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PROVIDER INITIATED TESTING AND COUNSELLING

FOR PRESUMPTIVE TB CASES AND TB PATIENTS

TRAINING MANUAL FOR LABORATORY TECHNICIANS



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Central TB Division Directorate General of Health services Ministry of Health and Family Welfare Government of India, New Delhi



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FOREWORD

The END TB STRATEGY aims to end the global Tuberculosis epidemic, by reducing the TB deaths by 955 and to cut new cases by 90% between 2015 and 2035. It emphasizes on early diagnosis, treatment and prevention for all TB patients including co-infected with HIV. TB is most common Opportunistic infection and leading cause of death among people living with HIV.

Joint collaborative efforts by Government of India's Revised National Tuberculosis Control Program (RNTCP) and National AIDS Control Program (NACP) has helped in mitigating the effects of dual burden of HIV & TB in country, needs acceleration.

National Framework for HIV TB collaborative activities NOV 2013 and National HIV testing guidelines 2016 recommend Provider Initiated Testing and Counselling (PITC) among presumptive TB and diagnosed TB cases as crucial intervention for early diagnosis of HIV and further linkage to care support treatment to reduce mortality among co-infected patients.

In order to ensure access to quality diagnosis, multitasking by Lab technicians is recommended by National TB HIV coordination committee 2016 and it is critical to train staff to improve quality and effectiveness of HIV testing services.

This "Provider Initiated Testing and Counselling for TB:T raining manual for Laboratory Technicians " has been developed to guide the Lab technicians regarding procedures of HIV testing services and PITC among presumptive TB and diagnosed TB cases. The valuable inputs provided by experts from RNTCP and NACP in developing this document are appreciated.

We encourage use of this training manual to deliver quality TB HIV collaborative services in country.

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PREFACE

HIV is the most powerful known risk factor for progression of Tuberculosis infection to active TB disease. Early diagnosis of HIV is critical for expanding linkage to care, support and treatment and prevents HIV transmission.

To end AIDS epidemic as a public health threat by 2030, countries around the globe are embarking on the Fast Track Strategy 90-90-90, which call for diagnosing 90% of estimated HIV cases, 90% of diagnosed people with HIV to receive ART and 90% of those on ART to have suppressed viral load by 2020.National AIDS Control Program(NACP) IV aims to reduce new infection and includes strengthening HIV testing services as a important package of services.

WHO consolidated guidelines on HIV, 2015 and National HIV counselling Testing services Guidelines (HCTS),2016 recommend offering routine HIV testing to all presumptive and diagnosed TB cases, partners of known HIV positive TB patients ,decentralization of HIV testing facilities , task sharing & multitasking of HIV testing responsibilities in order to reduce coverage gaps and improve access to HIV prevention, treatment, care and support.

RNTCP and NACP jointly implement HIV-TB collaborative activities as per the National Framework for HIV-TB in India ,in which Provider Initiated testing and counselling(PITC) among presumptive TB cases and TB patients is key strategy for early diagnosis of HIV .PITC is accompanied by package of HIV related prevention ,treatment, care and support services. NACP aims to implement the revised National HIV testing guidelines 2016 and to further strengthen PITC among presumptive TB and diagnosed TB cases.

"Provider Initiated Testing and Counselling for presumptive TB cases and TB patients :Training manual for Laboratory Technicians " is intended to build Knowledge & skills of Laboratory technicians for basic operational guidance on PITC , Whole Blood Finger Prick test ,recording and reporting of PITC etc and represents an effort to improve patient centric ,quality of HIV testing services.

I appreciate efforts made by all those involved in developing this training manual and urge states to ensure training and provide high quality services to all those seeking HIV testing services.

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(DR K.S.SACHDEVA)

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The "**Provider Initiated Testing and Counselling for presumptive TB cases and TB patients: Training manual for Laboratory Technicians** "has been prepared jointly by National AIDS control Organisation (BSD-HIV/TB), Central TB Division, Ministry of Health and Family Welfare, Government of India under the guidance of Dr S.D. Khaparde (DDG- TB) Central TB Division, Dr K.S.Sachdeva (DDG BSD) National AIDS Control Organisation.

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ABBREVIATIONS:

NACO-National AIDS Control Organization NACP-National AIDS Control Programme CTD -- Central TB Division RNTCP - Revised National Tuberculosis Control Programme HIV -Human Immunodeficiency Virus **TB-Tuberculosis** NRHM -National Rural Health Mission SACS- State AIDS Control Society **DTO-District TB Officer** DAPCU-District AIDS Prevention and Control Unit DNO- District HIV Nodal Officer STS-Senior Treatment Supervisor STLS-Senior Tuberculosis Laboratory Supervisor DMC-Designated Microscopy Centre ICTC-Integrated Counselling and Testing Centres SA- ICTC- Stand Alone - ICTC PPP-ICTC- Public Private Partnership- ICTC F-ICTC - Facility Integrated Counselling and Testing Centres PITC -Provider Initiated Testing and Counselling WBFPT-Whole Blood Finger Prick Test ART- Anti Retroviral Therapy LAC-Link ART Centre PHI-Peripheral Health Institution ARV- Anti Retroviral Drug ATT-Anti Tubercular Treatment DRTB- Drug Resistant Tuberculosis CPT- Co-trimoxazole Preventive Therapy PLHIV-People Living With HIV/AIDS HRG - High Risk Group IDU- Intravenous Drug User **TI-Target Intervention** FSW- Female Sex Worker MSM- Men Having Sex with Men ICF- Intensified Case Finding **IPT-** Isoniazid Preventive Therapy CMIS-Computer Management Information System SIMS-Strategic Management Information System USP - Universal Safety Precautions

PEP- Post Exposure Prophylaxis

CHAPTER 1: INTRODUCTION

The adult HIV prevalence in India is estimated to be 0.26 % (0.22% - 0.32%) in 2015 translating into 2.1 million people living with HIV/AIDS (PLHIV) in 2015. This is third highest burden in the world. On the other hand, India is highest Tuberculosis (TB) burden country in the world with an estimated 2.2 million new TB cases occurring annually. While TB is commonest opportunistic infection (OI) in HIV-infected individuals, HIV infection is an important risk factor for acquiring TB infection and its progression to active TB. HIV/TB together is a fatal combination with extremely high death rates (15 to 18%) reported among HIV-infected TB cases notified under Revised National TB Control Programme (RNTCP). Overall, TB is estimated to cause about 25% of all deaths among PLHIV in India. Though only 5% of incident TB patients are HIV-infected, in absolute terms it means more than 100,000 cases annually and ranks second in the world and accounts for about 10% of the global burden of HIV-associated TB. Early detection of HIV/TB cases and prompt provision of Anti-Retroviral Treatment (ART) and Anti-TB Treatment (ATT) are key interventions to reduce mortality rates significantly. Globally, it has been estimated that less than half of all TB patients with HIV receive an HIV test; hence, HIV testing in TB settings needs to be scaled up. Ministry of Health and Family Welfare, Government of India, recognized magnitude of HIV/TB co-infection and realized the need of collaboration of both NACP and RNTCP programmes for better management of TB/HIV co-infection and the two programmes jointly implementing well-planned HIV/TB collaborative activities across the country. The current National Framework for HIV/TB Collaborative Activities, November 2013 aims to significantly reduce the morbidity and mortality due to HIV/TB co-infection through prevention, early detection and prompt management of both HIV and TB.

NACP-RNTCP Coordination Mechanisms and Activities at Various Levels:

It is important to ensure robust and coordinated efforts between these two national programmes at all levels to achieve sustained and successful outcomes. Coordination has been ensured by forming national and state TB/HIV coordination committees; national and state technical working groups; and district coordination committees (DCCs). The in-charge of SA-ICTC should regularly participate in monthly HIV/TB coordination meetings at the district level, which will help to bridge identified implementation gaps and support

continuous improvement towards uniform efficient implementation of HIV/TB collaborative activities.

A 'four-pronged strategy' has been envisaged to ensure strong collaboration and coordination between the NACP and RNTCP. It entails prevention, early detection of HIV/TB, prompt treatment and management of TB/HIV cases.

1.1 Prevention of TB-HIV

3 I's strategy for reduction in the burden of TB among PLHIV includes the following:

- 1. Intensified case finding (ICF)
- 2. Isoniazid preventive therapy (IPT)
- 3. Infection control for tuberculosis (IC)

1.1.1 Intensified Case Finding (ICF):

WHO recommended 'Four symptom screening' of TB is highly sensitive to identify a presumptive TB cases. If a patient does not have any of these four symptoms; TB can be confidently ruled-out in 98 out of 100 cases. Thus all individuals accessing HIV Counselling and Testing Services (HCTS) as well as HIV care services through confirmatory or screening sites of HIV testing facilities, ART, Link ART, Link ART Plus, Care support centres and Targeted interventions should be screened for TB.

All people living with HIV (PLHIV) should be regularly screened for TB using clinical symptom based algorithm consisting of current cough, fever, weight loss or night sweats at the time of initial presentation for HIV care and at every visit to a health facility or contact with a healthcare worker afterwards. Similarly, children living with HIV who have any of the following symptoms - poor weight gain, fever or current cough or contact history with TB case-may have TB and should be evaluated for TB and other conditions.

Individuals who have symptoms or signs suggestive of TB, irrespective of their HIV status, should be referred to RNTCP diagnostic and treatment facility. For this purpose, NACP and RNTCP promote the establishment co-located facilities.

Presumptive Pulmonary TB refers to a person with <u>any of the symptoms and signs</u> suggestive of TB including:-

-Cough for > <u>2 weeks</u>
-Haemoptysis
-Fever >2 weeks
-<u>Significant weight loss.</u>
-Any pulmonary abnormality in chest radiograph

<u>Note</u>: In addition, contacts of microbiologically confirmed TB patients, PLHIV, Diabetics, Malnourished, cancer patients, patients on immuno- suppressants or steroids should be regularly screened for sign and symptoms of TB

Presumptive Paediatric TB refers to children with

- Persistent fever and / or cough for more than 2 weeks
- Loss of weight*/no weight gain

and/or

- History of contact with infectious TB case**.
- *History of unexplained weight loss or no weight gain in past 3 months; loss of weight is defined as loss of >5% body weight as compared to highest weight recorded in last 3 months.
- **In a symptomatic child contact with a person with any form of active TB within last 2 years may be significant.

Presumptive TB cases are those who have cough of two weeks, or more, with or without other symptoms suggestive of TB in adults and adolescents and/or fever and/or cough of recent onset lasting for >2 weeks, recent unexplained loss of weight and history of exposure to an infectious TB patient (smear positive) in children. In people living with HIV, cough of any duration is suggestive of TB.

1.1.2 Isoniazid preventive therapy (IPT) for PLHIV at ART centre /Link ART-Plus and Link ART Centres

IPT is one of the 3Is that are globally recommended for prevention of incident TB among PLHIVs. Isoniazid is the most effective Bactericidal Anti TB drug available currently. While it protects against progression of latent TB infection to active disease i.e. reactivation, it also prevents TB re-infection post the exposure to an open case of TB. This is provided at ART centre/Link ART-plus and LACs.

(For details plz refer to Operational Manual for Isoniazid preventive therapy, June 2016 at link below:

<u>http://naco.gov.in/NACO/Quick_Links/Publication/Basic_Services/Training_Modules_</u> <u>on_HIV-TB_Training/Operational_Manual_IPT/</u>)

1.1.3 Infection Control for TB:

When patients remain undiagnosed and untreated for tuberculosis, there is risk of transmission of tuberculosis infection at health care facilities. Early diagnosis and prompt treatment of TB will rapidly make TB patients non-infectious and ultimately will break the chain of transmission.

Ensuring appropriate Administrative, Environmental and Personal Protective Measures as recommended in the Airborne Infection Control Guidelines is of utmost importance in reducing the risk of transmission of TB at HIV TB care settings.

1.2 Early detection

Early detection of TB and HIV is crucial. The programme identifies the following important strategies to ensure diagnosis of HIV and TB at all service delivery facilities:

1. Provider Initiated Testing and counselling (PITC) for HIV for all TB and presumptive TB cases

2. Rapid diagnostics for detection of TB and DR-TB in PLHIV

India is successfully implementing the Intensified TB HIV case finding activities, which emphasize HIV testing of all presumptive and confirmed TB cases and, TB screening of all individuals impending for HCTS and for all PLHIV at HIV care settings and prompt treatment for persons affected with HIV/TB.

Chapter 2: PROVIDER INITIATED HIV TESTING AND COUNSELLING (PITC) FOR PRESUMPTIVE TB CASES AND TB PATIENTS

2.1: HIV Testing and Counselling

HIV/AIDS counseling /education is a confidential dialogue between a client and a counsellor aimed at providing information on HIV/AIDS and bringing about behavior change in the client. It is also aimed at enabling the individual to take a decision regarding HIV testing and to understand implications of the test results. Individuals can access HCTS in two ways:

- **1. Self- initiated:** Individuals who self-perceive their risk and need for HIV testing and thus voluntarily approach for HIV Counselling and Testing Services (HCTS).
- 2. Provider-initiated: Individuals referred by a health-care provider for HIV testing.

In case of provider-initiated HCTS, the individual must receive pre-test counselling about HIV testing to make an informed choice, with an option to "opt-out". The process of informed consent and information related to testing should be documented in the counselling register. Health-care providers should offer HCTS in a confidential manner, without stigma or discrimination. The HIV screening test may be done in the outpatient department (OPD)/ inpatient department (IPD)/ emergency settings or at a general laboratory. If the individual is found reactive for HIV at screening, such individuals should be referred to a SA-ICTC with a Linkage form (**Annexure 1**) for confirmation of the HIV diagnosis. All individuals found HIV positive at SA-ICTC should be promptly linked to an ART centre.

NACP also recommends the establishment of provider-initiated HIV screening at all designated STI / RTI clinics (DSRCs) and designated microscopy centres (DMCs) under the RNTCP.

Box 1: Provider-initiated HCTS may be offered to the following priority populations: a) All pregnant women b) Babies born to HIV-positive women c) Untested children of women living with HIV (WLHIV) d) Children presenting with suboptimal growth or severe acute malnutrition, delay in developmental milestones, oral thrush, severe pneumonia and sepsis e) Patients who present with signs and symptoms suggestive of HIV/AIDS in any health-care setting including emergency Individuals who faced sexual assault f) g) Before initiating PEP and as a follow-up testing h) Patients with TB or presumptive TB, Kala-azar, hepatitis B or C, or STI/RTI STI/RTI clinic attendees i) Sexual partners/spouses of PLHIV j) Any other situation where the health-care provider feels HIV testing is essential k)

In PITC, health care worker or counselor provides basic information on HIV, the testing process, clinical and prevention benefits of testing and potential risk of discrimination. The clients are also informed about their "**right to refuse**" the offer of HIV testing and that declining the test will not affect their access to other services. Individuals are also informed about follow-up services, and only then they are offered the test. The health worker should clearly ask each client "**do you agree to get tested for HIV or not?**" and that she/he is free to "**opt out**" i.e. choose not to get tested. If a client does not "opt out" then he/she is tested for HIV followed by provision of post-test counseling. The content of pre and post-test information for WBFPT is discussed in details in **Annexure-13**.

2.3: Procedure at the DMC for presumptive TB cases and TB patients:

- All diagnosed and presumptive TB cases attending the designated microscopy centre (DMC) would be assessed for HIV status by the DMC laboratory technician (LT). If HIV testing facility is available at same facility LT will refer presumptive and diagnosed TB cases for HIV testing at the facility. For those DMCs where there is no co-located facility for HIV testing, LT will conduct HIV screening test using Whole Blood Finger Prick Test (WBFPT) as per NACO HIV counselling testing services guidelines.
- 2. DMC LT after taking the first sputum sample will ensure following steps:
 - a. If the patient is known to be HIV positive (e.g. referred in from ART centres), the information regarding the HIV status will be immediately

noted in the RNTCP laboratory register (**Annexure 2**). In case of presumptive TB whose HIV status is HIV negative and has been tested within the past six months, the same will be recorded in laboratory register and will not be referred further for any confirmation as per national policy.

- b. In case of presumptive TB case or TB patient whose HIV status is not known or HIV negative (with test result beyond six months), and the health facility does not have co-located SA-ICTC/F-ICTC ,LT at DMC would conduct HIV screening test to bridge the gap in knowing the HIV status. Individual should be counseled about the need for getting tested for HIV and if an individual gives consent for HIV test then it will be recorded in Counselling register at HCTS screening facility (Annexure 3). If the test result is negative then it should be recorded in RNTCP laboratory register and RNTCP request form for examination of biological specimen for TB (Annexure 4) and if the test results is screened positive for HIV then the individual will be referred to SA-ICTC for confirmation of the HIV with the linkage form in triplicate (Annexure 1)
- c. In cases where only the sputum samples reach to the DMC (in absentia of patient), due to the on-going nature of this process, the patient will be called later on and will be offered HIV test. However, HIV testing should be offered to all diagnosed and presumptive TB cases whose sputum was collected at the collection points if the collection centre is having HIV screening facility. At the time of transportation of the sputum specimens, the HIV test result should be documented in the **RNTCP request form for examination of biological specimen for TB**, which will then be updated into the laboratory register by the DMC LT.
- 3. LT is designated staff for conducting HIV screening test at DMC, otherwise any paramedical staff designated for HIV screening (PHN/LHV/ANM/MPW-male/ pharmacist) in the health facility will ensure each individual screened for HIV will be given pre-test counselling with informed consent documented in registers (Annexed at 2 & 3), perform post –test counselling by maintaining confidentiality at each step.

Test results:

If an individual found non-reactive on HIV screening, the laboratory report (**Annexed at 5**) duly signed by the medical officer should be given to the individual during post-test counselling, on the same day. HIV screening site will provide HIV status (Negative & opt out) to the individual and if the screening test is positive then the patient will be refer to the HIV confirmatory site (e.g. SA-ICTC) for the confirmation of HIV diagnosis along with date of HIV screening test and PID number .The counselor at the HIV testing confirmatory site (SA-ICTC) will provide the feedback regarding HIV status (Positive/Negative/Indeterminate/Opted out) is to be recorded in the linkage form and in registers maintained at HIV testing facilities. DMC LT will update the laboratory and Counselling register based on the feedback on the linkage form.

2.4: Procedure at the HIV testing Confirmatory site (SA-ICTC):

- All individuals coming to the ICTCs/F-ICTCs will be offered counselling and testing as per the norms and standard operating procedures of the National AIDS Control Programme (NACP). The counselor at the HIV testing confirmatory site (SA-ICTC) will provide HIV test results in lab report (Annexure-6) along with the post test counselling.
- 2. All referrals will be recorded in the counselling register.
- 3. All Presumptive or diagnosed TB cases that are known HIV positive as evidenced by the HCTS records and reports and patients tested HIV negative within last 6 months will not be re-tested. Patients who had an indeterminate result beyond 28 days will be offered the test.
- 4. For patients with HIV positive results at confirmatory site (SA-ICTC), the counselor will link the patient to the nearest ART centre available in the district/state. This will be done by giving same referral and linkage form (Annexure-1). The patient will be given the contact details of the district programme managers for any assistance needed. The counsellor will document the HIV status, date of HIV testing and PID number in linkage form as a feedback to LT of DMC. The counsellor will also assist the DMC LT to update the laboratory register with information on HIV status.

Chapter 3:WHOLE BLOOD FINGER PRICK TEST FOR HIV SCREENING OF PRESUMPTIVE TB CASES AND TB PATIENTS:

National HIV counselling Testing services Guidelines 2016 includes HIV testing services principally at:

(a) Facility-based services and

(b) Community-based services (CBS).

(a) **Facility-based HCTS** (screening or confirmation) are offered to individuals accessing health-care facilities functioning as per the OPD timings of the institution where the HCTS facility is located. However, SACS should ensure that at least HIV screening test services are available after normal work hours.

(b) **Community-based screening** (**CBS**) is an important approach to enhance the outreach and coverage of priority populations and for improving early diagnosis of people who seldom use clinical services, including men and adolescents in high-prevalence settings and high risk groups (HRG) populations. To improve HCTS access and coverage, community-based HIV screening is carried out through various approaches.

Intensified TB case finding is integrated and offered at all HIV testing facilities (screening and confirmatory sites both) irrespective of their test results and to all populations receiving HIV care services, Intensified TB case finding in clinical and outreach settings will facilitate early detection of HIV-associated TB and linkage to treatment.

It is envisaged by NACP as per the revised National HIV counselling Testing services Guidelines 2016, to increase the access of at-risk populations to HCTS in a cost-effective manner, NACO in addition to establishing SA-ICTC at the CHC and higher levels, has evolved a strategy with the RCH programme for integrating HIV screening at all primary health centres (PHCs) and high-delivery points across India and all DMCs under HIV-TB Collaborative activities. They are labeled as facility integrated counselling and testing centres (F-ICTCs) and should be appropriately linked to the nearest SA-ICTC. HIV screening at all F-ICTCs will be implemented through their existing staff with due sensitization, orientation, guidance, monitoring and supervision by the linked SA-ICTC.

This mechanism of taking HCTS closer to the people may increase the uptake of services while reducing transportation costs and waiting times for those seeking services. Further, integrating HCTS into the general health system will ensure sustainability, cost-effectiveness and facilitate the mainstreaming of HCTS. It is envisaged by the NACP guideline that all DMC will have a co-located HIV testing facility and will promote establishment of HIV screening centres using whole blood finger prick test (WBFPT) at RNTCP DMC facilities not having co-located HCTS. This will help in coverage of all presumptive TB cases and TB patients with HIV testing services and ensure early detection of TB/HIV patients and linkages to HIV care and support services.

The DMC facility without a co-located SA-ICTC/F-ICTC will use whole blood fingerprick test kits for HIV screening, which is easy to perform and provides results within 30 minutes. Need-based quantities of these test kits will be supplied on a regular basis by the district HIV/AIDS nodal officer through the linked SA-ICTC.

These test kits need to be stored between 2°C and 8 °C in the refrigerator available at the health facility. The temperature track indicator (TTI) should be monitored and recorded in temperature log book (**Annexure 7**) regularly, for any change in colour, by the staff incharge of HIV screening. Kits that show a change in colour in the TTI should not be used and promptly replaced through the linked SA-ICTC. The generated bio-waste should be disposed of as per the infection control guidelines.

3.1: HIV Screening Strategy

Whole blood finger prick test for HIV (WBFPT)

Considering importance of HIV testing of TB patients, Presumptive TB cases and the gap in coverage due to lack of co-located HIV and TB testing facilities, all diagnosed and presumptive TB cases will be offered HIV screening test using WBFPT at DMC's. The aim is to detect HIV infection early among diagnosed and presumptive TB cases to enable linkage to care, support and treatment thereby reduce mortality and morbidity.

A screening test used, especially for a disease with low incidence, must have very good specificity as well as sensitivity. The rapid HIV test kits using whole blood, used by NACP have very high sensitivity and specificity (both close to 99%). The fact that whole blood rather

than serum can be used in these tests and very high sensitivity makes them suitable for use as screening test.

It can be used at facilities with limited resources or expertise below the stand-alone ICTC level. It can be easily used by paramedical health worker after minimal capacity building. The laboratory technician at RNTCP DMC would perform the test and the institutional health care provider (pharmacist, staff nurse, ANM etc.) would be trained for provision of pre-test counselling. All patients who are found reactive with WBFPT would be referred to nearest stand-alone ICTC for comprehensive pre and post-test counselling and confirmation of HIV status as per NACO HCTS guidelines.

Who can perform the WBFPT?

A trained laboratory technician, staff nurse, medical officer or any trained health care provider can perform screening test at a health facility.

3.2: Procedure at DMC:

The Lab Technician will be performing the screening test for HIV at RNTCP DMC. Details of procedure are described below under the following headings:

- Rapid Tests
- Collection of blood by finger prick technique for the screening HIV rapid tests
- Performance of screening test for diagnosis of HIV
- Do's and Don'ts of testing
- Quality control

1. Rapid tests

Rapid tests are in vitro qualitative tests for the detection of antibodies to Human Immunodeficiency Viruses (HIV) types 1 and 2. Rapid card testing OR whole blood finger prick test for HIV is used for screening of HIV infection. This is to be confirmed by two other rapid tests if reactive. The individual will be referred to SA-ICTC for confirmation of HIV through linkage form (Annexure 1).

Individual will be registered in lab register and F-ICTC register (Annexed at 2 & 3) and 23 digit PID no. will be given. Pre test counseling as per National HIV counselling Testing services Guidelines 2016 is done (**Annexure 13**) and the presumptive and diagnosed TB cases are offered HIV test. If an individual consents to undergo the test, than signature or thumb impression is to taken in column no. 11 of F-ICTC register and prick is done (Annexure 3).

Collection of blood by finger prick technique for the screening HIV rapid tests is described below:

In case of HIV testing, pre-test counseling and obtaining informed consent of an individual is absolutely essential before collecting the sample.

Blood is to be collected by finger prick technique for performing the screening HIV rapid tests. This is to be done at DMC by LT and in field by ANMs or any other trained healthcare provider.

Step wise procedure:

- 1. Gloves should be worn and sterilized /disposable lancets/needles must be used.
- 2. Ask the individual to sit comfortably and lower the arm (the finger should be lower than the elbow) from which the sample is to be taken.
- 3. Choose the fingertip of the middle or ring finger for adults. (This is applicable to all above 1 year of age).
- 4. Clean finger tip with alcohol; allow to air dry. Do not touch the area
- 5. Gently squeeze and release the area to be pricked until it is red
- 6. Position the hand palm side up .Place the lancet/ needle away from centre on the fingertip. Firmly press the lancet/needle against the skin and puncture the skin. Dispose of the lancet/needle in a safe way into the sharps discard jar containing 1% sodium hypochlorite (Figure:5).
- Wipe away the first drop of blood with a sterile gauze pad and then throw the gauze in the discard jar containing 1% sodium hypochlorite solution (or Figure 6 discard the gauze and gloves in to the waste bucket with the yellow bag)
- 8. Holding the finger lower than the elbow, apply gentle intermittent pressure to the base of the punctured finger a few times

- 9. Following the directions of the kit, apply a full drop to the specimen pad in the rapid card directly so that the specimen pad is adequately soaked or use the disposable pipette provided by the manufacturer to transfer the required amount of sample from the fingertip onto the specimen pad on the rapid card
- 10. Once the required amount of specimen has been collected, pressure must be applied gently at the puncture site with a gauze to ensure that there is no further bleeding from the site
- 11. Continue the test procedure as per the given SOP / process outlined in the kit insert.

Don'ts of Finger Puncture

- Do not puncture the side or the tip of the finger
- Do not puncture parallel to the grooves of the fingerprint
- Do not puncture the index finger
- Do not puncture the little finger
- Do not puncture the fingers of child less than 12 months of age





Figure 1: Recommended site and direction of finger puncture

Figure 2: Select the site to be pricked



Figure3: Clean the finger with alcohol. Work from the middle out to reduce contamination. Allow the area to dry.



Figure 4: Prick finger as shown



Figure 5: Discard Lancet in puncture proof jar containing 1% sodium hypocloride solotion Figure 6: Discard the gauze and gloves in to the waste bucket with yellow bag

Performance of Rapid tests for diagnosis of HIV:

Rapid HIV detection test kits include all necessary reagents and require no other specialized equipment .These tests typically require 20 to 30 minutes(or as specified in the kit insert) to obtain a result and results are interpreted visually after the time from the beginning of the testing process as specified in the kit insert

These rapid cards have HIV antigens immobilized on a porous membrane. The whole blood specimen is put on the sample pad and flows through the membrane during the performance of test and the antibodies if present in the patient specimen are absorbed on to the coated antigen. A dot or a line visibly forms on the membrane in the result area when the antigen and antibody is present in the specimen combine. Tests in addition have an inbuilt procedural control dot or line. The exact process of test performance , time after which the result is to be read and interpretation of the test depends on the manufacturer's instructions in the kit insert that are specific to the particular rapid test. A visual line/dot at both the test and control sites indicates a positive test result, a line/dot only at the control location indicates a negative test result, and the absence of a line at the control site means the test is invalid.

Test procedure

- 1. Bring the test kit to room temperature.
- 2. Lay out the test strips on a white paper towel on a clean flat surface, take the test device out of the protective wrapper and label with the pregnant woman details.
- 3. Wear gloves and perform fingerpick as explained.
- 4. Draw up the required amount of whole blood specimen from the finger tip using one of the disposable pipettes supplied (use only the pipette supplied and do not reuse). After obtaining the required amount of blood, press the pricked area with clean gauze to stop the bleeding and ask the patient to meanwhile continue pressing with the gauze until bleeding stops. Proceed with the testing process
- 5. Holding the pipette vertically over the sample pad, add specimen (as per amount specified) carefully and allow to absorb. Ensure air bubbles are not introduced into the sample port
- 6. Discard the pipette into the discard jar with 1% sodium hypochlorite after dropping the required amount of specimen onto the rapid card

- 7. Complete the next steps of adding any more reagents (if required) as specified in the kit insert of the rapid card
- 8. Set timer for the time as specified in the kit insert. Allow the specified time for the reaction to occur
- 9. Read test results immediately after the time as specified in the kit insert
- Record test result in the patient result form as reactive (if dot/band appears) or negative.
- 11. Refer the patient to nearest SA- ICTC centre for confirmation if the screening test is reactive(by filling the Linkage Form Annexure 1)

Some illustrative examples (figures 7, 8 and 9) are shown below

Reactive 2 lines of any intensity appear in both the control and patient areas.	PATIENT* PATIENT* PATIENT* PATIENT* *CONTROL *CONTROL *CONTROL *CONTROL
Non-reactive 1 line appears in the control area and no line in the patient area.	

Figure 7



Reactive / Positive

Non-Reactive

Figure 8



Figure 9

In case of HIV 1 and HIV 2 co-infection, three dots in the test pad would be visible in case of reactive test results

There are only three possible outcomes for HIV antibody rapid card tests

- 1. Reactive or "Positive"
 - Test band
 - Control band
- 2. Non-reactive or "Negative"
 - Control band only
- 3. Invalid
 - No control band present
 - Test band may be present but control absent
 - Test has failed repeat with new card

Invalid results - what do you do?

- Repeat test
- If repeatedly invalid:
 - Assume problem with test product or procedure
 - Run external controls
- Identify cause of problem
- Inform supervisor
- Take corrective actions

Do's and Dont's of rapid HIV testing

DO's

- Do store kit in refrigerator or cool packs at all times
- Do follow package insert instructions
- Do consider any results presumptive until confirmatory assays have been performed
- Do use a new disposable pipette and device for each specimen tested
- Do use supplied pipette to drop the blood from the finger stick onto the device
- Do use control specimen at least once before taking the kit from SA- ICTC centre
- Do run the test immediately after removing the test cassette from foil pouch
- Do bring all reagents to room temperature before testing
- Do perform tests at room temperature

After reading, confirming and recording the test result, discard the used material including the used HIV test card into the discard jar containing 1% sodium hypochlorite solution

DONT's

- Don't use the kit or any kit components after the expiry date
- Don't freeze the kit
- Don't use the same disposable pipette and device for multiple samples
- Don't pipette by mouth
- Don't use any device if the pouches have been perforated
- Don't mix reagents from different kits
- Don't drop blood droplets directly from fingertip onto device if the kit insert. A disposable pipette must be used to transfer the specimen from the fingertip to the specimen pad on the rapid card device

Universal Safety Precautions (USP):

Staff working in the blood collection room and laboratory should observe simple precautions while handling blood and blood products. These include: Using gloves when handling blood

samples Using disposable needles and syringes for drawing blood Practicing routine handwashing before and after any contact with blood samples Disposing of sharp instruments safely as per procedure, e.g. discard disposable syringes in a puncture-resistant container after disinfection with bleach solution. In areas where such work is undertaken a source of clean water should be maintained.

Post Exposure Prophylaxis (PEP):

Drugs for PEP should be made available to any staff member who is accidentally exposed to HIV in all facilities which have an ICTC as early as 2 hours and within 24 hours of the accidental exposure and not later than 72 hours. The protocol for administration of PEP drugs is available on the NACO website. The facility should have an assigned PEP focal point/person. It is important to ensure that health-care staff are aware of the hospital PEP procedures, and the name and contact information of the PEP focal point/person as well as the location where the PEP drugs are stored.

- Needle stick, puncture wounds, cuts, open skin contaminated by spills or splashes should be washed thoroughly with soap and water
- Report injury to the laboratory in-charge or site in-charge as the case
- Assess individual for Post Exposure Prophylaxis (PEP). PEP, preferably should be started within 2 hours and no later than 72 hours of the accidental exposure
- Appropriate medical evaluation, treatment and counseling should be provided
- For details on PEP, please refer to NACO Guidelines for Post Exposure Prophylaxis on <u>www.nacoonline.org</u>

3.3: Screening WBFP test report:

- If the test result on the initial screening test is negative: The LT will hand over report of HIV screening test to an individual provided with the signature of a Medical officer. Laboratory Report at HCTS Screening Facilities is **annexed at 5**. The institutional healthcare provider should also provide post-test counselling to all clients. He should be educated on measures to stay negative and the concept of window period.
- If the screening test result is positive: The LT should NOT fill test report instead the individual is referred to nearest SA-ICTC with Linkage and referral form in triplicate (Annexure-1 (one copy for record at referring Peripheral Health Institution (PHI) and 2 copies to be sent to SA-ICTC with the individual) for confirmation. Although WBFPT is highly sensitive, there is a miniscule probability of a false positive result. Therefore "HIVreactive" result on WBFPT is not confirmatory and HIV status can be confirmed at NACO stand-alone ICTC's only after 3 tests as per NACO HIV Testing guidelines. On the contrary if the test result is non-reactive it is accepted as negative result and no additional confirmation is required. If screening test is "HIV-reactive" the health worker should reassure him and explain that WBFPT is only indicative and it is necessary for the client /patient to visit nearest ICTC for confirmation. At SA- ICTC a trained counselor provides standard pre-test and post-test counseling, performs testing as per NACO HIV testing guidelines and provides report in a standard NACO reporting format. SA- ICTC Counsellor will fill both copies and return one copy to individual and another copy to referring PHI MO. The MO DMC should use copies in record to check with SA-ICTC counsellor whether referred individual are received at ICTC.
- The report after final confirmatory testing is given to the individual in person maintaining confidentiality and with post-test counseling. Post-test counseling emphasizes and reinforces the pre test counseling. Following a positive result, the immune status of an individual is assessed by doing a CD4 cell count and the case is referred with the same linkage & referral form for complete evaluation to an ART centre. All this is done in accordance with the National HIV counselling Testing services Guidelines.
- Shared Confidentiality: A strategy of shared confidentiality is adopted for care of clients and patients screened with whole blood finger prick test. The MO and other health staff

need to know HIV status so as to ensure linkage of infected person to appropriate care, support and treatment. Hence the SA-ICTC counsellor should provide feedback on the result of HIV test to referring doctor at the earliest. The feedback may be provided through the referral form after consultation with the individual.

Recording Test results: The test results must be documented in existing DMC laboratory register, in a separate format at the end of register (Annexure 8)

3.4: Recording and Reporting

Record of test result: Counselling Register at HCTS Screening Facilities and existing laboratory register at DMC should be maintained for documentation of test results. Below information to be recorded :

- a. Date of screening
- b. Whether the patient's found "reactive" on WBFPT are referred to SA-ICTC for confirmation-Yes/No
- c. Result of HIV test at stand- alone ICTC (as per feedback from SA-ICTC)

These critical data items may be incorporated into DMC Laboratory registers by dedicating last few pages to record information on screening for all diagnosed TB cases.

Monthly reporting:

	•		-			0	e	e Blood Finge	
Name of DM Month:			N	lame of S	A-ICT	C link	ted to:		District: Year:
WBFP Test									1 our
		Total							
	n at a c	tional number ttended t DMC during the month	Num scree usin WBI dur Mor	ened for ng re SPT re ing w	umber ound active on BFPT	ref SA	umber erred to A-ICTC for ïrmation	Number confirmed HIV positive	
TB Patien									
Presumpti TB cases	ve								
Total									
Stock positi	on:				1				_
Opening Stock of	No. test-l receiv	of kits ut		est-kits during 10nth	Was	0	Closing	Requirement for next month	
test Kits	duri mon	ing F	For sting	For control	if a	ny	Stock	(include one month buffer)	
Name of rep	orting	Officer :							Signature

Monthly DMC level report on HIV screening using WBFPT should follow same reporting cycle as RNTCP monthly PHI report. The DMC MO may send this report to taluka health officer or block medical officer and district health officer or CMHO along with other reports generated at the PHI. The District DR TB and TB/HIV supervisor should then obtain copies of these DMC wise reports, from office of District Health officer for compilation. District level HIV screening report is just numerical compilation of DMC reports. This report should be sent

to State TB Officer and SACS electronically by 15th of every month. A copy of this report should also be shared with DAPCU officer or counsellor of headquarter ICTC in non-DAPCU districts, to ensure un-interrupted logistics supply. The format for district level reports is as shown below:

BFP Test	ing :											Year:
	To num atter at D dur th mo	ber ded MC ing e	Numb screen using WBFI durin Mont	ed g PT g	Numl foun reacti on WBF	d ive	Num referr SA-I(fo confirm	ed to CTC r	C	Number onfirmed HIV positive		
TB Patien	ts											
Presumpti	ve											
TB cases												
Total												
tock positi	0 n											
Opening Stock of	No. of test-kit receive	s d	No. of t utilized the n	du 1011	ring th		′astage f any	Closin Stocl	\mathbf{O}	Requirer for ne mont	xt h	
test Kits	during month		For testing		For ontrol		•			(include month bu		

The State TB/HIV coordinator should ensure compilation of district wise reports into an excel sheet format mentioned below and send to Central TB Division and NACO. A copy of the same should be shared with SACS. This format is just numerical compilation of district wise monthly screening reports as shown below:

Monthly State level report on HIV screening using Whole blood finger prick test Name of State :

Month: ____

WBFP Testing :

Year:_____

	Total number attended at DMC during the month	Number screened using WBFPT during Month	Number found reactive on WBFPT	Number referred to SA-ICTC for confirmation	Number confirmed HIV positive
TB Patients					
Presumptive					
TB cases					
Total					

Stock position

Opening Stock of test Kits	No. of test-kits received during month	No. of test-kitsutilized duringthe monthForFortestingcontrol		Wastage if any	Closing Stock	Requirement for next month (include one month buffer)	
Name of ren	orting persor		control				
1	State TB O						Signatu Date:

Key Messages

- HIV screening using whole blood finger prick test helps in early detection of HIV infected individual, thus helping early linkage to care and support
- Whole Blood finger prick test (WBFPT) should be used only for HIVscreening at health facilities.
- 3. WBFPT is only a screening test and **HIV reactive result is not confirmatory**
- Confirmation of HIV positive status can be done only after three "reactive" test results using different principles atNACO stand-alone ICTC
- DMC LT should communicate screening test result to medical officer and NOT to the patient directly.
- 6. If test result is "Non-Reactive" medical officer should provide a signed report to the patient along with post-test information. If test result is "Reactive", no report is given to the patient. Instead a referral form is filled and patient is referred to nearest ICTC for confirmation of HIV status
- Maintenance of cold chain for storage and transportation of test kits is critical for reliability of screening test results
- The Lab technician at DMC should prepare monthly DMC level HIV screening report and MO DMC should submit this along with RNTCP monthly PHI report

3.5: Logistics Management:

Transportation and storage of test kits: Whole blood HIV test kits should be stored at a cool temperature (2 to 8 degrees or as per manufacturer's instructions). Hence they should be transported in cold chain from the state level storage site to the point of use. These test kits for use at DMC may be supplied from SACS or district level store to stand alone ICTC using the Indent form for HCTS commodities(**Annexure 9**) same as used for other HIV test kits,. The supply from SA-ICTC to the DMC is primarily the responsibility of DAPCU officers /District HIV nodal officer in non DAPCU districts.

The SACS, DAPCU officer /DNO, DTO, District ICTC supervisor and SA-ICTC counsellor should ensure uninterrupted supply of WBFPT kits to all identified DMC. They should also ensure that kits are stored at SA- ICTC and the DMC in refrigerator while for transportation to DMC, cold box or vaccine carriers obtained from district health authorities should be used.

Stock maintenance: The supplies at all level should be based on consumption. The DMC PHI should have enough stock as per consumption of previous month plus a buffer stock of one month consumption, at the beginning of every month. The stock supply should not be in quantity less than 1 box (30 tests) since the buffer solution etc. cannot be divided. In addition to this at district level one box ear-marked for each DMC (doing screening) should be available as buffer. Hence at any given point of time the stock of whole blood test kits in the district should be sufficient to last 3 months (1 month consumption+1 month buffer +1 month buffer at district level).

Stock / inventory management of reagents and consumables:

The LT's should follow a well defined inventory management system. Inventory management means proper maintenance of adequate stocks to ensure uninterrupted service. Inventory (or stock) is the supplies and materials needed for test performance that the LT's will be given to carry for performing the tests.

The Stock reporting structure for all HCTS facilities is reflected in the figure below:

Every screening facility (storing and testing) has to submit a weekly status report of commodities in the prescribed format (Annexure 10/ already existing stock register) and as per the time lines indicated in the table below:



Figure 8: Reporting structure for HCTS facilities for stock status

All HCTS facilities should also update stock status details as present in the SIMS format (Annexure 11) by the 5th of every month.

It is necessary to ensure that an appropriate feedback mechanism is established for efficient functioning of all HCTS facilities.



Figure 9: Feedback mechanism Whole blood finger prick test

Note:

- 1. HIV test kits should be stored at temperature between 2 to 8 °C at all levels
 - a) Ensure maintenance of cold chain while transporting HIV test kits from the Storage unit to HIV testing facility
 - b) Use the FEFO (First-Expiry, First-Out) rule: First supplies that are likely to expire are to be taken out/ supplied first
 - c) Meticulously maintain stock and temperature log records
 - d) Protect from heat, light, moisture/rain, dust, pests and fire
- At DMC level stock of 2 month (including 1 month consumption + 1 month buffer) should be maintained and at district level buffer stock of 1 month i.e. total stock of 3 months should be available at the beginning of month.
3.6: Quality Control (QC)

Quality Control for HIV Rapid testing includes:

- Testing of samples with known results to verify if the procedure is working properly
- Interpreting the presence or absence of inbuilt control bands/lines within the device itself

If an error occurs, do not perform or report results until you have corrected the error.

External Quality Assurance Scheme:

Testing of blood sample is the commonest way to know one's HIV status. Knowing HIV status a HIV non reactive person can zealously protect him/ herself from HIV infection throughout life and HIV reactive person can lead a positive life with services like psychosocial support, provision of ART, community care home treatment of opportunistic infection etc. Thus HIV testing occupies very large portion of the entire HIV/ AIDS prevention & control programme. Not only HIV test but accurate HIV test is the vital. False HIV reactive report can lead negative consequences in the life of an individual for eg. social discrimination, denial of access to basic requirements of life, psychosocial stress. On the other side false HIV non reactive result can spread the infection faster. Accuracy of HIV testing does not depend upon on single individual or one factor. A team of individual is responsible for it. The team comprises kit manufacturer, sample collector, laboratory technician, DEO, counselor. To maintain a high quality of HIV testing EQAS has been started

Include the PHI under the EQAS sample testing procedure through SA-ICTC for Quality Assurance of the testing.

4.5: Capacity Building:

Implementation of HIV screening programme at facilities other than the SA-ICTC is challenging. Therefore all the concerned staff should undergo modular training. Along with this state and district level officials should be sensitized on regular basis regarding importance of this activity.

All TB trainings should include HIV testing using WBFPT.

Chapter 4: ROLES AND RESPONSIBILITIES:

1. DMC Laboratory Technician:

- i. Perform HIV screening test using whole blood finger prick test& prepare the test report of HIV antibody test given to the individual who detected as non reactive(Annexure-5)
- ii. Document screening test results on DMC laboratory register
- Prepare monthly DMC report on HIV screening using WBFPT and submit to MO
- iv. Ensure storage of testing kits at cool temperature (2 to 8 degrees centigrade) maintain the Daily Temperature Log Sheet (Annexure-8) & send the weekly stock report by every Monday to SA-ICTC.
- v. Co-ordinate with RNTCP supervisors (STLS/STS) to ensure screening of all Presumptive TB cases and TB patients
- vi. Maintain confidentiality of test results within health system (shared confidentiality)
- vii. Follow universal precaution and ensure safe disposal of biomedical waste material
- viii. Ensure that those tested "reactive" are linked to nearest stand -alone ICTC at the earliest along with the (Annesure-1)

2. District ICTC supervisors / District DR-TB and TB-HIV supervisor /ICTC counsellor/RNTCP STLS:

- i. Facilitate training of all DMC LT's and institutional Health care provider providers at district level
- ii. Facilitate implementation of HIV screening using WBFPT at all DMC's.
- iii. Facilitate recording and reporting at all screening facilities in their jurisdiction.
- iv. Facilitate uninterrupted supply of test kits in cold chain along with other required logistics.
- v. Facilitate confirmation of HIV test results at nearest stand-alone ICTC for all patients found "reactive" at DMC

- vi. Ensure provision of feedback by SA-ICTC counsellor on test result to referring MO
- vii. Ensure appropriate and timely linkages of all detected HIV positive individuals to care, support and treatment

3. Medical Officer DMC PHI:

- i. Ensure availability of whole blood test kits at the DMC
- ii. Ensure storage of kits at cool temperature (2 to 8 degrees centigrade) using refrigerator.
- iii. Review performance of testing and referral fortnightly and ensure timely submission of reports monthly reports in SIMS
- iv. Review records maintained by LT regularly
- v. Ensure those tested positive on WBFPT are linked to the nearest SA- ICTC at the earliest
- vi. Ensure universal precautions such as use of hand gloves, appropriate disinfection procedures, safe handling of sharps etc. by LT
- vii. Ensure disposal of biomedical waste along with other hazardous hospital waste as per guidelines
- viii. Ensure the timely submission of weekly stock report to SA-ICTC

4. DAPCU officer (DNO) / District TB Officer/ Taluka or Block medical officer:

- i. Prepare micro-plan for establishing F-ICTC's at all DMC's to ensure 100% functional co-location of HIV and TB testing facilities for the district.
- ii. Ensure training of all DMC MO, LT and concerned institutional DOT providers at district level
- Ensure implementation of HIV screening using WBFPT at all RNTCP DMC not having testing facility
- iv. Ensure recording and reporting at all screening facilities in their jurisdiction
- v. Ensure uninterrupted supply of test kits in cold chain
- vi. Ensure 100% referral of TB patients found "reactive" to nearest stand-alone ICTC for confirmation
- vii. Ensure provision of feedback by ICTC counselors on test results to referring doctor

- viii. Ensure appropriate and timely linkages of all detected HIV positive individuals to care and support
- ix. Review performance of this centres regularly during routine monthly review meetings

5. Nodal officer for TB/HIV in State AIDS Control Society /State TB office/State TB HIV coordinator:

- i. Ensure close coordination between state TB office and SACS to facilitate universal coverage of TB patients with HIV testing services
- ii. Ensure 100% functional co-location of HIV and TB testing facilities in the state through establishing F-ICTC's at all DMC's
- iii. Ensure national, state and district level trainings for implementation of WBFPT testing, as mentioned in this document
- iv. Ensure uninterrupted supply of test kits and necessary logistics at the point of use.
- v. Ensure storage and transportation of HIV test Kits in cold chain from state level to point of use
- vi. Develop mechanism for review of implementation of HIV screening at district and state level
- vii. Regular supervision, monitoring and evaluation for smooth implementation
- viii. Ensure prompt and timely reporting to NACO and Central TB Division

A. Group Discussion:

Time: 15 minutes

Materials: Flipchart, Markers

- I. Quickly divide participants into manageable groups,
- II. Explain that the task
- III. Tell groups to brainstorm /discuss among group and subsequently in wider group on following points:

1. Benefits of Provider-initiated Testing and counselling

- 2. Challenges /Barriers to HIV testing
- **3.** Patient-centered care
- 4. Confidentiality and consent
- 5. Stigma & Discrimination

B. Role Plays

Time: 15 Min

- **1. Pre test Information**
- 2. Sharing the result of Test
- 3. Referral and feedback

5. ANNEXURES:

- Annexure 1: Linkage form for HCTS facilities (in triplicate) NACO
- Annexure 2: RNTCP Laboratory Register
- Annexure 3: Counselling Register at HCTS Screening Facilities (FICTC/PPP-ICTC)
- **Annexure 4: RNTCP Form for Referral for Diagnosis**
- **Annexure 5: Laboratory Report at HCTS Screening Facilities**
- Annexure 6: Laboratory Report at HCTS Confirmatory Facilities (SA-ICTC)
- **Annexure 7: Temperature log book at HCTS Facilities**
- Annexure-8: Format for recording HIV screening with whole blood finger prick test at DMC
- **Annexure 9: Indent form for HCTS commodities**
- Annexure 10: Stock register at HCTS Screening Facilities
- Annexure 11: SIMS reporting format for HCTS Screening Facilities (FICTC & PPP-ICTC)
- **Annexure 12: Dashboard Indicators for HCTS Screening Facility**
- **Annexure 13: Pre-test Information for clients or patients**

Annexure 14: Office Memorandum NACO -Multitasking by Laboratory technicians

Annexure-1: Linkage form for HCTS facilities (in triplicate)

National AIDS Control Organization Linkage Form (in triplicate) for HCTS facilities	National AIDS Control Organization Linkage Form (in triplicate) for HCTS facilities	National AIDS Control Organization Linkage Form (in triplicate) for HCTS facilities		
Copy-1 (to be retained at the facility referring the individual)	Copy-2 (to be carried by the Individual to the referred facility & to be retained at referred facility)	Copy-3 (to be retained by the individual)		
Referred by: SA-ICTC/FICTC/PPP-ICTC/TI/STI/Others Referred to: ART/SA-ICTC/RNTCP/TI/STI/Others	Referred by: SA-ICTC/FICTC/PPP-ICTC/TI/STI/Others Referred to: ART/ SA-ICTC / RNTCP / TI /STI/ Others	Referred by: SA-ICTC/F-ICTC/PPP-ICTC/TI/STI/Others_ Referred to: ART/ SA-ICTC / RNTCP / TI /STI/ Others		
Referred by: Name & Address of facility	Referred by: Name & Address of facility	Referred by: Name & Address of facility		
To be filled by the facility referring the individual	To be filled by the facility referring the individual	To be filled by the facility referring the individual		
Details of the individual being referred:	Details of the individual being referred:	Details of the individual being referred:		
PID Number:	PID Number:	PID Number:		
Name:	Name:	Name:		
Age: Sex:Contact No.:	Age: Sex: Contact No.:	Age: Sex:Contact No:		
Category (Tick mark):	Category (Tick mark):	Category (Tick mark):		
ANC/DIL/PNC/General/Exposed infant/HRG	ANC/DIL/PNC/General/Exposed infant/HRG	ANC/DIL/PNC/General/Exposed infant/HRG		
Purpose of referral:	Purpose of referral:	Purpose of referral:		
Date of referral:	Date of referral:	Date of referral:		
Name and address of the facility referred to:	Name and address of the facility referred to:	Name and address of the facility referred to:		
Details of the staff referring the individual:	Details of the staff referring the individual:	Details of the staff referring the individual:		
Name :	Name :	Name :		
Designation:	Designation:	Designation:		
Contact No.:	Contact No.:	Contact No.:		
Signature:	Signature:	Signature:		
To be filled by the facility referring the individual after feedback from referred center	To be filled by the referred center staff			
Has the individual reached : Yes No If individual was referred to SA-ICTC, has the individual been tested for HIV? Yes/No If individual was referred to ART center, has the individual been registered there? Yes/No Remarks:	 Has the individual reached : Yes No If individual was referred to SA-ICTC, has the individual been tested for HIV? Yes/No If individual referred to ART center, has the individual been registered there? Yes/No Remarks: Name of staff documenting this information: 			

Annexure 2: RNTCP Laboratory Register

							Reasons for Examination*		Re	esults					
Lab Serial	Date	Name in	1 00	Sex M/F/	Complete address (for	Name of	Diagnosis		Follow-up				Status (P,N,U)	Sign	Remarks
No.	Date	Full	Age	TS- TG	new patients) Phone No.	referring Diagnosis Health Facility		TB No.	Regimen NT/PT	Month	Α	В	(1,11,0)		Kemai KS

• If sputum is examined for diagnosis, put a tick () mark in the space under "Diagnosis" sputum is examined for repeat diagnosis, put 'RE' in the space under" Diagnosis"

• If sputum is for follow-up of patients on treatment, write the patient's TB No. in the space under "Follow up", treatment regimen and month of follow up

• Points to be mentioned in the remarks column: date of starting treatment, treatment regimen, TB No, Referral details, MDR-TB suspect identified and remarks on unblinded rechecking of slides during OSE visits by the STLS, etc.

• HIV status: P-Positive; N-Negative; U-Unknown

Annexure 3: Counselling Register at HCTS Screening Facilities (FICTC/PPP-ICTC)

SI No ·Dat e of Visi tPI D Nam refAddres sContac t No.Type of Individu alReferre d by (In- referral)Age (See (Complete d years)Consente d for HIV testing (if Consente d of HIV testing (if Consente Signature Signature s creenin gDate of Post-test referr al toOut- referr al to

16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
							(Please fill th	ened reacti is part afte from SA-IC	r getting	1	f positive PW	/ DIL delivere		
Nam e of HIV test kit	Batc	Expir	for	Syphi	Suspe cted for TB	If yes, referred to RNTCP	Date of HIV Confirmati on report	HIV Status of individu al	Whether the report given to Individu al	Date of Deliver Y	Outcome of pregnanc y	If Live Birth, whether ARV prophylax is initiated to the baby	If Live Birth, whethe r the baby linked to SA- ICTC	Remark S
								1						

Column No	Specification / Code
2,12,14,18,23,26	DD/MM/YYYY
11,19,21,22,25,2	
8,29	(1) Yes, (2) No
7	(1) ANC, (2) DIL, (3) Breast feeding women, (4) General Individuals
	(1) OBG/GYN, (2) TI NGO, (3) Link Worker, (4) RNTCP/DMC, (5) STI clinic ,
8, 15	(6) Other (7) SA-ICTC
10	(1) Male, (2) Female, (3) TG
13, 20	(1) Reactive, (2) Non-reactive
	(1) OBG/GYN, (2) TI NGO, (3) Link Worker, (4) RNTCP/DMC, (5) STI clinic ,
15	(6) Other
24	(1) Positive, (2) Negative, (3) Indeterminate
27	(1) Live Birth-single (2) Live birth-twins (3) MTP/Abortion , (4) Still birth,

RNTCP Request Form For Examination Of Biological Specimen For TB (Required for Diagnosis of TB, Drug Sensitivity Testing and Follow up)								
	· · · ·	nt Info				up)		
Patient Name		A	ge (in y	vrs)		Gender: M Gender:	ΠTG	
Patient Mobile No. or		S	pecime	n		Sputum		
other contact no.				Collection		Other(specify)		
				1/YY)				
						ctive 🗆 Unknown		
Patient address with			-	-		TB Case Diabetes		
landmark				cco 🗖 Smoker				
						Specify)		
Name referring facility (PHI,	I/DMC/DR-TB Centre/Laboratory/ Others):			Shay ID:				
Health Establishment ID (NI	IKSHAY):	RI	NTCP T	B Reg No		Or	cable	
State:	District: Tuberculo	sis Unit	: (TU):					
Reason for Testing:			()_					
	Dru	g Sensit	tive TB					
Diagnosis (NIKSHAY ID)	- Fo	ollow u	p (Smear and cult	ure)			
				B Reg. No	-			
H/o anti TB Rx for > 1month			ΙΚSHA					
Presumptive TB		R	egimer	i: 🗆 New	D Pre	viously Treated		
Private Referral				End IP	End CP			
Presumptive NTM		P	ost Tre	atment: 🗆6M		□ 18M □ 24M		
•	Drug	g Resist						
Drug Susceptibility Testing(•	w-Up (Smear and	Culture)			
	New Previously treated			T TB Reg No				
	At diagnosis			B NIKSHAY ID:				
	Contact of MDR/RR TB		Regimen:					
MDR TB (provide	Follow-up SM +ve		Regimen for H Mono/Poly resistant TB					
first line DST	Private referral		Regimen for MDR/RR -TB					
	Discordance resolution		\square Regimen for MDR/RR -TB + FQ/SLI resistant					
Presumptive H mono/n	poly (provide first and second line DST)			egimen for XDR-T	В			
	MDR/RR TB at Diagnosis			egimen with Beda	aquiline for N	IDR TB+ FQ/SLI resista	nce	
	months culture positive			egimen with Beda	aquiline for XI	DR-TB		
	3month for persistent culture Positive		Regimen with Bedaquiline for failure of regimen for MDR -TB					
XDR TB (provide	(treatment month)		±FQ/	SLI resistant				
	Culture reversion			egimen with Beda	aquiline for fa	ilure of regimen for X	DR-TB	
	Failure of MDR/RR-TB regimen			egimen for mixed	l pattern resis	tance		
	Recurrent case of second line treatment		т	reatment 🗆 🛛 M	Ionth 🔲	Week:		
	Discordance resolution							
Test Requested:								
· ·				<u> </u>				
	L CBNAAT L Culture L	_ DS	Т	Line Pro	be Assay	Gene Sequen	cing	
Other (Please Specify):_				· · · · · · · · · · · · · · · · · · ·				
Requestor Name, Designation	ion and Signature:							
Contact Number:	Email ID:							
Results:	Results: CDL NIKSHAY ID Generated: C							
Microscopy (ZN D Florescent)								
Lab Sr. No. Visual appearance Result								
		Negat	ive	Scanty	1+	2+	3+	
Sample A	<u> </u>							
Sample B								
Date tested: [Date Reported: Reported b	oy:			•	•	-	
						(Name	e and Signature)	

Annexure 4: RNTCP Form for Referral for Diagnosis

Note that RNTCP forms are to be provided by RNTCP centreA

Annexure 5: Laboratory Report at HCTS Screening Facilities

NATIONAL AIDS CONTROL ORGANIZATION
HIV Counselling & Testing Service (HCTS) Facility
Name of HCTS Facility:
(SA-ICTC/F-ICTC/PPP-ICTC/TI-ICTC etc.):
Address:
LABORATORY REPORT FORM FOR HCTS SCREENING FACILITY (CONFIDENTIAL)
PID Number:
Name of Individual: Age: - - - -
Date of HIV screening
Result of HIV Antibody test: Non-Reactive
Batch No:
Name of HIV Test Kit
Date of follow-up testing (if applicable):
(Please bring this report during follow-up testing)
Signature of Staff conducting HIV Screening Signature of Medical Officer
Note: (1) This report may be signed by the in-charge Medical Officer of the facility or any Medical Officer.
(2) To maintain strict confidentiality, the signed HIV test report must be given only to the individual.

Annexure 6: Laboratory Report at HCTS Confirmatory Facilities (SA-ICTC)

NATIONAL AIDS CONTROL ORGANIZATION								
La	boratory Test Report form	for HCTS Confirmatory facili	ty					
Name & Address of the SA	A-ICTC:							
Name: Surname	Middle name	First Name						
Gender: O Male D Female Transgender Age:								
PID No.:	PID No.: Lab ID No.:							
Date & Time of Blood Drav	vn:	(DD/MM/YY)	(HH:MM)					
Test Details:								
 Date & Time of specified 	specifier type used for testing (textone). Serving rubbind y whole blood							
 Column 2 and 3 to 								
Column 1	Column 2	Column 3	Column 4					
Name of the HIV kit	Reactive/Nonreactive Reactive/Nonreactive Reactive/Nonreactive it (R/NR) for HIV-1 (R/NR) for HIV-2 (R/NR)		Reactive/Nonreactive					
	(R/NR) for HIV-1 antibodies	(R/NR) for HIV-2 antibodies	(R/NR) for HIV antibodies					
Test I:		• • •	(R/NR) for HIV					
		• • •	(R/NR) for HIV					
Test I:		• • •	(R/NR) for HIV					
Test I: Test II: Test III: Interpretation of the result Specimen is negative for Specimen is positive for \$	antibodies t: Tick (✓) relevant or HIV antibodies or HIV-1 antibodies for HIV antibodies (HIV-1 an nate for HIV antibodies. Col	antibodies	(R/NR) for HIV antibodies					
Test I: Test II: Test III: Interpretation of the result Specimen is negative for Specimen is positive for \$	antibodies t: Tick (✓) relevant or HIV antibodies for HIV-1 antibodies for HIV antibodies (HIV-1 an nate for HIV antibodies. Col o-status at identified referro	d HIV-2; or HIV-2 alone) lect fresh sample in 2 weeks al laboratory through ART ce.	(R/NR) for HIV antibodies					

Annexure 7: Temperature log book at HCTS Facilities

	National AIDS Control Organization Daily Temperature Log Sheet (HIV Counselling & Testing Services Facility)									
Name	Name of HCTS Facility (SA-ICTC/F-ICTC/PPP/TI etc):									
Addro	Address:									
Name	Name of the Staff:									
Desig	nation:			Contact No:						
Name	e of In-cha	rge of HCTS Facilit	ty:							
Desig	nation:			Contact No:						
	Γ	Month:	Year:							
		АМ		РМ	Remarks					
Day	Time	Temperature	Time	Temperature		Signature				
	Thire	(in ⁰ C)	Time	(in ⁰ C)						
1										
2										
3										
4										
5										
6										
7										
8										
9	9									
10	10									

Annexure 8: Format for recording HIV screening with whole blood finger prick test at DMC

Sr. no	Date	Lab serial number	Name	Presu mptive TB case or TB patient	TB numbe r/Niksh ay ID	Result (Reactiv e/ Non- reactive)	Date of referral to Stand alone ICTC for confirmati on	Result of HIV test at stand- alone ICTC: Pos/ Neg/ Indetermina te /opted- out) **	Remarks

* Print this format and paste on last 3-4 pages of DMC laboratory register) **Source feedback received from stand-alone ICTC Remark may include -not reached, not tested etc.

Annexure 9: Indent form for HCTS commodities

National AIDS Control Organization HIV Counselling & Testing Service (HCTS) Facility INDENT FORM FOR SA-ICTC/F-ICTC/PPP-ICTC/TI-ICTC

(to be filled by the staff of HCTS facility)

Name of HCTS Facilit	t y:		
(SA-ICTC/F-ICTC/PPP	-ICTC/TI-ICTC etc.):	 	
Address:		 	
Name of the Staff:		 	
Designation:		 Contact No:	
Email id:		 	
Name of In-charge H	CTS facility:	 	
Designation:		 Contact No:	

The following items are required for HIV screening:

	D. Details of the item Quantity requested Consumption Balance available a facility	Quantity	Monthly	Balance available at	Quantity	Status of last supply		
S. No.		facility	supplied	Date	Quantity issued			
1								
2								
3								

Signature of the Staff (Receiving the consignment) Name: Signature of the Staff (Supplying the consignment) Name:

Designation:

Contact No.

Date: __/ __/ ____

Designation:

Contact No.

Date: __/ __/____

Signature of Officer In-charge

Annexure 10: Stock register at HCTS Screening Facilities

DD/MM/YY (Daily)	Name of Kit	Batch No.	Expiry Date (DD/MM/YY)	Opening Stock	No. of test kits Received in this month	No. of test kits utilized	No. of Expired test kits (return)	Wastage / Damage (if any)	Control	Closing Stock	
А	В	С	D	E	F	G	н	I	J	K= (E+ F- G- H- I-J)	

Notes:

1. All HCTS facilities which already have a stock register for stock of kits other than HIV should maintain HIV stock details in the same register.

2. This format is only for facilities (such as PPP-ICTC) which may not have their own existing stock register.

3. SACS will not print this register

Annexure 11: SIMS reporting format for HCTS Screening Facilities (FICTC & PPP-ICTC)

	Unique F-ICTC Code			F-ICTC	name								
			MONT	THLY REPORTIN	IG FORMAT: F-	ICTC / PPP-ICT	rC						
				SECTION	A. IDENTIFIC	ATION							
Name	of Centre:					Type of F-							
Linked SA-ICTC name :						Linked SA	-ICTC Code:						
Address:						Pin Code:							
Block/ Mandal/ Taluka: District:						State:							
Reporting Period: From:// To://			Month		Year:								
Name	Name of Officer In-charge (F-ICTC):												
Contact number: Phone:				Mobile									
Email	Address:				7. F-ICTC Location:								
SECTI	ON B. BASIC INDICATO	DRS											
			·	1. PROGRESS M	ADE DURING	THE MONTH							
Sl.no	Basic Indicators				Pregnant Women					General Individual			
Sinto				ANC	DIL	PNC	Total	Male	Female	TS / TG	Total		
1 Total new ANC individuals registered during the month							0						
2 Number of individuals provided pre-test Counselling					0				0				
3 Number of Individuals screened for HIV (using WBFP test)						0				0			
4 Number of Individuals provided post-test counselling							0				0		
5 Number of Individuals found HIV reactive after Screened Test							0				0		

5.1	(out of sl. No. 5)Number confirmed HIV positive at SA-ICTC			0				0				
5.2	(out of sl.No. 5) Number Confirmed HIV negative at SA-ICTC			0				0				
6	Number of Individuals tested for Syphilis (using RPR Test)			0				0				
6.1	(out of sl no. 6)Number of Individuals found reactive for Syphilis			0				0				
7	(out of sl no. 2)Number of TB suspect individuals identified			0				0				
2. LINKAGE & REFERRAL												
			In Referra	ıl								
Sl.no	Department/ Organisation	Tested Screened reactive in 1st test				Out Referral						
1	OBG / GYN (ANC Clinic)											
2	Targeted Intervention NGOs											
3	Link Worker											
4	RNTCP											
5	STI Clinic											
6	Others											
	3. Delivery & ARV prophylaxis details (only for H	IV positive Pregnar	nt women delivered	in this institut	ion) fill wherev	er applicable						
	Indicator Description											
	(only for DIL)	Live	Birth	Still	birth	Τα	otal					
1	Number of HIV positive Pregnant women Delivered in this facility, During this month						0					
2	Number of HIV exposed babies initiated on ARV prophylaxis(Syp NVP/Syp ZDV/LPV)						0					
3	(Out of Sl.no.1) No of HIV exposed babies linked to nearest SA ICTC for getting EID services						0					

	4. STOCK STATUS OF HIV TEST KITS (Number of Tests)												
Sl.no	Consumables	Name of Kit	Expiry Date *	Opening Stock	Received	Consumed	Control	Wastage / Damage/ Expired	Closing Stock	Average Monthly Consumption	Stock sufficient for how many months		
1	WBFP Test Kit								0		0		
2	HIV Rapid Test Kit								0		0		
3	Syphilis Test Kit								0		0		
4	Syp NVP								0		0		
5	Availability of essential STI/F	Yes/No											

Annexure 12: Dashboard Indicators for HCTS Screening Facility

National AIDS Control Organization													
Dashboard Indicators at Screening facilities													
(to be displayed at the facility & duly updated for every month)													
Name of Facility Financial Year													
	-							FIII					-
Indicator	Apr	Ma y	Jun	Jul	Aug	Sep t	Oct	Nov	Dec	Jan	Feb	Ma r	Total
ANC individuals :			<u> </u>		<u> </u>				<u> </u>				
Total new ANC individuals													
registered during the month													
Number of individuals provided													
pre-test counselling													
Number of Individuals													
screened for HIV by WBFP test													
Number of Individuals found													
HIV reactive after 1st Test													
Number of HIV positive													
Deliveries conducted													
General Individuals:													
Number of individuals provided													
pre-test counselling													
Number of Individuals													
screened for HIV by WBFP test													
Number of Individuals found													
HIV reactive after 1st Test													

Pre- test information

What is HIV/AIDS?

HIV is a Human Immunodeficiency virus which gradually destroys body's immune system.HIV infection cannot be detected immediately since the infected person may not feel sick for several years. As the body's immune system is slowly weakened, the person becomes more vulnerable to acquiring opportunistic infections and diseases. If undetected and not managed even at this stage, the person becomes unable to fight even minor infections and become severely ill. This stage is called Acquired Immuno-Deficiency Syndrome (AIDS).

How is HIV transmitted?

The following are the four important modes of transmission of HIV:

- 1. Unprotected sex
- 2. HIV infected blood or blood products
- 3. Unsterilized needles, syringes or lancets
- 4. HIV infected mother to her baby during pregnancy, childbirth or during breastfeeding

HIV is not transmitted through hugging, kissing, having food together or mosquito bites

How to know whether one is HIV infected?

The only way to know if one has HIV or not is through a blood test. This test is done free of cost at the designated counselling and testing centre

To avoid unnecessary travel for HIV testing Government of India has provided HIV screening facility at RNTCP DMC's also. These facilities provide only one test using a finger prick. Laboratory technicians are trained to perform these tests.

If the test result is "non-reactive", it is highly reliable and a report regarding same will be provided by medical officer.

If the test is found "reactive", report cannot **be provided** because a single reactive test result is not confirmatory. To confirm the test result three separate tests are required to be performed. The facility for these is available at the nearest ICTC.

Along with confirmed test report ICTC also provides detailed counselling before and after performing the test

What are the benefits of HIV testing?

HIV has no permanent cure at present, but with the availability of highly effective antiretroviral drugs (ARV) it is considered a chronic manageable illness. If ARV is received in time and taken regularly the HIV infected person can lead a normal life. The ARV are provided free of cost by the Government of India under National AIDS Control Programme. The benefits accrued with ARV is maximum if HIV is detected at the earliest and the infected person is promptly linked to care and support services.

Tuberculosis is the most common opportunistic infection in HIV infected persons. TB and HIV together is a fatal combination. Therefore all TB patients are offered provider initiated HIV testing and counselling (PITC). This helps to detect HIV early among TB patients so that care and support (ART + CPT) is initiated in time to save and improve quality of life.

Post-test information:

If WBFPT screening test result is "non-reactive": Measures necessary to remain negative are the A, B, C mentioned below:

- A-Abstain—Choose not to have unsafe sexual intercourse
- **B-B**e faithful to one partner
- C-Use Condoms correctly and consistently

Window period:

The window period represents period of **time between** initial infection with HIV and the time when HIV antibodies can be detected in the blood (about 6 to 12 weeks) by HIV test. A blood test performed during window period may yield a negative test result. Therefore these cases require further testing after 12 weeks. This decision to perform repeat test is taken by medical officer considering risk profile of the client/patient.

If WBFPT screening tests result is "reactive":

One **"reactive"** result is just indicative, for confirmation the patient must visit nearest ICTC. The ICTC counsellor provides detailed pre-test counselling, conducts three separate tests and provide post-test counselling. Further the client/patient is linked to all necessary services including treatment, care and support offered by the National AIDS Control Programme

Annexure 14: Office Memorandum NACO -Multitasking by Laboratory technicians

T-22020/77(2005-NACO/BSD (HIV-TB) Government of India Ministry of health and Family Welfare Department of AIDS Control (National AIDS Control Organization) 6th Floor Chandralok Building, 36, Janpath, New Delhi, 110001 Duted: 03.07.2012 To. Project Directors, All State AIDS Control Societies Subject: Multi-tasking of HIV and TB testing by Laboratory Technicians at ICTC and DMC Dear Sir. As you are aware the NAPC and RNTCP have strong functional collaboration for implementation of joint TB/HIV activities. While NACP implements intensified case finding (ICF) at all its facilities, RNTCP implements HIV testing of all registered TB patients. These activities are aimed at early detection of HIV infected TB cases and their prompt linkage to ART and ATT. It is also known that HIV being concentrated epidemicthe NACP diagnostic and treatment facilities are concentrated more in areas with high HIV prevalence (Category A and B districts) and TB being a generalized epidemic, the RNTCP diagnostic and treatment facilities are more decentralized. Therefore a gap exists in terms of co-located diagnostic and treatment The National Technical Working Group (NTWG) on HIV/TB in its meeting at NACO on 23/12/2011, deliberated on the issue of gap in infrastructure specifically pertaining to ICTC Fz. DMC, and measures to bridge the same. NACP and RNTCP have provided contractual laboratory technicians (LT) at ICTC and DMCin all states and UT. Optimal utilization of this existing resource under NACP and RNTCP is one of the stepstowards bridging this gap. The NTWG therefore recommendedmulti-tasking by both NACP and RNTCP laboratory technicians to increase number of functional, co-located HIV and TB testing facilities. Accordingly it is decided that the DMC Laboratory Technicians should perform HIV testing at DMCs without a stand-alone HIV testing facility and ICTC laboratory technician should perform sputum smear examination when there is no LT at the DMC (either due to short term absence or vacancy). To facilitate such multitaskingRNTCP officers may facilitate release of DMC LT for training in HIV testing and NACP counterparts to release ICTC LTfor training in smear microscopy. Both the programme managers may also ensure that routine programme functions are minimally affected in doing so. You are hereby requested to implement the NTWG decision in co-ordination with RNTCP Thanking you Yours Sincerely Dr.R.S. Gupta 03107 2012 Deputy Director General (Basic Services) Tel: 011-435009 Copy for information to-PS to DG NACO DDG (TB), Central TB Division

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