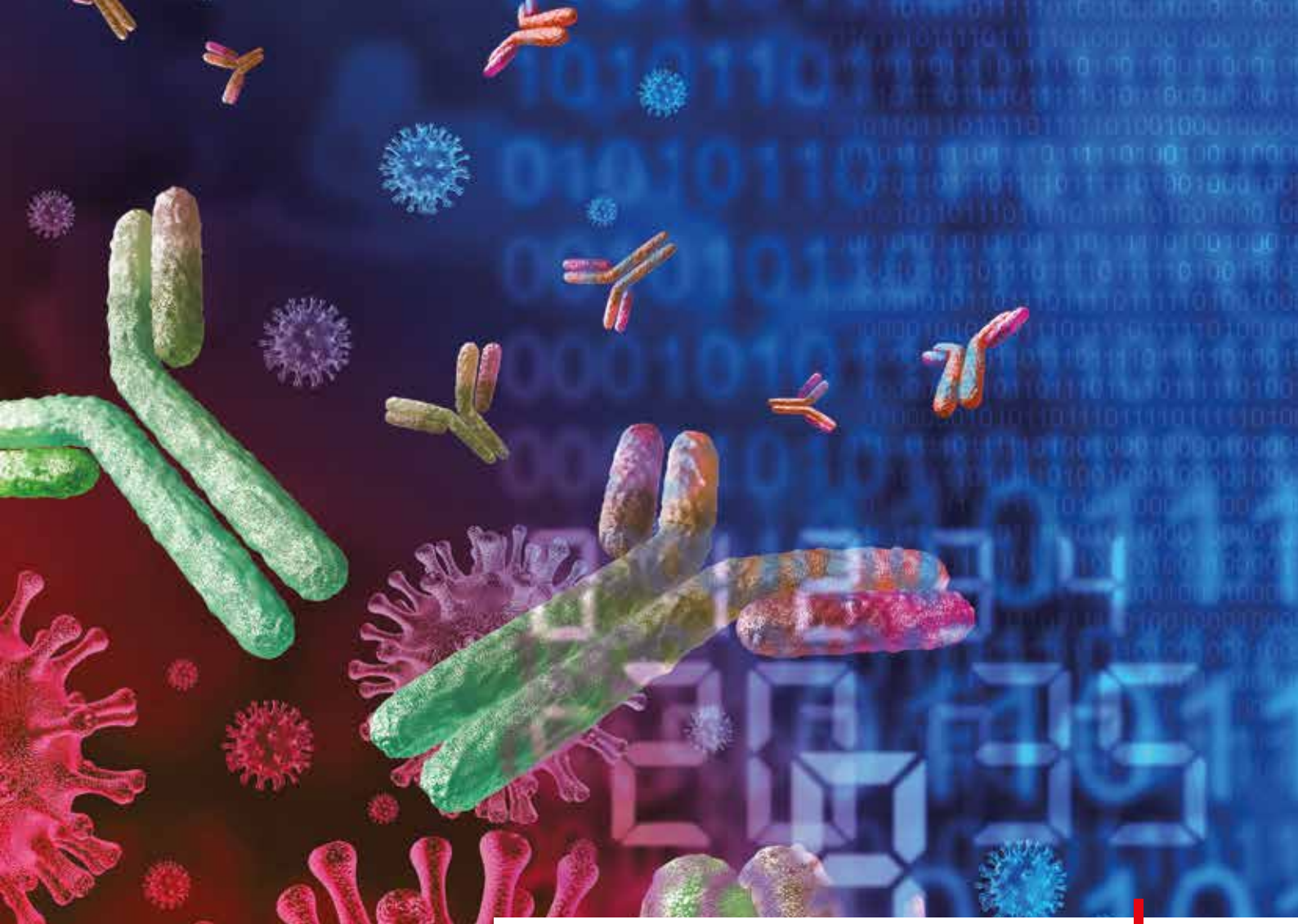

# Target product profile for readers of rapid diagnostic tests

World Health Organization

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ISBN 978-92-4-006717-2 (electronic version)
ISBN 978-92-4-006718-9 (print version)



Design and layout by Interligar - Branding & Design

# Target product profile for readers of rapid diagnostic tests

Lateral-flow rapid diagnostic tests (RDTs) continue to play a vital role in global health in the management and diagnosis of infectious diseases, including malaria, HIV and COVID-19. Visually interpreted RDTs, more than any other class of diagnostics, fulfil WHO's ASSURED criteria,[1] enabling their use at the lowest levels of health care and in self-testing.[2] Their utility is, however, compromised every time a test is incorrectly performed or interpreted or its result is not available in a timely manner for clinical decision-making and surveillance.

As companion tools, RDT readers promote more consistent, accurate test performance, interpretation and reporting, as recognized in a revision of the ASSURED criteria[3] and in comparisons of manual and automatic reports of positivity.[4]

This target product profile (TPP) addresses various types of RDT reader, with no prioritization:

- a dedicated hardware **instrument** or an **app** that operates on a general-purpose mobile device such as a tablet or phone;
- a reader designed for **professional use** by a health-care worker or other representative of a **health programme** (such as a disease control programme, a laboratory service of a ministry of health or a private health-care system) or for **lay use** (i.e., self- and home testing);
- one that acts within the narrow bounds of a **non-medical** reader, recording the user's interpretation of the test as the definitive result and transmitting the reader's interpretation only for non-medical uses such as public health surveillance, monitoring, evaluation and external quality assessment, or one that serves as a **medical** reader, which provides its interpretation to its user as a basis for diagnosis and treatment as a regulated medical device or in vitro diagnostic; and
- a reader offered by the manufacturer of the RDT or provided independently for use with one or more RDT brands.

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1 Mabey D, Peeling R, Ustianowski A, Perkins MD. Diagnostics for the developing world. Nat Rev Microbiol. 2004;2:231–40 (doi: 1038/nrmicro841).

2 Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing. Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/WHO-2019-nCoV-Ag-RDTs-Self_testing-2022.1).

3 Land KJ, Boeras DI, Chen XS, Ramsay AR, Peeling RW. REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. Nat Microbiol. 2019;4:46–54 (doi: 10.1038/s41564-018-0295-3).

4 Adah P, Maduka O, Obasi O, Doherty O, Oguntoye S, Seadon K et al. The role of the Deki Reader™ in malaria diagnosis, treatment and reporting: Findings from an Africare pilot project in Nigeria. Malar J. 2018;17:221 (doi: 10.1186/s12936-018-2356-8).

A statement in this TPP that applies to only one type of reader is preceded by the name of that type in the colour code shown below.

| Category | Type |
|---|---|
| Device architecture | • **Instrument**: dedicated hardware, as most readers have been<br>• **App**: software that operates on general-purpose mobile devices |
| Use case | • **Professional use**: by a health-care worker<br>• **Lay use**: self-testing and similar use by the general public |
| Intended use | • **Medical**: shows its interpretation of the RDT to the user<br>• **Non-medical**: does not show its interpretation to the user<br>(Both send data to the health programme.) |
| Optical technology | • **Colorimetric**: detection from changed presence, intensity or colour of a line illuminated by visible light; includes tests that can be read visually, with no instrument<br>• **Fluorescent**: detectable, typically in otherwise darkness, by emission of a line near one wavelength when excited near another wavelength<br>• **Luminescent**: similar to fluorescent but without excitation |

Most readers in the category of device architecture are of one type or the other, but a reader may have aspects of each, e.g.:

- an app that requires a physical accessory to hold the RDT in front of the camera or
- an instrument that relies on an app on a wirelessly connected phone.

Such hybrid readers have certain app-only and other instrument-only characteristics.

While all readers must be capable of reporting results automatically to the associated health programme, the complete set of data features specified by this TPP need not be available in the reader itself if those features are available in a digital health system with which the reader is integrated. Features for the management and analysis of the data generated by readers are not covered in this TPP.

This TPP is a companion to diagnostic TPPs that state the required characteristics of a particular test. Some aspects of a reader, such as diagnostic sensitivity and specificity, can be evaluated only as a system of a particular test plus reader and should follow the requirements in the relevant diagnostic TPP.

For each characteristic of the TPP, an optimal criterion is to be achieved by product developers if feasible and a minimal criterion if the optimal is not feasible. When the two columns are merged, the optimal and minimal criteria are the same.

Development of this TPP is described in Annex 1.

**Table 1**. TPP for RDT readers

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| **General** | | | |
| 1. Intended use | Non-medical: To collect user interpretations and other data from RDTs<br><br>Medical: To interpret RDTs to aid clinical decisions and to collect other data from RDTs<br><br>The reader may be used in screening, diagnosis or management of disease.<br><br>The reader transmits test data, patient data entered by the user and contextual data to the health programme. | Same as minimal plus<br><br>To support proper test performance | A non-medical reader does not show its interpretation to the user. For medical readers, in most countries each combination of reader and test is subject to medical regulation. |
| 2. Target use setting | All levels of health care as well as non-health-care settings[5] | | Examples of non-health-care settings: homes, schools, workplaces, transport hubs, high-traffic areas |
| 3. Target operator | Professional use: Health-care worker, including community health worker, with at least basic literacy and minimal training or any health-care worker with additional training<br><br>Lay use: Person with at least basic literacy but no formal education in a relevant field of health care or medical discipline<br><br>App: Person with access to a mobile device and basic app skills<br><br>The operator may have requirements for access that must be met by the reader. | | Examples of lay users:<br><br>self-testers, caretakers, workplace screeners, school screeners<br><br>Accessibility: To design a reader appropriately, see Web Content Accessibility Guidelines[6] and characteristic 28. |

[5] Ghani AC, Burgess DH, Reynolds A, Rousseau C. Expanding the role of diagnostic and prognostic tools for infectious diseases in resource-poor settings. Nature. 2015;528:S50–2 (doi: 10.1038/nature16038).

[6] https://www.w3.org/TR/WCAG21/.

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| **Physical** | | | |
| 4. Number of tests performed at one time | Instrument: Operates with one test at a time | Instrument: Offered in two or more configurations:<br>• Single-bay: operates with one test at a time<br>• Multi-bay: operates with multiple tests in parallel, with random access and capability of testing different analytes simultaneously | See characteristics 20 and 21 on timing of interpretation. Parallel, random-access testing: In "walk away" mode, while one test develops in the reader, a user can start additional tests for more analytes for the same patient or for other patients. A multi-bay instrument may therefore provide throughput of multiple single-bay instruments at lower cost, space or administration, although with less flexibility and more complexity for the user. |
| | App: Operates with one test at a time | App: Interprets one test at a time, and can guide administration of multiple tests in parallel, tracking the timing of each | |
| 5. Size (instrument only) | Small, portable table-top device | | Appropriate size may depend on the features of the instrument. The instrument should be designed to be moved easily and to withstand drops and impacts associated with portable (not necessarily handheld) devices (see characteristic 28). |
| 6. Additional physical components required for use (app only) | Acceptable if they are readily portable and nearly universal (not specific to a few models of mobile devices or RDTs) | None | Acceptable example for minimal: an optical calibration card. Dependence on such components is not optimal because of costs, logistics and (if not single-use) maintenance. |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| **Operational** | | | |
| 7. Power requirement (instrument only) | Local 100–240 V AC, 50 or 60 Hz mains power | Same as minimal plus<br>User-replaceable rechargeable battery sufficient for an 8-h shift or user-replaceable single-use batteries | The reader's documentation should explain the electrical interfaces, including power consumption, cord length, mains plug style and single-use battery model, so that implementers can plan accordingly. |
| 8. Lighting of the operating environment | Any setting in which the user can see well enough to run the test<br>Infrequently, the reader may signal that it cannot operate in the current lighting and should indicate how the lighting should be changed to enable operation. | Any setting in which the user can see well enough to run the test | Examples:<br>• indoors without artificial lighting<br>• indoors with no windows and fluorescent lighting<br>• mixed lighting<br>• outdoors in direct sunlight<br>• outdoors in dappled, moving shadows from a tree<br>• outdoors in shade with indirect sunlight bounced off a red or blue wall |
| 9. General operating environment (instrument only) | 10–40 °C and ≤ 90% non-condensing humidity at an altitude ≤ 2500 m; can withstand dusty conditions and water splashes | 5–45 °C and ≤ 98% non-condensing humidity at an altitude ≤ 4000 m; can withstand dusty conditions and water splashes | |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| 10. Training for operation | Professional use: ≤ 2 h with options for remote or self-training | Professional use: ≤ 1 h with options for remote and self-training. Support provided for training of trainers | Assumed that users already have experience with RDTs. In view of the roles of professional users and the features of professional readers, these products typically do require training. |
| | Lay use: No training necessary. The user must be able to use the reader correctly when presented with it, its instructions for use and any other labelling. | Lay use: Same as minimal plus<br>The reader enables frequent users to perform tests in an abbreviated workflow that is appropriate for them. (New users are expected to require more support.) | Assumed that users lack experience with RDTs and that the RDT is designed for lay use. Like self-test RDTs, a self-test reader must be designed and demonstrated to be usable without training.<br>For both professional and lay use, see also characteristics 21 and 22. |
| 11. Biosafety (instrument only) | Easy decontamination of surfaces with 70% isopropyl alcohol, 70% ethyl alcohol or a bleach solution with 0.5% chlorine | | |
| 12. Service and maintenance | Instrument: Weekly maintenance (including any software updates) of < 10 min by an operator; mean time to failure of ≥ 36 months or 30 000 tests; self-check alerts operator to instrument errors or warnings; operator-involved calibration check at set intervals | Instrument: No maintenance required; software updated automatically or manually, depending on health programme preference; mean time to failure of ≥ 48 months or 40 000 tests; self-check alerts operator to instrument errors or warnings; no operator-involved calibration check required | |
| | App: Software updated automatically or manually depending on health programme preference and within the limits of the update policy of each mobile device, as necessary to ensure compatibility with the latest operating system (OS) | | |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| **Compatible mobile devices and RDTs** | | | |
| 13. Compatible mobile devices (app only) | The app maker shall publish and maintain a list of Android mobile devices and OS versions, including low-priced devices and older versions, that have been determined to be compatible with the app.<br><br>Devices that use the app shall remain functional for other apps and uses. | Same as minimal plus<br><br>Most Android (lay use: and iOS and iPadOS) mobile devices with a rear-facing camera that are readily available in low- and middle-income countries (LMICs).<br><br>The app maker may provide an optical performance check to allow users to enable operation on any device that passes the check. | At present, the capability of the camera of a mobile device for RDT analysis, particularly as a medical reader, is difficult if not impossible to determine from its advertised specifications.<br><br>The minimal may be adequate for health programmes that provide mobile devices to their health-care workers.<br><br>The optimal is intended for use in scenarios with less control, including "bring your own device". |
| 14. Reader-oriented features of compatible RDTs | The reader's manufacturer shall publish and maintain a list of compatible RDT models.<br><br>The reader shall be compatible with RDTs that have user markings on them. | Same as minimal plus<br><br>The reader shall be compatible with RDTs that were not necessarily designed for use with a reader, e.g.,<br>• RDTs with no computer-vision-friendly markings<br>• strips without a plastic cassette ("dipsticks")<br><br>The reader shall be compatible with multiple brands and types of RDTs.<br><br>The reader shall use 1D and 2D barcodes, if present on the RDT, to identify the model, lot, expiration or serial number. | User markings: It is common for users to write the name of the patient or another identifier on the RDT.<br><br>No medical reader is expected to be "universal" in the sense of reading all RDT models, as the reader's performance must be validated with each RDT model.<br><br>Barcoded serial numbers can enable tracing of each test, verification of authenticity and prevention of reuse, but they may remain rare in LMICs, partly because of the cost. In view of lack of standardization of their content, the design of barcodes should be integrated between reader and RDT, which is beyond the scope of this document. |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| 15. Compatible RDT types by result type | • Qualitative | • Qualitative<br>• Semi-quantitative threshold, by comparison of intensity of a test line to a reference<br>• Semi-quantitative levels, such as low, medium or high<br>• Quantitative | The design of semi-quantitative and quantitative tests may require integration between reader and RDT, which is beyond the scope of this document. |
| 16. Compatible RDT types by optical technology | Instrument: Colorimetric (visible), fluorescent or luminescent lateral flow assays | Instrument: Colorimetric (visible), fluorescent and luminescent lateral flow assays | The design of fluorescent and luminescent tests may require integration between the reader and RDT, which is beyond the scope of this document. |
| | App: Colorimetric (visible) lateral flow assays | | |
| 17. Compatible RDT types by number of lines, including test and control | 2 or 3 | 2, 3, 4 or more | Example of a three-line test: a malaria test with a control line and lines for *Plasmodium falciparum* and *vivax* |
| **Functional** | | | |
| 18. Language support | For each country in which the reader is deployed, one popular language, such as the official language or de facto national language, and any language mandated by local regulatory or trade compliance requirements | Same as minimal plus additional languages to enable use by other residents of that country | |
| 19. Operating modes (instrument only) | The reader provides "read now" mode, in which the user presents the test to the reader and the reader promptly interprets the test. | The reader provides "read now" mode (see minimal) and "walk away" mode, in which the user presents the test to the reader at the start of the development period, and the reader controls when the test is interpreted. | In "walk away" mode, the reader may be able to release a positive result before the development period has elapsed, if the RDT manufacturer provides for this. |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| 20. Help provided by the reader in timing of RDT interpretation | None | In "read now" mode, the reader shall provide a countdown timer to prompt the user when the RDT is ready to be read and before expiration of the reading period. The reader shall set the times according to each RDT's quick reference instructions (QRI) or job aid. The possibility of overriding the elapsed time limits shall be configurable by the health programme.<br>App: During the countdown, the user shall be able to use the mobile device for other tasks and still receive a prompt from the app when the RDT is ready to be read. | Regarding elapsed time data, see characteristics 23 and 29. |
| 21. Help provided by the reader on other aspects of RDT instructions | None | The reader shall provide the user with access to RDT instructions equivalent to the QRI or job aid.<br>The reader may provide enhanced instructions, such as videos, audio and photographic examples of results. | Minimal: Users should follow regular instructions for use of the RDT, as they would without the reader.<br>Optimal: If the reader provides enhanced instructions, their role in regulatory authorization of the test should be considered, as should their usability for both new and frequent users (see characteristic 12).<br>Regardless of this characteristic, the reader will include instructions for use, such as how to place the RDT and properly illuminate it. |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| 22. Quality control for each test | • Check of the RDT's control line<br>• Instrument: Check of the optical system<br>• App: Check of sufficient photographic quality<br>• Check of sufficient clearance of the sample<br>Failures will result in warnings to the user and in the record, and critical failures will prevent release of a result. | Same as minimal plus<br>• Check of elapsed time to reading of result<br>• Check of sample applied to wrong well<br>• Check of expiration by date<br>• Professional use: Check of expected results when running quality control (QC) samples | |
| 23. Help provided by the reader after determination of the result (lay use only) | The reader displays basic result terms such as "positive", "negative" and "invalid" | The reader displays extended result messages from the QRI of each test.<br>Each health programme can provide messages for each type of result of each test, with referral and other resources. | Other examples of basic result terms, depending on the test, are "reactive", "non-reactive" and "invalid".<br>Extended result messages often explain the meaning and potential limitations of a result. |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| **Performance** | | | |
| 24. Qualitative colorimetric RDTs: agreement of reader with expert visual interpretation | ≥ 95% | ≥ 98% | Expert visual interpretation typically requires a panel of skilled operators who directly view the RDT (not a photo of the RDT).<br>For RDTs designed and manufactured for visual interpretation, a reader is unlikely to improve on expert visual interpretation in terms of diagnostic performance metrics such as sensitivity, specificity and limit of detection.<br>A reader's evaluation should be planned carefully, with consideration of the performance requirements for the assay. Performance with faint lines (low positives) should be assessed, as should the reader's rates of invalid and indeterminate results as compared with expert visual interpretation. |
| 25. RDTs other than qualitative colorimetric: performance | Equivalent to state-of-the-art readers | | |
| **Compliance** | | | |
| 26. Compliance with medical standards for design and manufacture (medical only) | • ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes<br>• IEC 61010-2-101:2018 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic medical equipment<br>• Applicable standards associated with the above | | |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| **Data features within the reader** | | | |
| 27. Diagnostic data collected | • Brand and type of test as entered by the user<br>• Underlying values and outcome of quality controls (see characteristic 23)<br>• Non-medical: Result as entered by the user<br>• Result as calculated by the reader<br>• Intermediate data used to calculate the result (e.g., intensities of test and control lines) | Replace first item in minimal with:<br>• Brand and type of test, by photographing the test or its packaging<br>Same as rest of minimal plus<br>• Lot number and expiration date of the test (possibly by photographing the test and its packaging)<br>• RDT instruction version<br>• RDT photograph(s) used to calculate the result<br>• Specimen type (e.g., whole blood, serum) and volume<br>• Other relevant diagnostic data entered by the user | Each health programme should be able to choose whether to require their users to enter lot and expiration data.<br>Because of limited connectivity and storage in many settings, the reader should provide appropriate options for image resolution and cropping. Multiple images may be appropriate: one cropped to the region of the control and test lines for evidence of the result, and another of the entire RDT for supervision of the type of test. Health programmes may prefer to transmit images only in certain cases, such as faint lines and invalid results or during certain research programmes. As noted in characteristic 16, images of the entire RDT may include patient-identifiable information. |
| 28. Patient/case data collected | As determined by the health programme and in compliance with local regulations (e.g., patient identification, location, consent, symptoms) | | Data needs should be balanced with the burden of data entry on users.<br>As noted in the preface, data features can be provided by integrating the reader with a digital health system with those capabilities. |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| 29. Contextual data collected | • User identification (lay use: if required by the health programme)<br>• Location of testing as text entered manually, such as an address or facility name (if enabled by the health programme)<br>• Time and date of test<br>• Manufacturer and model name of reader<br>• Instrument: Serial number of reader<br>• Reader software or firmware version<br>• App: Model of mobile device<br>• App: OS version | Same as minimal plus<br>• Automatic geolocation of test (e.g., via GPS) (if enabled by the health programme)<br>• Reader operational data for administration, maintenance and performance metrics (e.g., self-checks, calibration, quality control samples)<br>• Others as determined by the health programme | Almost all these data can and should be collected automatically rather than entered manually. |
| 30. Methods for data entry | • Typing | • Typing<br>• Scanning 1D and 2D barcodes | The user can choose one of these methods for entering the types of data listed above. When possible, the reader should instead collect data automatically or enable the user to select from lists, to avoid data-entry errors. |
| 31. Non-volatile memory and storage | Professional use:<br>≥ 200 patient results<br>≥ 20 QC results<br><br>Lay use:<br>≥ 50 patient results | Professional use:<br>≥ 1000 patient results<br>≥ 100 QC results | Reader memory is intended as a log of recent results and a temporary repository of results awaiting transmission to a server with the data connectivity features described later.<br><br>At least certain images should be kept with recent results. See characteristic 29 for considerations of image types.<br><br>App: This assumes the mobile device has enough space. |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| 32. Role-based access control (professional use only) | Provides access to specific data and reader features for users with different roles | | Roles may include data managers at several levels (e.g., supervisor, site administrator, national manager) and RDT user (health-care worker) |
| **Data connectivity** | | | |
| 33. Data connectivity methods | Instrument: mobile network, Wi-Fi, USB or Bluetooth | Instrument: mobile network and at least one of Wi-Fi, USB, Bluetooth or Ethernet | Throughout this section, as noted in the preface, data features can be provided by integrating the reader with a digital health system with those capabilities. |
| | App: mobile network or Wi-Fi as provided by the mobile device | | |
| 34. Handling of intermittent or low-bandwidth connections | The user shall be able to perform tests (medical: and receive results) offline, in which case the reader shall transmit those data when back online. | Same as minimal plus<br>The reader shall transmit automatically (without user action) in the background when back online, prioritizing basic data elements before sending larger, secondary elements such as images. | |
| 35. Data exchange standards | The reader supports FHIR® or JSON | The reader supports FHIR® and JSON | For connections to systems such as laboratory information systems, electronic health records, national registries and surveillance systems |
| 36. Data destination | The health programme shall be able to choose the destination(s) of the reader's data. | | The reader's manufacturer and other groups should require permission from the health programme to receive any data. |
| 37. Data ownership | The health programme shall be able to manage the reader in compliance with local regulations on data ownership. | | |

**Table 1**. *continued*

| Characteristic | Minimal | Optimal | Notes |
|---|---|---|---|
| 38. Security and privacy | To facilitate use by health programmes in accordance with the laws, regulations and policies in their settings and with best practices, the reader shall provide configurable features so that personal data can be:<br>(a) gathered transparently to users and patients, including consent,<br>(b) collected and processed only for purposes compatible with the health programme's purposes,<br>(c) limited to what is relevant and necessary,<br>(d) collected accurately,<br>(e) stored in identifiable form no longer than necessary and<br>(f) secured for integrity and confidentiality, with encryption at rest and in transmission. | | (a)–(f) are adapted from the European Union General Data Protection Regulation 2016/679 (GDPR), article 5, sec. 1. Note that not all the GDPR is relevant or appropriate to this reader in these settings. |
| **Pricing and accessibility** | | | |
| 39. Pricing applicable to all public programmes, nongovernmental organizations and international organizations in LMICs | Pricing should be as low as sustainably possible while maintaining quality, based on evidence of the cost of goods sold plus a reasonable profit margin, ensuring security of supply and a fair return on investment for suppliers.<br>Pricing should be affordable, transparently published and inclusive of all fees, including any for warranties, support and software updates. | | |

# **Annex 1.** Development of this target product profile

This TPP was developed according to a process based on the WHO Target Product Profiles, Preferred Product Characteristics, and Target Regimen Profiles: Standard Procedure, version 1.03 dated 7 December 2021.

The process was led by Francis Moussy, WHO, and Wallace White and Rigveda Kadam, FIND, the global alliance for diagnostics, with advice from Sarah Charnaud, WHO.

The need for a TPP was assessed in September 2021 and confirmed within WHO. After a review of previous TPPs, diagnostic practices and need, an initial draft was written. The lead authors created a TPP Development Group of 40 leading scientists, experts, public health officials and regulators in this field, with due attention to geographical and gender representation. All members completed the WHO declaration of interests form, with the provision that feedback from members with declared interests in this field would be analysed separately (Tables 1 and 2).

During February and March 2022, all Development Group members received a draft of the TPP and completed an online survey to elicit their scores for every minimal and optimal item in the TPP of their rating of agreement on a Likert scale: 1, fully disagree; 2, mostly disagree; 3, neither agree nor disagree; 4, mostly agree; and 5, fully agree. As an alternative to a Likert score, members could mark "No opinion on content area". Comments were requested on all items and were required when members marked that they did not agree (Likert score, 1–3). The levels of agreement (considered as "mostly agree" or "fully agree") were high, averaging 92% and at least 80% for every item, as shown in Fig. 1. The lead authors reviewed all comments regardless of Likert score and revised the TPP accordingly, when practical, to address a criticism, incorporate a suggestion or avoid a clear misunderstanding of the intent.

Once the lead authors had agreed on the next draft, WHO posted it[1], with announcements on mailing lists and social media by WHO and FIND teams, for a public consultation over 28 days during August and September 2022. Anyone could respond by completing a typical WHO submission form[2], identifying themselves and listing their comments and suggested amendments.

A total of 27 individuals or organizations submitted 137 requests for changes. In the same way as for the survey of the development group, the lead authors reviewed all comments and revised the TPP when appropriate and feasible. The proposed revisions to the Performance section were reviewed by the Development Group members without conflicts of interest (Table 1).

WHO then released the current version of the TPP.

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[1] https://www.who.int/news-room/articles-detail/Call_for_public_consultation-Target_Product_Profile-TPP-for_readers_of_rapid_diagnostic_tests_RDT_readers

[2] https://cdn.who.int/media/docs/default-source/in-vitro-diagnostics/calls/tpp_commentform_rdt_readers_2022_08.docx?sfvrsn=254f11a9_2

**Table 1**. Members of the TPP Development Group with no conflict of interest, by affiliation at the time of participation

| Name | Affiliation(s) | Country of residence |
|---|---|---|
| John Bimba | Bingham University Nigeria; Zankli Research Centre | Nigeria |
| Mary Garcia | Royal Melbourne Hospital | Australia |
| Mohammed Majam | Ezintsha, University of the Witwatersrand | South Africa |
| Mothepane Phatsoane Gaven | Ezintsha, University of the Witwatersrand | South Africa |
| Lara Noble | Wits Diagnostic Innovation Hub, University of the Witwatersrand | South Africa |
| Lesley Scott | Wits Diagnostic Innovation Hub, University of the Witwatersrand | South Africa |
| Muzamil Mahdi Abdel Hamid | Institute of Endemic Diseases, Medical Campus, University of Khartoum | Sudan |
| Jane Akinyi Aduda | Jomo Kenyatta University of Agriculture and Technology | Kenya |
| Rosanna Peeling | London School of Hygiene & Tropical Medicine | United Kingdom |
| Cédric Yansouni | McGill University Health Centre, Divisions of Infectious Diseases and Medical Microbiology; J.D. MacLean Centre for Tropical Diseases, McGill University | Canada |
| Nikki Pai | McGill University; Research Institute of the McGill University Health Centre | Canada |
| Abidan Nambajimana | University of Gitwe; Partners in Health; Stansile | Rwanda |
| Kaiser Shen | US Agency for International Development | USA |
| Ngor Pengby | National Centre for Parasitology, Entomology and Malaria Control | Cambodia |
| Michael Aidoo | Centers for Disease Control and Prevention | USA |
| Valter Pereira de Oliveira | Health Regulatory Agency | Brazil |
| Paulyne Wairimu | Pharmacy and Poisons Board; African Union Development Agency–New Partnership for Africa's Development | Kenya |
| Trevor Peter | Clinton Health Access Initiative | USA |
| Najma A. Salim | Clinton Health Access Initiative | Kenya |
| Azraa Mohamed | Clinton Health Access Initiative | South Africa |
| Purnima Ranawat | Catalyst Management Services/ Swasti | India |
| Andualem Aklilu | KNCV Tuberculosis Foundation | Ethiopia |
| Yohannes Demissie Babo | KNCV Tuberculosis Foundation | Ethiopia |
| Stijn Deborggraeve | Médecins Sans Frontières | Belgium |
| Bernhard Weigl | Global Health Labs; University of Washington | USA |
| Denise Habimana | PATH | USA |
| Shiri Brodsky | PATH | USA |

**Table 2**. Members of the TPP Development Group *with* a conflict of interest related to their roles with companies, whether for- or non-profit, relevant to RDT readers, by affiliation at the time of participation

| Name | Affiliation(s) | Country of residence |
|---|---|---|
| Clayton Sims | Dimagi | USA |
| Peter Lubell-Doughtie | Ona | USA |
| Bryan Richards | SystemOne | South Africa |
| Emily Adams | Mologic; Liverpool School of Tropical Medicine | United Kingdom |
| Paul Isabelli | Audere | USA |
| Thomas Scherr | Pragma Health; Vanderbilt University | USA |
| Ling Koh | Becton Dickinson | USA |
| David Bermejo Peláez | Spotlab | Spain |
| Jack Richards | ZiP Diagnostics; Royal Melbourne Hospital | Australia |
| Patrick Vaughan | DCN Diagnostics | USA |
| Patrick Coffey | DCN Diagnostics | USA |
| Santiago Ferro | Ferro Consulting; Fio | Canada |

**Fig. 1**. Distributions of Likert scores in the survey completed by the Development Group

| Section | Characteristic | Agreement with Min | Agreement with Opt | Response count | |
|---|---|---|---|---|---|
| | Preface | | | | |
| General | 1. Intended use | 98% | 98% | 40 | |
| | 2. Description of the device | 95% | 97% | 38 | 2 |
| | 3. Target use setting | 93% | 95% | 39 | 1 |
| | 4. Target operator | 92% | 97% | 37 | 3 |
| | 5. Target population | 100% | 100% | 37 | 3 |
| Physical | 6. Number of tests performed at a time | 90% | 90% | 40 | |
| | 7. Size (instrument only) | 100% | 100% | 35 | 5 |
| | 8. Additional physical components required for use (app only) | 82% | 95% | 37 | 3 |
| Operational | 9. Power requirement (instrument only) | 86% | 94% | 36 | 4 |
| | 10. Lighting of the operating environment | 90% | 87% | 39 | 1 |
| | 11. General operating environment (instrument only) | 91% | 94% | 33 | 7 |
| | 12. Training time needed | 88% | 88% | 40 | |
| | 13. Biosafety (instrument only) | 94% | 94% | 34 | 6 |
| | 14. Service and maintenance | 84% | 92% | 37 | 3 |
| Compatible mobile devices and RDTs | 15. Compatible mobile devices (app only) | 84% | 95% | 37 | 3 |
| | 16. Reader-oriented features of compatible RDTs | 85% | 83% | 40 | |
| | 17. Compatible RDT types by result | 92% | 95% | 39 | 1 |
| | 18. Compatible RDT types by optical technology | 97% | 95% | 37 | 3 |
| | 19. Compatible RDT types by number of lines, including test and control | 84% | 82% | 38 | 2 |
| Functional | 20. Operating modes (instrument only) | 97% | 95% | 37 | 3 |
| | 21. Help provided by the reader on timing of RDT interpretation | 80% | 88% | 40 | |
| | 22. Help provided by the reader on other aspects of RDT instructions | 97% | 98% | 39 | 1 |
| | 23. Quality control for each test | 92% | 95% | 38 | 2 |
| | 24. Help provided by the reader after determination of the result (lay use only) | 95% | 95% | 40 | |
| Performance | 25. Colorimetric RDTs: agreement of reader with expert visual interpretation | 84% | 89% | 37 | 3 |
| | 26. Colorimetric RDTs: accuracy and limit of detection | 86% | 89% | 37 | 3 |
| | 27. Fluorescent and luminescent RDTs: performance | 91% | 94% | 33 | 7 |
| Compliance | 28. Compliance with medical standards for design and manufacturing (IVD reader only) | 97% | 97% | 33 | 7 |
| Data features within the reader | 29. Diagnostic data collected | 90% | 97% | 39 | 1 |
| | 30. Patient/case data collected | 92% | 87% | 39 | 1 |
| | 31. Contextual data collected | 90% | 90% | 40 | |
| | 32. Methods for data entry | 87% | 92% | 37 | 3 |
| | 33. Memory | 92% | 92% | 37 | 3 |
| | 34. User access rights | 95% | 95% | 37 | 3 |
| Data connectivity | 35. Data connectivity methods | 97% | 97% | 38 | 2 |
| | 36. Handling of intermittent connections | 95% | 95% | 39 | 1 |
| | 37. Data exchange standards | 83% | 83% | 30 | 10 |
| | 38. Data destination | 89% | 92% | 36 | 4 |
| | 39. Data ownership | 92% | 92% | 36 | 4 |
| | 40. Security and privacy | 100% | 100% | 34 | 6 |
| Pricing and accessibility | 41. Pricing within the public sector in LMICs | 94% | 94% | 36 | 4 |
| | Final comments | | | | |
| | Average | 91% | 93% | 37 | 3 |

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