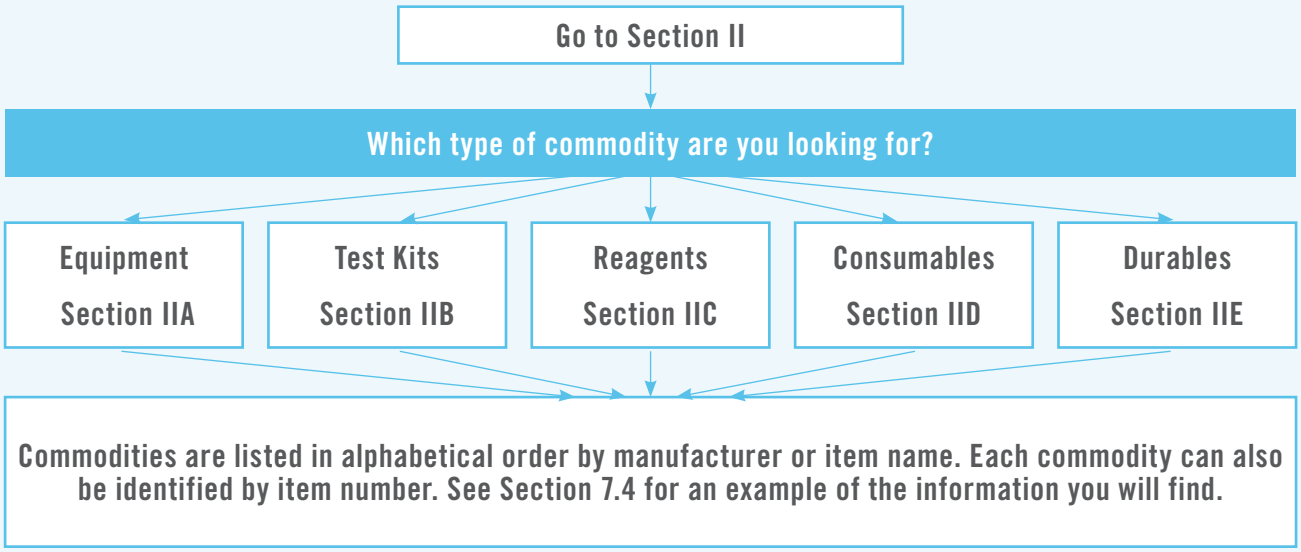
It is important to understand the differences between these items, as this is how you will find more information about them in the tool.

7.3 Identify specifications for a commodity using the specification tables

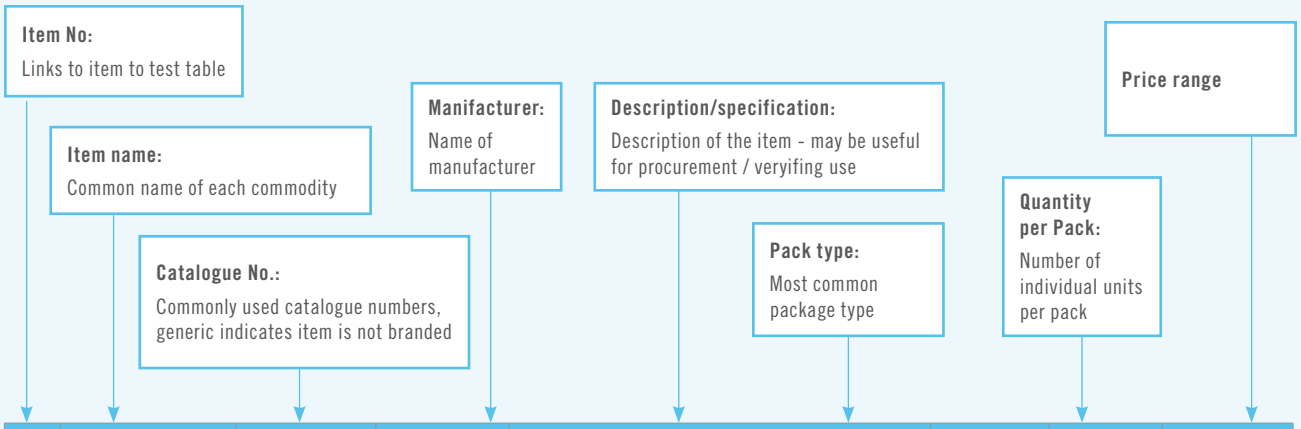
Why are specifications important?

A good specification or product description will ensure the end user gets the correct commodity to perform a test.

Specifications are also important when it is necessary to procure generic, that is, non-branded, items. Some tests require branded items and these commodities have been listed where necessary.



7.4 Information contained within the specification tables: Example section IIC Consumables



Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/ pack	Price range, USD
353	Pipette tip, 0,5-10 µl	Generic		Non-sterile, autoclavable pipette tips, translucent, specific for brand of 0,5-10 µl adjustable volume pipette	Pack	1000	15 - 40
354	Pipette tip, 0,5-10 µl filter / aerosol barrier	Generic		Sterile, filter-tip, DNase-, Rnase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 0,5-10 µl adjustable volume pipette	Box	96	5 - 50
349	Pipette tip, 0,5-20 µl	Generic		Non-sterile, autoclavable pipette tips, translucent, specific for brand of 10-20 µl adjustable volume pipette	Pack	1000	15 - 40
350	Pipette tip, 0,5-20 µl filter / aerosol barrier	Generic		Sterile, filter-tip, DNase-, Rnase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 10-20 µl adjustable volume pipette	Box	96	5 - 50
351	Pipette tip, 10-200 µl	Generic		Non-sterile, autoclavable pipette tips, translucent, specific for brand of 100-200 µl adjustable volume pipette	Pack	1000	8 - 55
352	Pipette tip, 10-200 µl filter / aerosol barrier	Generic		Sterile, filter-tip, DNase-, Rnase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 10-200 µl adjustable volume pipette	Box	96	5 - 50
500	Pipette tip, 1-5 ml filter / aerosol barrier	Generic		Sterile, filter-tip, DNase-, Rnase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 1-5 ml adjustable volume pipette	Box	96	25 - 50

7.5 Working with "scalable units"

It is important to recognize that there are inherent challenges associated with scaling up quantities of laboratory commodities. Unlike pharmaceuticals, some laboratory commodities may be used in multiple platforms or for multiple tests and use/quantities per test may vary by country, region, locality and site, depending upon the prevailing standards employed. A classic example is blood collection supplies, where needle holders are difficult to quantify and often result in an overwhelming excess of the commodity. Such wastage must be avoided at all costs. It is therefore essential that national programmes identify laboratory commodity quantities required according to the site and country requirements. This tool can help guide the decision-making process on quantities but should never be used as a tool for quantification, which requires a much greater level of complex input data. Estimates for the number of commodities required for 1000 tests are shown in the two shaded columns of the table in Section 7.2. Please note that, where possible, controls have been included in quantifications. These are clearly indicated in the tables.

8. QUANTIFICATION ADJUSTMENT STEPS

Quantification should always be based on more than one source of information. For detailed technical information on quantification of laboratory commodities, the user is referred to other tools that have been developed for this purpose. The most recent ones are:

USAID: DELIVER PROJECT: Quantification of health commodities: laboratory commodities companion guide forecasting consumption of laboratory commodities (19).

USAID: DELIVER PROJECT. The logistics handbook: a practical guide for the supply chain management of health commodities. Arlington, VA, USAID: DELIVER, Task Order 1. 2011 (21).

ForLab. This is a diagnostic forecasting software developed by USAID, JSI, SCMS and CHAI and suitable for national level planning. ForLab utilizes product consumption data, service statistics data, and demographic/morbidity data for forecasting laboratory commodity needs.

The following are recommended sources of information that can be used to perform quantification:

- *Quantification by test*
  This tool provides quantification data by test, according to manufacturers' recommendations and package inserts. Programmes should refine this information to suit standards employed at the country, regional or site level.
- *Consumption data*
  Consumption data are obtained from historical data on quantities of a product used and are typically reported by sites per month or per quarter. Daily consumption data can be found in laboratory registers and aggregated consumption data can be found in monthly and annual facility-level and programme-level reports where a logistics management and information system captures these data from service delivery points.
- *Service statistics data*
  These historical data, captured at the programme level or facility level, include the number of patient visits to facilities, services provided, or people who received a specific testing service within a given time period. These data must be used with caution, as repeat testing, quality control, and training tests are not always captured at the laboratory level.
- *Demographic/morbidity data*
  These data reflect the proportion of a specific population estimated to be affected and estimates the number of episodes of a given health condition that will occur in a common denominator of the population. These data may serve as a starting-point for new programmes when no existing consumption or service uptake data are available.
- *Programme/target data*
  These data are not related to the actual numbers of patients being served, volume of commodities being used, or capacity of the supply chain to manage the volume of commodities required. These data are best used for advocacy and resource mobilization, not for procurement of commodities. Avoid using these data in laboratory commodity quantification.

Once the quantification per test has been performed, it is recommended (7) that quantification adjustment occurs to account for the following parameters:

- *Existing stock*
  Existing stock is the stock in hand, or current inventory status of the laboratory commodity to be quantified. It is determined by counting the laboratory commodity currently in stock.
- *Product wastage*
  Laboratory testing always results in some wastage of supplies as a result of spillage, incorrect measurement or other damage. In an effective process safety management system, wastage should be minimized and should never exceed 3–10% of the total quantity required.
- *Lead time stock*
  Lead time stock is the stock kept on hand and used in the time between the ordering of new stock and the receipt and availability of the new stock.

Lead time is the amount of time (in months) it takes from the issue of an order until the commodity is received and available for use. Examples of lead times include:

- *The central level*
  The time from the issue of an order by the central store until the supply has been received in the central store and is ready for distribution to the site. Note that lead time includes all steps (such as, Ministry of Health approvals, finance release, customs inspections, delivery to the central store, etc.).
- *The laboratory level*
  The time from the issue of an order by a laboratory manager until the supply has been received in the laboratory store and is ready for use. Note that lead time includes all steps (such as, district/central level approvals, finance release, customs inspections, delivery to the central store, distribution to the laboratory, accessioning and receipt by the laboratory store, etc.).

It is crucial that the central and site levels maintain a record of the lead time for every laboratory commodity. The lead time will likely differ for different types of commodity (for example, expensive items may require longer approval times, short shelf-life items may have to be expedited).

To calculate lead time stock:

Total lead time stock required for each laboratory commodity:

Lead time stock required = average monthly requirement × number of months.

- *Buffer stock*

This is an estimate of stock kept on hand to protect against:

- delayed deliveries
- markedly increased usage/demand
- other unexpected events.

Accuracy of buffer stock requirements depends upon close monitoring of stock levels and incidents over a period of time. Monitoring should be continual and the quality of buffer stock requirement data will increase over time (18).

The total buffer stock is measured in months:

Buffer stock required = annual requirement/12 (= monthly requirements) × number of months buffer stock is required.

Logisticians and laboratory managers should maintain records for every laboratory commodity.

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10. SECTION I - TEST TABLES

10.1 SECTION IA: COMMODITIES BY SPECIMEN COLLECTION

COMMODITIES BY SPECIMEN COLLECTION: DRIED BLOOD SPOT

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Shelf-life	Temperature requirement	Document/package/link	Comment
264	Dried blood spot collection cards	Generic	B	100 cards/pack	100	1000	10	N/A	N/A	N/A	N/A
332	Humidity indicator card	Generic	C	100 cards/pack	100	1000	10	N/A	N/A	N/A	N/A
366	Silica gel packs	Generic	C	100 packs/box	50	1000	20	N/A	N/A	N/A	N/A
362	Bag, sealable plastic specimen	Generic	C	100 bags/pack	100	1000	10	N/A	N/A	N/A	N/A
267	Forceps, non-metallic	Generic	C	1 unit		1000		N/A	N/A	N/A	N/A
239	Bag, biohazard wastes	Generic	C	100 bags/pack		1000		N/A	N/A	N/A	N/A
263	Dressing/adhesive plaster/band aid strip	Generic	C	1 roll/pack		1000		N/A	N/A	N/A	N/A
368	Swab, 70% alcohol	Generic	C	100 swabs/box	100	1000	10	N/A	N/A	N/A	N/A
266	Fine-tip marker pen (black)	Generic	C	1 unit		1000		N/A	N/A	N/A	N/A
270	Gloves - multiple sizes, powder-free	Generic	C	100 gloves/box	50	1000	20	N/A	N/A	N/A	N/A
338	Lancet, infant	Generic	C	100 lancets/box	100	1000	10	N/A	N/A	N/A	N/A
336	Lancet, 21G	Generic	C	100 lancets/box	100	1000	10	N/A	N/A	N/A	N/A
392	Dried blood spot card drying rack	Generic	D	1 unit		1000		N/A	N/A	N/A	N/A
401–403	Laboratory coat	Generic	D	1 unit		1000		N/A	N/A	N/A	N/A
393	Goggles/eye protection	Generic	D	1 unit		1000		N/A	N/A	N/A	N/A
364	Sharps container, medium	Generic	D	1 unit		1000		N/A	N/A	N/A	N/A

COMMODITIES BY SPECIMEN COLLECTION: CAPILLARY WHOLE BLOOD (HEEL/FINGERSTICK)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Shelf-life	Temperature requirement	Document/ package/link	Comment
250	Capillary tubes	Generic	C	50 tubes/box	50	1000	20	N/A	N/A	N/A	Refer to manufacturer's instructions for specific type of capillary tubes required (such as, EDTA, heparin)
656	Specimen transfer devices	Generic	C	N/A	N/A	1000	N/A	N/A	N/A	N/A	N/A
338	Lancet, infant	Generic	C	100 lancets/box	100	1000	10				
336	Lancet, 21G	Generic	C	100 lancets/pack	100	1000	10				
239	Bag, biohazard wastes	Generic	C	100 bags/pack		1000					
263	Dressing/adhesive plaster/band aid strip	Generic	C	1 roll/pack		1000					
368	Swab, 70% alcohol	Generic	C	100 swabs/box	100	1000	10				
266	Fine-tip marker pen (black)	Generic	C	1 unit		1000					
335	Labels, adhesive (for labelling tubes/ containers)	Generic	C	100 labels/roll	100	1000	10				
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box	50	1000	20				
401–403	Laboratory coat	Generic	D	1 unit		1000					
393	Goggles/eye protection	Generic	D	1 unit		1000					
364	Sharps container, medium	Generic	D	1 unit		1000					

COMMODITIES BY SPECIMEN COLLECTION: VENOUS WHOLE BLOOD, SERUM, PLASMA

IItem no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of UoM required	Shelf-life	Temperature requirement	Document/package/link	Comment
372	Tourniquet, adult	Generic	C	1 unit		1000					
241	Blood collection needle, 21G	Generic	C	20 needles/ box	20	1000	50				
240	Needle holder	Generic	C	250 needle/ holders		1000					
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box	50	1000	20				
335	Labels, adhesive (for labelling tubes/ containers)	Generic	C	100 labels/ roll	100	1000	10				
266	Fine-tip marker pen (black)	Generic	C	1 unit		1000					
368	Swab, 70% alcohol	Generic	C	100 swabs/ box	100	1000	10				
247	Blood collection tubes	Generic	C	1000 tubes/ pack	1000	1000	10			http://gssh.co/wi0T66	Refer to assay manufacturer's instructions for specific type of blood collection tubes required (such as, EDTA or heparin containing tubes)
263	Dressing/adhesive plaster/band aid strip	Generic	C	1 roll/pack		1000					
364	Sharps container, medium	Generic	C	1 unit		1000					
239	Bag, biohazard wastes	Generic	C	100 bags/ pack	50	1000					
262	Cotton wool	Generic	C	100 /pack	50	1000	20				
401–403	Laboratory coat	Generic	D	1 unit		1000					
409	Scissors	Generic	D	1 unit		1000					
405	Phlebotomy chair, with arm rest	Generic	D	1 unit		1000					
406	Phlebotomy grips (for patients to squeeze)	Generic	D	1 unit		1000					

IItem no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of UoM required	Shelf-life	Temperature requirement	Document/package/link	Comment
408	Rack, test tubes, 14-mm diameter	Generic	D	1 unit		1000					
393	Goggles/eye protection	Generic	D	1 unit		1000					
17	Centrifuge, benchtop, non-refrigerated	Generic	E	1 unit		1000	Serum/ plasma				For preparation of serum and plasma specimens

10.2 SECTION IB: HIV RDT

HIV RDT: ABON™ HIV-1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE, ABON BIOPHARM HANGZHOU CO. LTD

HIV-1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device is an in vitro diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens. Time to result 10 to 20 minutes. Initial sensitivity 100% (95% confidence interval 99.2–100%), final specificity 99.7% (95% confidence interval 98.9–100%) (Source: WHO PQ Public Report for ABON™ HIV-1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (PQDx 0141-051-00) http://goo.gl/7aCS1u). Commodities for specimen collection are not included in the kit. Commodities for specimen transfer are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units req.	Specimen type	Shelf-life	Temperature requirement	Document/ package/link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
546	ABON™ HIV-1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IHI-T402	B	40 tests/kit	40	1000	25	Serum, plasma, capillary and venous whole blood	24 months	Store at 2-30°C	http://goo.gl/7aCS1u	WHO, GF	WHO PQ, ROW	Kit includes 40x specimen droppers
2 – Test run														
534	Blood collection consumables	Generic	C					Venous blood, capillary blood, serum, plasma						For plasma and venous whole blood, use EDTA-K2/ sodium heparin; for capillary whole blood, use heparinized capillary tubes (50µl)
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box										
385, 386, 387	Biohazard waste container	Generic	D	1 Unit										
46	Timer, digital	Generic	E	1 Unit										

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units req.	Specimen type	Shelf-life	Temperature requirement	Document/ package/link	Eligibility criteria	Regulatory status	Comment
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: ALERE DETERMINE™ HIV-1/2, ALERE MEDICAL CO. LTD.

Alere Determine™ HIV-1/2 is an in vitro, visually read, qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood.
The test is intended as rapid test to detect antibodies to HIV-1/HIV-2 from infected individuals. Time to result 15 to 60 minutes.
For WHO PQ, ROW regulatory version, initial sensitivity 100% (95% confidence interval 99.1–100%), final specificity 98.93% (95% confidence interval 97.8–99.6%) (Source: WHO PQ public report for Alere Determine™ HIV-1/2 (PQDx 0033-013-00) http://goo.gl/JmGZVp).
For CE marked regulatory version, sensitivity 100%, specificity 99.68% (Source: Alere Determine™ HIV-1/2 package insert http://goo.gl/22GVrB)
All commodities listed in the Test run section of the test table below are suitable for both CE marked and WHO PQ ROW regulatory versions of the product, unless specified.
Commodities for specimen collection and transfer are not included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Cold/ cool chain	Document/ package/l ink	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
201	Alere Determine™ HIV-1/2	7D2342	B	20 tests/kit	20	1000	50	Serum, plasma, capillary and venous whole blood	14 months	No, store between 2–30°C	http://goo.gl/22GVrB	WHO, GF, USAID	WHO PQ, ROW	
		7D2343	B	100 tests/ kit	100	1000	10							
202	Alere Determine™ HIV-1/2	7D2346	B	20 tests/kit	20	1000	50	Serum, plasma, capillary and venous whole blood	14 months	No, store between 2–30°C	http://goo.gl/22GVrB	GF, USAID	CE marked	
		7D2347	B	100 tests/ kit	100	1000	10							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Capillary, venous blood, serum, plasma						For venous whole blood and plasma specimens, use tubes containing EDTA
544	Capillary tubes (EDTA)	7D2222	C	100 tubes / pack	100	1000	10	Capillary whole blood	12–18 months	Store at 4–25°C			ROW	For use with WHO PQ, ROW regulatory version of the assay (catalogue no.: 7D2342 and 7D2343)
252	Capillary tubes (EDTA)	7D2227	C	100 tubes/ pack	100	1000	10	Capillary whole blood	12–18 months	Store at 4–25°C			CE marked	For use with CE marked assay (catalogue no.: 7D2346 and 7D2347)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Cold/ cool chain	Document/ package/l ink	Eligibility criteria	Regulatory status	Comment
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								N/A
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							For serum/plasma
41	Pipette/pipettor 200	Generic	E	1 unit		1000								For serum/plasma
46	Timer, digital	Generic	E	1 unit		1000								N/A
199	Chase buffer	7D2243	R	2.5 ml / bottle		1000		Whole blood	12–18 months	Store at 2–30°C				For whole blood samples
3 – Control														
459	Controls, HIV-positive		R			1000								Controls are not available for this kit; consider using QC specimens
460	Controls, HIV-negative		R			1000								

HIV RDT: ALERE DETERMINE™ HIV-1/2 AG/AB COMBO, ALERE MEDICAL CO. LTD.

Alere Determine™ HIV-1/2 is an in vitro, visually read, qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. The test is intended as rapid test to detect antibodies to HIV-1/HIV-2 from infected individuals. Time to result 15 to 60 minutes.
For WHO PQ, ROW regulatory version, initial sensitivity 100% (95% confidence interval 99.1–100%), final specificity 98.93% (95% confidence interval 97.8–99.6%) (Source: WHO PQ public report for Alere Determine™ HIV-1/2 (PQDx 0033-013-00) http://goo.gl/JmGZVp).
For CE marked regulatory version, sensitivity 100%, specificity 99.68% (Source: Alere Determine™ HIV-1/2 package insert http://goo.gl/22GVrB)
All commodities listed in the Test run section of the test table below are suitable for both CE marked and WHO PQ ROW regulatory versions of the product, unless specified.
Commodities for specimen collection and transfer are not included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document /package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
548	Alere Determine™ HIV-1/2 Ag/Ab Combo	7D2643	B	100 tests/ kit	100	1000	10	Serum, plasma, fingerstick and venous whole blood	10 months	Store at 2–30°C	http://goo.gl/ y2ejvY	WHO, GF, USAID	ROW, WHO PQ	
200	Alere Determine™ HIV-1/2 Ag/Ab Combo	7D2646	B	20 tests/kit	20	1000	50	Serum, plasma, fingerstick and venous whole blood	12 months	Store at 2–30°C	http://gssh. co/1cGS5gh	GF, USAID	CE mark	
		7D2647	B	100 tests/ kit	100	1000	10							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous blood						For whole blood and plasma specimens, use EDTA collection tubes
544	Capillary tubes (EDTA)	7D2222	C	100 tubes/ pack	100	1000	10	Fingerstick whole blood	12–18 months	Store at 4–25°C				Alternative products; for use with ROW regulatory version of the assay
549	Microsafe capillary tubes	7D2223	C	100 tubes/ pack	100	1000	10	Fingerstick whole blood	12–18 months	Store at 4–25°C				
252	Capillary tubes (EDTA)	7D2227	C	100 tubes/ pack	100	1000	10	Fingerstick whole blood	12–18 months	Store at 4–25°C			CE marked	For use with CE marked regulatory version

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document /package/ link	Eligibility criteria	Regulatory status	Comment
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							For serum/ plasma
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								For serum/ plasma
46	Timer, digital	Generic	E	1 unit		1000								
199	Chase buffer	7D2243	R	2.5 ml bottle		1000		Fingerstick, venous whole blood	12–18 months	Store at 2–30°C				
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: AWARE™ HIV-1/2 OMT, CALYPTE BIOMEDICAL CORPORATION

Aware™ HIV-1/2 OMT (oral fluid) test is a single-use, qualitative, visually read, in vitro immunoassay for the detection of antibodies to HIV type 1 (HIV-1) and type 2 (HIV-2) in human oral fluid specimens (oral mucosal transudate). The test is intended for use as a point-of-care aid in the clinical diagnosis of HIV infection. It can be used as a component of a multi-test algorithm in conjunction with other approved HIV-antibody assays, including other rapid tests. Time to result 20 to 45 minutes.
Sensitivity 99.2%, specificity 99.93% (Source: Aware™ HIV-1/2 OMT Rapid Antibody Test package insert http://goo.gl/5fj0Zv).
Commodities for oral fluid specimen collection and transfer are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM required	Specimen type	Shelf-life	Temperature requirements	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
539	Aware™ HIV-1/2 OMT Rapid Antibody Test	98164	B	100 tests/ kit	100	1000	10	Human oral mucosal transudate (oral fluid) specimens	18 months	Store at 2–30°C	http://goo.gl/5fj0Zv	USAID list	ROW	98166 contains English IFU, 98169 contains English & Russian IFU, 98164 labelled and contains Arabic, English, French, Spanish, Portuguese, & Russian IFU
		98166		1 test/kit	1		1000							
		98169		1 test/kit	1		1000							
2 – Test run														
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
									30 days once thawed	Store at 2–8°C				

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM required	Specimen type	Shelf-life	Temperature requirements	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
3 – Control														
533	Aware™ HIV-1/2 OMT Control Pack	98131	R	15 tests/kit	15	1000			12 months	Store at 20°C	http://goo.gl/5fj0Zv			Each kit includes 0.25 ml x nonreactive, 0.25 ml x HIV-1 positive, 0.25 ml x HIV-2 positive controls. Do not re-freeze control pack reagents

HIV RDT: BIOTRACER™ HIV-1/2 RAPID CARD, BIO FOCUS CO. LTD.

BioTracer™ HIV-1/2 Rapid Card is an immunochromatography-based one-step in vitro diagnostic test for qualitative detection of antibodies to HIV-1 and HIV-2 in serum, plasma, or whole blood. Time to result 5 to 20 minutes. Sensitivity 99.9%, specificity 99.7% (Source: information from the manufacturer http://goo.gl/E9PrRy). Commodities for specimen collection and transfer are not included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM required	Specimen type	Shelf-life	Temperature requirements	Document / package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
553	BioTracer™ HIV-1/2 Rapid Card	11112	B	30 tests/kit	30	1000	34	Serum, plasma, capillary and venous whole blood	18 months	Store at 1–30°C	http://goo.gl/E9PrRy	USAID	ROW	
		11135		100 tests/kit	100	1000	10							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Capillary, venous blood, serum, plasma						
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
349	Pipette tip, 5–20 µl	Generic	C	1000 tips/ pack	1000	1000	1							Serum, plasma, whole blood
40	Pipette/ pipettor 20	Generic	E	1 unit		1000								Serum, plasma, whole blood
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000							Controls are not available for this kit; consider using QC specimens	
459	Controls, HIV-positive		R			1000								

HIV RDT: CLEARVIEW® COMPLETE HIV-1/2, ALERE NORTH AMERICA, INC.

Clearview® COMPLETE HIV-1/2 assay is a single-use immunochromatographic test for the detection of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2) in fingerstick whole blood, venous whole blood, and serum or plasma specimens. The Clearview® COMPLETE HIV-1/2 assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms. Time to result 15 to 20 minutes.
Sensitivity 99.7% (95% confidence interval 98.9–100%) for HIV-1; 100% (95% confidence interval 98.2–100%) for HIV 2. Specificity 99.9% (95% confidence interval 99.6–100%) (Source: Clearview® COMPLETE HIV-1/2 package insert http://goo.gl/3QK4g7).
Fingerstick:
Commodities for fingerstick specimen collection and transfer are included in the kit.
Venous whole blood, serum, plasma:
Commodities for collection and transfer of venous whole blood, plasma, and serum specimens are not included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirements	Document /package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
542	Clearview® COMPLETE HIV-1/2	92111	B	25 tests/kit	25	1000	40	Serum, plasma, fingerstick or venous whole blood	24 months	Store at 8 –30°C	http://goo.gl/3QK4g7	USAID	FDA-approved	Distributed by Alere North America, Inc.; manufactured by Chembio Diagnostic Systems, Inc.; distributed by Chembio Diagnostic Systems, Inc. as SURE CHECK HIV-1/2 Assay (Cat # HIV202). Kit includes commodities for collection of fingerstick whole blood

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirements	Document /package/ link	Eligibility criteria	Regulatory status	Comment
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Venous blood, serum, plasma						For whole blood and plasma specimens, use tubes with citrate, heparin, or EDTA
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
353	Pipette tip, 0.5–10 µl	Generic	C	1000 tips/ pack		1000								For specimens other than fingerstick whole blood
556	Pipette/ pipettor 10	Generic	C	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
541	Clearview® HIV Reactive/ Nonreactive Controls	92112	R	3x100 tests/ kit	100	1000	10		24 months	Store at 2–8°C				Kit includes 1 x HIV-1 reactive control (0.25 ml); 1 x HIV 2 reactive control (0.25 ml); 1 x nonreactive control (0.25ml)

HIV RDT: COMBAIDS RS ADVANTAGE, SPAN DIAGNOSTICS

Combaids RS Advantage is a solid-phase immunosorbent assay (SPIA) for detection of antibodies to HIV-1 & HIV-2 in human whole blood / serum / plasma with inbuilt control dot (Rapid Test). Time to result 30 to 40 minutes. Commodities for specimen collection are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirements	Document/ package/link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
560	Combaids RS Advantage	51SP200-48	B	48 tests/kit	48	1000	21	Serum, plasma, capillary and venous whole blood	15 months	Store at 2–8°C	http://goo.gl/MqZLB7 http://goo.gl/uV7bNH	USAID	ROW	Kit includes HIV-1 positive control, HIV-2 positive, and HIV-negative control; Disposable plastic droppers
		51SP200-96		96 tests/kit	96	1000	11							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous blood, serum, plasma						For plasma or whole blood specimens, use tubes containing EDTA or heparin
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
395	Graduated cylinder, 100 ml	Generic	D	1 unit		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000								
41	Pipette/pipettor 200	Generic	E	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								

HIV RDT: DIAGNOSTIC KIT FOR HIV (1+2) ANTIBODY (COLLOIDAL GOLD), SHANGHAI KEHUA BIO-ENGINEERING CO LTD (KHB)

Diagnostic kit for HIV (1+2) antibody (colloidal gold) is a visually read immunochromatographic, lateral flow assay for the qualitative determination of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. Time to result 4 to 30 minutes. Final sensitivity 100% (95% confidence interval 97.7–100%), final specificity 100% (95% confidence interval 98.8–100%) (World Health Organization. HIV Assays: Operational Characteristics Report 14 / Simple/Rapid tests http://goo.gl/HX1Cnv). Commodities for sample collection and transfer are not provided in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirements	Document / package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
198	Diagnostic kit for HIV (1+2) antibody (colloidal gold)	KH-R-02	B	50 tests/kit	50	1000	20	Serum, plasma, capillary and venous whole blood	18 months	Store at 4–30°C	http://goo.gl/CrKf4k http://goo.gl/HX1Cnv	WHO, GF, USAID	ROW	
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Capillary, venous blood, serum, plasma						
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000								For all specimen types
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								For all specimen types
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: DPP® HIV-1/2 ASSAY, CHEMBIO DIAGNOSTIC SYSTEMS, INC.

DPP® HIV-1/2 Assay is a single-use immunochromatographic test for the detection of antibodies to human immunodeficiency virus types 1 and 2 (HIV-1/2) in oral fluid, fingerstick whole blood, venous whole blood, serum, or plasma samples. DPP HIV-1/2 Assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms. Time to result: 25 to 40 minutes for oral fluid; 10 to 25 minutes for fingerstick, venous whole blood, serum, plasma.
For US FDA-approved regulatory version (Source: DPP® HIV-1/2 Assay package insert http://goo.gl/zOM3sh):
Oral fluid specimens:
HIV-1 sensitivity 98.9% (95% confidence interval 98.0–99.4%); HIV-2 sensitivity 100% (95% confidence interval 98.3–100%); specificity 99.9% (95% confidence interval 99.7–99.9%).
Commodities for oral fluid specimen collection and transfer are included in the kit
Fingerstick specimens:
HIV-1 sensitivity 99.8% (95% confidence interval 99.2–99.9%); HIV-2 sensitivity 100% (95% confidence interval 98.3–100%); specificity 100% (95% confidence interval 99.8–100%). Only sample loops for fingerstick specimen collection and transfer are included in the kit. Other commodities for fingerstick specimen collection need to be purchased separately.
Venous whole blood, serum, and plasma specimens:
HIV-1 sensitivity: 99.9% (95% confidence interval 99.4–99.9%); HIV-2 sensitivity 100% (95% confidence interval 98.3–100%); specificity 99.9% (95% confidence interval 99.7–99.9%).
Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit.
All commodities listed in the test run section of the test table below are suitable for both ROW and US FDA-approved regulatory versions of the product.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
535	DPP® HIV-1/2 Assay	65-9506-0	B	20 tests/kit	20	1000	50	Oral fluid, serum, plasma, venous or fingerstick whole blood	24 months	Store at 2–30°C	http://goo.gl/zOM3sh	USAID	ROW	Kit includes 20 swabs for oral fluid collection; 20 disposable 10 µl sample loops
536	DPP HIV-1/2 Assay	65-9500-0	B	20 tests/kit	20	1000	50	Oral fluid, serum, plasma, venous or fingerstick whole blood	23 months	Store at 2–30°C	http://goo.gl/zOM3sh	GF	US FDA approved	Kit includes 20 swabs for oral fluid collection; 20 disposable 10 µl sample loops

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package link	Eligibility criteria	Regulatory status	Comment
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous blood, serum, plasma						For venous whole blood or plasma specimens, use tubes containing EDTA, citrate, or heparin
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
353	Pipette tip, 0.5–10 µl	Generic	C	1000 tips/ pack		1000								Optional; for specimens other than fingerstick whole blood.
556	Pipette/ pipettor 10	Generic	E	1 unit		1000								
46	Timer, digital	Generic	E		1 unit		1000							
385, 386, 387	Biohazard waste container	Generic	D		1 unit		1000							
3 – Control														
538	DPP HIV-1/2 Control Pack	60-9552-0		R	Kit	50 tests per each control	1000			24 months	Store at 2–8°C	http://goo.gl/zOM3sh		

HIV RDT: FIRST RESPONSE® HIV-1-2.O CARD TEST, PREMIER MEDICAL CORPORATION LTD.

First Response® HIV-1-2.O Card Test is intended for use by health care professionals and is a qualitative, screening, in vitro diagnostic test for detection of antibodies of all classes specific to HIV-1 (including group O) and HIV-2 in human serum, plasma or whole blood. The test kit is not automated and does not require any additional instrumentation. Reactive samples should be confirmed by another assay. Time to test results 5 to 15 minutes. Initial sensitivity 100%, final specificity 98.8% (Source: List of diagnostics eligible to tender for procurement by WHO in 2014 http://goo.gl/3ixDCe).
Fingerstick:
Commodities for fingerstick specimen collection and transfer are included in the kit.
Venous whole blood, serum, plasma: Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
213	First Response® HIV-1-2.O Card Test	I05FRC30	B	30 tests/ kit	30	1000	34	Serum, plasma, whole blood	23 months	Store at 4–30°C	http://goo.gl/RqrSgw	WHO, GF, USAID	CE marked	Kit includes 30 x 10µl pipettes, 30 x twist lancets, and 30 x 70% isopropyl alcohol swabs
2 – Test run														
534	Blood collection consumables	Generic	C					Venous blood, serum, plasma						For venous whole blood or plasma specimens, use tubes containing EDTA, citrate, or heparin
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box										
385, 386, 387	Biohazard waste container	Generic	D	1 Unit										
46	Timer, digital	Generic	E	1 Unit										
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: GENIE™ FAST HIV-1/2 ASSAY, BIO-RAD LABORATORIES

Genie™ Fast HIV-1/2 Assay is an immunochromatographic (ICT or lateral migration) assay to detect anti-HIV-1 and anti-HIV-2 antibodies in human serum, plasma, venous blood and capillary blood. Time to result 10 to 30 minutes. Sensitivity: 100% (95% confidence interval 99.7–100%) for HIV-1, all types of specimens, and 100% (95% confidence interval 96.7–100%) for HIV-2, all types of specimens. Overall specificity in hospitalized patients 99.5% (95% confidence interval 98.9–99.8%), with 99.3% and 99.1% for serum and plasma, respectively, 100% for whole venous blood and capillary blood (Source: manufacturer's package insert http://goo.gl/ji0RHg, http://goo.gl/yHdDPa). Fingerstick: Commodities for fingerstick specimen collection and transfer are not included in the kit.
Venous whole blood, serum, plasma: Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
545	Genie™ Fast HIV-1/2 Assay	72327 72330	B	25 tests/ kit 50 tests/ kit	25 50	1000	40 20	Serum, plasma, venous and capillary blood	18 months	Store at 2–30°C	http://goo.gl/ji0RHg http://goo.gl/yHdDPa	GF, USAID	CE marked	Kit includes 50 pipettes for depositing serum, plasma and venous blood
2 – Test run														
534	Blood collection consumables	Generic	C					Venous blood, capillary blood, serum, plasma						For venous whole blood or plasma specimens, use tubes containing EDTA-K2, lithium heparinate, ACD (citrate-dextrose). For capillary blood, use plastic pipette without anticoagulant (not provided)
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box										
385, 386, 387	Biohazard waste container	Generic	D	1 Unit										
46	Timer, digital	Generic	E	1 Unit										
3 – Control														
460	Controls, HIV-negative		R		1000								Controls are not available for this kit; consider using QC specimens	
459	Controls, HIV-positive		R		1000									

HIV RDT: HIV-1/2 STAT-PAK®, CHEMBIO DIAGNOSTIC SYSTEMS, INC.

HIV-1/2 STAT-PAK is a single-use immunochromatographic, rapid screening test for the detection of antibodies to human immunodeficiency virus types 1 and 2 (HIV-1/2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. HIV-1/2 STAT-PAK is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV 2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms. Time to result 15 to 20 minutes. Initial sensitivity 99.29% (95% confidence interval 97.9–100%), final specificity 100% (95% confidence interval 99.4–100%) (Source: WHO PQ public report for HIV-1/2 Stat-Pak® (PQDx 0007-006-00) http://goo.gl/63cUIU).
Fingerstick:
Only sample loops for fingerstick specimen collection and transfer are included in the kit. Other commodities for fingerstick specimen collection need to be purchased separately.
Venous whole blood, serum, plasma:
Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
204	HIV-1/2 STAT-PAK®	HIV101 (60-9500-0)	B	20 tests/kit	20	1000	50	Serum, plasma, venous or fingerstick whole blood	24 months	Store at 8–30°C	http://goo.gl/jKtp9N http://goo.gl/63cUIU	WHO, GF, USAID	WHO PQ, ROW	Kit includes 20 disposable 5 µl sample loops for collection and transfer of fingerstick whole blood or for transfer of venous whole blood, serum, and plasma specimens Product code HIV101 cross referenced to product code 60-9500-0; both codes represent the same product

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous whole blood, serum, plasma						For venous whole blood or plasma specimens, use tubes containing EDTA, citrate, or heparin. For fingerstick whole blood, use sample loop provided with the kit
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves / box		1000								
353	Pipette tip, 0.5–10 µl	Generic	C	1000 tips/ pack		1000								Optional; for specimens other than fingerstick whole blood
556	Pipette/ pipettor 10	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
562	Rapid HIV-1/2 Antibody Test Kit Controls	HIV104	R	50 tests/ each control/ package	50 tests/ control	1000	20		24 months	Store at 2–8°C			ROW	Available from manufacturer as accessory; non-WHO PQ; Contains 1 HIV-1 reactive control 0.25 ml, 1 HIV-2 reactive control 0.25 ml, 1 HIV nonreactive control 0.5 ml

HIV RDT: HIV-1/2 STAT-PAK® DIPSTICK, CHEMBIO DIAGNOSTIC SYSTEMS, INC.

HIV-1/2 STAT-PAK DIPSTICK assay is a single-use, immunochromatographic screening test which uses a cocktail of antigens to detect antibodies to HIV-1 and 2 in serum, plasma or whole blood. Reactive results are supportive evidence of exposure to HIV-1/2 and can be used to support a clinical diagnosis of HIV-1 or HIV 2. Nonreactive results, however, should not be used to exclude infection with HIV-1 or 2. Time to result 15 to 20 minutes. Initial sensitivity 100% (95% confidence interval 99.1–100%), final specificity 99.7% (95% confidence interval 98.97–99.9%). (Source: WHO PQ public report for HIV-1HIV-1/2 STAT-PAK® Dipstick (PQDx 0008-006-00) http://goo.gl/gnGu9D)
Fingerstick:
Sample loops for fingerstick specimen collection and transfer are included in the kit. Other commodities for fingerstick specimen collection need to be purchased separately.
Venous whole blood. Serum, plasma:
Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
206	HIV-1/2 STAT-PAK® Dipstick	HIV303	B	30 tests/ kit	30	1000	33	Serum, plasma, venous or fingerstick whole blood	24 months	Store at 8–30°C	http://goo.gl/ja2Yje http://goo.gl/gnGu9D	WHO, GF, USAID	ROW, WHO PQ	Kit includes 30 disposable 5µl sample loops for collection and transfer of fingerstick whole blood or for transfer of venous whole blood, serum, and plasma specimens
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous whole blood, serum, plasma						For venous whole blood or plasma specimens, use tubes containing EDTA, citrate, or heparin. For fingerstick whole blood, use sample loop provided with the kit
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves / box		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
353	Pipette tip, 0.5–10 µl	Generic	C	1000 tips/pack		1000								Optional; for specimens other than fingerstick whole blood
556	Pipette/ pipettor 10	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
562	Rapid HIV-1/2 Antibody Test Kit Controls	HIV104	R	50 tests/ each control/ package	50 tests/ control	1000	20		24	Store at 2–8°C			ROW	Available from manufacturer as accessory; non-WHO PQ; Contains 1 HIV-1 reactive control 0.25 ml, 1 HIV-2 reactive control 0.25 ml, 1 HIV nonreactive control 0.5 ml

HIV RDT: HIVSAV 1/2/0 RAPID SEROTEST™, SAVYON DIAGNOSTICS

HIVSav 1/2/0 Rapid SeroTest™ is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1, HIV-2, and subtype O in whole blood, serum or plasma to aid in the diagnosis of HIV infection. Time to result 10 to 20 minutes. Sensitivity 99.9% (95% confidence interval 99.4–100.0%); specificity 99.9% (95% confidence interval 99.4–100.0%) (Source: HIVSav 1/2/0 Rapid SeroTest™ manufacturer's package insert http://goo.gl/yZZCi3).
Fingerstick:
Commodities for fingerstick specimen collection and transfer are not included in the kit.
Venous whole blood, serum, plasma:
Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
547	HIVSav 1/2/0 Rapid SeroTest™	A41112	B	25 tests/kit	25	1000	40	Serum, plasma, fingerstick and venous whole blood	15 months	Store at 2–30°C	http://goo.gl/yZZCi3	USAID	ROW	Kit includes disposable plastic pipettes for transfer of venous whole blood, serum, or plasma specimens.
		B41112		50 tests/kit	50		20							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Venous blood, fingerstick, serum, plasma						For fingerstick specimens, use heparinized capillary tubes. No anticoagulant required for venous whole blood or plasma specimens.
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/link	Eligibility criteria	Regulatory status	Comment
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens.
459	Controls, HIV-positive		R			1000								

HIV RDT: ICARE HIV-1&2 RAPID SCREEN TEST (WHOLE BLOOD/SERUM/PLASMA), JAL INNOVATION

iCARE One-Step HIV1&2 Whole Blood/Serum/Plasma Test (2 lines) is a rapid immunochromatographic direct binding test for the visual detection of HIV antibodies in whole blood, serum or plasma samples in the diagnosis of HIV infection. Time to result 15 minutes. Sensitivity 99%, specificity 100% (Source: information from manufacturer http://goo.gl/UxGB0r

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Sample type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
566	iCARE HIV-1&2 Rapid Screen Test (Whole blood/ serum/ plasma	IT1001	B	40 tests/kit	40	1000	25	Serum, plasma, capillary or venous whole blood	24 months	Store at 4–30°C	http://goo.gl/UxGB0r	USAID	ROW	Contains micropipettes for specimen transfer
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Venous blood, fingerstick, serum, plasma						
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: IMMUNOCOMB® II HIV-1&2 BISPOT, ORGENICS LTD.

ImmunoComb® II HIV-1&2 BiSpot kit is a rapid test for serological diagnosis of human immunodeficiency virus (HIV). Intended for qualitative and differential detection of antibodies to HIV types 1 and 2 (HIV-1 and HIV-2) in human serum or plasma. Time to result 40 minutes. Initial sensitivity 100% (95% confidence interval 99.1–100%), final specificity 99.4% (95% confidence interval 98.5–99.8%) (Source: WHO PQ public report for ImmunoComb® II HIV-1&2 BiSpot (PQDx 0036-014-00) http://goo.gl/e5d9Eq).
Commodities for specimen collection and transfer are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Sample type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
190	ImmunoComb® II HIV-1&2 BiSpot	60432002	B	36 tests/ kit	36	1000	28	Serum or plasma	15 months	Store at 2–8°C	http://gssh.co/15zusHl http://goo.gl/e5d9Eq	GF, USAID, WHO	WHO PQ, ROW	Kit includes HIV-1/2 positive control and HIV-negative control
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes containing EDTA, citrate, or heparin
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							
409	Scissors	Generic	D	1 unit		1000								
41	Pipette/pipettor 200	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
618	Shaker	Generic	E	1 unit		1000								Optional
46	Timer, digital	Generic	E	1 unit		1000								

HIV RDT: INSTI™ HIV-1/ HIV-2 ANTIBODY TEST, BIOLYTICAL LABORATORIES

INSTI™ HIV-1/HIV-2 Antibody Test is a single-use, rapid, flow-through in vitro qualitative immunoassay for the detection of antibodies to human immunodeficiency virus type 1 and type 2 in human EDTA whole blood, fingerstick blood, serum or EDTA plasma. The test is intended for use by trained personnel in medical facilities, clinical laboratories, emergency care situations, and physicians' offices as a diagnostic test capable of providing results in less than one minute. Although suitable for near-patient or point-of-care testing, the INSTI HIV-1/HIV-2 Antibody Test is not suitable for home testing. Time to result: 1 to 5 minutes. Initial sensitivity 100% (95% confidence interval 99.1–100%), final specificity 99.7% (95% confidence interval 98.9–100%) (Source: WHO PQ report for INSTI™ HIV-1/HIV-2 Antibody Test (PQDx 0002-002-00) http://goo.gl/Hm03m5)
INSTI™ HIV-1/HIV-2 Antibody Test with support material (catalogue no. 90-1012 and 901022) includes commodities for fingerstick specimen collection and transfer.
INSTI™ HIV-1/HIV-2 Antibody Test without support material (catalogue no. 90-1021) does not include commodities for specimen collection and transfer.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test per UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ Link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
550	INSTI™ HIV-1/HIV-2 Antibody Test with support materials	90-1012	B	1 test/kit	1	1000	1000	Serum, plasma, fingerstick and venous whole blood	15 months	Store at 15–30°C	http://goo.gl/Hm03m5 http://goo.gl/XBxexU http://goo.gl/5IVLdG	WHO, GF	WHO PQ, ROW	Includes support materials: Single-use alcohol swabs; single-use sterile lancets; single-use pipette capable of dispensing 50µl
		90-1022		48 tests/kit	48		21							
551	INSTI™ HIV-1/HIV-2 Antibody Test without support materials	90-1021	B	48 tests/kit	48	1000	21	Serum, plasma, fingerstick and venous whole blood	15 months	Store at 15–30°C	http://goo.gl/Hm03m5 http://goo.gl/5IVLdG	WHO, GF	WHO PQ, ROW	No support materials provided

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test per UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ Link	Eligibility criteria	Regulatory status	Comment
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick (for assay with catalogue no. 90-1021), venous blood, serum, plasma						For venous whole blood and plasma specimens, use tubes containing EDTA. For fingerstick specimens, no anticoagulant required
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000	1							For use with INSTI™ HIV-1/ HIV-2 Antibody Test without support materials (catalogue no. 90-1021)
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
552	INSTI™ HIV-1/HIV-2/ HIV-Negative Controls	90-1031	R	Kit	60 tests/ control/ kit	1000	17	N/A	12 months	Store at ≤20°C			ROW	Kit includes HIV-1 positive (3 vials x 0.4 ml), HIV-2 positive (12 vials x 0.4 ml), and HIV-negative control (12 vials x 0.4 ml). Each vial is sufficient for 20 tests
									28 days once thawed	Store at 2–8°C				

HIV RDT: MULTISPOT HIV-1/ HIV-2 RAPID TEST, BIO-RAD LABORATORIES

Multispot HIV-1/HIV-2 Rapid Test is a single-use qualitative immunoassay to detect and differentiate circulating antibodies to HIV-1 and HIV-2 in fresh or frozen human serum and plasma. This rapid HIV-1/HIV-2 test kit is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in fresh or frozen human serum or plasma. This test is suitable for use in multi-test algorithms designed for statistical validation of an HIV screening test result or as part of an HIV-1/HIV-2 diagnostic testing algorithm that includes differentiation of HIV-1 and HIV-2 antibodies. Time to result ~15 minutes. Sensitivity: 100% (95% confidence interval 99.94–100.00%) for antibodies to HIV-1; 100% (95% confidence interval 99.76–100%) for antibodies to HIV-2. Specificity 99.93% (95% confidence interval 99.79–100.00%) for serum specimens; 99.91% (95% confidence interval 99.77–100.00%) for plasma specimens. (Source: Multispot HIV-1/HIV-2 Rapid Test manufacturer's package insert http://goo.gl/qoOD6y) Commodities for specimen collection and transfer are not provided.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes containing EDTA, sodium citrate, sodium heparin and SST
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								For plasma specimens, use tubes containing EDTA, sodium citrate, sodium heparin and SST
342	Paper towels	Generic	C	1 Pack		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000								
377	Tubes, test, 12 mm × 75 mm, with caps	Generic	C	1000 tubes/ case		1000								Use glass or polypropylene test tubes (do not use polystyrene)
408	Rack, test tubes, 14 mm diameter	Generic	D	1 unit		1000								
41	Pipette/pipettor 200	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
531	Sodium hypochlorite solution (0.5%)	Generic	R			1000								

HIV RDT: ORAQUICK ADVANCE® HIV-1/2 RAPID ANTIBODY TEST, ORASURE TECHNOLOGIES INC.

OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is a single-use, qualitative immunoassay for detection of antibodies to HIV-1 and HIV-2 in oral fluid, plasma, fingerstick or venepuncture whole blood. OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple tests are available, this test should be used in appropriate multi-test algorithms. Time to result 20 to 40 minutes.
Oral fluid:
Sensitivity 99.3% (95% confidence interval 98.4–99.7%) for HIV-1; 100% (95% confidence interval 98.2–100%) for HIV-2. Specificity 99.8% (95% confidence interval 99.6–99.9%). Commodities for collection and testing of oral fluid specimens are provided in the kit.
Plasma:
Sensitivity 99.6% (95% confidence interval 98.9–99.8%) for HIV-1; 100% (95% confidence interval 98.2–100%) for HIV-2. Specificity 99.9% (95% confidence interval 99.6–99.9%). Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for venous whole blood, plasma, and serum specimen transfer are included in the kit.
Fingerstick:
Sensitivity 99.6% (95% confidence interval 98.5–99.9%) for HIV-1; 100% (95% confidence interval 98.2–100%) for HIV-2. Specificity 100% (95% confidence interval 99.7–100%). Only sample loops for fingerstick specimen collection and transfer are included in the kit. Other commodities for fingerstick specimen collection need to be purchased separately.
OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is sold in 2 sizes: 25 tests per kit and 100 tests per kit.
(Source of information: OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test manufacturer's package insert http://goo.gl/lTViSM)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
655	OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test	1001-0079	B	25 tests/kit	25	1000	40	Oral fluid, plasma, fingerstick and venous whole blood	30 months	Store at 2–27°C	http://goo.gl/lTViSM http://goo.gl/OYfqop	USAID	FDA approved	Includes 25 specimen collection loops for collection of fingerstick whole blood or transfer of venous whole blood, plasma and serum specimens. Flat pad for oral fluid specimen collection is integrated in testing device
		1001-0078		100 tests/ kit	100		10							Includes 100 specimen collection loops for collection of fingerstick whole blood or transfer of venous whole blood, plasma and serum specimens. Flat pad for oral fluid specimen collection is integrated in testing device

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous whole blood, plasma						For venous whole blood specimens, use tubes containing EDTA, sodium citrate, sodium heparin. For plasma specimens, use tubes containing EDTA. For fingerstick specimen, use specimen collection loops (provided).
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
571	OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls	1001-0077	R	3 vials/kit		1000			12 months	Store at 2–8°C	http://goo.gl/vb6h1F http://goo.gl/OYfqop		FDA approved	1 x 0.2 ml HIV-1 positive control, 1 x 0.2 ml HIV-2 positive control, and 1 x 0.2 ml negative control

HIV RDT: ORAQUICK RAPID HIV-1/2 ANTIBODY TEST, ORASURE TECHNOLOGIES INC.

The OraQuick Rapid HIV-1/2 Antibody Test is a visually read, qualitative immunochromatographic assay for detection of antibodies to HIV-1 and HIV-2 in oral fluid, plasma, serum, fingerstick or venepuncture whole blood. Time to result 20 to 40 minutes. Initial sensitivity 100%; final specificity 99.2% (Source: List of diagnostics eligible to tender for procurement by WHO in 2014 http://goo.gl/3ixDCe).
Oral fluid:
Commodities for collection and testing of oral fluid specimens are provided in the kit.
Venous whole blood, plasma, serum:
Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit in limited amount.*
Fingerstick:
Sample loops for fingerstick specimen collection and transfer are included in the kit in limited amount.* Other commodities for fingerstick specimen collection need to be purchased separately.*

* OraQuick Rapid HIV-1/2 Antibody Test is marketed in 2 configurations: 100 tests per kit and 500 tests per kit.
100 tests/kit assay with catalogue no.5X4-0010 includes 5 specimen collection loops
500 tests/kit assay with catalogue no. 5X4-0012 includes 25 specimen collection loops
(Source of information: OraQuick Rapid HIV-1/2 Antibody Test manufacturer's package insert http://goo.gl/GFkEph)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
218	OraQuick Rapid HIV-1/2 Antibody Test	5X4-0010	B	100 tests/ kit	100	1000	10	Oral fluid, plasma, fingerstick and venous whole blood	30 months	Store at 2–30°C	http://goo.gl/GFkEph	WHO, GF, USAID	ROW	Includes 5 specimen collection loops for collection of fingerstick whole blood or transfer of venous whole blood, plasma, and serum specimens. Flat pad for oral fluid specimen collection is integrated in testing device
		5X4-0012		500 tests/ kit	500		2							Includes 25 specimen collection loops for collection of fingerstick whole blood or transfer of venous whole blood, plasma, and serum specimens. Flat pad for oral fluid specimen collection is integrated in testing device

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous whole blood, serum, plasma						No specific anticoagulant required
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000								
654	Loop	1001-0144	C	5/pack	5	1000	200							Provided by manufacturer free of charge at point of order
		1001-0145		25/pack	25		40							
353	Pipette tip, 0.5–10 µl	Generic	C	1000 tips/ pack		1000								Optional; can be used for specimen collection in lieu of loops
556	Pipette/ pipettor 10	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
571	OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls	1001-0077	R	3 vials/kit		1000			12 months	Store at 2–8°C	http://goo.gl/vb6h1F http://goo.gl/OYfqop		FDA approved	1 x 0.2 ml HIV-1 positive control, 1 x 0.2 ml HIV-2 positive control, and 1 x 0.2 ml negative control

HIV RDT: REVEAL® G3 RAPID HIV-1 ANTIBODY TEST (REVEAL G3), MEDMIRA LABORATORIES INC.

Reveal® G3 Rapid HIV-1 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to HIV-1 in human serum or plasma. Reveal® G3 Rapid HIV-1 Antibody Test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple rapid tests are available, this test should be used in appropriate multi-test algorithms. Time to result 1 to 2 minutes. Sensitivity 99.8% (95% confidence interval 99.2–100%) for serum specimens; 99.8% (95% confidence interval; 99.0–100%) for plasma specimens. Specificity 99.1% (95% Confidence Interval; 98.8–99.4%) for serum specimens; 98.6% (95% Confidence Interval; 98.4–98.8%) for plasma specimens.
Commodities for specimen collection are not provided. Commodities for specimen transfer are included in the kit.
(Source: Reveal G3 Rapid HIV-1 Antibody Test (Reveal G3) manufacturer's package insert http://goo.gl/TB1d5H)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
555	Reveal G3 Rapid HIV-1 Antibody Test (Reveal G3)	815311000591	B	30 tests/ kit	30	1000	34	Serum, Plasma	12 months	Store at 2–30°C	http://goo.gl/TB1d5H	USAID	FDA approved	Kit includes positive and negative test controls; disposable pipettes for specimen transfer
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes containing EDTA, heparin, or sodium citrate
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves / box		1000								
531	Sodium hypochlorite solution (0.5%)	Generic	R			1000								
237, 238, 239	Bag, biohazard wastes	Generic	C	100 bags/ pack		1000								
494	Liquid waste container with cap	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								

HIV RDT: RIGHTSIGN® HIV-1.2.O RAPID TEST CASSETTE, HANGZHOU BIOTEST BIOTECH CO. LTD.

The HIV-1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to human immunodeficiency virus (HIV) type 1, type 2 and subtype O in whole blood, serum or plasma to aid in the diagnosis of HIV infection. Time to result 10 to 20 minutes. Sensitivity >99.9% (95% confidence interval 99.5–100.0%); specificity 99.5% (95% confidence interval 99.0–99.8%).
Commodities for collection and transfer of fingerstick specimen are not provided.
Commodities for collection of venous whole blood, plasma, serum specimens are not provided. Commodities for transfer of venous whole blood, serum, plasma specimens are included in the kit.
(Source: RightSign HIV-1.2.O Rapid Test Cassette manufacturer's package insert http://goo.gl/r9jq67)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
572	RightSign□ HIV-1.2.O Rapid Test Cassette	IHIV-C42	B	25 tests/kit	25	1000	40	Serum, plasma, fingerstick and venous whole blood		Store at 2–30°C	http://goo.gl/r9jq67	USAID	CE marked	Kit includes droppers for transfer of venous whole blood, serum, plasma specimens
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous blood, serum, plasma						Use heparinized capillary tubes for fingerstick specimens
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: SD BIOLINE HIV-1/2 3.0, STANDARD DIAGNOSTICS, INC.

SD BIOLINE HIV-1/2 3.0 kit is a rapid, qualitative test for the detection of antibodies to certain isotypes (IgG, IgM, IgA) specific to HIV-1 including subtype O and HIV-2 simultaneously in human serum, plasma or whole blood. SD BIOLINE HIV-1/2 3.0 is intended as an aid in the diagnosis of infection with HIV-1/2. Time to result 10 to 20 minutes. Initial sensitivity 99.8% (95% confidence interval 98.8–100%), final specificity 99.9% (95% confidence interval 99.2–100%) (Source: WHO PQ report for SD Bioline HIV-1/2 3.0 (PQDx 0027-012-00) http://goo.gl/Ps5HKQ).
SD Bioline HIV-1/2 3.0 is marketed in 2 configurations: 30 tests/kit (catalogue no. 03FK10), does not include commodities for specimen collection and transfer. 25 tests/kit (catalogue no. 03FK16), includes commodities for fingerstick specimen collection and transfer

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
565	SD Bioline HIV-1/2 3.0	03FK10	B	30 tests/kit	30	1000	34	Serum, plasma, capillary and venous whole blood	24 months	Store at 1–30°C	http://goo.gl/69jk8A http://goo.gl/Ps5HKQ	WHO, GF, USAID	WHO PQ, ROW	Blood collection accessories and capillary pipettes are not included
		03FK16	B	25 tests/kit	25	1000	40							Kit contains 25 x capillary pipettes, 25 x lancets, 25 x alcohol swabs
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Venous blood, capillary blood (for 30 test/ kit version with cat no. 03FK10), serum, plasma						For venous whole blood and plasma specimens, use tubes containing EDTA, heparin, or sodium citrate. No anticoagulant required for capillary whole blood specimens
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000	96	1000	1							For venous whole blood, plasma, and serum specimens
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								For venous whole blood, plasma, and serum specimens
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: SD BIOLINE HIV AG/AB COMBO, STANDARD DIAGNOSTICS, INC.

SD BIOLINE HIV Ag/Ab Combo test kit is a rapid, qualitative test for the detection of HIV-1 p24 antigen and antibodies to certain isotypes (IgG, IgM and IgA) specific to HIV-1 including subtype O and/or HIV-2 simultaneously in human serum, plasma or whole blood. Time to result 20 to 30 minutes. Initial sensitivity 100% (95% confidence interval 99.1–100%), final specificity 99.1% (95% confidence interval 98.0–99.7%). (Source: WHO PQ report for SD Bioline HIV Ag/Ab Combo (PQDx 0069-012-00) http://goo.gl/hPoZb1).
SD Bioline HIV Ag/Ab Combo is marketed in 2 configurations:
30 tests/kit (catalogue no. 03FK30), does not include commodities for specimen collection and transfer.
25 tests/kit (catalogue no. 03FK35), includes commodities for fingerstick specimen collection and transfer.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
561	SD Bioline HIV Ag/Ab Combo	03FK30	B	30 tests/ kit	30	1000	34	Serum, plasma, capillary and venous whole blood	18 months	Store at 1–30°C	http://goo.gl/1ocoIs http://goo.gl/hPoZb1	WHO, GF, USAID	WHO PQ, ROW	Blood collection accessories and capillary pipettes are not included
		03FK35	B	25 tests /kit	25	1000	40							Kit contains 25 x capillary pipettes, 25 x lancets, 25 x alcohol swabs
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Capillary (for 30 test kit with cat no. 03FK30), venous blood, serum, plasma						For venous whole blood and plasma specimens, use tubes containing EDTA, heparin, or sodium citrate. No anticoagulant required for capillary whole blood specimens
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves / box		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							For venous whole blood, plasma, and serum specimens
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								For venous whole blood, plasma, and serum specimens
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: SIGNAL® HIV, SPAN DIAGNOSTICS LTD.

Signal® HIV is a flow-through immuno-dot test format for detection of antibodies to HIV-1 and HIV-2 in human serum / plasma. Signal® HIV detects all major subtypes of HIV-1 including group M-subtypes A, B, C and group O. Time to result 10 minutes. Sensitivity 100%, specificity 100% (determined by testing cocktail of highly purified recombinant antigens comprising of immunodominant region of envelope antigens gp120, gp41, and gp36 for both HIV-1 and HIV-2) (Source: Signal® HIV manufacturer's product brochure http://goo.gl/MqZLB7).
Commodities for specimen collection and transfer are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
557	Signal® HIV	51FT100-10	B	10 tests/ kit	10	1000	100	Serum or plasma	15 months	Store at 2–8°C	http://goo.gl/ MqZLB7	USAID	ROW	
		51FT100-50		50 tests/ kit	50		20							
		51FT100-60		100 tests/ kit	100		10							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: SURE CHECK® HIV-1/2 ASSAY, CHEMBIO DIAGNOSTIC SYSTEMS, INC.

SURE CHECK® HIV-1/2 Assay is a single-use immunochromatographic test for the detection of antibodies to HIV-1 and HIV-2 in fingerstick whole blood, venous whole blood, and serum or plasma specimens. SURE CHECK® HIV-1/2 Assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms. Time to result 15 to 20 minutes. Initial sensitivity 99.8% (95% confidence interval 98.8–100%), final specificity 99.9% (95% confidence interval 99.2–100%) (Source: WHO PQ public report for SURE CHECK® HIV-1/2 Assay (PQDx 0054-006-00) http://goo.gl/Mtv9K0). Commodities for collection and transfer of fingerstick specimens are included in the kit. Commodities for collection and transfer of venous whole blood, plasma, and serum samples are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
564	SURE CHECK® HIV-1/2 Assay	HIV201 (60-9527-0)	B	25 tests/ kit	25	1000	40	Serum, plasma, venous or fingerstick whole blood	24 months	Store at 8–30°C	http://goo.gl/J19Tgr http://goo.gl/Mtv9K0	WHO, GF	WHO PQ	Kit includes commodities for collection and transfer of fingerstick specimens. Product code HIV201 cross referenced to product code 60-9527-0; both codes represent the same product
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Venous blood, serum, plasma						For venous whole blood and plasma specimens, use tubes containing EDTA, heparin, or citrate
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves / box		1000								
556	Pipette/ pipettor 10	Generic	E	1unit		1000								For specimens other than fingerstick whole blood
353	Pipette tip, 0.5–10 µl	Generic	C	1000 tips/ pack	1000	1000	1							
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
562	Rapid HIV-1/2 Antibody Test Kit Controls	HIV104	R	50 tests/ each control/ package	50 tests/ control	1000	20		24	Store at 2–8°C			ROW	Available from manufacturer as accessory; non-WHO PQ; Contains 1 HIV-1 reactive control 0.25 ml, 1 HIV-2 reactive control 0.25 ml, 1 HIV nonreactive control 0.5 ml

HIV RDT: UNI-GOLD™ HIV, TRINITY BIOTECH PLC

Uni-Gold™ HIV test is a single reagent assay for the detection of antibodies to human immunodeficiency virus types 1 and 2 in serum, plasma or whole blood. Time to result 10 to 20 minutes. Initial sensitivity 99.76% (95% confidence interval 98.7–100%), final specificity 99.85% (95% confidence interval 99.2–100%) (Source: WHO PQ report for Uni-Gold™ HIV (PQDx 0149-052-00) http://goo.gl/IOEV6B).
Fingerstick:
Disposable pipettes for fingerstick specimen collection and transfer are included in the kit. Other commodities for fingerstick specimen collection need to be purchased separately.
Venous whole blood. Serum, plasma:
Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
229	Uni-Gold™ HIV	1206502	B	20 tests/ kit	20	1000	50	Serum, plasma, fingerstick and venous whole blood	12 months	Store at 2–27°C	http://goo.gl/IOEV6B	WHO, GF, USAID	WHO PQ, ROW	Kit includes 20 disposable pipettes
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous blood, serum, plasma						
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

HIV RDT: UNI-GOLD™ RECOMBIGEN® HIV, TRINITY BIOTECH PLC

Uni-Gold™ Recombigen® HIV-1/2 is a single-use rapid immunoassay, for the qualitative detection of antibodies to HIV-1 and/or HIV-2 in serum, plasma and whole blood (venepuncture and fingerstick). Uni-Gold™ Recombigen® HIV-1/2 is intended for use in point-of-care settings as an aid in diagnosis of infection with HIV-1 and/or HIV-2. Time to result 10 to 12 minutes. Sensitivity 100% (95% confidence interval 99.5-100.0%) for HIV-1; 99.3% (95% confidence interval 97.1-99.9%) for HIV-2. Specificity 99.7% (95% Confidence interval 99.0-100%) for serum, 99.8% (95% Confidence interval 99.2-100%) for plasma, and 99.8% (95% Confidence interval 99.2-100%) for whole blood in high risk population. (Source: Uni-Gold™ Recombigen® HIV manufacturer's package insert http://goo.gl/KZ1WoX)
Fingerstick:
Disposable pipettes for fingerstick specimen collection and transfer are included in the kit. Other commodities for fingerstick specimen collection need to be purchased separately.
Venous whole blood. Serum, plasma:
Commodities for collection of venous whole blood, plasma, and serum specimens are not included in the kit. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
558	Uni-Gold™ Recombigen® HIV	1206506	B	20 tests/kit	20	1000	50	Serum, plasma, fingerstick and venous whole blood	12 months	Store at 2–27°C	http://goo.gl/KZ1WoX	USAID	FDA approved	Kit includes 20 disposable pipettes for use with serum, plasma or venous whole blood, and controls; 20 disposable fingerstick sample collection and transfer pipettes for use with fingerstick whole blood
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous blood, serum, plasma						For venous whole blood and plasma specimens, use tubes containing EDTA, acid citrate dextran (ACD), or heparin

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit	1	1000								
3 – Control														
559	Uni-Gold™ Recombigen® HIV Controls Kit	1206530	R	3 controls x 500 µl/vial		1000	10		Unknown	Store at 2–8°C	http://goo.gl/KZ1WoX			Kit includes 1 vial with HIV-1 positive, 1 vial with HIV-2 positive, and one vial with HIV-negative controls

HIV RDT: VIKIA HIV-1/2, BIOMÉRIEUX

VIKIA HIV-1/2 is an immunochromatographic test for the qualitative detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. Time to result 30 minutes. Initial sensitivity 99.4% (95% confidence interval 98.1–99.9%), final specificity 99.9% (95% confidence interval 99.2–100%) (Source: WHO PQ public report for VIKIA HIV-1/2 (PQDx 0150-016-00) http://goo.gl/NrB3Up).
Fingerstick: Commodities for collection and transfer of fingerstick specimens are not provided.
Venous whole blood. Serum, plasma:
Commodities for collection of venous whole blood, plasma, and serum specimens are not provided. Commodities for transfer of venous whole blood, plasma, and serum specimen are included in the kit.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
573	VIKIA HIV-1/2	31112	B	25 tests/ kit	25	1000	40	Serum, plasma, fingerstick and venous whole blood	21 months	Store at 4–30°C	http://goo.gl/4sPNqN	WHO, GF	WHO PQ, CE marked	Disposable droppers for transfer of venous whole blood, plasma, or serum specimens
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous blood, serum, plasma						For venous whole blood and plasma specimens, use tubes containing EDTA, sodium citrate, or lithium heparin. For fingerstick whole blood specimen, use 75 µl heparinized capillary tubes
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves / box		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

10.3 SECTION IC: HIV EIA

HIV EIA: BIOELISA HIV-1+2 AG/AB, BIOKIT SA.

bioelisa HIV-1+2 Ag/Ab is ELISA test for the detection of antibodies to HIV-1 (group M, O) or HIV-2 and HIV-p24 antigen in human serum or plasma samples in clinical laboratories and as a first-line screening assay in blood centres. Initial sensitivity is 100% (95% CI 99.2–100%); final specificity is 99.4% (95% CI 98.4–99.8%) (Source: WHO PQ public report for bioelisa HIV-1+2 Ag/Ab (PQDx 0183-060-00) http://goo.gl/nkUvaW).
Commodities for specimen collection and transfer are not provided.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
574	bioelisa HIV-1+2 Ag/Ab	3000-1172	B	1 x 96 tests/kit	96	1000	11	Serum, plasma	9 months	Store at 2–8°C	http://goo.gl/nkUvaW	WHO, GF	CE marked, WHO PQ	Negative, HIV-1 positive, HIV-2 positive, and HIV-1 p24 positive controls are included in the kit
		3000-1173		5 x 96 tests/kit	480		3							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with EDTA, ACD, lithium heparin, sodium heparin, or sodium citrate
107	Water, distilled	Generic	R			1000								
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
342	Paper towels	Generic	C	1 pack		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000								
347	Pipette tip, 100–1000 µl	Generic	C	1000 tips/ pack		1000								
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
42	Pipette/ pipettor 1000	Generic	E	1 unit		1000								
361	Reagent reservoirs for ELISA	Generic	C	pack		1000								Pack size varies depending upon manufacturer
389	Bottle, dispensing/ wash	Generic	D	1 unit		1000								
394	Graduated cylinder, 1000 ml	Generic	D	1 unit		1000								
592	Graduated cylinder, 25 ml	Generic	D	1 unit		1000								
30	Incubator, general purpose	Generic	E	1 unit		1000	1							
32	Microplate/ ELISA plate reader	Generic	E	1 unit		1000	1							450 nm filter is required; reference filter of 620 nm or 630 nm is advisable
33	Microplate/ ELISA plate washer	Generic	E	1 unit		1000	1							
46	Timer, digital	Generic	E	1 unit		1000								
494	Liquid waste container with cap	Generic	D	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								

HIV EIA: ELECSYS® HIV COMBI PT, ROCHE DIAGNOSTICS

Immunoassay for the in vitro qualitative determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 in human serum and plasma. This assay is indicated as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. This assay is also indicated in testing serum or plasma specimens to screen individual organ donors when specimens are obtained while the donor's heart is still beating. The assay does not discriminate among HIV-1 antibody, HIV-2 antibody, or HIV p24 antigen reactivity. The electrochemiluminescenceimmunoassay "ECLIA" is intended for use on Elecsys and COBAS immunoassay analysers. Total duration of assay: 27 minutes. Sensitivity 100%, specificity 99.81% (Source: Elecsys® HIV Combi PT manufacturer's package insert http://goo.gl/6zZpi1).
Commodities for specimen collection and transfer are not provided.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
575	Elecsys® HIV Combi PT	05390095190	B	100 tests/ kit	100	1000	10	Serum, plasma	5 months	Store at 2–8°C	http://goo.gl/3tHxmG http://goo.gl/6zZpi1	GF	TGA (ARTG listed)	For use with COBAS® modular platform (COBAS e 411, COBAS e 601, COBAS e 602); MODULAR®ANALYTICS E 170; Elecsys® 2010 analyser
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with lithium heparin, K2-EDTA and K3-EDTA
576	CalSet vials	11776576322	C	2 x 56 bottles/ case	112	1000	1							
107	Water, distilled	Generic	R			1000								
577	ProCell	11662988122	R	6 x 380 ml / case		1000								For Elecsys 2010 and COBAS e 411 analysers
578	CleanCell	11662970122	R	6 x 380 ml/ case		1000								
579	Elecsys SysWash	11930346122	R	500 ml / bottle		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
580	Adaptor for SysClean	11933159001	C	1 unit		1000								For Elecsys 2010 and COBAS e 411 analysers
581	Elecsys 2010 AssayCup	11706802001	C	60 x 60 vessels / case		1000								
582	Elecsys 2010 AssayTip	11706799001	C	30 x 120 tips/case		1000								
582	Elecsys 2010 AssayTip	11706799001	C	30 x 120 tips/case		1000								
583	ProCell M	04880340190	R	2 x 2 L / case		1000								For MODULAR ANALYTICS E170, COBAS e 601 and COBAS e 602 analysers
584	CleanCell M	04880293190	R	2 x 2 L / case		1000								
585	PC/CC-Cups	03023141001	C	12 cups / Pack		1000								
586	ProbeWash M	03005712190	R	12 x 70 ml/ case		1000								
587	PreClean M	03004899190	R	5 x 600 ml / case		1000								
588	AssayTip/AssayCup Combimagazine M	12102137001	C	48 magazines x 84 reaction vessels or pipette tips, waste bags /case		1000								
589	WasteLiner	03023150001	C	Pack		1000								
590	SysClean Adaptor M	03027651001	C	1 unit		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
3 – Control														
591	ElecsysR PreciControl HIV	05162645190	R	3 x 2 x 2 ml / kit		1000			Unknown	Store at 2–8°C				Kit includes 2 x 2 ml each of PreciControl HIV-1, 2, and 3

HIV EIA: GENSCREEN™ ULTRA HIV AG-AB, BIO-RAD LABORATORIES

Genscreen™ ULTRA HIV Ag-Ab is a qualitative enzyme immunoassay kit for the detection of HIV p24 antigen and antibodies to HIV-1 (groups M and O) and HIV-2 in human serum or plasma. This kit can be used for both HIV Ag and HIV Ab screening. Initial sensitivity 100% (95% confidence interval 99.2% - 100%); final specificity 99.24% (95% confidence interval 98.2% - 99.8%) (Source: WHO PQ report for Genscreen™ ULTRA HIV Ag-Ab (PQDx 0096-031-00) http://goo.gl/s5zShW)
Commodities for specimen collection and transfer are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
563	Genscreen™ ULTRA HIV Ag-Ab	72386	B	1 plate – 96 tests/kit	96	1000	11	Serum, plasma	18 months	Store at 2–8°C	http://gssh.co/15E90dq http://goo.gl/s5zShW	WHO, GF	CE marked, WHO PQ	Positive and negative controls are included; 3 controls required for each test batch, with negative control in triplicate; therefore, each batch will include 5 controls
		72388		5 plates – 480 tests/kit	480		3							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with EDTA, heparin, citrate, ACD-based anticoagulants
107	Water, distilled	Generic	R			1000								
106	Sodium hypochlorite solution (5–10%)	Generic	R	1 L/bottle		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
342	Paper towels	Generic	C	1 pack		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								
361	Reagent reservoirs for ELISA	Generic	C	pack		1000								Pack size varies depending upon manufacturer
389	Bottle, dispensing/ wash	Generic	D	1 unit		1000								
394	Graduated cylinder, 1000 ml	Generic	D	1 unit		1000								
395	Graduated cylinder, 100 ml	Generic	D	1 unit		1000								
592	Graduated cylinder, 25 ml	Generic	D	1 unit		1000								
30	Incubator, general purpose	Generic	E	1 unit		1000	1							
32	Microplate/ ELISA plate reader	Generic	E	1 unit		1000	1							450 nm, 490 nm and 620–700 nm filters required
33	Microplate/ ELISA plate washer	Generic	E	1 unit		1000	1							

HIV EIA: GENSCREEN™ HIV-1/2 VERSION 2, BIO-RAD LABORATORIES

Genscreen™ HIV-1/2 Version 2 is a qualitative enzyme immunoassay for detection of antibodies to HIV-1 and HIV-2 in human serum or plasma. Sensitivity 100% for HIV-1 and HIV-2; specificity 99.98% (blood bank donors) (Source: Genscreen™ HIV-1/2 Version 2 manufacturer's package insert http://goo.gl/IJf5hR).
Commodities for specimen collection and transfer are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
594	Genscreen™ HIV-1/2 Version 2	72278	B	1 plate – 96 tests/kit	96	1000	11	Serum, plasma	18 months	Store at 2–8°C	http://goo.gl/IJf5hR	GF	CE marked	Negative, positive, and cut-off controls are included; 3 controls required for each test batch, with cut-off control in triplicate; therefore, each batch will include 5 controls;
		72279		5 plates – 480 tests/kit	480		3							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with EDTA, heparin, citrate, ACD-based anticoagulants
107	Water, distilled	Generic	R			1000								
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
342	Paper towels	Generic	C	1 Pack		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								
361	Reagent reservoirs for ELISA	Generic	C	1 pack		1000								Pack size varies depending upon manufacturer
389	Bottle, dispensing/ wash	Generic	D	1 unit		1000								
394	Graduated cylinder, 1000 ml	Generic	D	1 unit		1000								
395	Graduated cylinder, 100 ml	Generic	D	1 unit		1000								
592	Graduated cylinder, 25 ml,	Generic	D	1 unit		1000								
30	Incubator, general purpose	Generic	E	1 unit		1000								
32	Microplate/ ELISA plate reader	Generic	E	1 unit		1000								450 nm and 620–700 nm filters required
33	Microplate/ ELISA plate washer	Generic	E	1 unit		1000								

HIV EIA: GS HIV COMBO AG/AB EIA, BIO-RAD LABORATORIES

GS HIV Combo Ag/Ab EIA is an enzyme immunoassay for the simultaneous detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2 in human serum or plasma. Sensitivity 100% (95% confidence interval 99.70% -100%) for HIV-1 known positive population; 100% (95% confidence interval 98.11% - 100%) for HIV-2 known positive population. Specificity 99.87% (95% confidence interval 99.76% - 99.93%) for low risk population; 99.75% (95% confidence interval 98.60% - 99.96%) for low risk paediatric population (Source: GS HIV Combo Ag/Ab EIA manufacturer's package insert http://goo.gl/K37Gk1).
Commodities for specimen collection and transfer are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
595	GS HIV Combo Ag/Ab EIA	26217	B	192 tests/ kit	192	1000	6	Serum, plasma	18 months	Store at 2–8°C	http://goo.gl/K37Gk1	GF	FDA approved	Can be used with generic microplate reader and washer; approved for use with the EVOLIS™ Automated Microplate System. Controls are included; 7 controls must be run on each plate
		26218		960 tests/ kit	960		2							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with potassium EDTA, sodium citrate, sodium and lithium heparin
107	Water, distilled	Generic	R			1000								
596	Wash solution concentrate	25261	R	120 ml/ bottle		1000				Store at 2–8°C				For product code 26218 (960 tests)
597	Stopping solution	25260	R	120 ml/ bottle		1000				Store at 2-8°C				
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
342	Paper towels	Generic	C	1 pack		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000								
347	Pipette tip, 100–1000 µl	Generic	C	1000 tips/ pack		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								
42	Pipette/ pipettor 1000	Generic	E	1 unit		1000								
359	Pipette, serological, 10.0 ml	Generic	C	200/case		1000								
530	Pipette, serological, 25.0 ml	Generic	C	200/case		1000								
598	Pipette, serological, 50.0 ml	Generic	C	100/case		1000								
599	Container, polypropylene, 5 ml	Generic	C	1 pack		1000								For preparation of Working TMB Solution (do not use polystyrene)
361	Reagent reservoirs for ELISA	Generic	C	1 pack		1000								Pack size varies depending upon manufacturer
389	Bottle, dispensing/ wash	Generic	D	1 unit		1000								
394	Graduated cylinder, 1000 ml	Generic	D	1 unit		1000								
395	Graduated cylinder, 100 ml	Generic	D	1 unit		1000								
592	Graduated cylinder, 25 ml	Generic	D	1 unit		1000								
30	Incubator, general purpose	Generic	E	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
32	Microplate/ ELISA plate reader	Generic	E	1 unit		1000								450 nm and 615–630 nm filters required
33	Microplate/ ELISA plate washer	Generic	E	1 unit		1000								Must be capable of dispensing 400 µL per well, cycling five times, and soaking for 30–60 sec between each wash
600	EVOLIS™ System	89700	E	1 unit		1000								Automated microplate processor, an alternative to combination of generic microplate reader and washer

HIV EIA: LIAISON® XL MUREX HIV AB /AG, DIASORIN S.P.A.

LIAISON® XL MUREX HIV Ab / Ag assay uses chemiluminescence immunoassay (CLIA) technology for the combined qualitative determination of p24 antigen of human immunodeficiency virus type 1 (HIV-1) and specific antibodies to both human immunodeficiency virus type 1 (group M and group O) and/or human immunodeficiency virus type 2 (HIV-2) in human serum or plasma samples. The test has to be performed on the LIAISON® XL analysers only. Sensitivity 100% (95% confidence interval 99.44% - 100%), specificity 99.5% (95% confidence interval 99.49% - 99.82%) (Source: LIAISON® XL MUREX HIV Ab / Ag manufacturer's package insert http://goo.gl/5U4rfc).
Commodities for specimen collection and transfer are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/l ink	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
601	LIAISON® XL MUREX HIV Ab / Ag	310260	B	200 tests/Kit	200	1000	5	Serum, plasma	18 months	Store at 2–8°C	http://goo.gl/5U4rfc	GF	CE marked	For use with dedicated LIAISON® XL instrument
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with sodium citrate, potassium EDTA, lithium and sodium heparin, potassium oxalate, ACD, or CPDA (citrate-phosphate-dextrose-adenine)
602	LIAISON® XL platform	I0050	E	1 unit		1000								
603	LIAISON® XL Cuvettes	X0016	C	7200/box		1000								
604	LIAISON® XL Disposable Tips	X0015	C	6912/box		1000								
605	LIAISON® XL Starter Kit	319200	C	3000 tests/kit		1000								
606	LIAISON® XL Wash/System Liquid	319100	R	6 vials/box		1000								
607	LIAISON® XL Waste Bag	X0025	C	50 bags/box		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/l ink	Eligibility criteria	Regulatory status	Comment
3 – Control														
608	LIAISON® XL murex Control HIV Ab/Ag (neg & pos)	310261	R	2 x 2.5 ml negative control; 1 x 2.5 ml HIV-positive control; 1 x 2.5 ml HIV Ag positive control/kit		1000			24 months	Store at 2–8°C			CE marked	For use with LIAISON® XL Murex HIV Ag/Ab assay

HIV EIA: MUREX HIV – 1.2.O, DIASORIN S.P.A.

Enzyme immunoassay for the detection of antibodies to human immunodeficiency virus types 1 (HIV-1, HIV-1 group O) and 2 (HIV-2) in human serum or plasma. The assay is intended to screen individual human donors for the presence of antibodies to HIV-1, including group O, and HIV-2 or as an aid to the diagnosis of HIV infection. Specificity 99.91% (95% confidence interval 99.82% - 99.97%) for blood donor samples; 100% (95% confidence interval 99.75% - 100%) for clinical samples (Source: Murex HIV – 1.2.O manufacturer's package insert http://goo.gl/nMt6Al). Commodities for specimen collection and transfer are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
609	Murex HIV – 1.2.O	9E25-01	B	1 plate – 96 tests/ kit	96	1000	11	Serum, plasma	12 months	Store at 2–8°C	http://goo.gl/nMt6Al	GF	CE marked	Can be used in manual, semi-automated or automated way. Controls included; 5 controls must be run on each plate; therefore, 96 tests include control runs
		9E25-02		5 plates – 480 tests/kit	480		3							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with citrate or EDTA
611	Stop solution (1N sulphuric acid)	N0164	R	15 x 60 ml /case		1000		N/A	24 months	Store at ambient temperature				Alternatively, analytical grade concentrated sulphuric acid (18.0M can be used for in-house preparation of stop solutions
612	Stop solution (1N sulphuric acid)	N0165	R	60 ml/vial		1000		N/A	24 months	Store at ambient temperature				
107	Water, distilled	Generic	R			1000								
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
342	Paper towels	Generic	C	1 pack		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							
347	Pipette tip, 100–1000 µl	Generic	C	1000 tips/ pack	1000	1000	1							
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								
42	Pipette/ pipettor 1000	Generic	E	1 unit		1000								
361	Reagent reservoirs for ELISA	Generic	C	1 pack		1000								Pack size varies depending upon manufacturer
389	Bottle, dispensing/ wash	Generic	D	1 unit		1000								
30	Incubator, general purpose	Generic	E	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
32	Microplate/ ELISA plate reader	Generic	E	1 unit		1000								
33	Microplate/ ELISA plate washer	Generic	E	1 unit		1000								

HIV EIA: MUREX HIV AG/AB COMBINATION, DIASORIN DARTFORD

Murex HIV Ag/Ab Combination is an enzyme immunoassay for improved detection of seroconversion to human immunodeficiency virus types 1 (HIV-1, HIV-1 group O) and detection of anti-HIV-2 antibodies. The assay is intended to screen individual human donors for the presence of HIV p24 antigen and antibodies to HIV-1, including group O, and HIV-2 or as an aid to the diagnosis of HIV infection. Initial sensitivity 100% (95% confidence interval 99.2–100%), final specificity 99.7% (95% confidence interval 98.9–100%) (Source: WHO PQ public report for Murex HIV Ag/Ab Combination (PQDx 0144-043-00) http://goo.gl/hs6Msd).
Commodities for specimen collection and transfer are not provided.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package / link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
610	Murex HIV Ag/Ab Combination	7G79-09	B	1 plate – 96 tests/ kit	96 (	1000	11	Serum, plasma	12 months	Store at 2–8°C	http://goo.gl/hs6Msd	GF	WHO PQ, CE marked	Can be used in manual, semi-automated or automated way. Controls included; 6 controls must be run on each plate; therefore, 96 tests include control runs
		7G79-11		5 plates – 480 tests/ kit	480		3							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with citrate or EDTA
611	Stop solution (1N sulphuric acid)	N0164	R	15 x 60 ml /case		1000			24 months	Store at ambient temperature				Alternatively, analytical grade concentrated sulphuric acid (18.0M can be used for in-house preparation of stop solutions
612	Stop solution (1N sulphuric acid)	N0165	R	60 ml/vial		1000			24 months	Store at ambient temperature				
107	Water, distilled	Generic	R	N/A		1000								
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package / link	Eligibility criteria	Regulatory status	Comment
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							
347	Pipette tip, 100–1000 µl	Generic	C	1000 tips/ pack	1000	1000	1							
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								
42	Pipette/ pipettor 1000	Generic	E	1 unit		1000								
361	Reagent reservoirs for ELISA	Generic	C	1 pack		1000								Pack size varies depending upon manufacturer
389	Bottle, dispensing/ wash	Generic	D	1 unit		1000								
30	Incubator, general purpose	Generic	E	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
32	Microplate/ ELISA plate reader	Generic	E	1 unit		1000								
33	Microplate/ ELISA plate washer	Generic	E	1 unit		1000								

10.4 SECTION ID: HIV SUPPLEMENTAL ASSAYS

HIV SUPPLEMENTAL ASSAY: GEENIUS™ HIV-1/2 CONFIRMATORY ASSAY, BIO-RAD LABORATORIES

Geenius™ HIV-1/2 Confirmatory Assay is a single-use immunochromatographic test for the confirmation and differentiation of individual antibodies to HIV-1 and HIV-2 in fingerstick whole blood, venous whole blood, serum or plasma samples. The Geenius™ HIV-1/2 Confirmatory Assay is intended for use as an additional test to confirm the presence of antibodies to HIV-1 and HIV-2 for specimens found to be repeatedly reactive by screening procedures. Time to result 20 to 30 minutes. Sensitivity 100.0% (95% confidence interval 99.4–100%) for HIV-1; 100.0% (95% confidence interval 98.7–100%) for HIV-2. Specificity 100.0% (95% confidence interval 99.1-100%) for blood donors; 100.0% (95 % confidence interval 99.3–100%) for hospitalized patients; 100.0% (95% confidence interval 98.6–100.0%) for specimens with false-positive results by ELISA. (Source: Geenius™ HIV-1/2 confirmatory assay manufacturer's package insert http://goo.gl/vFRHGn)
Fingerstick:
Commodities for collection and transfer of fingerstick specimens are provided.
Venous whole blood, serum, plasma:
Commodities for collection and transfer of venous whole blood, plasma, and serum specimens are not provided.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
613	Geenius™ HIV-1/2 confirmatory assay	72460	B	20 tests/kit	20	1000	50	Serum, plasma, fingerstick and venous whole blood	18 months	Store at 2–30°C	http://goo.gl/vFRHGn	GF	CE marked	Includes 20 x 15 µl microtubes capillarity plastic pipettes for fingerstick protocol
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous blood, serum, plasma						For venous blood or plasma specimens, use tubes with citrate, heparin, or EDTA
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
556	Pipette/ pipettor 10	Generic	E	1unit		1000								
40	Pipette/ pipettor 20	Generic	E	1unit		1000								
353	Pipette tip, 0.5–10 µl	Generic	C	96 tips /box		1000								
349	Pipette tip, 5–20 µl	Generic	C	1000 tips/ pack		1000								
46	Timer, digital	Generic	E	1unit		1000								
3 – Control														
614	Geenius™ HIV-1/2 Confirmatory Controls	72329	R	Kit	20	1000				Store at 2–8°C	http://goo.gl/9hmycU			

HIV SUPPLEMENTAL ASSAY: HIV BLOT 2.2, MP BIOMEDICALS ASIA PACIFIC PTE LTD.

HIV BLOT 2.2 is a qualitative enzyme immunoassay for the in vitro detection of antibodies to HIV-1 and HIV-2 in human serum or plasma. It is intended for use as a more specific supplemental test on human serum or plasma specimens found repeatedly reactive using screening procedures such as ELISA.
Commodities for specimen collection and transfer are not included.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
615	HIV BLOT 2.2	07-11030-036	B	36 tests/kit	36	1000	28	Serum, plasma	11 months	Store at 2–8°C	http://goo.gl/4zcfcv	WHO, GF	CE marked	Strong reactive control and weak reactive control are included in the kit
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with EDTA, heparin, or sodium citrate
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
342	Paper towels	Generic	C	1 Pack		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000								
397	Graduated cylinder, 500 ml	Generic	D	1 unit		1000								
593	Graduated cylinder, 250 ml	Generic	D	1 unit		1000								
395	Graduated cylinder, 100 ml,	Generic	D	1 unit		1000								
616	Pipette, serological, 2.0 ml	Generic	C	500/case		1000								
40	Pipette/ pipettor 20	Generic	E	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
349	Pipette tip, 5–20 µl	Generic	C	1000 tips/ pack	1000	1000	1							
617	Pump, liquid jet vacuum with safety bottle	Generic	E	1 unit		1000								
267	Forceps, non-metallic	Generic	C	1 unit		1000								
618	Shaker	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
494	Liquid waste container with cap	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								

HIV SUPPLEMENTAL ASSAY: INNO-LIA® HIV I/II SCORE, FUJIREBIO EUROPE N.V.

INNO-LIA® HIV I/II Score is an immunoassay for the confirmation and discrimination of antibodies to HIV-1, HIV-1 group O and HIV-2 in human serum and plasma. The assay also differentiates between HIV-1 and HIV-2 infections. It is intended as a supplementary assay on specimens found to be reactive using an anti-HIV screening procedure. Sensitivity: 100% (95% confidence interval 98.6–100%) for HIV-1 positive specimens; 100% (95% confidence interval 96.9–100%) for HIV-2 positive specimens. Specificity 96.7% (95% confidence interval 94.0–98.2%) for screened-negative blood donor specimens; 96.1% (95% confidence interval 92.5–98.0%) for clinical samples (Source: INNO-LIA® HIV I/II Score manufacturer's package insert http://goo.gl/TTVCxK). Commodities for specimen collection and transfer are not included

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
619	INNO-LIA® HIV I/II Score	80540	B	20 tests/kit	20	1000	50	Serum, plasma	12 months	Store at 2–8°C	http://goo.gl/TTVCxK	WHO, GF	CE marked	Negative and positive controls are included. Fully automated strip processing possible using FujirebioAuto-LIA™ 48, Auto-LiPA™ 48 or AutoBlot 3000(H). The interpretation of the strips can be done by visual analysis or by LiRAS™ for infectious diseases interpretation software
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with EDTA, heparin, or citrate
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
342	Paper towels	Generic	C	1 pack	1	1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
592	Graduated cylinder, 25 ml	Generic	D	1 unit		1000								
398	Graduated cylinder, 50 ml	Generic	D	1 unit		1000								
395	Graduated cylinder, 100 ml,	Generic	D	1 unit		1000								
347	Pipette tip, 100–1000 µl	Generic	C	1000 tips/ pack		1000								
42	Pipette/ pipettor 1000	Generic	E	1 unit		1000								
40	Pipette/ pipettor 20	Generic	E	1 unit		1000								
349	Pipette tip, 5–20 µl	Generic	C	1000 tips/ pack		1000								
617	Pump, liquid jet vacuum with safety bottle	Generic	E	1 unit		1000								
267	Forceps, non-metallic	Generic	C	1 unit		1000								
618	Shaker	Generic	E	1 unit		1000								
56	Vortex mixer	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
494	Liquid waste container with cap	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								

HIV SUPPLEMENTAL ASSAY: NEW LAV BLOT I, BIO-RAD LABORATORIES

NEW LAV BLOT I kit is intended to the detection of human anti-HIV-1 antibodies in serum or plasma by immunoblotting in order to confirm a positive anti-HIV-1 response and specify its antigenic specificity within the scope of AIDS diagnosis.
Commodities for specimen collection and transfer are not provided

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
620	NEW LAV BLOT I	72251	B	18 tests/kit	18	1000	56	Serum, plasma	18 months	Store at 2–8°C	http://goo.gl/U9Vgg2	GF	CE marked	Positive and negative controls are included in the kit
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with EDTA, heparin, or citrate
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
342	Paper towels	Generic	C	1 pack		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
397	Graduated cylinder, 500 ml	Generic	D	1 unit		1000								
593	Graduated cylinder, 250 ml	Generic	D	1 unit		1000								
395	Graduated cylinder, 100 ml	Generic	D	1 unit		1000								
616	Pipette, serological, 2.0 ml	Generic	C	500/case		1000								
40	Pipette/ pipettor 20	Generic	E	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
349	Pipette tip, 5–20 µl	Generic	C	1000 tips/ pack		1000								
617	Pump, liquid jet vacuum with safety bottle	Generic	E	1 unit		1000								
267	Forceps, non-metallic	Generic	C	1 unit		1000								
393	Goggles/eye protection	Generic	D	1 unit		1000								
618	Shaker	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
494	Liquid waste container with cap	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								

HIV SUPPLEMENTAL ASSAY: NEW LAV BLOT II, BIO-RAD LABORATORIES

NEW LAV BLOT II kit is intended to the detection of human anti-HIV-2 antibodies in serum or plasma by immunoblotting in order to confirm a positive anti-HIV-2 response and specify its antigenic specificity within the scope of AIDS diagnosis.
Commodities for specimen collection and transfer are not provided.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
621	NEW LAV BLOT II	72252	B	18tests/kit	18	1000	56	Serum, plasma	18 months	Store at 2–8°C	http://goo.gl/U402dQ	GF	CE marked	Negative and positive controls are included in the kit
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with EDTA, heparin, or citrate
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
342	Paper towels	Generic	C	1 pack		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves / box		1000								
397	Graduated cylinder, 500 ml	Generic	D	1 unit		1000								
593	Graduated cylinder, 250 ml	Generic	D	1 unit		1000								
395	Graduated cylinder, 100 ml,	Generic	D	1 unit		1000								
616	Pipette, serological, 2.0 ml	Generic	C	500/case		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
40	Pipette/ pipettor 20	Generic	E	1 unit		1000								
349	Pipette tip, 5–20 µl	Generic	C	1000 tips/ pack		1000								
617	Pump, liquid jet vacuum with safety bottle	Generic	E	1 unit		1000								
267	Forceps, non-metallic	Generic	C	1 unit		1000								
393	Goggles/eye protection	Generic	D	1 unit		1000								
618	Shaker	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
494	Liquid waste container with cap	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								

HIV SUPPLEMENTAL ASSAY: PEPTI-LAV 1/2, BIO-RAD LABORATORIES

PEPTI_LAV 1-2 is a discrimination test for HIV-1 and HIV-2 antibodies by enzyme immunoassay.
Commodities for specimen collection and transfer are not provided.

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
622	PEPTI-LAV 1-2	72253	B	10 tests/kit	10	1000	100	Serum, plasma	4 months	Store at 2–8°C	http://goo.gl/7k7UoU	GF	CE marked	
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Serum, plasma						For plasma specimens, use tubes with EDTA, heparin, or citrate
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
342	Paper towels	Generic	C	1 pack		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
395	Graduated cylinder, 100 ml,	Generic	D	1 unit		1000								
360	Pipette, serological, 5.0 ml	Generic	C	200/case		1000								
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000								
617	Pump, liquid jet vacuum with safety bottle	Generic	E	1 unit		1000								
267	Forceps, non-metallic	Generic	C	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
393	Goggles/eye protection	Generic	D	1 unit		1000								
618	Shaker	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
494	Liquid waste container with cap	Generic	D	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative, in-house or purchased		R			1000								Controls must be obtained separately
459	Controls, HIV-positive, in-house or purchased		R			1000								

10.5 SECTION IE: NUCLEIC ACID-BASED TESTS

NUCLEIC ACID-BASED TEST: ABBOTT REALTIME HIV-1 ASSAY, ABBOTT MOLECULAR INC.

Diagnostic characteristics	Description of characteristics
Name of analyser	***m*2000rt instrument for realtime amplification and detection.**
Name of test	Abbott RealTi***me*** HIV-1 assay
Catalogue no.	Manual sample preparation: 6L18-90, 6L18-80, 6L18-70, 2G31-90, 2G31-80, 2G31-70, 4J70-24, 1L68-00, 6L83-00, 9K15-01 ***m*24 sample preparation: 6L18-90, 6L18-80, 6L18-70, 2G31-90, 2G31-80, 2G31-70, 4J70-24, 1L68-00, 6L83-00, 9K15-01, 03N06-01** ***m*2000sp automated sample preparation: 6L18-90, 6L18-80, 6L18-70, 2G31-90, 2G31-80, 2G31-70, 4J70-24, 1L68-00, 6L83-00, 9K15-01, 9K14-02**
Description	**In vitro PCR assay for quantitation of HIV-1 RNA in plasma over the range of 40 to 10 000 000 copies/ml. It is intended for use as an aid for disease prognosis and for assessment of viral response to antiretroviral treatment. Not for donor screening for HIV-1. Not a diagnostic test to confirm the presence of HIV-1 infection.** **This assay is designed to detect group M subtypes A–H, group O, and group N. One copy of HIV-1 RNA is equivalent to 1.7 ± 0.1 international units (IU) based on the WHO 1st International Standard for HIV-1 RNA for nucleic acid-based techniques (NIBSC 97/656).** **Abbott RealTi*me* HIV-1 assay can be used with one of three methods of sample preparation: (i) manual (for laboratories with low throughput requirements); (ii) automated sample preparation using the *m*24sp instrument (for laboratories with mid-throughput requirements; or (iii) automated sample preparation using the *m*2000sp instrument (for laboratories with high throughput requirements))** **Instrumentation to perform Abbott RealTi*me* HIV-1 assay includes the *m*24 instrument for automated sample preparation (optional), the *m*2000sp instrument for automated sample preparation (optional), and the *m*2000rt instrument for realtime amplification and detection.** **The package of *m*2000sp with *m*2000rt is marketed as the Abbott *m*2000 RealTi*me* System and provides automation from barcoded laboratory tube through patient result.**
Pre-installation requirements	Suitable for level III and IV laboratories with stable 24-h power
Operating conditions	***m*2000sp and *m*2000rt: 15–30°C; 30–80% humidity non-condensing at 30°C or below; 0–2000 m altitude** ***m*24: 15–35°C; 5–80% humidity non-condensing at 30°C or below; 0–2000 m altitude**
Items supplied with analyser	Data station, monitor and printer, and barcode scanner (hand-held in the case of ***m*24**) are supplied with ***m*24, *m*2000sp and *m*2000rt.**
Required accessories	Abbott RealTi***me*** HIV-1 m2000 ROW System Combined Application CD-ROM 1L68-09 or higher
Optional accessories	Unknown
Turnaround time	***m*24**: extraction time (incl. loading of instrument) ~ 3.5 hours ***m*2000sp**: from 2.5 hours for 24 samples to 5.5 hours for 96 samples ***m*2000rt**: Amplification and detection cycle ~ 3 hours.
Capacity (per run)	***m*24**: from 1 to 24 samples ***m*2000sp**: 93 patient samples + 3 controls; ***m*2000rt**: 93 patient samples + 3 controls
Throughput per technician / per day	***m*24: up to 48 samples (2 batches of 24 samples) per 8 hour day** ***m*2000sp: Up to 192 samples (2 batches of 96 samples) per 8 hour day;** ***m*2000rt: Up to 288 samples (sample preparation and extraction can be limiting factor)**

Diagnostic characteristics	Description of characteristics
Sample needed and stability	*m*2000sp and *m*24: Freshly drawn whole blood may be held at 15–30°C for up to 6 hours or at 2–8°C for up to 24 hours prior to centrifugation. After centrifugation, plasma, which is required for the Abbott RealTi*m*e HIV-1 qualitative assay, may be stored at 15–30°C for up to 24 hours or at 2–8°C for up to 5 days. If longer storage is required, it may be stored at –70°C *m*2000rt: PCR-ready samples from manual or *m*2000sp sample preparation/extraction protocol
Sample preparation and protocol complexity	*m*2000sp automated sample preparation: Moderately complex. Steps include vortexing (assay calibrators, each control and specimens, pipetting, centrifuge, etc.). Once 96 well plate is loaded and placed in *m*2000rt, process is walk away
Reagent stability and storage requirements	Maximum shelf-life upon manufacture: Abbott RealTi*m*e HIV-1 Amplification Reagent Kit 2G31-90: 18 months (except for Thermostable r*Tth* Polymerase Enzyme 56685: Per control date on vendor certificate of analysis) Abbott RealTi*m*e HIV-1 Control Kit 2G31-80: 18 months Abbott RealTi*m*e HIV-1 Calibrator Kit 2G31-70: 18 months Abbott *m*Sample Preparation System RNA Kit 04J70-24: 18 months Reagents, controls, and calibrators must be shipped on dry ice and must be stored at ≤ –10°C when not in use; reagent may be reused up to three times within 2 weeks; the Abbott mSample Preparation SystemRNA (4 x 24 preps) must be stored at 15–30°C
Cost per test	$11 to $20; price includes cost of reagents and consumables and depends on expected volumes and negotiation with Abbott
Cost per instrument	*m*2000sp automated sample preparation: US$ 120 000 *m*24: US$ 90 000 *m*2000*rt*: US$ 38 000 (with *m*2000sp) – Add US$ 6000 for all manual extraction items
Installation	Yes
Training	Fully-trained lab tech required; dedicated training on instrument
Maintenance/calibration	Once an Abbott RealTi*m*e HIV-1 calibration is accepted and stored, it may be used for six months. During this time, all subsequent samples may be tested without further calibration unless: • An Abbott RealTi*m*e HIV-1 Amplification Reagent Kit with a new lot number is used. • An Abbott *m*Sample Preparation System (4 × 24 preps) with a new lot number is used. • An Abbott RealTi*m*e HIV-1 application file for a different sample volume is used. • A new Abbott RealTi*m*e HIV-1 application specification file is installed. Pure dye optical re-calibration of the Abbott RealTi*m*e HIV-1 assay specific dyes (FAM, VIC, or ROX) is performed per the calibration procedures section of the Abbott *m*2000*rt* operations manual. Routine preventive maintenance required for the *m*2000sp, *m*24 and *m*2000*rt*. In case of breakdown, vendor-trained technician required to repair.
Internal QC	Controls are included as part of reagent kit and required for each preparation run for FDA-approved assays
External QA	*m*2000rt: Amenable to external QA
URL	http://www.abbottmolecular.com/products/infectious-diseases/realtime-pcr/hiv-1-assay.html

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
449	Abbott Molecular Inc. Abbott RealTi*me* HIV-1 Amplification Reagent Kit	2G31-90,	B	24 tests/ kit	24	1000	11	Plasma	18 months	Store at to–10°C	http://goo.gl/vzJOCJ http://goo.gl/K5mnmk http://goo.gl/akqpyJ	WHO, GF	WHO PQ, CE marked	Each batch of 96 tests should include 3 controls; therefore, up to 93 patient specimens can be processed during one run
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Plasma						
450	Abbott *m*Sample Preparation Systems $_{RNA}$	4J70-24	R	96/kit	96	1000	11	Plasma	18 months	Store at 15–30°C				Commodities required for manual sample preparation or sample preparation using m24 or *m*2000sp instruments. Abbott Adhesive cover Applicator is supplied with *m*2000*rt* instrument
453	Abbott 96-Well Optical Reaction Plates	4J71-70	C	20 plates/ pack	1920	1000	0.5							
452	Abbott Reaction Vessels, 5 ml	4J71-20	C	2000/pack	2000	1000	0.5							
454	Abbott Optical Adhesive Covers	4J71-75	C	100/pack	9600 (100 runs of 96 samples)	1000	0.1							
455	AbbottAdhesive Cover Applicator	9K32-01	C	1 unit		1000								
456	Abbott RealTi*me* Splash- Free Support Base	9K31-01	C	5/pack		1000								
464	Abbott RealTi*me* HIV-1 Calibrator Kit	2G31-70	R	12 calibration events /kit	12 calibration events performed occasionally	1000			18 months	Store at ⩽ –10°C.		WHO list, GF list	WHO PQ, CE marked	
347	Pipette tip, 100–1000 µl	Generic	C	1000 tips/ pack		1000								
348	Pipette tip, 100–1000 µl filter/aerosol barrier	Generic	C	96 tips/ box		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack		1000								
352	Pipette tip, 10–200 µl filter/ aerosol barrier	Generic	C	96 tips/ box		1000								
474	Abbott Reagent Vessels, 200 ml	4J71-60	C	90/pack	1440 (15 runs of 96 samples)	1000	0.7							For manual sample preparation or sample preparation using ***m***24 or m2000sp instruments
468	Abbott 96 Deep-Well Plate	4J71-30	C	32 plates/ pack	3072	1000	0.3							
469	Abbott Master Mix Tubes/Caps	4J71-80	C	150 units / pack	14400 (150 runs of 96 samples)	1000	0.07							For ***m***2000sp and ***m***24 instruments; tubes may be used for additional purposes
629	Disposable tips (DiTis), 1000 µl	4J71-10	C	2304 tips/ pack	260 (2.7 runs of 96 samples on ***m***2000sp)	1000	4							Specifically for use with ***m***2000sp and ***m***24
630	Disposable tips (DiTis), 200 µl	4J71-17	C	2304 tips/ pack	2304 (24 runs of 96 samples on ***m***2000sp)	1000	0.5							Specifically for use with ***m***2000sp and ***m***24
623	Internal control vial (1.4 ml)	03N19-01	C			1000								For ***m***24 only
624	Internal control vial (1.4 ml) cap	03N20-01	C			1000								For ***m***24 only
376	Tubes, microcentrifuge, 1.5 ml, screw cap	04G71-50 or generic equivalent	C	100 tubes/ pack		1000								For manual and ***m***24 sample preparation
625	Stand, magnetic separator for 5 ml reaction vessels	Generic	D	1 Unit		1000								For manual sample preparation. Can be ordered as ***m***2000 ***m***Sample Preparation System Start Up Kit (02N28-03)
507	Stand, magnetic separator for 1.5 ml tubes	Generic	D	1 unit		1000								
626	Eppendorf PCR cooler or StrataCooler 96 benchtop cooler	Generic	D	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
457	Abbott *m*2000 Sample Preparation System Start Up Kit	2N28-03	D			1000								For manual sample preparation
627	Rack, reaction vessels, 5 ml	Generic	D	1 unit		1000								For manual sample preparation
407	Rack, test tubes, 0.5 ml, 1.5 ml, 2.0 ml centrifuge	Generic	D	1 unit		1000								For manual sample preparation
29	Heating block)	Generic	E	1 unit		1000								For manual sample preparation
412, 413	Thermometer	Generic	E	1 unit		1000								For manual sample preparation
46	Timer, digital	Generic	E	1 unit		1000								For manual sample preparation
628	Plate, 96 well polypropylene	Generic	C	50/case		1000								For manual sample preparation (optional)
631	Repeat pipettor, 40–50 µl	Generic	E	1 unit		1000								For manual sample preparation (optional)
632	Pipette tips, repeater/ dispenser, 50 µl	Generic	C	96 tips/ box	96	1000	11							For manual sample preparation (optional)
633	Pipette, transfer disposable, 1000 µl	Generic	C	500/pack		1000								For manual sample preparation (optional)
31	Microcentrifuge (non-refrigerated)	Generic	E	1 unit		1000								
543	Centrifuge (for 96-well plates)	Generic	E	1 unit		1000								For manual sample preparation
494	Liquid waste container with cap	Generic	D	1 unit		1000								For manual sample preparation
451	Abbott *m*2000*rt* Optical Calibration Kit	4J71-93	R	Kit	Unknown	1000			18 months	Store at 15–30°C				For *m*2000*rt* instrument

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
17	Centrifuge, benchtop, non-refrigerated	Generic	E	1 unit		1000								
472	Applicator, cotton tip	Generic	C			1000								
505	Gloves – multiples sizes, powder-free	Generic	C	100 gloves/ box		1000								
475	Tubes, microcentrifuge, 1.7 ml, RNase-free	Generic	C	100 tubes/ pack		1000								
466	Tubes, test, 16 mm	Generic	C	100/pack		1000								
470	Biosafety cabinet class I/II	Generic	E	1 unit		1000								
42	Pipette/pipettor 1000	Generic	E	1 unit		1000								
41	Pipette/pipettor 200	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
401-403	Laboratory coat	Generic	D	1 unit		1000								
393	Goggles/eye protection	Generic	D	1 unit		1000								
237, 238, 239	Bag, biohazard wastes	Generic	C	100 bags/ pack		1000								
56	Vortex mixer	Generic	E	1 unit		1000								
471	Water, RNase/ DNase free	Generic	R	100 ml/ bottle		1000								
3 - Control														
463	Abbott RealTi*me* HIV-1 Control Kit	2G31-80	R	3 controls, 8 vials each /kit	8 runs	1000			18 months	Store at ⩽ –10°C		GF list, USAID list	WHO PQ, CE marked	Kit includes HIV-1 high positive control, HIV-1 low positive control and HIV-1 negative control

NUCLEIC ACID-BASED TEST: ABBOTT REALTIME HIV-1 QUALITATIVE ASSAY, ABBOTT MOLECULAR, INC.

Diagnostic characteristics	Description of characteristics
Name of analyser	***m*2000rt instrument for realtime amplification and detection.**
Name of test	**Abbott RealTi*me* HIV-1 Qualitative assay**
Catalogue no.	Manual sample preparation: 4N66-90, 4N66-80, 6K12-24, 9K15-01, 4N66-01 and 4N66-66 (optional). ***m*2000sp automated sample preparation: 4N66-90, 4N66-80, 6K12-24, 9K15-01, 9K14-02, 4N66-01 and 4N66-66 (optional)**
Description	**Abbott RealTi*me* HIV-1 Qualitative Assay is an in vitro amplification assay for the qualitative detection of HIV-1 nucleic acids from human plasma and dried blood spots (DBS).** **It is intended to be used as an aid in the diagnosis of HIV-1 infection in paediatric and adult subjects. This assay is not intended to be used as a donor screening test for HIV-1.** **Assay sensitivity is 110 copies/ml for plasma samples and 2500 copies/ml for whole blood samples using the DBS procedure. This assay is designed to detect group M subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G, subtype H and group N, group O. One copy of HIV-1 RNA is equivalent to 1.7 ± 0.1 IU based on the WHO 1st International Standard for HIV-1 RNA for nucleic acid-based techniques (NIBSC 97/656).** **Abbott RealTi*me* HIV-1 Qualitative Assay can be used with one of two methods of sample preparation: (i) manual (for laboratories with low throughput requirements) or (ii) automated sample preparation using the *m*2000sp instrument (for laboratories with high throughput requirements))** **Instrumentation to perform Abbott RealTi*me* HIV-1 Qualitative Assay includes the *m*2000sp instrument for automated sample preparation (optional) and the *m*2000*rt* instrument for realtime amplification and detection.** **Package of the *m*2000sp with *m*2000rt is marketed as the Abbott *m*2000 RealTi*me* System and provides automation from barcoded laboratory tube through patient result.**
Pre-installation requirements	Suitable for level III and IV laboratories with stable 24-h power
Operating conditions	**15–30°C; 30–80% humidity non-condensing at 30°C or below; 0–2000 m altitude**
Items supplied with analyser	Data station, monitor and printer, and barcode scanner are supplied with the ***m*2000sp** and ***m*2000*rt***
Required accessories	Abbott RealTi***m***e HIV-1 Qualitative ***m*2000 System Combined Application CD-ROM 4N66-01 or higher**
Optional accessories	Abbott RealTi***m***e HIV-1 UNG (uracil-N-glycosylase) Protocol 4N66-66
Turnaround time	***m*2000sp: from 2.5 hours for 24 samples to 5.5 hours for 96 samples** ***m*2000rt: Amplification and detection cycle ~ 3 hours**
Capacity per run	***m*2000sp automated sample preparation: Up to 94 patient samples + 2 controls per run** ***m*2000rt: Up to 94 patient samples + 2 controls per run**

Throughput per technician per day	***m*2000sp automated sample preparation: Up to 188 samples (2 batches of 94 samples) per 8 hour day;** ***m*2000rt: Up to 282 samples per technician per day (sample preparation and extraction can be limiting factor)**
Sample needed and stability	***m*2000sp or manual sample preparation: Freshly drawn whole blood may be held at 15-30°C for up to 6 hours or at 2–8°C for up to 24 hours prior to preparing plasma samples through centrifugation or prior to preparing DBS samples. After centrifugation, plasma may be stored at 15–30°C for up to 24 hours or at 2–8°C for up to 5 days. If longer storage is required, it may be stored at –10 to –30°C for up to 30 days or at –70°C or lower. Multiple freeze/thaw cycles should be avoided and should not exceed three freeze/thaw cycles.** **DBS may be made on Whatman 903 card (or equivalent) using blood obtained from a heel or fingerstick or collected in a blood collection tube. DBS cards may be stored at 15–30°C for up to 12 weeks or at 2–8°C or –10°C or colder for up to 12 weeks.** ***m*2000*rt*: PCR-ready samples from manual or *m*2000sp sample preparation/extraction protocol**
Sample preparation and protocol complexity	***m*2000sp automated sample preparation: Moderately complex. Steps include vortexing (assay calibrators, each control and specimens, pipetting, centrifuge, etc.). Once 96 well plate is loaded and placed in the *m*2000rt, process is walk away**
Reagent stability and storage requirements	**Maximum shelf-life upon manufacture:** **Abbott RealTi*m*e HIV-1 Qualitative Amplification Reagent Kit 4N66-90: 18 months (except for Thermostable r*Tth* Polymerase Enzyme 56685: Per control date on vendor certificate of analysis)** **Abbott RealTi*m*e HIV-1 Qualitative Control Kit 4N66-80: 18 months** **Abbott *m*Sample Preparation System$_{DNA}$ Kit 6K12-24 : 18 months** **Reagents, controls, and calibrators must be shipped on dry ice and must be stored at ⩽ –10°C when not in use; reagent may be reused up to three times within 2 weeks; the Abbott *m*Sample Preparation System$_{DNA}$ must be stored at 15–30°C; the UNG required for the Abbott RealTi*m*e HIV-1 UNG Protocol 4N66-66 must be stored at –15 to –25°C**
Cost per test	**US$ 13.02; price includes cost of reagents and consumables**
Cost per instrument	***m*2000sp automated sample preparation: US$ 120 000** ***m*2000rt: US$ 38 000 (with *m*2000sp) – Add US$ 6000 for all manual extraction items**
Installation	Yes
Training	**Fully-trained lab tech required; dedicated training on instrument**
Maintenance/calibration	Routine preventive maintenance required for the ***m*2000sp** and ***m*2000rt.** In case of breakdown, vendor-trained technician required to repair
Internal QC	Controls are included as part of reagent kit and required for each preparation run for FDA-approved assays
External QA	***m*2000rt: Amenable to external QA**
URL	**http://www.abbottmolecular.com/products/infectious-diseases/realtime-pcr/realtime-hiv1-qualitative.html**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
540	Abbott RealTi***me*** HIV-1 Qualitative Amplification Reagent Kit	4N66-09	B	96 tests/ kit	96	1000	11	Plasma, dried blood spots (DBS)	18 months; r***Tth*** Polymerase Enzyme 56685: per control date on vendor certificate of analysis	Ship on dry ice, store at ry–10°C	http://goo.gl/3eOfU0 http://goo.gl/JlUMsu	WHO, GF	CE marked, WHO PQ	Each batch of 96 tests should include 2 controls; therefore, up to 94 patient specimens can be processed during one run
2 –Test run														
534	Blood collection consumables	Generic	C			1000		Plasma, (DBS)						
451	Abbott ***m***2000***rt*** Optical Calibration Kit	4J71-93	R	Kit		1000			18 months	Store at 15–30°C				Commodities required for manual sample preparation or sample preparation using ***m***2000sp instrument. Abbott Adhesive Cover Applicator is supplied with the ***m***2000***rt*** instrument
634	Abbott ***m***Sample Preparation System $_{DNA}$	6K12-24	R	4 x 24/kit	96	1000	11		18 months	Store at 15–30°C				
453	Abbott 96-Well Optical Reaction Plates	4J71-70	C	20 plates/ pack	1920	1000	0.5							
454	Abbott Optical Adhesive Covers	4J71-75	C	100/pack	9600 (100 runs of 96 samples)	1000	0.1							
455	Abbott Adhesive Cover Applicator	9K32-01	C	1 unit		1000								
452	Reaction Vessels, 5 ml	4J71-20	C	2000/pack	2000	1000	0.5							
456	Abbott Splash-Free Support Base	9K31-01	C	5/pack		1000								
56	Vortex mixer	Generic	E	1 unit		1000								
40, 41, 42	Calibrated pipettes/ pipettors, 20–1000 µl	Generic	E	1 unit		1000								
348, 352	Pipette tip, 20–1000 µl filter/aerosol barrier	Generic	C	96 tips/ box		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
637	Ethanol, USP Grade 190–200 proof (95–100% ethanol)	Generic	R	2.5L/ bottle	Varies	1000								For manual and ***m***2000sp sample preparation. DO NOT use ethanol that contains denaturants
31	Microcentrifuge (non-refrigerated)	Generic	E	1 unit		1000								
625	Stand, magnetic separator for 5 ml reaction vessels	Generic	D	1 unit		1000								For manual sample preparation. Can be ordered as the ***m***2000 ***m***Sample Preparation System Start Up Kit (02N28-03)
507	Stand, magnetic separator for 1.5 ml tubes	Generic	D	1 unit		1000								
626	Eppendorf PCR cooler or StrataCooler 96 benchtop cooler	Generic	D	1 unit		1000								
457	***m***2000 ***m***Sample Preparation System Start Up Kit	02N28-03	D			1000								For manual sample preparation
627	Rack, reaction vessels, 5 ml	Generic	D	1 unit		1000								For manual sample preparation
407	Rack, test tubes, 0.5 ml, 1.5 ml, 2.0 ml centrifuge	Generic	D	1 unit		1000								For manual sample preparation
29	Heating block	Generic	E	1 unit		1000								For manual sample preparation
412, 413	Thermometer	Generic	E	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
376	Tubes, microcentrifuge, 1.5 ml, screw cap	04G71-50 or generic equivalent	C	100 tubes/ pack		1000								
471	RNase/DNase free water (Eppendorf or equivalent)	Generic	R	100 ml/ bottle		1000								
628	Plate, 96 well polypropylene	Generic	C	50/case		1000								For manual sample preparation (optional)
631	Repeat pipettor, 40-50 µl	Generic	E	1 unit		1000								For manual sample preparation (optional)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
632	Pipette tip, repeater/ dispenser, 50 µl	Generic	C	100 tips/ pack		1000								For manual sample preparation (optional)
543	Centrifuge (for 96-well plates)	Generic	E	1 unit		1000								For manual sample preparation
633	Pipette, transfer disposable, 1000 µl	Generic	C	500/pack		1000								For manual sample preparation (optional)
468	Abbott 96 Deep-Well Plate	4J71-30	C	32 plates/ pack	3072	1000	0.3							For the ***m***2000sp instrument only
469	Master Mix Tubes/Caps	4J71-80	C	150 units / pack	14400 (150 runs of 96 samples)	1000	0.07							For the ***m***2000sp instrument; tubes may be used for additional purposes
635	Sample racks, 13 mm	4J72-82	D			1000								Supplied with the ***m***2000sp instrument
474	Reagent Vessels, 200 ml	4J71-60	C	90/pack	1440 (15 runs of 96 samples)	1000	0.7							For the ***m***2000sp instrument only
629	Disposable tips (DiTis), 1000 µl	4J71-10	C	2304 tips/ pack	260 (2.7 runs of 96 samples on ***m***2000sp)	1000	4							Specifically for use with the ***m***2000sp
630	Disposable tips (DiTis), 200 µl	4J71-17	C	2304 tips/ pack	2304 (24 runs of 96 samples on ***m***2000sp)	1000	0.5							Specifically for use with the ***m***2000sp
468	Abbott 96 Deep-Well Plate	4J71-30	C	32 plates/ pack	3072	1000	0.3							For the ***m***2000sp instrument only
264	Dried blood spot collection cards	Generic	C	100 cards/ pack	100	1000	10							For DBS specimen collection
636	Bulk ***m***Lysis$_{DNA}$ Buffer	2N77-01	R	3 x 70 ml/		1000								For DBS processing only
477	Tubes, centrifuge, 50 ml (NUNC or equivalent)	Generic	C	500/case	500	1000	2							For DBS processing only (optional)
470	Biosafety cabinet class I/II	Generic	E	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
470	Biosafety cabinet class I/II	Generic	E	1 unit		1000								
385, 386, 387	Biohazard waste container	Generic	D	1 unit		1000								
494	Liquid waste container with cap	Generic	D	1 unit		1000								No bleach should be allowed to contact liquid waste. For manual sample preparation
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
401-403	Laboratory coat	Generic	D	1 unit		1000								
393	Goggles/eye protection	Generic	D	1 unit		1000								
237, 238, 239	Bag, biohazard wastes	Generic	C	100 bags/ pack		1000								
472	Applicator, cotton tip	Generic	C			1000								
3 - Control														
638	Abbott RealTi***me*** HIV-1 Qualitative Control Kit	4N66-80	R	2 controls, 12 vials each/kit	12 runs	1000	1		18 months	Ship on dry ice, store at ry–10°C	http://goo.gl/3eOfU0	WHO list, GF list	CE marked, WHO PQ	Each kit includes HIV-1 positive control and HIV-1 negative control

NUCLEIC ACID-BASED TEST: COBAS® AMPLIPREP/COBAS® TAQMAN® HIV-1 TEST, VERSION 2.0, ROCHE MOLECULAR SYSTEMS, INC.

Diagnostic characteristics	Description of characteristics
Name of analyser	**COBAS® TaqMan® 48 Analyzer or COBAS® TaqMan® 96 Analyzer for automated realtime amplification and detection**
Name of test	**COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0**
Catalogue no.	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0: 05212294190 COBAS® TaqMan® 48 Analyzer: 03279332001 COBAS® TaqMan® 96 Analyzer: 03121453001 COBAS® AmpliPrep Instrument: 03051315001
Description	**The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0 (v2.0) is a nucleic acid amplification test for the quantitation of HIV-1 RNA in plasma using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® 48 Analyzer or COBAS® TaqMan® 96 Analyzer for automated amplification and detection. The test can quantitate HIV-1 RNA over the range of 20–10 000 000 copies/ml. One copy of HIV-1 RNA is equivalent to 1.7 ± 0.1 IU based on the WHO 1st International Standard for HIV-1 RNA for nucleic acid-based techniques (NIBSC 97/656).** **The test is intended for use in conjunction with clinical presentation and other markers of disease progress for the clinical management of HIV-1 group M and HIV-1 group O infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment.** **The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 is not intended for use as a screening test for the presence of HIV-1 in blood or blood products or as a diagnostic test to confirm the presence of HIV-1 infection.**
Pre-installation requirements	Suitable for level III and IV laboratories with stable 24-h power
Operating conditions	**15–32°C; 24–80% humidity, non-condensing(up to 32°C); 0–2000 m altitude**
Items supplied with analyser	AMPLILINK Software, Version 3.2 Series 04862392001 or AMPLILINK Software, Version 3.3 Series 05807875001, barcode scanner (on COBAS AmpliPrep: on-board barcode scanner for reagent racks, reagent cassettes and specimen clips
Required accessories	XP Data Station for the AMPLILINK software, with printer: 03516440001
Optional accessories	COBAS p 630 instrument 05527503001 Docking Station 28127387001
Turnaround time	COBAS® AmpliPrep Instrument: Three racks of 24 specimens in approximately 5 hours; 216 seconds processing time per specimen COBAS® TaqMan® 48 Analyzer: Amplification and detection cycle takes 3 hours 5 minutes COBAS® TaqMan® 96 Analyzer: Amplification and detection cycle takes 3 hours 5 minutes, including automated transfer from COBAS AmpliPrep through a docking station
Capacity (per run)	COBAS® AmpliPrep Instrument: 72 samples per run (maximum), which can be analysed simultaneously. Batch size is 24 specimens per run. COBAS® TaqMan® 48 Analyzer: 2 independent segments of 24 samples each up to two different tests on board simultaneously; each thermal cycler can run individual PCR profiles. COBAS® TaqMan® 96 Analyzer: 24 samples per K-carrier. Up to 4 K-carriers can be amplified and detected at one time. Up to 8 K-carriers can be present on the instrument. Each thermal cycler can run individual PCR profiles.

Diagnostic characteristics	Description of characteristics
Throughput per technician / per day	COBAS® AmpliPrep Instrument: Up to 144 specimens per 8 hour shift, based on testing combinations and laboratory workflow COBAS® TaqMan® 48 Analyzer: Including processing time on COBAS® AmpliPrep, 48 samples (on an 8 hour shift) COBAS® TaqMan® 96 Analyzer: Including processing time on COBAS® AmpliPrep, 96 samples (on an 8 hour shift)
Sample needed and stability	COBAS® AmpliPrep Instrument: 850 µl of plasma specimens prepared from EDTA whole blood. Whole blood should be stored at 2–25°C for no longer than 24 hours prior to preparation of plasma specimens. Plasma may be transported/stored at room temperature (25–30°C) for up to 1 day, or at 2–8°C for up to 6 days, or frozen at -20 to -80°C. Plasma samples can be frozen and thawed up to five times. COBAS® TaqMan® 48 Analyzer: PCR-ready set-up samples from COBAS® AmpliPrep; processed specimens and controls should not be exposed to light after completion of specimen and control preparation. COBAS® TaqMan® 96 Analyzer: PCR-ready set-up samples from COBAS® AmpliPrep; processed specimens and controls should not be exposed to light after completion of specimen and control preparation.
Sample preparation and protocol complexity	COBAS® AmpliPrep Instrument: Plasma transferred to a properly identified, sterile screw-cap, polypropylene tube after centrifugation. Requires test-specific, barcoded, ready-to-use COBAS AmpliPrep Kits. Reagents are all liquid and ready-to-use but specimens require vortexing prior to testing. COBAS® TaqMan® 48 Analyzer and COBAS® TaqMan® 96 Analyser: run must be started within 120 minutes following completion of specimen and control preparation.
Reagent stability and storage requirements	The COBAS® AmpliPrep/COBAS® TaqMan® HIVManrep/COBASuirementsn 120 minutes following completion of specimen and control prepar The COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent, 03587797190, should be stored at 2°C to 30°C; shelf-life 24 months
Cost/test	COBAS® TaqMan® 48 Analyzer: TaqMan HIV-1 Test v2.0: US$ 9.40–25.00 in certain resource-limited settings. For details and eligibility criteria, see http://molecular.roche.com/globalaccessprogram/Pages/default.aspx COBAS® TaqMan® 96 Analyzer: TaqMan HIV-1 Test v2.0: US$ 20–30 per test (least developed countries); US$ 35–90 per test elsewhere
Cost/instrument	COBAS® AmpliPrep Instrument: approximately US$ 80 000–100 000 COBAS® TaqMan® 48 Analyzer: US$ 40 000–50 000 COBAS® TaqMan® 96 Analyzer: US$ 100 000–110 000, including docking station
Installation	Yes
Training	**Fully-trained lab tech required; 3–5 days dedicated training on instrument, refresher training may be required**
Maintenance/calibration	Annual maintenance. Routine preventive maintenance required. In case of breakdown, vendor-trained technician required to repair.
Internal QC	Controls are included as part of reagent kit
External QA	Amenable to EQA
URL	**http://goo.gl/8QRT3Z, http://goo.gl/CBd2VB**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
231	COBAS® AmpliPrep/ COBAS® TaqMan® HIV-1 Test v2.0	05212294190	B	48/kit	48	1000	21	Plasma	18 months	Store at 2–8°C	http://goo.gl/8QRT3Z , http://goo.gl/CBd2VB	WHO, GF	CE marked	High positive, low positive, and negative controls included
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Plasma						
445	COBAS® AmpliPrep/ COBAS® TaqMan® Wash Reagent	03587797190	R	5.1L/bottle		1000			24 months	Store at 2–30°C				
382	Sample Processing Units	03755525001	C	288/pack		1000								
378	Sample input tubes (S-tubes) with barcode clips	03137040001	C	288/pack		1000								
436	Racks of K-tips	03287343001	C	432/pack		1000								
437	K-tubes	03137082001	C	1152/box		1000								
438	Sample Rack (SK 24 rack)	028122172001	D	1 unit		1000								
439	Reagent Rack	028122199001	D	1 unit		1000								
440	Specimen Processing Unit Rack (SPU rack)	05471664001	D	1 unit		1000								
520	K-tube capper, motorized	03516539001	E	1 unit		1000								
639	K-tube capper	03339874001	D	1 unit		1000								
442	K-carrier	03341488001	D	1 unit		1000								
444	K-carrier Rack	03286436001	D	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
444	K-carrier Rack	03286436001	D	1 unit		1000								
443	K-carrier Transporter	03517519001	D	1 unit		1000								
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
348	Pipette tip, 100–1000 µl filter/aerosol barrier	Generic	C	96 tips /box		1000								
56	Vortex mixer	Generic	E	1 unit		1000								
371	Tissues, wipes	Generic	C	1 pack		1000								
494	Liquid waste container with cap	Generic	C	1 unit		1000								
31	Microcentrifuge (non-refrigerated)	Generic	E	1 unit		1000								
42	Pipette/pipettor 1000	Generic	E	1 unit		1000								
104	Ethanol (70%) for cleaning	Generic	R	1L/bottle		1000								

NUCLEIC ACID-BASED TEST: COBAS® AMPLIPREP/COBAS® TAQMAN® HIV-1 QUALITATIVE TEST, VERSION 2.0, ROCHE MOLECULAR SYSTEMS, INC.

Diagnostic characteristics	Description of characteristics
Name of analyser	**COBAS® TaqMan® 48 Analyzer or COBAS® TaqMan® 96 Analyzer for automated realtime amplification and detection**
Name of test	**COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0**
Catalogue no.	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test v2.0: 06693083190; COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent: 03587797190; COBAS® AmpliPrep/COBAS® TaqMan® Specimen Pre-Extraction Reagent: 06989861190; COBAS® TaqMan® 48 Analyzer: 03279332001; COBAS® TaqMan® 96 Analyzer: 03121453001; COBAS® AmpliPrep Instrument: 03051315001; AMPLILINK Software, Version 3.3 Series or higher, 05807875001; XP Data Station for AMPLILINK S/W with Printer, 03516440001
Description	**The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 is an in vitro diagnostic, total nucleic acid amplification test for the qualitative detection of HIV-1 DNA and RNA (or total nucleic acid, TNA) in human plasma or DBS using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 96 Analyzer for automated amplification and detection.** **The test is a diagnostic test, indicated for individuals who are suspected to be actively infected with HIV-1. Detection of HIV-1 TNA is indicative of active HIV infection. Can be used for detection of the presence of HIV-1 nucleic acid in infants born to mothers infected with HIV-1. The test is not intended for screening blood or plasma donors. The test can detect the presence of HIV-1 group M subtypes HIV-1 group N, and HIV-1 group O. The limit of detection of HIV-1 RNA is 20 cp/ml in EDTA Plasma and 300 cp/ml in DBS. One copy of HIV-1 RNA is equivalent to 1.7 ± 0.1 IU based on the 2nd International WHO Standard for HIV-1 RNA for nucleic acid-based techniques (NIBSC 97/650).**
Pre-installation requirements	Suitable for level III and IV laboratories with stable 24-h power
Operating conditions	**15–32°C; 24–80% humidity, non-condensing(up to 32°C); 0–2000 m altitude**
Items supplied with analyser	AMPLILINK Software, Version 3.3 Series: 05807875001; barcode scanner (on COBAS® AmpliPrep Instrument: on-board barcode scanner for reagent racks, reagent cassettes and specimen clips)
Required accessories	XP Data Station for the AMPLILINK S/W with printer: 03516440001;
Optional accessories	COBAS p 630 instrument 05527503001; Docking Station Short, 28127387001
Turnaround time	COBAS® AmpliPrep Instrument: Three racks of 24 specimens in approximately 5 hours; 216 seconds processing time per specimen COBAS® TaqMan® 48 Analyzer: Amplification and detection cycle takes 3 hours 5 minutes COBAS® TaqMan® 96 Analyzer: Amplification and detection cycle takes 3 hours 5 minutes, including automated transfer from COBAS® AmpliPrep through a docking station
Capacity (per run)	COBAS® AmpliPrep Instrument: 72 samples per run (maximum), which can be analysed simultaneously. Batch size is 24 specimens per run. COBAS® TaqMan® 48 Analyzer: 2 independent segments of 24 samples each up to two different tests on board simultaneously; each thermal cycler can run individual PCR profiles. COBAS® TaqMan® 96 Analyzer: 24 samples per K-carrier. Up to 4 K-carriers can be amplified and detected at one time. Up to 8 K-carriers can be present on the instrument.

Diagnostic characteristics	Description of characteristics
Throughput per technician / per day	COBAS® AmpliPrep Instrument: Up to 144 specimens per 8 hour shift, based on testing combinations and laboratory workflow COBAS® TaqMan® 48 Analyzer: Including processing time on AmpliPrep, 48 samples (on an 8 hour shift) COBAS® TaqMan® 96 Analyzer: Including processing time on AmpliPrep, 96 samples (on an 8 hour shift)
Sample needed and stability	COBAS® AmpliPrep Instrument: plasma samples prepared from EDTA whole blood or reconstituted dry blood spot samples prepared from 70 µl of whole blood applied on Whatman 903 filter card or the Munktell Specimen Collection card TFN Brand 5 or equivalent. Whole blood should be stored at 2–25°C for no longer than 24 hours prior to preparation of plasma samples. Plasma may be transported/stored at room temperature (25–30°C) for up to 1 day, or at 2–8°C for 5 days, or frozen at –20 to –80°C for 6 weeks. Plasma samples can be frozen and thawed up to three times. DBS can be stored for up to 3 months at ambient temperature in individual re-sealable bags with desiccant. COBAS® TaqMan® 48 Analyzer: PCR-ready set-up samples from COBAS® AmpliPrep; processed specimens and controls should not be exposed to light after completion of specimen and control preparation. COBAS® TaqMan® 96 Analyzer: PCR-ready set-up samples from COBAS® AmpliPrep; processed specimens and controls should not be exposed to light after completion of specimen and control preparation
Sample preparation and protocol complexity	COBAS® AmpliPrep Instrument: Plasma transferred to a properly identified, sterile screw-cap, polypropylene tube after centrifugation. Requires test-specific, barcoded, ready-to-use COBAS AmpliPrep Kits. Reagents are all liquid and ready-to-use, but specimens require vortexing prior to testing. DBS samples are transferred to S-tubes and dried whole blood eluted (10 min at 56°C, 1000 rpm) using pre-extraction reagent or PBS. COBAS® TaqMan® 48 Analyzer and COBAS® TaqMan® 96 Analyzer: the run should be started within 120 min following completion of specimen processing in COBAS® AmpliPrep Instrument.
Reagent stability and storage requirements	COBAS® AmpliPrep/COBAS® TaqMan® HIVManQualitative Test version 2.0, 06693083190, should be stored at 2°C to 8°C; shelf-life 22 months; COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent, 03587797190, should be stored at 2°C to 30°C; shelf-life 24 months; COBAS® AmpliPrep/COBAS® TaqMan® Specimen Pre-Extraction Reagent, 06989861190, should be stored at 2°C to 8°C; shelf-life 12 months
Cost/test	Unknown
Cost/instrument	COBAS® AmpliPrep Instrument: Approximately US$ 80 000–100 000 COBAS® TaqMan® 48 Analyzer: US$ 40 000–50 000 COBAS® TaqMan® 96 Analyzer: US$ 100,000–110 000, including docking station
Installation	Yes
Training	**Fully-trained lab tech required; 3–5 days dedicated training on instrument, refresher training may be required**
Maintenance/calibration	Annual maintenance. Routine preventive maintenance required. In case of breakdown, vendor-trained technician required to repair.
Internal QC	Controls are included as part of reagent kit
External QA	Amenable to EQA
URL	http://goo.gl/OZAMjR; http://goo.gl/c1FflA

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM required	Specimen type	Shelf-life	Cold/cool chain	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
640	COBAS® AmpliPrep/ COBAS® TaqMan® Qualitative HIV-1 Test v2.0	06693083190	B	48 tests/kit	48	1000	21	Plasma, dried blood spots (DBS)	22 months	Store at 2–8°C	http://goo.gl/OZAMjR; http://goo.gl/c1FflA	WHO, GF	WHO PQ; CE marked	HIV-1 positive and negative controls included
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Plasma, DBS						
445	COBAS® AmpliPrep/ COBAS® TaqMan® Wash Reagent	03587797190	R	5.1L/Bottle		1000			24 months	Store at 2–30°C	http://goo.gl/OZAMjR; http://goo.gl/c1FflA	WHO list, GF list	WHO PQ; CE marked	
641	COBAS® AmpliPrep/ COBAS® TaqMan® Specimen Pre-Extraction Reagent	06989861190	R	5 x 78 ml	350	1000			12 months	Store at 2–8°C	http://goo.gl/OZAMjR; http://goo.gl/c1FflA	WHO list, GF list	WHO PQ; CE marked	
382	Sample Processing Units	03755525001	C	288/pack		1000								
378	Sample input tubes (S-tubes) with barcode clips	03137040001	C	288/pack		1000								
436	Racks of K-tips	03287343001	C	432/pack		1000								
437	K-tubes	03137082001	C	1152/box		1000								
438	Sample Rack (SK 24 rack)	028122172001	D	1 unit		1000								
439	Reagent Rack	028122199001	D	1 unit		1000								
440	Specimen Processing Unit Rack (SPU rack)	05471664001	D	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM required	Specimen type	Shelf-life	Cold/cool chain	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
520	K-tube capper, motorized	03516539001	E	1 unit		1000								
639	K-tube capper	03339874001	D	1 unit		1000								
442	K-carrier	03341488001	D	1 unit		1000								
444	K-carrier Rack	03286436001	D	1 unit		1000								
443	K-carrier Transporter	03517519001	D	1 unit		1000								
264	Dried blood spot collection cards	Generic	C	100 cards/ pack	100	1000	10							
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
348	Pipette tip, 100–1000 µl filter/aerosol barrier	Generic	C	96 tips /box		1000								
56	Vortex mixer	Generic	E	1 unit		1000								
371	Tissues, wipes	Generic	C	1 pack	Varies	1000								
494	Liquid waste container with cap	Generic	C	1 unit		1000								
31	Microcentrifuge (non-refrigerated)	Generic	E	1 unit		1000								
42	Pipette/pipettor 1000	Generic	E	1 unit		1000								
104	Ethanol (70%) for cleaning	Generic	R	1L/bottle		1000								

NUCLEIC ACID-BASED TEST: NUCLISENS EASYQ® HIV-1 V.2.0, BIOMÉRIEUX SA

Diagnostic characteristics	Description of characteristics
Name of analyser	**NucliSENS EasyQ® instrument for automated amplification and detection**
Name of test	**NucliSENS EasyQ® HIV-1 v 2.0**
Catalogue no.	Semi-automated: 200305, 200293, 200292, 285056, 200309 and 285033 Automated: 280140,280130, 280131, 280132,280133, 280134, 285056,200309 and 285033
Description	**NucliSENS EasyQ® HIV-1 v 2.0 is a nucleic acid amplification assay for the quantitative determination of HIV-1 RNA in human EDTA plasma and EDTA whole blood spotted on cards (DBS). This assay is based on NASBA, an isothermal transcription-based amplification method, which amplifies RNA from an RNA target. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy be measuring changes in plasma/DBS (from EDTA whole blood) HIV-1 RNA levels during the course of antiretroviral treatment. The linear range of the NucliSENS EasyQ® HIV-1 v 2.0 is from 10 to 10 000 000 copies/ml. The assay can detect HIV-1 subtypes A, B, C, D, F, G, H, J, CRF01_AE, and CRF02_AG. Sample size is 0.1 ml, 0.5 ml, or 1 ml. NucliSENS EasyQ® HIV-1 v 2.0 is not a screening test for HIV-1 or a diagnostic test to confirm the presence of an HIV-1 infection. NucliSENS EasyQ® HIV-1 v 2.0 is part of the NucliSENS® HIV Solution. The NucliSENS HIV Solution is an automated system combining semi-automated or automated (optional) nucleic acid extraction with nucleic acid sequence-based amplification and realtime detection using molecular beacon probes. It includes NucliSENS® miniMAG® extraction system for a semi-automated extraction, NucliSENS® easyMAG® extraction system for an automated extraction, and NucliSENS EasyQ® amplification and detection system for an automated amplification and detection.**
Pre-installation requirements	Suitable for level III and IV laboratories
Operating conditions	**15–30°C (4–45°C for miniMAG®); maximum relative humidity 80% (0% for miniMAG®), non-condensing at 30°C; maximum altitude 2500 metres (2000 metres for EasyQ® and miniMAG®)**
Items supplied with analyser	Data station (may be linked with LIS using NucliSENtral™ software); barcode scanner (included with bioMérieux NucliSENS® easyMAG®).
Required accessories	**NucliSENS® easyMAG® configuration 280140, NucliSENS EasyQ® configuration 200309, Mini Strip Centrifuge 285056**
Optional accessories	Printer
Turnaround time	bioMérieux NucliSENS® miniMAG® : 12 samples: 45 minutes (1 miniMAG system) 24 samples: 60 minutes (2 miniMAG systems) bioMérieux NucliSENS® easyMAG®: 24 samples, lysis on board: 60 minutes 24 samples, lysis off board: 40 minutes bioMérieux NucliSENS EasyQ®: ~1.5 hours for 48 samples
Capacity (per run)	bioMérieux NucliSENS® miniMAG® : 12 patient samples (no controls) bioMérieux NucliSENS® easyMAG®: 1-24 patient samples per run bioMérieux NucliSENS EasyQ®: Up to 48 patient samples (minimum is 8 patient samples)
Throughput per technician / per day	**bioMérieux NucliSENS® miniMAG® : Up to 144 specimens (6 runs of 24 – 2 miniMAGs at the same time) bioMérieux NucliSENS® easyMAG®: Up to 168 extractions – lysis on-board workflow Up to 240 extractions – lysis in tube workflow bioMérieux NucliSENS EasyQ®: 192 samples (4 runs of 48)**

Diagnostic characteristics	Description of characteristics
Sample needed and stability	bioMérieux NucliSENS® miniMAG® : 100 – 1,000 µL plasma for NucliSENS EasyQ® HIV assay (sensitivity is higher with larger sample). DBS protocol available (CE marked protocol on EDTA whole blood on capillary whole blood) bioMérieux NucliSENS® easyMAG®: 100–1000 µL plasma for NucliSENS EasyQ® HIV assay (LOD is better with larger sample). DBS protocol available (CE marked protocol 100 µL EDTA whole blood and on 100 µL capillary whole blood). bioMérieux NucliSENS EasyQ®: Eluates extracted with miniMAG® or easyMAG®. Can be stored at 2–8°C; all reagents are stable until expiration date
Sample preparation and protocol complexity	bioMérieux NucliSENS®miniMAG® : Plasma or DBS are transferred to a lysis tube. After addition of silica, washing steps are performed on the miniMAG® system. Reagents are then ready to use. bioMérieux NucliSENS® easyMAG®: Entire extraction process takes place in a single sample compartment, which minimizes potential sample loss and cross contamination. Reagents are ready-to-use. bioMérieux NucliSENS EasyQ®: Moderate complexity. Dehydrated reagents are quickly reconstituted.
Reagent stability and storage requirements	NucliSENS® miniMAG® : The NucliSENS® Magnetic Extraction Reagent, 200293 should be stored at 2–8°C; shelf-life upon manufacture is 18 months The NucliSENS® Lysis Buffer (2 ml), 200292 should be stored at 2-30°C; shelf-life upon manufacture is 24 months NucliSENS® easyMAG®: The NucliSENS® easyMAG® extraction Buffer 1, 280130 should be stored at 2–30°C; shelf-life upon manufacture is 24 months NucliSENS® easyMAG® extraction Buffer 2, 280131 should be stored at 2–30°C; shelf-life upon manufacture is 18 months NucliSENS® easyMAG® extraction Buffer 3, 280132 should be stored at 2–8°C; shelf-life upon manufacture is 15 months NucliSENS® easyMAG® extraction Lysis Buffer, 280134 should be stored at 2–30°C; shelf-life upon manufacture is 24 months NucliSENS® easyMAG® magnetic silica, 280133 should be stored at 2–8°C; shelf-life upon manufacture is 18 months NucliSENS EasyQ®: NucliSENS EasyQ® HIV-1 v 2.0 test kit should be stored at 2–8°C; shelf-life upon manufacture is 18 months
Cost/test	The average price per test of EasyQ® HIV-1 v 2.0, including extraction and detection/ amplification is about €18.00 (US$ 23.75)
Cost/instrument	bioMérieux NucliSENS® miniMAG® : approximately €6800 (US$ 9000) bioMérieux NucliSENS® easyMAG®: approximately €72 000 (US$ 95 000) bioMérieux NucliSENS EasyQ®: approximately €37 100 (US$ 49 000)
Installation	Yes
Training	Fully-trained lab tech required; dedicated training on instrument, which requires strong computer skills
Maintenance/calibration	Routine preventive maintenance required. In case of breakdown, vendor-trained technician required to repair
Internal QC	Yes, a synthetic calibrator added in a known concentration at the extraction stage, functions as an internal control for the isolation, amplification and detection procedure
External QA	Unknown
URL	http://goo.gl/LXAzHB

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
488	NucliSENS EasyQ®HIV-1 V2.0	285033	B	48/kit	48	1000	21	Plasma, dried whole blood spots (DBS)	18 months	Store at 2–8°C	http://goo.gl/8smz2h , http://goo.gl/xyEqfk	WHO, GF	CE marked, WHO PQ	
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Plasma, DBS						
489	Biohit Tips	280146	C	48/pack	48	1000	21							For nucleic acid isolation using NucliSENS® easyMAG® (automated assay)
490	NucliSENS® easyMAG® disposables	280135	C	48/pack	48	1000	21							
491	Strip Plates Greiner	278303	C	48/pack	48	1000	21							
483	NucliSENS® easyMAG® Extraction Buffer 1	280130	R	4 x 1000 ml /pack		1000			24 months	Store at 2–30°C	http://goo.gl/xyEqfk	WHO list, GF list	CE marked, WHO PQ	
484	NucliSENS® easyMAG® Extraction Buffer 2	280131	R	4 x 1000 ml /pack		1000			18 months	Store at 2–30°C	http://goo.gl/xyEqfk	WHO list, GF list	CE marked, WHO PQ	
485	NucliSENS® easyMAG® Extraction Buffer 3	280132	R	4 x 1000 ml /pack		1000			15 months	Store at 2–8°C	http://goo.gl/xyEqfk	WHO list, GF list	CE marked, WHO PQ	
486	NucliSENS® easyMAG® Extraction Lysis Buffer	280134	R	4 x 1000 ml /pack		1000			24 months	Store at 2–30°C	http://goo.gl/xyEqfk N/A	WHO list, GF list	CE marked, WHO PQ	
487	NucliSENS® easyMAG® Magnetic Silica	280133	R	48 x 0.6 ml / pack	48	1000	21		18 months	Store at 2–8°C	http://goo.gl/xyEqfk	WHO list, GF list	CE marked, WHO PQ	
642	NucliSENS® Magnetic Extraction Reagents	200293	R	Kit		1000			18 months	Store at 2–8°C	http://goo.gl/8smz2h	WHO list, GF list	CE marked, WHO PQ	For nucleic acid isolation using NucliSENS® miniMAG® (semi-automated assay)
643	NucliSENS® Lysis Buffer (2 ml)	200292	R	48 x 2 ml / pack	48	1000	21		24 months	Store at 2–30°C	http://goo.gl/8smz2h	WHO list, GF list	CE marked, WHO PQ	
507	Stand, magnetics separator for 1.5 ml tubes	Generic	D	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
492	NucliSENS EasyQ® 8-Tube Caps	285051	C	48/pack	48	1000	21							
493	NucliSENS EasyQ® 8-Tube Strips	285048	C	48/pack	48	1000	21							
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000	20							
362	Bag, sealable plastic specimen	Generic	C	100 bags/ pack	100	1000	10							
264	Dried blood spot collection cards	Generic	C	100 cards/ pack	100	1000	10							
348	Pipette tip, 100–1000 µl filter/aerosol barrier	Generic	C	96 tips /box	96	1000	11							
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							
352	Pipette tip, 10–200 µl filter/ aerosol barrier	Generic	C	96 tips /box	96	1000	11							
500	Pipette tip, 1–5 ml filter/ aerosol barrier	Generic	C	50 tips /box	50	1000	20							
350	Pipette tip, 5–20 µl filter/ aerosol barrier	Generic	C	96 tips /box	96	1000	11							
371	Tissues, wipes	Generic	C	1 pack		1000								
503	Tube strips, PCR, 0.2 ml RNase-free with caps	Generic	C	100/pack	100	1000	10							Alternate to item 502
502	Tubes, microcentrifuge, 1.5 ml, RNase-free	Generic	C	100/pack	100	1000	10							
494	Liquid waste container with cap	Generic	C	1 unit		1000								
409	Scissors	Generic	D	1 unit		1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
17	Centrifuge, benchtop, non-refrigerated	Generic	E	1 unit		1000								
31	Microcentrifuge (non-refrigerated)	Generic	E	1 unit		1000								
495	Mixer, roller	Generic	E	1 unit		1000								
39	Pipette/pipettor 1	Generic	E	1 unit		1000								
42	Pipette/pipettor 1000	Generic	E	1 unit		1000								
40	Pipette/pipettor 20	Generic	E	1 unit		1000								
41	Pipette/pipettor 200	Generic	E	1 unit		1000								
499	Pipette/pipettor 5000	Generic	E	1 unit		1000								
506	Thermoshaker	Generic	E	1 unit		1000								
46	Timer, digital	Generic	E	1 unit		1000								
508	Vacuum system, 1.5 litres/m	Generic	E			1000								Alternate
56	Vortex mixer	Generic	E	1 unit		1000								
498	Water-bath	Generic	E	1 unit		1000								
104	Ethanol (70%) for cleaning	Generic	R	1L/bottle		1000								
504	Sodium hypochlorite solution (1%)	Generic	R			1000								
106	Sodium hypochlorite solution (5–10%)	Generic	R	1L/bottle		1000								
3 – Control														
496	Controls, HIV RNA negative, commercial		R			1000								Controls are not available for this kit; consider using QC specimens
497	Controls, HIV RNA positive, commercial		R			1000								

NUCLEIC ACID-BASED TEST: VERSANT: HIV-1 RNA 1.0 ASSAY (KPCR), SIEMENS HEALTHCARE DIAGNOSTICS

Diagnostic characteristics	Description of characteristics
Name of analyser	VERSANT® kPCR Molecular System
Name of test	VERSANT® HIV-1 RNA 1.0 Assay (kPCR)
Catalogue no.	10375763, 10375764, 04801677, 04801685, 10467524
Description	The VERSANT® HIV-1 RNA 1.0 Assay (kPCR)* is an in vitro nucleic acid amplification assay for quantitative measurement of HIV-1 RNA in fresh or frozen human plasma samples using the VERSANT kPCR Molecular System. The assay detects viral RNA over the range of 37 copies/ml to 11 000 000 copies/ml (referenced to the WHO HIV RNA 2nd International Standard (97/650) for IU/ml). The assay can detect group M subtypes A, C, D, F, G, H, circulating recombinant forms AE and AG, and group O VERSANT® kPCR Molecular System consists of the Sample Preparation Module for nucleic acids extraction, and the Amplification Detection Module, along with VERSANT® kPCR software. Closed-tube processing eliminates the need for clean room operations
Pre-installation requirements	Suitable for level III and IV laboratories
Operating conditions	18–30°C; 30–80% humidity, non-condensing; 0–2000 m altitude
Items supplied with analyser	VERSANT® kPCR Molecular System 10467524 includes the following: VERSANT® kPCR Molecular System SP with Heater/Shaker, 10282928 VERSANT® kPCR Molecular System SP Workstation w/ Barcode Scanner, 10702391 VERSANT® kPCR Molecular System AD, 10282939 VERSANT® kPCR Molecular System AD Workstation w/ Barcode Scanner, 10702393 VERSANT® kPCR Molecular System SP System Software v1.1 CD, 10471298 VERSANT® kPCR Molecular System AD System Software v1.1 CD, 10471300 VERSANT® kPCR Molecular System Test Definitions Non-US v1.1 CD, 10471299 VERSANT® kPCR Molecular System On-Line Help v1.1 CD, 10471301 VERSANT®kPCR Molecular System Software v1.1 Installation Kit, 10471297
Required accessories	N/A
Optional accessories	N/A
Turnaround time	Sample preparation system set-up <10 minutes; sample extraction <3 hours; amplification and detection <3 hours
Capacity (per run)	96 samples (89 clinical samples, 4 calibrators, and three controls) run in 6 hours
Throughput per technician / per day	up to 178 patient results per shift.
Sample needed and stability	Up to 500 µl input volume or 1 DBS (50–100 µ); whole blood collected in EDTA tubes can be stored for 6 hours at room temperature or for up to 24 hours at 2–8°C before centrifugation; plasma may be stored for up to 24 hours at room temperature or for up to 5 days at 2–8°C
Sample preparation and protocol complexity	(i) load the dedicated sample preparation reagents into a trough; (ii) place them on the module; (iii) load plasma samples onto the sample carrier; and (iv) place the sample carriers on the auto-load tray of the VERSANT Sample Prep module. From that point, sample prep module is fully automated
Reagent stability and reagent stability	VERSANT® HIV-1 RNA Assay 1.0 (kPCR), IVDD (Box 1), 10375763: Store at –30 to –10°C; shelf-life 12 months; VERSANT® HIV-1 RNA Assay 1.0 (kPCR) IVDD (Box 2), 10375764: Store at –90 to –60°C; shelf-life 12 months VERSANT® Sample Preparation 1.0 Reagents, IVDD (Box 1), 04801677: Store at 15–30°C; shelf-life 24 months. VERSANT® Sample Preparation 1.0 Reagents, IVDD (Box 2), 04801685: Store at 2–8°C; shelf-life 24 months
Cost/test	Unknown
Cost/instrument	Unknown
Installation	Yes
Training	Fully-trained lab technician, 3–5 days dedicated training on instrument, refresher training may be required
Maintenance/calibration	Routine preventive maintenance required. In case of breakdown, vendor-trained technician required to repair
Internal QC	Controls are included as part of reagent kit and required for each preparation run
External QA	Amenable to EQA
URL	http://www.healthcare.siemens.com/molecular-diagnostics/molecular-diagnostics-in-vitro-diagnostics/versant-hiv-1-rna-1-assay

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
447	VERSANT® HIV-1 RNA 1.0 (kPCR) Kit, IVDD Box 1	10375763	B	96 tests/kit	96	1000	11	Plasma	12 months	Store at –30 to –10oC	http://goo.gl/9xApSy	WHO, GF	WHO PQ, CE marked	
644	VERSANT® HIV-1 RNA (kPCR) Kit, IVDD Box 2	10375764	B	96 tests/kit	96	1000	11		12 months	Store at –90 to –60°C	http://goo.gl/9xApSy	WHO, GF	WHO PQ, CE marked	Contains negative, low positive, and high positive controls and two calibrators
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Plasma						Use EDTA tubes
528	VERSANT® Sample Preparation 1.0 Reagents, IVDD (Box 1)	04801677	R	96/box	96	1000	11		24 months	Store at 15–30°C		WHO, GF	WHO PQ, CE marked	
645	VERSANT® Sample Preparation 1.0 Reagents, IVDD (Box 2)	04801685	R	96/box	96	1000	11		24 months	Store at 2–8°C		WHO, GF	WHO PQ, CE marked	
348	Pipette tip, 100–1000 µl filter/aerosol barrier	Generic	C	96 tips/box	96	1000	11							
359	Pipette, serological, 10.0 ml	Generic	C	200/case		1000								
530	Pipette, serological, 25.0 ml	Generic	C	200/case		1000								
524	VERSANT® 1000 µl Pipette Tips	06635759	C			1000								
525	VERSANT® 300 µl Pipette Tips	06635767	C			1000								

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
526	VERSANT® 96-well, 2 ml Nuclease-free, Sterile Deep-well Plates	06691055	C			1000								
529	VERSANT® Barcoded 96-well Semi-skirted Polypropylene Plates for PCR	06653412	C			1000								
523	VERSANT® Large and Small Reagent Troughs	10489008	C			1000								
527	VERSANT® Optical Caps, 8 × strip	06653439	C			1000								
42	Pipette/pipettor 1000	Generic	E	1 unit		1000								
56	Vortex mixer	Generic	E	1 unit		1000								
31	Microcentrifuge (non-refrigerated)	Generic	E	1 unit		1000								
646	Water, deionized	Generic	R			1000								
531	Sodium hypochlorite solution (0.5%)	Generic	R			1000								
647	Tubes, test, polypropylene, 13 mm × 75 mm	Generic	C	100/pack	100	1000	10							For the 32-position sample carrier, use 11 x 60 mm to 14 x 100 mm sample tubes with inner d ⩾ 9mm
648	Tubes, test, polypropylene, 16 mm × 75 mm	Generic	C	100/pack	100	1000	10							For the 24-position sample carrier, use 14.5 x 60 mm to 18 x 100 mm sample tubes
649	Microcide SQ	Generic	C	1 vial	Varies	1000								

10.5 SECTION IF: CD4 ENUMERATION

CD4 ENUMERATION: ALERE PIMA™, ALERE TECHNOLOGIES GMBH

Diagnostic characteristics	Description of characteristics
Name of analyser	**Alere Pima™ Analyser**
Name of test	**Pima™ CD4 Test**
Catalogue number	260100025, 260100100, 260300003
Description	**Pima™ CD4 is an automated, image-based immune haematology test intended for the rapid in vitro enumeration of CD3+/CD4+ T cells (T-helper cells) absolute count in capillary or venous whole blood. Pima™ CD4 is intended to be used for the on-going monitoring of absolute CD4 lymphocyte counts in patients with documented diagnosis of an immunodeficiency disease. The Pima™ CD4 test is intended for in vitro diagnostic use.** **The Pima™ CD4 test comprises a disposable Pima™ CD4 test cartridge and the Pima™ Analyser. The disposable Pima™ CD4 test cartridge takes up approximately 25 µl of sample and contains dried reagents needed to perform the test. The Pima™ CD4 test is performed within the Pima™ CD4 test cartridge and no part of the Pima™ Analyser has contact with the sample at any time in the testing process.**
Pre-installation requirements	Could be used at all laboratory levels if qualified staff available
Operating conditions	**Temperature: 10–40°C; altitude: 0–2000 m; relative humidity: 10–95% (no condensation); storage temperature: 2–50°C; environment: protect from direct sunlight, humidity and dust**
Items supplied with analyser	260300003 Pima Analyser: 1 x Pima Analyser (260300001), 1 x Pima Bead Standard (260400011), 1 x power transformer, 1 x EU power cable 260300004 Instrument and Accessory pack: 1 x Pima Analyser (260300001), 1 x power transformer, 1 x EU Power cable, 1 x Pima Bead Standard (260400011), 1 x Pima Printer (260400007), 1 x Pima Analyser Bag (260400001), 1 x Connectivity Pack I (260400015) 260300006 Pima Analyser (CN): 1 x Pima Analyser with Chinese user interface, 1 x power transformer, 1 x EU power cable, 1 x Pima Bead Standard (260400011)
Required accessories	**None**
Optional accessories	260400007 Alere Pima™ Printer: includes 1 x Pima Printer, 1 x Pima Printer user guide, 1 x roll thermal paper I, coated, non-adhesive; 260400001 Pima™ Analyser bag; 260400009 Pima™ Printer paper I; 260400010 Pima™ Printer paper II; volumetric or transfer pipette (for venous blood); UPS/voltage regulator; 260400017 Alere Power Pack (external battery) incl. connector cable for Pima Analyser; 260400040 Alere Solar Solution: 1 x solar panel (260400041), 1 x power pack (260400015); 260400015 Alere Connectivity Pack 1: Samba3G-E modem with USB extension cable; 260400016 Alere Connectivity Pack 2: CT63 Terminal USB powered modem with mini USB connection cord and external FME antenna; 2560400046 Alere connectivity Pack 3: USB to ethernet adaptor. All the connectivity solutions come with a free Alerenet sim, data, free hosting on a tier 4 secure server and free use of the Datapoint Analytics Package.
Turnaround time	20 minutes
Capacity	3 tests per hour, no batching capability
Throughput per technician / per day	24 tests/8 hour day
Sample needed and stability	25 µl of capillary (fingerstick) blood wicked directly into the sample collector contained in the Pima cartridge or 25 µl of venous blood collected in EDTA anticoagulant tube. Cartridge must be inserted and tested within 5 minutes of sample application. When using venous blood, sample is stable for 36 hours from time of draw
Sample preparation and protocol complexity	No sample preparation required. Walk-away operation
Reagent stability and storage requirements	The Alere Pima™ CD4 cartridge should be stored at 2–30°C temperature range. Shelf-life is 12 months at 2–30°C
Cost/test	US$ 6–12
Cost/instrument	US$ 6500–12 000
Installation	No
Training	**2 days**
Maintenance/calibration	Not required
Internal QC	Each Alere Pima™ CD4 cartridge includes internal reagent control, instrument control, reagent expiry control, and sample volume control. The Pima Bead Standard is an internal standard for daily quality control on the Pima Analyser. It comprises two ready-to-use test cartridges, Pima Beads [Normal] and Pima Beads [Low], with set amounts of fluorescent spots. Daily QC should be performed before testing of patient samples or after any relocation of the Pima Analyser. Each test takes approx. 7 minutes.
External QA	Compatible with Pima: QASI and UK-NEQAS
URL	**http://alerehiv.com/hiv-monitoring/alere-pima-cd4/**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
58	Alere Pima™ CD4 Test Cartridge	260100100	B	100 tests/ kit	100	1000	10	Capillary or venous whole blood	12 months	Store at 2–30°C	http://goo.gl/CMyunA	WHO, GF	CE marked	For use with Alere Pima™ Analyser
		260100025		25 tests/kit	25	1000	40							
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Fingerstick, venous blood						For venous whole blood, use tubes containing EDTA
254	Alere Printer Paper 1	260400009	C	10 roll/pack		1000								Required if customer uses Alere Pima™ Printer
650	Alere Printer Paper 2	260400010	C	10 roll/pack		1000								Required if customer uses Alere Pima™ Printer
253	Finger Stick Collection Kit	260400199	C	100/kit	100	1000	10							Only for fingerstick procedure
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								N/A
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							Only for venepuncture procedure
3 – Control														
57	Alere Pima™ Bead Standard	260400011	R	1 pack		1000			6 months from opening the kit package	Unknown				

CD4 ENUMERATION: BD FACSCOUNT™ SYSTEM, BD BIOSCIENCES

Diagnostic characteristics	Description of characteristics
Name of analyser	**BD FACSCount™ instrument**
Name of reagent	**BD FACSCount™ Reagent Kit (Absolute CD4, CD8, CD3 counts)** **BD FACSCount™ CD4 Reagent Kit (Absolute and percentage CD4 counts)**
Catalogue no.	BD FACSCount™ instrument: 337858 BD FACSCount™ Reagent Kit (Absolute CD4, CD8, CD3 counts): 340167 BD FACSCount™ CD4 Reagent Kit (Absolute and percentage CD4 counts): 339010 BD FACSCount™ Controls: 340166
Description	**The BD FACSCount™ system is a bead based, no-lyse, no-wash dedicated analyser for enumeration of CD4 absolute counts and percentages or CD4, CD8 and CD3 T-cell counts. For use with whole blood. Reportable range: CD4 1–2000 cells/µl, CD8 1–2000 cells/µl, CD3 1–3500 cell/µl. Convection-cooled laser, precision less than 10% CV**
Pre-installation requirements	Suitable for level II, III and IV laboratories depending upon required throughput
Operating conditions	**Unknown**
Items supplied with analyser	BD FACSCount™ system (computer, monitor, and printer are integrated into instrument), workstation, coring station
Required accessories	**Cleaning tubes (343685), caps for cleaning tubes (343514), pipette tips in bulk (340293 or equivalent), thermal paper roll (332839), workstation for sample preparation, CD4 software disk, UPS/voltage regulator, barcode reader**
Optional accessories	N/A
Turnaround	60–120 minute incubation for BD FACSCount™ Reagent Kit or 30 minute incubation for BD FACSCount™ CD4 Reagent Kit; 2–3 minutes per test
Capacity	20 per hour, after initial 60–120 minute incubation for BD FACSCount™ Reagent Kit or 30 minute incubation for BD FACSCount™ CD4 Reagent Kit
Throughput per technician / per day	**30–80/day**
Sample needed and stability	EDTA whole blood should be stored at 20-25°C in the dark. BD FACSCount™ Reagent Kit: Minimum of 200 µl of whole blood is required for the test; staining to take place within 48 hours of blood draw; analysis to take place within 48 hours of staining. BD FACSCount™ CD4 Reagent Kit: Minimum of 100 µl of whole blood is required for the test; staining to take place within 24 hours of blood draw; analysis to take place within 48 hours of staining
Sample preparation and protocol complexity	Required. Process: (i) Add blood to reaction tube; (ii) vortex; (iii) Incubate reaction tubes at 20–25°C; (iv) Add fixative to the tube; and (v) Vortex sample and run on the instrument.
Reagent stability and storage requirements	BD FACSCount™ Reagent kit: must be stored at 2–8°C; shelf-life is 23 months BD FACSCount™ CD4 Reagent Kit: must be stored at 2–8°C; shelf-life is 15 months BD FACSCount™ Control kit: must be stored at 2–8°C; shelf-life is 24 months
Cost/test	Volume based; ranges from approximately US$ 3.50–10.00 per test
Cost/instrument	Approximately US$ 30 000
Installation	Yes
Training	**2–5 days**
Maintenance/calibration	Required annually. In case of breakdown, vendor-trained technician required to repair.
Internal QC	BD provides bead-based controls
External QA	Compatible with CD4 EQA programs
URL	**http://www.bdbiosciences.com/instruments/facscount/index.jsp**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
63	BD FACSCount™ CD4 Reagent Kit (50)	339010	B	50 tests/kit	50	1000	20	Venous whole blood	15 months	Store at 2–8°C	http://goo.gl/tpEMOq	WHO, GF	WHO PQ, CE marked	For enumeration of absolute CD4 counts and for determination of CD4 percentage
66	BD FACSCount™ Reagent Kit (50)	340167	B	50 tests/kit	50	1000	20		23 months		http://goo.gl/awTlNk	WHO, GF	WHO PQ, CE marked	For enumeration of absolute counts of CD4+, CD8+, and CD3+ T lymphocytes
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Venous blood						Use Vacutainer K2 or K3 EDTA blood collection tubes or equivalent
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves /box		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								
255	Cleaning tubes	343685	C	20/pack		1000								
651	Caps for cleaning tubes	343514	C	20/pack		1000								
370	Thermal paper	322839	C	5 rolls/ pack		1000								
46	Timer, digital	Generic	E	1 unit		1000								
65	BD FACS™ Flow Sheath Fluid	342003	R	20 litres/ pack		1000								
56	Vortex mixer	Generic	E	1 unit		1000								
3 – Control														
62	BD FACSCount™ CD4 Control Kit (25)	340166	R	25 /vial	25 test runs	1000		Whole blood	24 months	Store at 2–8°C	http://goo.gl/tpEMOq			

CD4 ENUMERATION: BD FACSPRESTO™ NEAR-PATIENT CD4 COUNTER, BD BIOSCIENCES

Diagnostic characteristics	Description of characteristics
Name of analyser	**BD FACSPresto™ Near-Patient CD4 Counter**
Name of reagent	**BD FACSPresto™ Cartridge** **BD FACSPresto™ Cartridge Kit**
Catalogue no.	BD FACSPresto™ Near-Patient CD4 Counter: 651000 BD FACSPresto™ Cartridge: 657681 BD FACSPresto™ Cartridge Kit: 655495
Description	**BD FACSPresto™ Near-Patient CD4 System consists of BD FACSPresto™ Counter and BD FACSPresto™ cartridge which contains dried fluorochrome-conjugated antibody reagents. This automated system is intended for in vitro enumeration of CD4 absolute count, CD4 percentage and haemoglobin concentration in human capillary and venous blood specimens.**
Pre-installation requirements	Suitable for remote locations and resource-limited settings
Operating conditions	**Unknown**
Items supplied with analyser	BD FACSPresto™ instrument packaging includes: Portable instrument Power supply Adaptor cords Instrument cover Work station Printer paper USB flash drive BD FACSPresto™ power supply adaptor BD FACSPresto™ Near-Patient CD4 counter Instruction for use
Required accessories	**None**
Optional accessories	BD FACSPresto™ Instrument Carrying Case 658210 BD FACSPresto™ Solar Charge Kit (includes solar panel, solar generator and power supply) 658212 BD FACSPresto™ Solar Generator 658885 BD FACSPresto™ Car Battery Charger Adaptor (12V DC power adaptor) 658860
Turnaround	18 minute incubation, 4 minutes per test
Capacity	More than ten patient results per hour when incubate cartridge outside the instrument
Throughput per technician / per day	**Up to 60 tests when incubate cartridge outside the instrument**
Sample needed and stability	Venepuncture or fingerstick whole blood collected in EDTA anticoagulant. Blood is stable up to 24 hours after draw if stored in EDTA tube at 20–25°C. Sample is stable for up to 2 hours after addition of sample to cartridge
Sample preparation and protocol complexity	Process: (i) collect venepuncture blood in EDTA tube; (ii) transfer blood by pipette from EDTA tube to cartridge; (iii) incubate cartridge for 18 minutes inside or outside the instrument. Fingerstick blood may be added directly to cartridge
Reagent stability and storage requirements	BD FACSPresto™ Cartridge: must be stored at 4–31°C; shelf-life is 12 months
Cost/test	To be determined
Cost/instrument	To be determined
Installation	Yes
Training	**Less than 1 day**
Maintenance/calibration	No preventive or routine maintenance is required for daily operation in the field. If a problem is encountered, a local resource can be contacted to arrange for a replacement instrument.
Internal QC	The instrument quality control feature automatically checks counting accuracy at the beginning of the day after the self-test, and on demand. Cartridge QC runs automatically at every cartridge run.
External QA	Compatible with commercially available process control. Compatible with CD4 EQA programs
URL	**http://goo.gl/Si1qg0 ; http://goo.gl/2kDVi3**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of UoM units required	Specimen type	Shelf-life	Temperature requirement	Document/ package/ link	Eligibility criteria	Regulatory status	Comment
1 – Required kit or equipment														
652	BD FACSPresto™ Cartridge	657681	B	100 tests/ kit	100	1000	10	Capillary or venous whole blood	12 months	Store at 4–31°C	http://goo.gl/Si1qg0	WHO, GF	WHO PQ, CE marked	Kit does not include consumables for blood collection by fingerstick
653	BD FACSPresto™ Cartridge Kit	655495	B	100 tests/ kit	100	1000	10							Kit includes consumables for blood collection by fingerstick
2 – Test run														
534	Blood collection consumables	Generic	C			1000		Venous blood; fingerstick (for product with catalogue no. 657581)						For venous blood, use tubes with EDTA
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/ box		1000								
351	Pipette tip, 10–200 µl	Generic	C	1000 tips/ pack	1000	1000	1							For venepuncture whole blood samples when BD FACSPresto™ Cartridge Kit is used
41	Pipette/ pipettor 200	Generic	E	1 unit		1000								
3 – Control														
460	Controls, HIV-negative		R			1000								Controls are not available for this kit; consider using QC specimens
459	Controls, HIV-positive		R			1000								

11. SECTION II - SPECIFICATION TABLES

11.1 SECTION IIA: EQUIPMENT

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements	Price range, US$
470	Biosafety cabinet class I/II	Generic		Biosafety cabinet for working with potentially infectious materials. Type-tested to EN 12469 (or equivalent) for biosafety cabinets, ISO 14644.1 Class 3 air quality, IEC 61010-1 electrical safety and IEST-RP filtration. Work access opening approx. 200 mm with audible alarm. Main construction: high-quality (304) stainless steel. Panels and work surface to be constructed from stainless steel with welded monolithic sealed structure. Viewing panel constructed from Plexiglas (or suitable equivalent) and can be raised via sliding mechanism. Cabinet should be supplied with height-adjustable stand on lockable castors. Two internal electrical outlets (user to specify type)	Anemometer, UPS/voltage regulator	Vacuum, electrical outlets	Yes	Yes	Annual	Annual service, recalibrate when moved	5000–20 000
17	Centrifuge, benchtop, non-refrigerated	Generic		Centrifuge with brushless motor and lid lock during operation. Up to at least 4000 relative centrifugal force (RCF). Digital display showing time remaining, rpm and RCF. Run options: short/pulse mode, timed and continuous	Swing-out rotor with 4 or 6 buckets OR fixed angle rotor with 12 or more places. Rotor or buckets must come with aerosol-tight lids. Adaptors or rotors (if fixed angle), minimum of 12 places for 5 ml, 7 ml and 10 ml blood collection tubes. Adaptors for 50 ml tubes		No	Yes	Yes, should be serviced as part of general laboratory equipment	Yes	2000–10 000
543	Centrifuge (for 96-well plates)	Generic		Centrifuge for centrifugation of 96-well plates. Capable of up to 5 000 g	Plate rotor/block for 96-well plates		No	Yes	Yes, should be serviced as part of general laboratory equipment	Yes	500–1000

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements	Price range, US$
600	EVOLIS™ System	89700	Bio-Rad Laboratories	Fully automated microplate processor; includes computer, monitor, printer, software (1 system); for use with GS HIV Combo Ag/Ab EIA	Disposable conductive tips for the detection of samples on EVOLIS™ system; 300 µl (18 x 960) (cat# 89611). Disposable conductive tips for the detection of reagents on EVOLIS™ system; 1100 µl (10 x 960) (cat # 89612)	Workstation table (cat # 25161)			Yes	Yes	
29	Heating block	Generic		Heating block incubator, compact design, capacity for 2 × heating blocks, temperature range: ambient to +120°C, LCD display	Blocks for 1.0 ml, 1.5 ml and 2.0 ml tubes, and 5 ml reaction vessels		No	Yes	Yes, should be serviced as part of general laboratory equipment	Yes	800–5000
30	Incubator, general purpose	Generic		General-purpose incubator, stainless steel, weldless interior, minimum of three adjustable stainless steel shelves. Adjustable feet for levelling. Warm air or water jacket design. Full length inner glass door. Heating elements isolated from internal chamber for safety. LED display with audible/visual over-temperature alarm. Access port for connection to chart recorder. Medium sized, approx. size: 20–150 litres. Range: ambient to +60°C (min), accuracy: ± 0.5°C	Carry case plus sufficient consumables for 250 tests		No	Yes	Yes, should be serviced as part of general laboratory equipment	Yes	
639	K-tube capper	03339874001	Roche Molecular Systems, Inc.	K-tube capper for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0							
520	K-tube capper, motorized	03516539001	Roche Molecular Systems, Inc.	K-tube capper, motorized, for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0							

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements	Price range, US$
602	LIAISON® XL platform	I0050	DiaSorin S.p.A.	Fully automated chemiluminescence analyser, performing complete sample processing (sample pre-dilutions, sample and reagent dispensing, incubations, wash processes, etc.) as well as measurement and evaluation; for use with LIAISON® XL MUREX HIV Ag/Ab	LIAISON® XL Cuvettes (cat # X0016), LIAISON® XL Disposable Tips (cat # X0015), LIAISON® XL Starter Kit (cat # 319200), LIAISON® XL Wash/System Liquid (cat # 319100)		Yes	Yes	Yes	Yes	
31	Microcentrifuge (non-refrigerated)	Generic		Microcentrifuge for centrifugation of small test tubes (0.2, 0.5, 1.0, 1.5 and 2.0 ml tubes). Capable of up to 14 000 rpm. Compact design with brushless motor and lid lock during operation. Digital display showing time remaining and rpm. Run options: pulse mode, timed and continuous. Timer in 1 s increments	Rotors for 1.0 ml, 1.5 ml and 2.0 ml tubes, aerosol-resistant rotor lid, UPS/voltage regulator		No	No	Yes, should be serviced as part of general laboratory equipment	Yes	2000–7000
32	Microplate/ ELISA plate reader	Generic		Microplate reader for 96-well microtitre plates. Includes variable speed shaker. Alphanumeric keypad, LCD display and capability to create, edit or run at least ten protocols. Wavelength range 380–900 nm (minimum), dynamic range 0–4.0 optical density (OD), resolution 0.001 OD, accuracy < 2%, linearity < 1%, repeatability < 1.5%	Blocks for 1.0 ml, 1.5 ml and 2.0 ml tubes		No	Yes	Yes, should be serviced as part of general laboratory equipment	Yes	7000–60 000
33	Microplate/ ELISA plate washer	Generic		Microplate washer for 96-well microtitre plates. Includes capacity for timed shaking and soak, times programmable up to 50 min. To include 3 × 1 litre (minimum volume) bottles (wash, rinse and waste), low wash bottle liquid volume sensor and interchangeable 8 × and 12 × manifolds. Alphanumeric keypad, LCD display and capability to create, edit or run at least ten protocols. Dispense precision ⩽ 4% CV, residual volume ⩽ 3 µl/well	Buffer, water and waste bottles (1 litre minimum), UPS/voltage regulator		No	No	Yes, should be serviced as part of general laboratory equipment	Yes	6500–9000

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements	Price range, US$
495	Mixer, roller	Generic		Mixer for rolling/rocking tubes			No	No	Yes, should be serviced as part of general laboratory equipment	Desirable, depends on model, site funds, etc.	1500–5000
39	Pipette/ pipettor 1	Generic		Single channel pipette/pipettor (0.1–1 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	Pipette stand (1 per set of 1 µl, 10 µl, 100 µl and 1000 µl pipettes), spare parts kit, washers, etc., depending on model/ manufacturer		No	Yes	No		80–500
556	Pipette/ pipettor 10	Generic		Single channel pipette/pipettor (0.5–10 µl). Mechanical, adjustable volume with tip ejector, autoclavable	Pipette stand (1 per set of 1 µl, 10 µl, 100 µl and 1000 µl pipettes), spare parts kit (washers, etc. – depends upon model/ manufacturer)		No	Yes	No		80–500
40	Pipette/ pipettor 20	Generic		Single channel pipette/pipettor (1–20 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	Pipette stand (1 per set of 1 µl, 10 µl, 100 µl and 1000 µl pipettes), spare parts kit (washers, etc. – depends upon model/ manufacturer)		No	Yes	No		80–500
41	Pipette/ pipettor 200	Generic		Single channel pipette/pipettor (10–200 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	Pipette stand (1 per set of 1 µl, 10 µl, 100-µl and 1000 µl pipettes), spare parts kit (washers, etc. – depends upon model/ manufacturer)		No	Yes	No		80–500

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements	Price range, US$
42	Pipette/ pipettor 1000	Generic		Single channel pipette/pipettor (10–1000 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	Pipette stand (1 per set of 1 µl, 10 µl, 100 µl and 1000 µl pipettes), spare parts kit (washers, etc. – depends upon model/ manufacturer)		No	Yes	No		80–500
499	Pipette/ pipettor 5000	Generic		Single channel pipette/pipettor (1000–5000 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl accuracy ± 0.12 µl	Pipette stand (1 per set of 1 µl, 10 µl, 100 µl and 1000 µl pipettes), spare parts kit (washers, etc. – depends upon model/ manufacturer)		No	Yes	No		80–500
43	Pipette/ pipettor mechanical repeater/ dispenser	Generic		Adjustable repeater pipette for 1.0–10 ml volumes			No	Yes	No		80–500
44	Pipette/ pipettor, multichannel 10–100	Generic		Multichannel (8) channel pipette/ pipettor (1–10/20 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl			No	Yes	No		500–900
631	Repeat pipettor, 40–50 µl	Generic		Repeater pipettor adjustable to 40–50 µl volumes			No	Yes	No		80–500
617	Pump, liquid jet vacuum with safety bottle	Generic		Liquid jet vacuum pump for generation of a vacuum and to siphon off liquids and vapours (if necessary, with a suction main or condensation trap connected upstream)							
618	Shaker	Generic		1-, 2-, or 3-dimentional shaker with optimized speed and tilt for gel blotting, washing and staining. Speed 0–60 rpm			No	No	No		1500–5000

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements	Price range, US$
506	Thermoshaker	Generic		Shaking heating block capable of mixing and warming microcentrifuge tubes, up to 100°C with accuracy +/- 2°C at 60°C, mixing frequency of approx. 1200–1400 rpm						Yes	500–2000
46	Timer, digital	Generic		Digital laboratory timer, multichannel (2 or more), channels may be independent, count-up or count-down, audible sound signals end of pre-set time	Spare batteries (× 5)		No	No			7–25
47	Timer, mechanical	Generic		Mechanical timer, up to 60–120 min in 1-min intervals. Reset at any time. Audible sound at end of pre-set time			No	No			2–10
508	Vacuum system – 1.5 litres/m	Generic		Vacuum system – 1.5 litres/m for bioMérieux's NucliSENS EasyQ® HIV-1 v2.0 assay can be substituted with dedicated pipettes							
56	Vortex mixer	Generic		Vortex mixer. Application: laboratory mixer for vortex different size tubes; handles small (0.5 ml, 1 ml, 2 ml, 3 ml, 5 ml, 10 ml) and larger (15 ml, 50 ml) test tubes. Variable speed, epoxy coated to reduce chemical and mechanical erosion. Suction feet for stability. Adjustable speed, 300–3000 rpm. Continuous or touch option. Provided with flat rubber platform	Platform attachment for 1.5 ml, 2.0 ml, 10 ml, 15 ml and 50 ml tubes		No	No	No		100–800
498	Water-bath	Generic		Circulating water-bath, stainless steel tank, digital, ambient +5°C max 100°C. Corrosion resistant exterior for easy cleaning. Constant mixing for even temperature distribution in the working volume and increased heat transfer. Temperature uniformity ± 0.05°C	National Institute of Science and Technology or equivalent traceable certificate thermometer, floating tube holders for 1.0 ml, 1.5 ml and 2.0 ml tubes. UPS/ voltage regulator						500–2000

11.2 SECTION IIB: KITS

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
546	ABON™ HIV-1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IHI-T402	ABON Biopharm Hangzhou Co., Ltd	ABON™ HIV-1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device manufactured by ABON Biopharm Hangzhou Co., Ltd., is an in vitro diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection	Kit	40 tests	Store at 2–30°C	http://goo.gl/7aCS1u	24		Kit includes 40 x specimen droppers
449	Abbott RealTi***me*** HIV-1 Amplification Reagent Kit	2G31-90	Abbot Molecular Inc.	In vitro RT-PCR assay for quantitation of HIV-1 in plasma. CE marked, WHO PQ	Kit	96 tests; 4 x 24 tests/ pack	Ship on dry ice; store at ≤ –10°C when not in use	http://goo.gl/K5mnmk	18		
540	Abbott RealTi***me*** HIV-1 Qualitative Amplification Reagent Kit	4N66-90	Abbot Molecular Inc.	Kit is a constituent of Abbott RealTi***me*** HIV-1 Qualitative Assay, which is intended for the qualitative detection of HIV-1 nucleic acids from human plasma and dried blood spots (DBS). Kit contains internal control and amplification reagent pack, which includes thermostable r***Tth*** polymerase enzyme, HIV-1 oligonucleotide reagent, and activation reagent	Kit	96 tests; 4 x 24 tests/ pack	Ship on dry ice; store at ≤ –10°C when not in use	http://goo.gl/wNjn4f	18 (except for Thermostable r***Tth*** Polymerase Enzyme 56685: Per control date on vendor certificate of analysis)	697–2654	http://goo.gl/oi7Qnu

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
201	Alere Determine™ HIV-1/2	7D2342	Alere Medical Co. Ltd.	In vitro, visually read, qualitative immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum, plasma, and whole blood. WHO PQ, ROW	Kit	20	Store at 2–30°C	http://goo.gl/22GVrB	14	33	
		7D2343				100				65–161	
202	Alere Determine™ HIV-1/2	7D2346	Alere Medical Co. Ltd.	In vitro, visually read, qualitative immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum, plasma, and whole blood. CE marked	Kit	20	Store at 2–30°	http://goo.gl/22GVrB	14		
		7D2347				100					
200	Alere Determine™ HIV-1/2 Ab/Ab Combo	7D2646	Alere Medical Co. Ltd.	In vitro, visually read, qualitative immunoassay for the simultaneous detection of free non-immunocomplexed HIV-1 p24 antigen (Ag) and antibodies (Ab) to HIV-1 and HIV-2 in serum, plasma, fingerstick or venous whole blood; CE marked	Kit	20	Store at 2–30 °	http://gssh.co/1cGS5gh	12		
		7D2647				100					
548	Alere Determine™ HIV-1/2 Ab/Ab Combo	7D2643	Alere Medical Co. Ltd.	In vitro, visually read, qualitative immunoassay for the simultaneous detection of free non-immunocomplexed HIV-1 p24 antigen (Ag) and antibodies (Ab) to HIV-1 and HIV-2 in serum, plasma, fingerstick or venous whole blood; WHO PQ, ROW	Kit	100	Store at 2–30°	http://goo.gl/y2ejvY	10		
58	Alere Pima™ CD4 Test Cartridge	260100100	Alere Technologies GmbH	Disposable cartridge for determination of absolute counts of T-helper cells in whole blood using Pima™ Analyser. CE marked, WHO PQ	Kit	100	Store at 2–30 °	http://goo.gl/CMyunA	12	600–1485	
		260100025				25					

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
		260100025				25					
539	Aware™ HIV-1/2 OMT Rapid Antibody Test	98164	Calypte Biomedical Corporation	Single-use, qualitative, visually read, in vitro immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human oral mucosal transudate (oral fluid) specimens. ROW	Kit	100	Store at 2–30°	http://goo.gl/5fj0Zv	18		98166 contains English IFU, 98169 contains English & Russian IFU, 98164 labelled and contains Arabic, English, French, Spanish, Portuguese, & Russian IFU
		98166				1					
		98169				1					
63	BD FACSCount™ CD4 Reagent Kit (50)	339010	Becton, Dickinson and Company, BD Biosciences	Enables simultaneous enumeration of absolute CD4 counts and determination of CD4 percentages in unlysed whole blood. For use with BD FACSCount™ instrument. CE marked, WHO PQ	Kit	50	Store at 2–8°C	http://goo.gl/tpEMOq	15 months	220–340	
66	BD FACSCount™ CD4 & CD3 Reagent Kit (50)	340167	Becton, Dickinson and Company, BD Biosciences	A 50-test kit in unit test format that uses a no-lyse, no-wash, whole blood method for enumeration of absolute CD4, CD8, and CD3 counts. Designed for use in the FACSCount™ system. CE marked, WHO PQ	Kit	50	Store at 2–8°C	http://goo.gl/awTlNk	23 months	205–300	
652	BD FACSPresto™ Cartridge	657681	Becton, Dickinson and Company, BD Biosciences	Cartridge for in vitro enumeration of CD4 absolute count, CD4 percentage and haemoglobin concentration in human capillary and venous blood specimens. For use only with BD FACSPresto™ Near-Patient CD4 Counter. CE marked, WHO PQ.	Kit	100	Store at 4–31°C	http://goo.gl/Si1qg0	12		Alternative products: BD FACSPresto™ Cartridge Kit includes consumables for blood collection by fingerstick
653	BD FACSPresto™ Cartridge Kit	655495	Becton, Dickinson and Company, BD Biosciences	Cartridge for in vitro enumeration of CD4 absolute count, CD4 percentage and haemoglobin concentration in human capillary and venous blood specimens. For use only with BD FACSPresto™ Near-Patient CD4 Counter. CE marked, WHO PQ.	Kit	100	Store at 4–31°C	http://goo.gl/Si1qg0	12		

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
574	Bioelisa HIV-1+2 Ag/Ab	3000-1172 3000-1173	BIOKIT, SA	ELISA test for the detection of antibodies to HIV-1 (group M, O) or HIV-2 and HIV-p24 antigen in human serum or plasma samples in clinical laboratories and as a first-line screening assay in blood centres. CE marked, WHO PQ	Kt	96 480	Store at 2–8°C	http://goo.gl/nkUvaW	9		Kit includes negative, HIV-1 positive, HIV-2 positive, and HIV-1 p24 positive controls
553	BioTracer™ HIV-1/2 Rapid Card	11112 11135	BioFocus Co., Ltd.	Immunochromatography-based one-step in vitro diagnostic test for qualitative detection of antibodies to HIV-1 and HIV-2 in serum, plasma, or whole blood. ROW	Kit	30 100	Store at 1–30°C	http://goo.gl/E9PrRy	18		
542	Clearview® COMPLETE HIV-1/2	92111	Chembio Diagnostic Systems, Inc.; distributed by Alere North America, Inc.	Single-use rapid immunochromatographic test for detection of antibodies to HIV-1 and HIV-2. Includes lancet	Kit	25	Store at 8–30°C	http://goo.gl/3QK4g7	24		Distributed by Alere North America, Inc.; manufactured by Chembio Diagnostic Systems, Inc.; distributed by Chembio Diagnostic Systems, Inc. as SURE CHECK® HIV-1/2 Assay (Cat # HIV202). Kit includes commodities for collection fingerstick whole blood
231	COBAS® AmpliPrep/ COBAS® TaqMan® HIV-1 Test v2.0	05212294190	Roche Molecular Systems, Inc.	Nucleic acid amplification test for the quantitation of HIV-1 RNA in plasma using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® 48 Analyser or COBAS® TaqMan® 96 Analyser for automated amplification and detection. WHO PQ, CE marked	Kit	48	Store at 2–8°C	http://goo.gl/8QRT3Z , http://goo.gl/CBd2VB	18	460–1090	High positive, low positive, and negative controls included

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
640	COBAS® AmpliPrep/ COBAS® TaqMan® Qualitative HIV-1 Test v2.0	06693083190	Roche Molecular Systems, Inc.	In vitro diagnostic, total nucleic acid amplification test for the qualitative detection of human immunodeficiency virus type 1 (HIV-1) DNA and RNA (or total nucleic acid, TNA) in human plasma or dried blood spots using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® Analyser or COBAS® TaqMan® 96 Analyser for automated amplification and detection. WHO PQ, CE marked	Kit	48	Store at 2–8°C	http://goo.gl/OZAMjR; http://goo.gl/c1FflA	22		HIV-1 positive and negative controls included
560	Combaids RS Advantage	51SP200-48	Span Diagnostics	Solid-Phase Immunosorbent Assay (SPIA) is an immuno-dot test format for detection of antibodies to HIV-1 and HIV-2 in human whole blood/serum/plasma with inbuilt control dot (Rapid Test). ROW	Kit	48	Store at 2–8°C	http://goo.gl/MqZLB7	15	37	Kit includes HIV-1 positive control, HIV-2 positive, and HIV-negative control; Disposable plastic droppers
		51SP200-96				96				70	
198	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	KH-R-02	Shanghai Kehua Bio-engineering Co. Ltd. (KHB)	Rapid lateral flow immunochromatographic test	Kit	50	Store at 4–30°C	N/A	15		
536	DPP® HIV-1/2 Assay	65-9500-0	Chembio Diagnostic Systems, Inc.	A single-use immunochromatographic test for the detection of antibodies to HIV-1/2 in oral fluid, fingerstick whole blood, venous whole blood, serum, or plasma samples. FDA approved	Kit	20	Store at 2–30°C	http://goo.gl/zOM3sh	23		Kit includes 20 swabs for oral fluid collection; 20 disposable 10 µl sample loops
535	DPP® HIV-1/2 Assay	65-9506-0	Chembio Diagnostic Systems, Inc.	A single-use immunochromatographic test for the detection of antibodies to HIV-1/2 in oral fluid, fingerstick whole blood, venous whole blood, serum, or plasma samples. ROW	Kit	20	Store at 2–30°C	http://goo.gl/zOM3sh	24		Kit includes 20 swabs for oral fluid collection; 20 disposable 10 µl sample loops

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
575	Elecsys® HIV Combi PT	05390095190	Roche Diagnostics	The electrochemiluminescence immunoassay for the in vitro qualitative determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 in human serum and plasma. The assay does not discriminate among HIV-1 antibody, HIV-2 antibody, or HIV p24 antigen reactivity. ROW	Kit	100	Store at 2–8°C	http://goo.gl/3tHxmG http://goo.gl/6zZpi1	5		For use with COBAS® modular platform (COBAS e 411, COBAS e 601, COBAS e 602); MODULAR® ***ANALYTICS*** E 170; Elecsys® 2010 analyser
213	First Response® HIV-1-2.O Card Test	I05FRC30	Premier Medical Corporation Ltd	Rapid Immunochromatographic Card Test for the detection of Antibodies to HIV-1 & 2 in Human Whole Blood/Serum/ Plasma. CE marked	Kit	30	Store at 4–30°C	http://goo.gl/RqrSgw	23	21–48	Kit includes 30 x 10 µl pipettes, 30 x twist lancets, and 30 x 70% isopropyl alcohol swabs
613	Geenius™ HIV-1/2 Confirmatory Assay	72460	Bio-Rad Laboratories	A single-use immunochromatographic test for the confirmation and differentiation of individual antibodies to human immunodeficiency virus types 1 and 2 (HIV-1 and HIV-2) in fingerstick whole blood, venous whole blood, serum or plasma samples; is intended for use as an additional test to confirm the presence of antibodies to HIV-1 and HIV-2 for specimens found to be repeatedly reactive by screening procedures	Kit	20	Store at 2–30°C	http://goo.gl/vFRHGn	18		Includes 20 x 15 µl microtubes capillarity plastic pipettes for fingerstick protocol
545	Genie™ Fast HIV-1/2 Assay	72327	Bio-Rad Laboratories	RDT for detection of anti-HIV-1 and anti-HIV-2 antibodies in serum, plasma and whole blood, CE marked	Kit	25	Store at 2–30°C	http://goo.gl/ji0RHg	18		Kit includes 50 pipettes for depositing serum, plasma and venous blood
		72330				50		http://goo.gl/yHdDPa			Kit includes 50 pipettes for depositing serum, plasma and venous blood

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
563	Genscreen™ ULTRA HIV Ag-Ab	72386	Bio-Rad Laboratories	Screening kit for the detection of HIVP24 antigen and antibodies to HIV-1 and HIV-2 in human serum/plasma by enzyme immunoassay, CE marked	Kit	96 (1 plate)	Store at 2–8°C	http://gssh.co/15E90dq http://goo.gl/s5zShW	18		Positive and negative controls are included; three controls required for each test batch, with negative control in triplicate; therefore, each batch will include five controls
		72388				480 (5 plates)					
594	Genscreen™ HIV-1/2 Version 2	72278	Bio-Rad Laboratories	Screening kit for the detection of antibodies to HIV-1 and HIV-2 in human serum/plasma by enzyme immunoassay, CE marked	Kit	96 (1 plate)	Store at 2–8°C	http://goo.gl/lJf5hR	18		Negative, positive, and cut-off controls are included; three controls required for each test batch, with cut-off control in triplicate; therefore, each batch will include five controls;
		72279				480 (5 plates)					
595	GS HIV Combo Ag/Ab EIA	26217	Bio-Rad Laboratories	EIA kit for the simultaneous qualitative detection of HIV p24 antigen and antibodies to HIV-1 groups M and O and HIV-2 in human serum or plasma. Intended for manual use and for use with the Bio-Rad EVOLIS™ Automated Microplate System. Cannot be used to distinguish between the presence of HIV p24 antigen, HIV-1 antibody, or HIV-2 antibody in a sample. Not for screening blood donors. FDA approved	Kit	192 (2 plates)	Store at 2–8°C	http://goo.gl/K37Gk1	18		Seven controls must be run on each plate
		26218				960 (10 plates)					
204	HIV-1/2 STAT-PAK®	HIV101 (60-9500-0)	Chembio Diagnostic Systems, Inc.	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum, plasma or whole blood. Includes chase buffer. Sample size 5 µl. WHO PQ, ROW	Kit	20	Store at 8–30°C	http://goo.gl/jKtp9N	24		Kit includes 20 disposable 5 µl sample loops for collection and transfer of fingerstick whole blood or for transfer of venous whole blood, serum, and plasma specimens. Product code HIV101 cross referenced to product code 60-9500-0; both codes represent the same product

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
206	HIV-1/2 Stat-Pak® Dipstick	HIV303	Chembio Diagnostic Systems, Inc.	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum, plasma, or whole blood. Includes chase buffer. Sample size 5 µl. ROW, WHO PQ	Kit	30	Store at 8–30°C	http://goo.gl/ja2Yje	24	25	Kit includes 30 disposable 5 µl sample loops for collection and transfer of fingerstick whole blood or for transfer of venous whole blood, serum, and plasma specimens
547	HIVSav 1/2/0 Rapid SeroTest™	A41112	Savyon Diagnostics	Rapid test for qualitative detection of antibodies to HIV-1, HIV-2 and HIV subtype O in whole blood, serum or plasma	Kit	25	Store at 2–30°C	http://goo.gl/yZZCi3	15		Kit includes disposable plastic pipettes for transfer of venous whole blood, serum, or plasma specimens
		B41112				50					Kit includes disposable plastic pipettes for transfer of venous whole blood, serum, or plasma specimens
615	HIV Blot 2.2	07-11030-036	MP Biomedicals Singapore	Qualitative enzyme immunoassay for the in vitro detection of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2) in human serum or plasma. It is intended for use as a more specific supplemental test on human serum or plasma specimens found repeatedly reactive using methods such as enzyme-linked immunosorbent assay (ELISA)	Kit	36	Store at 2–8°C	http://goo.gl/4zcfcv	11		
566	iCARE HIV-1&2 Rapid ScreenTest (Whole Blood/ Serum/Plasma)	IT1001	JAL Innovation	Rapid immunochromatographic direct binding test for the visual detection of HIV antibodies in whole blood, serum or plasma samples in the diagnosis of HIV infection. One-step HIV test cassette adopts double antigen sandwich method	Kit	40	Store at 4–30°C	http://goo.gl/UxGB0r	24		Contains micropipettes for specimen transfer

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
190	ImmunoComb® II HIV-1&2 BiSpot	60432002	Orgenics Ltd.	Indirect rapid solid-phase EIA for qualitative and differential detection of antibodies to HIV-1 and HIV-2 in serum or plasma; WHO PQ	Kit	36	Store at 2–8°C	http://gssh.co/15zusHl	15		
619	INNO-LIA™ HIV I/II Score	80540	Fujirebio Europe N.V.	Line immunoassay for the confirmation and discrimination of antibodies to HIV-1, HIV-1 group O and HIV-2 in human serum and plasma; CE marked	Kit	20	Store at 2–8°C	http://goo.gl/TTVCxK	12		Fully automated strip processing possible using Auto-LIA™ 48, Auto-LiPA™ 48 or AutoBlot 3000(H). Automated reading and interpretation of the strips possible using LiRAS® for Infectious Diseases
551	INSTI™ HIV-1/HIV-2 Antibody Test without support material	90-1021	bioLytical Laboratories, Inc.	Single-use, rapid, flow-through in vitro qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in EDTA whole blood, fingerstick blood, serum or EDTA–plasma. WHO PQ, ROW	Kit	48	Store at 15–30°C	http://goo.gl/Hm03m5 http://goo.gl/5IVLdG	15		No support materials provided
550	INSTI™ HIV-1/HIV-2 Antibody Test with support materials	90-1012	bioLytical Laboratories, Inc.	Single-use, rapid, flow-through in vitro qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in EDTA whole blood, fingerstick blood, serum or EDTA–plasma, WHO PQ, ROW	Kit	1	Store at 15–30°C	http://goo.gl/Hm03m5 http://goo.gl/XBxexU http://goo.gl/5IVLdG	15		Includes support materials: single-use alcohol swabs; single-use sterile lancets; single-use pipette capable of dispensing 50 µl
		90-1022				48					
601	LIAISON® XL MUREX HIV Ab / Ag	310260	DiaSorin S.p.A.	Sandwich chemiluminescent assay for the combined screening of HIV p24 Ag and HIV Ab. CE marked	Kit	200	Store at , 2–8°C	http://goo.gl/5U4rfc	18		For use with dedicated LIAISON® XL instrument
537	Multispot HIV-1/HIV-2 Rapid Test	25228	Bio-Rad Laboratories	RDT for detection and differentiation of HIV-1 and HIV-2 antibodies in serum and plasma, FDA approved	Kit	50	Store at 2–8°C; can be stored for 3 months at 20–30°C	http://goo.gl/qoOD6y	12 at 2–8°C; 3 at 20–30°C		

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
609	Murex HIV – 1.2.O	9E25-01 9E25-02	DiaSorin S.p.A.	EIA kit for the simultaneous qualitative detection of HIV p24 AG and HIV AB in serum and plasma. CE marked	Kit	96 (1 plate) 480 (5 plates)	Store at 2–8°C	http://goo.gl/nMt6Al	12	1.36/test 1.36/test	Can be used in manual, semi-automated or automated way. Controls included; five controls must be run on each plate; therefore, 96 tests include control runs
610	Murex HIV Ag/Ab Combination	7G79-09 7G79-11	DiaSorin S.p.A. – UK Branch	EIA kit for the simultaneous qualitative detection of HIV p24 AG and HIV AB in serum and plasma. WHO PQ, CE marked	Kit	96 (1 plate) 480 (5 plates)	Store at 2–8°C	http://goo.gl/hs6Msd	12	113–189; 1.96/test 413; 1.96/ test	Can be used in manual, semi-automated or automated way. Controls included; six controls must be run on each plate; therefore, 96 tests include control runs
620	NEW LAV BLOT I	72251	Bio-Rad Laboratories	Confirmation kit for anti-HIV-I antibodies detection in human serum and plasma by immunoblotting, CE marked	Kit	18	Store at 2–8°C	http://goo.gl/U9Vgg2	18	317–936	
621	NEW LAV BLOT II	72252	Bio-Rad Laboratories	Confirmation kit for anti-HIV-2 antibodies detection in human serum and plasma by immunoblotting, CE marked	Kit	18	Store at 2–8°C	http://goo.gl/U402dQ	18		
488	NucliSENS EasyQ® HIV-1 V2.0	285033	bioMérieux	Nucleic acid amplification assay for the quantitative determination of HIV-1 RNA in human EDTA plasma and EDTA whole blood spotted on cards (DBS)	Kit	48	Store at 2–8°C	http://goo.gl/8smz2h , http://goo.gl/xyEqfk	18		

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
655	OraQuick ***ADVANCE***® Rapid HIV-1/2 Antibody Test	1001-0079	Orasure Technologies Inc.	Single-use, qualitative immunoassay for detection of antibodies to HIV-1 and HIV-2 in oral fluid, plasma, fingerstick or venepuncture whole blood. FDA approved	Kit	25	Store at 2–27°C	http://goo.gl/lTViSM http://goo.gl/OYfqop	30		Includes 25 specimen collection loops for collection of fingerstick whole blood or transfer of venous whole blood, plasma, and serum specimens. Flat pad for oral fluid specimen collection is integrated in testing device
		1001-0078				100					Includes 100 specimen collection loops for collection of fingerstick whole blood or transfer of venous whole blood, plasma, and serum specimens. Flat pad for oral fluid specimen collection is integrated in testing device
218	OraQuick Rapid HIV-1/2 Antibody Test	5x4-0010	OraSure Technologies Inc.	Single-use, qualitative immunoassay for detection of antibodies to HIV-1 and HIV-2 in oral fluid, plasma, fingerstick or venepuncture whole blood. ROW	Kit	100	Store at 2–30°C	http://goo.gl/GFkEph	30		Includes five specimen collection loops for collection of fingerstick whole blood or transfer of venous whole blood, plasma, and serum specimens. Flat pad for oral fluid specimen collection is integrated in testing device
		5 x 4-0012				500					Includes 25 specimen collection loops for collection of fingerstick whole blood or transfer of venous whole blood, plasma, and serum specimens. Flat pad for oral fluid specimen collection is integrated in testing device

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
622	PEPTI-LAV 1-2	72253	Bio-Rad Laboratories	Discrimination test for HIV-1 and HIV-2 antibodies by enzyme immunoassay (10 tests). CE marked	Kit	10	Store at 2–8°C	http://goo.gl/7k7UoU	4		
555	***Reveal***® G3 Rapid HIV-1 Antibody Test (***Reveal***® G3)	815311000591	MedMira Laboratories Inc.	The ***Reveal***® G3 Rapid HIV-1 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to human immunodeficiency virus type 1 (HIV-1) in human serum or plasma.	Kit	30	Store at 2–30°C	http://goo.gl/TB1d5H	12		Kit includes positive and negative test controls; disposable pipettes for specimen transfer.
572	RightSign® HIV-1.2.O Rapid Test Cassette	IHIV-C42	Hangzhou Biotest Biotech Co., Ltd.	Rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 and subtype O in whole blood, serum, plasma. CE marked	Kit	25	Store at 2–30°C	http://goo.gl/r9jq67			Kit includes droppers for transfer of venous whole blood, serum, plasma specimens
565	SD Bioline HIV-1/2 3.0	03FK10	Standard Diagnostics, Inc.	Immunochromatographic assay for the differential and qualitative detection of all isotypes (IgG, IgM, IgA) antibodies specific to HIV-1 including subtype O and HIV-2 simultaneously, in human serum, plasma or whole blood. ROW, WHO PQ	Kit	30	Store at 1–30°C	http://goo.gl/69jk8A http://goo.gl/Ps5HKQ	24	~ 55; 1.19–1.50/ test	Blood collection accessories and capillary pipettes are **not** included
		03FK16				25					Kit contains 25 x capillary pipettes, 25 x lancets, 25 x alcohol swabs
561	SD Bioline HIV Ag/ Ab Combo	03FK30	Standard Diagnostics, Inc.	Rapid, qualitative test for simultaneous detection of HIV p24 antigen and antibodies to all isotypes (IgG, IgM, IgA) specific to HIV-1 including subtype O and HIV-2 simultaneously in human serum, plasma or whole blood. ROW, WHO PQ	Kit	30	Store at 1–30°C	http://goo.gl/1ocoIs http://goo.gl/hPoZb1	18		Blood collection accessories and capillary pipettes are **not** included
		03FK35				25					Kit contains 25 x capillary pipettes, 25 x lancets, 25 x alcohol swabs
557	Signal® HIV	51FT100-10	Span Diagnostics Ltd.	Flow through immuno-dot test format for detection of antibodies to HIV-1 and HIV-2 in human serum/plasma (Rapid Test). ROW	Kit	10	Store at 2–8°C	http://goo.gl/MqZLB7	15	17	
		51FT100-50				50				80	
		51FT100-60				100				155	

Item no.	Item name	Catalogue no.	Manufacturer	Description/ specification	Pack type	Quantity per pack	Temperature requirement	Document/ package/ link	Shelf-life (months)	Price range, USD	Comment
564	SURE CHECK® HIV-1/2 Assay	HIV201 (60-9527-0)	Chembio Diagnostic Systems, Inc.	A single-use immunochromatographic RDT for the detection of antibodies to HIV-1 and HIV-2 in fingerstick whole blood, venous whole blood, and serum or plasma specimens. CE marked	Kit	25	Store at 8–30°C	http://goo.gl/J19Tgr http://goo.gl/Mtv9K0	24		Kit includes commodities for collection and transfer of fingerstick specimens. Product code HIV201 cross referenced to product code 60-9527-0; both codes represent the same product
229	Uni-Gold™ HIV	1206502	Trinity Biotech plc	Single reagent assay for detection of antibodies to HIV-1 and HIV-2 in serum, plasma or whole blood, WHO PQ, ROW	Kit	20	Store at 2–27°C	http://goo.gl/lOEV6B	12	32–35	Kit includes 20 disposable pipettes
558	Uni-Gold™ Recombigen® HIV	1206506	Trinity Biotech plc	Single reagent assay for detection of antibodies to HIV-1 and HIV-2 in serum, plasma or whole blood, FDA approved	Kit	20	Store at 2–27°C	http://goo.gl/KZ1WoX	12		Kit includes 20 disposable pipettes for use with serum, plasma or venous whole blood, and controls; 20 disposable fingerstick sample collection and transfer pipettes for use with fingerstick whole blood
447	VERSANT® HIV-1 RNA (kPCR) Kit, IVDD Box 1	10375763,	Siemens Healthcare Diagnostics	Reagents to perform in vitro nucleic acid amplification VERSANT HIV-1 RNA 1.0 assay for quantitative measurement of HIV-1 RNA in fresh or frozen plasma. CE marked, WHO PQ	Kit	96	Store at –30 to –10°C	http://goo.gl/9xApSy	12		
644	VERSANT® HIV-1 RNA (kPCR) Kit, IVDD Box 2	10375764	Siemens Healthcare Diagnostics	Four sets of calibrators and controls to perform VERSANT HIV-1 RNA 1.0 assay. CE marked, WHO PQ	Kit	96	Store at –90 to –60°C	http://goo.gl/9xApSy	12		
573	VIKIA HIV-1/2	31112	bioMérieux SA	Immunochromatographic rapid test for the qualitative detection of antibodies to HIV-1 and HIV-2 in human serum, plasma, and whole blood. CE marked, WHO PQ	Kit	25	Store at 4–30°C	http://goo.gl/4sPNqN	21		Disposable droppers for transfer of venous whole blood, plasma, or serum specimens

11.3 SECTION IIC: REAGENTS

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/ pack	Temperature requirement	Shelf-life (months)	Price range, USD
450	Abbott *m*Sample Preparation System RNA	04J70-24,	Abbott Molecular Inc.	RNA sample preparation kit	Kit	96	Store at 15–30°C	18	288
634	Abbot *m*Sample Preparation System $_{DNA}$	6K12-24	Abbott Molecular Inc.	Kit for sample preparation (extraction, concentration, and purification) for Abbott RealTi*me* HIV-1 Qualitative assay.	Kit	4 x 24 preps	Ambient temperature	18	
451	Abbott *m*2000rt Optical Calibration Kit	4J71-93	Abbott Molecular Inc.	Optical calibration kit for Abbott *m*2000rt RealTi*me* PCR analyser	Kit		Store at 15–30°C	18	
464	Abbott RealTi*me* HIV-1 Calibrator Kit	2G31-70	Abbott Molecular Inc.	Calibrator kit for calibration of the Abbott RealTi*me* HIV-1 assay when used for the quantitative determination of HIV-1 RNA in human plasma	Pack	12 calibration events	Ship on dry ice; store at ≤ –10°C when not in use	18	230
463	Abbott RealTi*me* HIV-1 Control Kit	2G31-80	Abbott Molecular Inc.	Control kit for each run of Abbott RealTi*me* HIV-1 Test Kit	Kit	3 controls with eight vials per control	Ship on dry ice; store at ≤ –10°C when not in use	18	230–820
638	Abbott RealTi*me* HIV-1 Qualitative Control Kit	4N66-80	Abbott Molecular Inc.	Kit contains positive and negative controls to perform Abbott RealTi*me* HIV-1 Qualitative assay. One positive and one negative control are required per run.	Kit	2 controls with 12 vials per control	Ship on dry ice; store at ≤ –10°C when not in use	18	
476	Alere HIV RDT Controls	7D2626	Alere Medical Co. Ltd.	Positive/negative control material for Alere HIV RDTs	Kit	100	Store at 4°C		
57	Alere Pima Bead Standard	260400011	Alere Technologies GmbH	Internal standards for daily control consisting of two ready-to-use cartridges, 1 low and one normal, consisting of immobilized fluorescent beads	Kit			6 month from opening the kit regardless of the number of tests done	50
533	Aware™ HIV-1/2 OMT Control Pack	98131	Calypte Biomedical Corporation	Controls for Calypte Aware™HIV-1/2 OMT Rapid Antibody Test	Kit	15	Store at –20°C	12	
							Store at 2–8°C	1 (after thawing)	
62	BD FACSCount™ CD4 Control Kit	340166	Beckton, Dickinson and Company, BD Biosciences	Includes zero, low, medium and high control beads for use in setting up the FACSCount™ system and checking linearity	Kit	25	Store at 2–8°C	24	185–330
65	BD FACSFlow™ Sheath Fluid	342003	Beckton, Dickinson and Company, BD Biosciences	BD FACSFlow™ Sheath Fluid for BD FACSCount™ system	Pack	20L	Ambient temperature		29–157
636	Bulk *m*Lysis$_{DNA}$ Buffer	2N77-01	Abbott Molecular Inc.	Buffer for sample preparation from dry blood spot specimens for Abbott RealTi*me* HIV-1 Qualitative assay	Bottle	3 x 70 ml	N/A		

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/ pack	Temperature requirement	Shelf-life (months)	Price range, USD
199	Chase Buffer	7D2243	Alere Medical Co. Ltd.	Chase buffer for Alere HIV RDTs to use with whole blood samples for	Bottle	2.5 ml	Store at 4°C	12–18	
578	CleanCell	11662970122	Roche Diagnostics	Measuring cell cleaning solution for Elecsys 2010 and COBAS e 411 analysers to perform Elecsys® HIV Combi PT assay	Case	6 x 380 ml			
584	CleanCell M	04880293190	Roche Diagnostics	Measuring cell cleaning solution for MODULAR ANALYTICS E170, COBAS e 601 and COBAS e 602 analysers to perform Elecsys® HIV Combi PT assay	Case	2 x 2 L			
541	Clearview® HIV Reactive/ Nonreactive Controls	92112	Chembio Diagnostic Systems, Inc.; distributed by Alere North America, Inc.	Controls for Clearview® Complete HIV-1/2 RDT. Each package includes: 1 HIV-1 reactive control (0.25 ml), 1 HIV 2 reactive control (0.25 ml), 1 nonreactive control (0.25 ml)		250 reactions/ each control/ package	Store at 2–8°C	24	
641	COBAS® AmpliPrep/ COBAS® TaqMan® Specimen Pre-Extraction Reagent	06989861190	Roche Molecular Systems, Inc.	Reagent for extraction of dried whole blood from DBS to be tested using COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0	5 x 78 ml	350 extractions	Store at 2–8°C	12	5–90
445	COBAS® AmpliPrep/ COBAS® TaqMan® Wash Reagent	03587797190	Roche Molecular Systems, Inc.	Wash reagent to perform COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0 using COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® 48 Analyser or COBAS® TaqMan® 96 Analyser	Bottle	5.1L	Store at 2–30°C	24	0.1–150
460	Controls, HIV-negative			QC specimens may be used as controls when controls are not available from manufacturer of an assay			Store at 2–8°C		
459	Controls, HIV-positive			QC specimens may be used as controls when controls are not available from manufacturer of an assay			Store at 2–8°C		
496	Controls, HIV RNA negative, commercial			Commercial controls required for viral load assays			Store at 2–8°C		
497	Controls, HIV RNA positive, commercial			Commercial controls required for viral load assays			Store at 2–8°C		
538	DPP® HIV-1/2 Control Pack	60-9552-0	Chembio Diagnostic Systems, Inc.	Quality control reagents for use with DPP® HIV-1/2 Assay	Kit	50 tests/ each control/ package	Store at 2–8°C	24	
579	Elecsys SysWash	11930346122	Roche Diagnostics	Wash water additive for Elecsys 2010 and COBAS e 411 analysers to perform Elecsys® HIV Combi PT assay	Bottle	1 x 500 ml			
591	ElecsysR PreciControl HIV	05162645190	Roche Diagnostics	Controls to perform Elecsys® HIV Combi PT assay	Kit	3 x 2 x 2 ml	Store at 2–8°C		

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/ pack	Temperature requirement	Shelf-life (months)	Price range, USD
104	Ethanol (70%) for cleaning	Generic		Ethanol (70%)	Bottle	1L			2.45–3.20
637	Ethanol, USP Grade 190–200 proof (95–100% ethanol)	Generic		Ethanol, 190 proof or 200 proof, that meets USP testing specifications	Bottle	2.5 L			60–62
614	Geenius™ HIV-1/2 Confirmatory Controls	72329	Bio-Rad Laboratories	Controls for use with Geenius HIV-1/2 Confirmatory Assay	Kit	1 x 120 µl positive control (20 tests), 1 x 120 µl negative control (20 tests)	Store at 2–8°C		
552	INSTI™ HIV-1/ HIV-2/HIV-Negative Controls	90-1031	bioLytical Laboratories, Inc.	Controls for use with INSTI™ HIV-1/HIV-2 Antibody Test	Kit	60 tests per each control per kit	Store at –20°C	12 months	
							Store at 2–8°C	28 days once thawed	
608	LIAISON® XL murex Control HIV Ab/Ag (neg & pos)	310261	DiaSorin S.p.A.	Controls for LIAISON® XL murex HIV Ab/Ag assay	Kit	2 x 2.5 ml negative control; 1 x 2.5 ml HIV-positive control; 1 x 2.5 ml HIV Ag positive control	Store at 2–8°C	24	
483	NucliSENS® easyMAG® Extraction Buffer 1	280130	bioMérieux SA	NucliSENS® reagents for nucleic acid isolation using NucliSENS® easyMAG® (automated assay)	Pack	4 x 1000 ml	Store at , 2–30°C	24	
484	NucliSENS® easyMAG® Extraction Buffer 2	280131	bioMérieux SA	NucliSENS® reagents for nucleic acid isolation using NucliSENS® easyMAG® (automated assay)	Pack	4 x 1000 ml	Store at 2–30°C	18	
485	NucliSENS® easyMAG® Extraction Buffer 3	280132	bioMérieux SA	NucliSENS® reagents for nucleic acid isolation using NucliSENS® easyMAG® (automated assay)	Pack	4 x 1000 ml	Store at 2–8°C	15	

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/ pack	Temperature requirement	Shelf-life (months)	Price range, USD
486	NucliSENS® easyMAG® Extraction Lysis Buffer	280134	bioMérieux SA	NucliSENS® reagents for nucleic acid isolation using NucliSENS® easyMAG® (automated assay)	Pack	4 x 1000 ml	Store at 2–30°C	24	
487	NucliSENS® easyMAG® Magnetic Silica	280133	bioMérieux SA	NucliSENS® reagents for nucleic acid isolation using NucliSENS® easyMAG® (automated assay)	Pack	48 x 0.6 ml	Store at 2–8°C	18	
642	NucliSENS® Magnetic Extraction Reagents	200293	bioMérieux SA	NucliSENS® consumables for nucleic acid isolation using NucliSENS® miniMAG® (semi-automated assay)	Kit		Store at 2–8°C	18	
643	NucliSENS® Lysis Buffer (2 ml)	200292	bioMérieux SA	NucliSENS® consumables for nucleic acid isolation using NucliSENS® miniMAG® (semi-automated assay)	Pack	48 x 2 ml	Store at 2–30°C	24	
571	OraQuick ***ADVANCE***® Rapid HIV-1/2 Antibody Test Kit Controls	1001-0077	OraSure Technologies Inc.	HIV-1 positive, HIV-2 positive, and negative controls for use with FDA-approved version of OraQuick ***ADVANCE***® Rapid HIV-1/2 Antibody Test (cat ## 1001-0078 and 1001-0079) and with OraQuick HIV-1/2 Rapid Antibody Test (cat ## 5X4-0010 and 5X4-0012)	Kit	3 vials	Store at 2–8°C	12	
587	PreClean M	03004899190	Roche Diagnostics	Detection cleaning solution for MODULAR ANALYTICS E170, COBAS e 601 and COBAS e 602 analysers to perform Elecsys® HIV Combi PT assay	Case	5 x 600 ml			
586	ProbeWash M	03005712190	Roche Diagnostics	Cleaning solution for run finalization and rinsing during reagent change for MODULAR ANALYTICS E170, COBAS e 601 and COBAS e 602 analysers to perform Elecsys® HIV Combi PT assay	Case	12 x 70 ml			
577	ProCell	11662988122	Roche Diagnostics	System buffer to perform Elecsys® HIV Combi PT assay on Elecsys 2010 and COBAS e 411 analysers	Case	6 x 380 ml			
583	ProCell M	04880340190	Roche Diagnostics	System buffer to perform Elecsys® HIV Combi PT assay on MODULAR ANALYTICS E170, COBAS e 601 and COBAS e 602 analysers	Case	2 x 2 L			
562	Rapid HIV-1/2 Antibody Test Kit Controls	HIV104	Chembio Diagnostic Systems, Inc.	Quality control reagents for use with HIV-1/2 STAT-PAK® Assay, HIV-1/2 STAT-PAK® Dipstick assay, and SURE CHECK® HIV-1/2 assay	Kit	50 tests/ each control/ package	Store at 2–8°C	24	
531	Sodium hypochlorite solution (0.5%)	Generic		Regular/concentrated bleach (0.5% sodium hypochlorite – NaOCl)		1	Store at ambient temperature		
504	Sodium hypochlorite solution (1%)	Generic		Regular/concentrated bleach (1% sodium hypochlorite – NaOCl)		1	Store at ambient temperature		
106	Sodium hypochlorite solution (5–10%)	Generic		Regular/concentrated bleach (5–10% sodium hypochlorite – NaOCl)	Bottle	1L	Store at ambient temperature		3 - 9
597	Stopping solution	25260	Bio-Rad Laboratories	Reagent for BIO-RAD GS HIV Combo Ag/Ab EIA cat # 26218	Bottle	120 ml	Store at 2–8°C		

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/ pack	Temperature requirement	Shelf-life (months)	Price range, USD
611	Stop solution (1N sulphuric acid)	N0164	DiaSorin Dartford	Stop solution for Murex HIV – 1.2.O and Murex HIV Ag/Ab Combination assays	Case	15 x 60 ml	Store at ambient temperature	24	
612	Stop solution (1N sulphuric acid)	N0165	DiaSorin Dartford	Stop solution for Murex HIV – 1.2.O and Murex HIV Ag/Ab Combination assays	Vial	1 x 60 ml	Store at ambient temperature	24	
559	Uni-Gold™ Recombigen® HIV Controls	1206530	Trinity Biotech plc	Controls for Uni-Gold™ Recombigen® HIV	Kit	Three controls 500 µl each	Store at 2–8°C		
528	VERSANT® Sample Preparation 1.0 Reagents Kit, IVDD (Box 1)	04801677	Siemens Healthcare Diagnostics	Sample preparation kit intended for the isolation and purification of nucleic acids for in vitro diagnostic applications. CE marked, WHO PQ	Kit	96	Store at 15–30°C	24	
645	VERSANT® Sample Preparation 1.0 Reagents Kit, IVDD (Box 2)	04801685	Siemens Healthcare Diagnostics	Sample preparation kit intended for the isolation and purification of nucleic acids for in vitro diagnostic applications. CE marked, WHO PQ	Kit	96	Store at 2–8°C	24	
596	Wash solution concentrate	25261	Bio-Rad Laboratories	Reagent for BIO-RAD GS HIV Combo Ag/Ab EIA cat # 26218	Bottle	120 ml	Store at 2–8°C		
646	Water, deionized	Generic		Water, deionized					
107	Water, distilled	Generic		Water, distilled					
471	Water, RNase/ DNase free	Generic		Water, RNase/DNase free	Bottle	100 ml			35–80

11.4 SECTION IID: CONSUMABLES

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/pack	Price range, USD
468	Abbott 96 Deep-Well Plate	4J71-30	Abbott Molecular Inc.	Abbott RealTi***me*** 96 deep-well plate for Abbott ***m***24sp and ***m***2000sp instruments	Pack	32	308
453	Abbott 96-Well Optical Reaction Plates	4J71-70	Abbott Molecular Inc.	96-Well Optical Reaction Plates for Abbott ***m***24sp and ***m***2000sp instruments	Pack	20	96
455	Abbott Adhesive Cover Applicator	9K32-01	Abbott Molecular Inc.	Plastic cover for realtime PCR plates for Abbott RealTi***me*** HIV-1 assay	Unit		
469	Abbott Master Mix Tubes/caps	4J71-80	Abbott Molecular Inc.	Tubes/caps used for realtime PCR into which master mix reagents are loaded for Abbott ***m***2000rt instrument	Pack	150 units	144
454	Abbott Optical Adhesive Covers	4J71-75	Abbott Molecular Inc.	Covers for realtime PCR plates that minimize interfering fluorescence and eliminates auto-fluorescent for Abbott ***m***2000rt instrument	Pack	100	
452	Abbott Reaction Vessels (5 ml)	4J71-20	Abbott Molecular Inc.	Reaction vessels for Abbott ***m***24sp and ***m***2000sp instruments	Pack	2000	180
474	Abbott Reagent Vessels (200 ml)	4J71-60	Abbott Molecular Inc.	Reagent vessels for Abbott ***m***24sp and ***m***2000sp instruments	Pack	90	44
456	Abbott RealTi***me*** Splash-Free Support Base	9K31-01	Abbott Molecular Inc.	Splash-Free Support Base for Abbott ***m***24sp and ***m***2000sp instruments	Pack	5	
580	Adaptor for SysClean	11933159001	Roche Diagnostics	For Elecsys 2010 and COBAS e 411 analysers to perform Elecsys® HIV Combi PT assay	Unit	1	
236	Alcohol wipes	Generic		Alcohol pads/wipes, approx. 30 mm × 30 mm individually wrapped	N/A	100	1–5
254	Alere Printer Paper 1	260400009	Alere Technologies GmbH	Thermal paper, coated, non-adhesive for Pima printer (Pima printer is optional accessory for Pima Analyser)	Pack	10 rolls	32
650	Alere Printer Paper 2	260400010	Alere Technologies GmbH	Thermal paper, coated, non-adhesive for Pima printer (Pima printer is optional accessory for Pima Analyser)	Pack	10 rolls	180
472	Applicator, cotton tip	Generic		Wooden or plastic stick with cotton tip used as a swab			
588	AssayTip/AssayCup Combimagazine M	12102137001	Roche Diagnostics	48 magazines x 84 reaction vessels or pipette tips, waste bags to perform Elecsys® HIV Combi PT assay on MODULAR ANALYTICS E170, COBAS e 601 and COBAS e 602 analysers	Case	48 magazines x 84 reaction vessels or pipette tips, waste bags	
237	Bag, biohazard waste, large	Generic		High-density polyethylene biohazard waste bag for floor-standing container (approx. 60 litres), must display international biohazard symbol, autoclavable up to 134°C, must meet country standards for impact and tear	Pack	100	70–230
238	Bag, biohazard waste, medium	Generic		High-density polyethylene biohazard waste bag for floor-standing container (approx. 35 litres), must display international biohazard symbol, autoclavable up to 134°C, must meet country standards for impact and tear	Pack	100	36–240
239	Bag, biohazard waste, small	Generic		High-density polyethylene biohazard waste bag for counter top (approx. 5–7 litres), must display international biohazard symbol, autoclavable up to 134°C, must meet country standards for impact and tear	Pack	100	110–125
362	Bag, sealable plastic specimen	Generic		Resealable specimen bag, clear, attached external document pocket	Pack	100	50–70

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/pack	Price range, USD
489	Biohit Tips	280146	bioMérieux SA	NucliSENS® consumables for nucleic acid isolation using NucliSENS® easyMAG® (automated assay)	Pack	48	
534	Blood collection consumables	Generic		Blood collection consumables required for HIV RDT – see sample collection section			
241	Blood collection needle, 21G	Generic		21G needle for blood collection	Box	20	35–45
248	Blood collection, BD Vacutainer Safety-Lock		Beckton, Dickinson and Company, BD Biosciences	Blood collection, BD Vacutainer Safety-Lok blood collection set	Pack	50	
247	Blood collection tubes	Generic		Preferably plastic, volume depends upon standard operating procedures and availability	Pack	100	
576	CalSet Vials	11776576322	Roche Diagnostics	Empty snap-cap bottles to perform Elecsys® HIV Combi PT assay	Case	2 x 56	
651	Caps for cleaning tubes	343514	Beckton, Dickinson and Company, BD Biosciences	Caps for cleaning tubes for use with BD FACSCount™ instrument	Pack	Unknown	15
250	Capillary tubes	Generic		Plastic, non-sterile, pre-defined volume capillary tube	Box	50 tubes	
252	Capillary tubes (EDTA)	7D2227	Alere Medical Co., Ltd.	Alere EDTA-coated capillary tubes for blood collection by fingerstick, CE marked	Pack	100	5–8
544	Capillary tubes (EDTA)	7D2222	Alere Medical Co., Ltd.	Alere EDTA-coated capillary tubes for blood collection by fingerstick, ROW	Pack	100	5–8
255	Cleaning tubes	343685	Beckton, Dickinson and Company, BD Biosciences	Cleaning tubes for FACSCount™ system – purchase with caps	Pack	20	15
599	Container, polypropylene, 5 ml	Generic		Polypropylene containers, 5 ml	Pack		
262	Cotton wool	Generic		Cotton wool, non-sterile			
630	Disposable tips (DiTis), 200 µl	4J71-17	Abbott Molecular, Inc.	200 µl disposable tips for ***m***2000sp automated sample preparation instrument and ***m***24 sample preparation instrument to perform Abbott RealTi***me*** HIV-1 (***m***2000sp and ***m***24) and Abbott RealTi***me*** HIV-1 Qualitative assays (***m***2000sp)	Pack	2304 tips	381
629	Disposable tips (DiTis), 1000 µl	4J71-10	Abbott Molecular, Inc.	1000 µl disposable tips for ***m***2000sp automated sample preparation instrument and ***m***24 sample preparation instruments to perform Abbott RealTi***me*** HIV-1 (***m***2000sp and ***m***24) and Abbott RealTi***me*** HIV-1 Qualitative assays (***m***2000sp)	Pack	2304 tips	381
263	Dressing/adhesive plaster/band aid strip	Generic		Roll of adhesive dressing for attaching gauze after blood draw			
264	Dried blood spot collection cards	Generic	Ahlstrom Munktell	Munktell TNF (multiple catalogue numbers)	Pack	100	
			GE Healthcare Life Sciences	Whatman 903™ (product code 10534320)			120–150
			Perkin Elmer Health Sciences, Inc.	Ahlstrom Grade 226 (product code GR226314520)			

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/pack	Price range, USD
581	Elecsys 2010 AssayCup	11706802001	Roche Diagnostics	Reaction vessels for Elecsys 2010 and COBAS e 411 analysers to perform Elecsys® HIV Combi PT assay	Case	60 x 60 vessels	
582	Elecsys 2010 AssayTip	11706799001	Roche Diagnostics	Pipette tips for Elecsys 2010 and COBAS e 411 analysers to perform Elecsys® HIV Combi PT assay	Case	30 x 120 tips	
266	Fine-tip marker pen (black)	Generic				1	
253	Finger Stick Collection Kit	260400199	Alere Technologies GmbH	Fingerstick sample collection kit. Kit contains: 4 x units of safety lancets (x 28) (260400101); 4x units of gauze swabs (x 25) (260400104), 1 x unit of alcoholic swabs (x 100) (260400103), 4 x units of plasters (x 26) (260400102)	Kit	100	100
267	Forceps, non-metallic	Generic		Forceps, plastic, disposable, flat end	Unit		1–22
505	Gloves – multiple sizes, powder-free	Generic		Vinyl/nitrile gloves, non-latex, powder-free designed for laboratory procedures and hospital ward use. Packed in dispenser box	Box	100	3–9
332	Humidity indicator card	Generic	N/A	Small visual humidity indicator cards, colour change indicator	Pack	100	
623	Internal control vial (1.4 ml)	03N19-01	Abbott Molecular Inc.	Vial for internal control for Abbott ***m***24 instrument			
624	Internal control vial (1.4 ml) cap	03N20-01	Abbott Molecular Inc.	Vial cap for internal control for Abbott ***m***24 instrument			
437	K-tubes	03137082001	Roche Molecular Systems, Inc.	K-tubes, rack (12 × 96) for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	Box	1152	3–915
335	Labels, adhesive (for labelling tubes/containers)	Generic		Adhesive specimen labels, approx. 30 mm × 60 mm	Roll	100	
336	Lancet, 21G	Generic		Contact-activated, single-use lancet, 21G, incision depth approx. 2.0 mm	Pack	100	20–35
338	Lancet, infant	Generic		Contact-activated, single-use lancet for infant heelstick	Box	100	260–290
654	Loop	1001-0144	OraSure Technologies Inc.	Loop for specimen collection for use with OraQuick HIV-1/2 Rapid Antibody Test	Pack	5	
		1001-0145				25	
549	Microsafe capillary tubes	7D2223	Alere Medical Co., Ltd.	Alere capillary tubes for blood collection by fingerstick	Pack	100	
649	Microcide SQ	Generic		Broad spectrum, hospital grade disinfectant	Vial	Varies	
240	Needle Holder	Generic		Blood collection needle holder (for blood collection tubes)	Pack	250	15–25
490	NucliSENS® easyMAG® disposables	280135	bioMérieux SA	NucliSENS® consumables for nucleic acid isolation	Pack	48	
492	NucliSENS EasyQ® 8-Tube Caps	285051	bioMérieux SA	NucliSENS® Consumables for nucleic acid amplification	Pack	48	
493	NucliSENS EasyQ® 8-Tube Strips	285048	bioMérieux SA	NucliSENS® Consumables for nucleic acid amplification	Pack	48	
342	Paper towels	Generic		Paper towels, 2-ply, 3-part fanfold or rolls	Pack		
585	PC/CC-Cups	03023141001	Roche Diagnostics	Cups to prewarm ProCell M and CleanCell M before use on MODULAR ANALYTICS E170, COBAS e 601 and COBAS e 602 analysers to perform Elecsys® HIV Combi PT assay	Pack	12	
478	Petri dish with cover	Generic		Use with BD FACSCount™	Unit	1	
353	Pipette tip, 0.5–10 µl	Generic		Non-sterile, autoclavable pipette tips, translucent, specific for brand of 0.5-10 µl adjustable volume pipette	Pack	1000	15–40

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/pack	Price range, USD
354	Pipette tip, 0.5–10 µl filter/ aerosol barrier	Generic		Sterile, filter-tip, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 0.5–10 µl adjustable volume pipette	Box	96	5–50
349	Pipette tip, 5–20 µl	Generic		Non-sterile, autoclavable pipette tips, translucent, specific for brand of 10–20 µl adjustable volume pipette	Pack	1000	15–40
350	Pipette tip, 5–20 µl filter/ aerosol barrier	Generic		Sterile, filter-tip, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 10–20 µl adjustable volume pipette	Box	96	5–50
351	Pipette tip, 10–200 µl	Generic		Non-sterile, autoclavable pipette tips, translucent, specific for brand of 10–100/200 µl adjustable volume pipette	Pack	1000	8–55
352	Pipette tip, 10–200 µl filter/ aerosol barrier	Generic		Sterile, filter-tip, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 10–100/20 µl adjustable volume pipette	Box	96	5–50
500	Pipette tip, 1–5 ml filter/aerosol barrier	Generic		Sterile, filter-tip, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 1–5 ml adjustable volume pipette	Box	50	25–50
347	Pipette tip, 100–1000 µl	Generic		Non-sterile, autoclavable, pipette tips, translucent, specific for brand of 100–1000 µl adjustable volume pipette	Pack	1000	25–50
348	Pipette tip, 100–1000 µl filter/ aerosol barrier	Generic		Sterile, filter-tip, DNase, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 100–1000 µl adjustable volume pipette	Box	96	7–180
632	Pipette tip, repeater/dispenser, 50 µl	Generic		Non-sterile, autoclavable, or sterile, pipette tips, translucent, specific for brand of 50 µl adjustable repeat pipettor	Pack	100	100–300
358	Pipette, serological, 1.0 ml	Generic		Serological pipette, 1.0 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	case	1000	260–300
616	Pipette, serological, 2.0 ml	Generic		Serological pipette, 2.0 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	case	500	160–190
360	Pipette, serological, 5.0 ml	Generic		Serological pipette, 5.0 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	case	200	80–110
359	Pipette, serological, 10.0 ml	Generic		Serological pipette, 10 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	case	200	100–120
530	Pipette, serological, 25.0 ml	Generic		Serological pipette, 25 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	case	200	220–250
598	Pipette, serological, 50.0 ml	Generic		Serological pipette, 50.0 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	case	100	230–270
633	Pipette, transfer disposable, 1000 µl	Generic		Polyethylene plastic pipettes suitable for blood banking, urine analysis, haematology, wet chemistry, microbiology, and serology	pack	500	5–70
628	Plate, 96 well polypropylene	Generic		Polypropylene plates suitable for liquid phase assays	case	50	90–160
436	Racks of K-tips	03287343001	Roche Molecular Systems, Inc.	Racks of K-tips (12 × 36) for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	pack	432	0.1–208
361	Reagent reservoirs for ELISA	Generic		Reservoirs for multichannel pipetting solutions into microtitre plates during ELISA	Pack		

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/pack	Price range, USD
378	Sample input tubes (S-tubes)	03137040001	Roche Molecular Systems, Inc.	Input S-tube barcode clips hold sample input tubes in the COBAS® AmpliPrep Instrument sample racks and have a barcode to identify the sample for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	Pack	288	0.1–228
382	Sample processing units	03755525001	Roche Molecular Systems, Inc.	Sample processing unit for pre-amplification for COBAS® AmpliPrep/ COBAS® TaqMan® HIV-1 Test v2.0	Unit	288	0.1–702
364	Sharps container, medium	Generic		Robust, durable sharps containing conforming to international safety standards, medium, approx. 5 litres	Unit	1	2–15
366	Silica gel packs	Generic		Silica gel packs, small, individual packs, with indicator	Box	100	5–20
491	Strip Plates Greiner	278303	bioMérieux SA	NucliSENS® Consumables for nucleic acid isolation using NucliSENS® easyMAG® (automated assay)	Pack	48	
656	Specimen transfer device	Generic		Specimen transfer devices (such as, micropipettes) required for capillary blood collection	Pack		
368	Swab, 70% alcohol	Generic			Box	100	1–5
590	SysClean Adaptor M	03027651001	Roche Diagnostics	Adaptor for SysClean M for MODULAR ANALYTICS E170, COBAS e 601 and COBAS e 602 analysers to perform Elecsys® HIV Combi PT assay	Unit	1	
370	Thermal Paper	322839	Becton, Dickinson and Company, BD Biosciences	Thermal paper roll for BD FACSCount™ instrument	Pack	5 rolls	8–75
371	Tissues, wipes	Generic		Tissues, wipes	Pack	Varies	
372	Tourniquet, adult	Generic		Rubber tourniquet with closure, adult	Unit	1	2–5
503	Tube strips, PCR, 0.2 ml, RNase-free with caps	Generic		0.2 ml PCR tubes in strips with caps, thin-walled, polyethylene	Pack	100	7–60
477	Tubes, centrifuge, 50 ml	Generic		50 ml Falcon tubes	Case	500	200–300
376	Tubes, microcentrifuge, 1.5 ml, screw cap	Generic		1.5 ml microcentrifuge tubes with screw caps	Pack	100	20–60
502	Tubes, microcentrifuge, 1.5 ml, RNase-free	Generic		1.5- ml microcentrifuge tubes with caps	Pack	N/A	10 - 50
475	Tubes, microcentrifuge, 1.7 ml, RNase-free	Generic		1.5 ml microcentrifuge tubes with screw caps	Pack	100	10–50
377	Tubes, test, 12 mm × 75 mm, capped	Generic		Test tubes, 12 mm x 75 mm, with caps	Case	1000	15–109
466	Tubes, test, 16 mm × 75 mm	Generic		Test tubes, 16 mm x 75 mm	Pack	100	
647	Tubes, test, polypropylene, 13 mm × 75 mm	Generic		Polypropylene test tubes, 13 mm x 75 mm	Pack	100	15–109
648	Tubes, Test, polypropylene, 16 mm × 75 mm	Generic		Polypropylene test tubes, 16 mm x 75 mm	Pack	100	15–109
524	VERSANT® 1000 µl pipette tips	US: 06635759	Siemens Healthcare Diagnostics	Pipette tips supplied for VERSANT			
525	VERSANT® 300 µl pipette tips	US: 06635767	Siemens Healthcare Diagnostics	Pipette tips supplied for VERSANT			

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Quantity/pack	Price range, USD
526	VERSANT® 96-well, 2 ml nuclease-free, sterile deep-well plates	US: 06691055	Siemens Healthcare Diagnostics	Microtitre plates supplied for VERSANT			
529	VERSANT® Barcoded 96-well semi-skirted polypropylene plates for PCR	US: 06653412	Siemens Healthcare Diagnostics	Siemens VERSANT® Barcoded 96-well semi-skirted polypropylene plates for PCR			
527	VERSANT® Optical Caps (8 × strip)	US: 06653439	Siemens Healthcare Diagnostics	Siemens VERSANT® optical caps, 8 × strip			
589	WasteLiner	03023150001	Roche Diagnostics	Waste bags for MODULAR ANALYTICS E170, COBAS e 601 and COBAS e 602 analysers to perform Elecsys® HIV Combi PT assay	Pack		

11.5 SECTION IIE: DURABLES

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Required accessory	Price range, USD
457	Abbott *m*Sample Preparation System Start Up Kit	02N28-03	Abbott Molecular Inc.	Eppendorf Cooler and two magnetic stands, magnetic stands for 1 × 5 ml reaction vessel and 1 × 1.5 ml tube, 1.5 ml screw top microfuge tubes and caps			
385	Biohazard waste container, large	Generic		Capacity of approx. 50 litres, made of high-density polypropylene, at least 40 µm thick, cleanable, meeting the country's standards for environmental and hygiene considerations	Unit		80–160
386	Biohazard waste container, medium	Generic		Capacity of approx. 25 litres, made of high-density polypropylene, at least 40 µm thick, autoclavable up to 134°C, meeting the country's standards for environmental and hygiene considerations	Unit		80–120
387	Biohazard waste container, small	Generic		Capacity of approx. 3–5 litres, made of high-density polypropylene, at least 40 µm thick, autoclavable up to 134°C, meeting the country's standards for environmental and hygiene considerations	Unit		
388	Blood collection tray (for phlebotomy supplies)	Generic		Phlebotomy tray, lightweight, easy to clean and disinfect, built-in test-tube rack for 16-mm tubes, swing-out or pull-out compartmentalized draws for supplies	Unit		50–90
389	Bottle, dispensing/wash, 500 ml	Generic		500 ml dispensing/wash bottle, plastic, vented with cap	Unit		
392	Dried blood spot card drying rack	Generic		Sturdy, easy to clean and disinfect dried blood spot card drying rack with capacity for a minimum of 20 cards at a time	Unit		
626	Eppendorf PCR cooler or StrataCooler 96 benchtop cooler	Generic		Stand for protection of temperature-sensitive samples at the bench. It is a superior replacement for an ice bath.	Unit		75–300
393	Goggles/eye protection	Generic		Safety goggles, curved lens, impact-resistant, adjustable headband, offers chemical splash and ultraviolet protection, ventilated	Unit		1.50–6
394	Graduated cylinder, 1000 ml	Generic		1000 ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing	Unit		45–658
395	Graduated cylinder, 100 ml	Generic		100 ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing	Unit		15–25
397	Graduated cylinder, 500 ml	Generic		500 ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing	Unit		25–30
593	Graduated cylinder, 250 ml	Generic		250 ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing	Unit		25–35
592	Graduated cylinder, 25 ml	Generic		25 ml graduated cylinder, hexagon base and spout, short line graduation with durable graduation and printing	Unit		15–20
398	Graduated cylinder, 50 ml, glass	Generic		50 ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing, glass	Unit		120
399	Graduated cylinder, 50 ml, non-glass	Generic		50 ml graduated cylinder, hexagon base and spout, polypropylene (or similar material), short line graduation with durable graduation and printing, non-glass	Unit		20–64
442	K-carrier	03341488001	Roche Molecular Systems, Inc.	K-carrier for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	Unit		
444	K-carrier rack	03286436001	Roche Molecular Systems, Inc.	K-carrier rack for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	Unit		
443	K-carrier transporter	03517519001	Roche Molecular Systems, Inc.	K-carrier transporter for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	Unit		

Item no.	Item name	Catalogue no.	Manufacturer	Description/specification	Pack type	Required accessory	Price range, USD
401	Laboratory coat, large	Generic	N/A	Laboratory coat, large, made from strong, lightweight, liquid resistant, breathable material. Long sleeves, elasticated cuffs and high neck closure. Material must be autoclavable	Unit		10–50
402	Laboratory coat, medium	Generic		Laboratory coat, medium, made from strong, lightweight, liquid resistant, breathable material. Long sleeves, elasticated cuffs and high neck closure. Material must be autoclavable	Unit		10–50
403	Laboratory coat, small	Generic		Laboratory coat, medium, made from strong, lightweight, liquid resistant, breathable material. Long sleeves, elasticated cuffs and high neck closure. Material must be autoclavable	Unit		10–50
494	Liquid waste container with cap	Generic		Waste container – with cap for proper disposal of PCR products	Unit		
405	Phlebotomy chair, with arm rest	Generic		Phlebotomy/blood draw chair, steel frame, height-adjustable swing-out arms, easy to clean and disinfect, weight capacity at least 136 kg	Unit		200–1000
406	Phlebotomy grips (for patients to squeeze)	Generic		Phlebotomy grips, rubber, used to encourage firm squeeze	Pack		
627	Rack, reaction vessels, 5 ml	Generic		Polypropylene (or similar material) or epoxy-coated wire rack for 5 ml reaction vessels	Unit		10–45
407	Rack, test tubes, 0.5 ml, 1.5 ml, 2.0 ml centrifuge	Generic		Polypropylene (or similar material) or epoxy-coated wire rack for 14-mm diameter test tubes	Unit		5–30
408	Rack, test tubes, 14 mm diameter	Generic		Polypropylene (or similar material) or epoxy-coated wire rack for 14 mm diameter test tubes	Unit		5–30
439	Reagent rack	028122199001	Roche Molecular Systems, Inc.	Reagent rack for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	Unit		
635	Sample racks, 13 mm	4J72-82	Abbott Molecular Inc.	Sample racks to hold controls and patient specimens during automatic sample preparation in the Abbott ***m***2000sp instrument. Supplied with the Abbott ***m***2000sp instrument	Pack		
438	Sample rack (SK 24 rack)	028122172001	Roche Molecular Systems, Inc.	Sample rack (SK 24 rack) for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	Unit		
409	Scissors	Generic		Metal scissors, plastic handle, approx. 15–30 cm in length	Unit		
440	Specimen processing unit rack	05471664001	Roche Molecular Systems, Inc.	Specimen processing unit rack for COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	Unit		
507	Stand, magnetic separator for 1.5 ml tubes	Generic		Stand for magnetic separation protocols using 1.5 ml tubes	Unit		50–200
625	Stand, magnetic separator for 5 ml reaction vessels	Generic		Stand for magnetic separation protocols using 5 ml tubes	Unit		~ 250
412	Thermometer, digital	Generic		Digital thermometer, must conform to internationally recognized standards	Unit		
413	Thermometer – non-digital	Generic		Non-mercury thermometer, must conform to internationally recognized standards	Unit		
523	VERSANT® Large and Small Reagent Troughs	US: 10489008	Siemens Healthcare Diagnostics	Siemens large and small reagent troughs			

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