

Standard Operationalization Plan of HIV and Syphilis dual rapid diagnostic test (Dual RDT) kits under NACP

The National AIDS and STD Control Program (NACP) in Phase-V aims to reduce annual new HIV infections and AIDS-related mortalities by 80% from the baseline value of 2010 and achieve 1st 95 by 2025-26. The scale up of interventions for early detections of HIV through enhanced approaches has been identified as an important strategy to achieve this goal. NACP-V in its third goal aims towards attainment of dual elimination of vertical transmission of HIV and Syphilis. NACP-V in its fourth goal aims to promoting universal access to quality STI/RTI services to at-risk and vulnerable populations.

The Dual RDT is a point-of-care screening test that detects anti-HIV and anti-*treponema pallidum* antibodies in single test device. The kit is leveraged to detect antibodies in human whole blood, serum, plasma. Dual RDT is a treponemal test (i.e., detects antibody to *Treponema pallidum* antigens) that can be leveraged for point of care screening of Syphilis (instead of laboratory based RPR testing) along with simultaneous screening of HIV 1 and 2 through single prick testing methodology. The implementation and scale-up of HIV and Syphilis Dual Rapid Diagnostic Test (Dual RDT) kits is an essential strategy to achieve NACP-V goals for early detection, management and control of HIV and Syphilis in India. This document details the technical and operational aspects for implementation of Dual RDT kits under NACP-V.

A. Operational Plan for Implementation

Dual RDT kit will be procured and supplied through NACO and used for HIV and Syphilis screening of the following populations and settings:

- High risk groups (HRGs) through community-based screening under Targeted Interventions (TI) projects/OSC/LWS
- STI attendees/clients at Designated STI/RTI Clinics (DSRC) or the DSRCs which are converted to Sampoorna Suraksha Kendras (SSK).
- Populations under prisons & other closed settings (P&OCS) interventions
- At-risk clients from bridge populations (BPs)



- Screening of at risk and high-risk groups in other settings as per the programmatic requirement.

Dual RDT kits for HIV and Syphilis **will not be used** for screening of following set of populations:

- Clients diagnosed and/or treated for syphilis
- PLHIV
- Routine screening of all TB positives at Treatment centres under CTD or a programmatic formulation
- **Pregnant women seeking services from ICTCs where they will be screened with the traditional HIV1,2,3 and RPR Test Kits.**
- **The screening of pregnant women for HIV and Syphilis at places other than ICTCs will be undertaken under NHM through Dual RDT Kit and the budget for the same has to be built up in the Annual PIP of the State.**

The National Guidelines on Elimination for Vertical Transmission for HIV and Syphilis (2024)¹ can be referred for recommendations on screening and management of HIV and Syphilis in pregnant women.

B. Operations for Screening and Management of Syphilis through Dual RDT

Reverse Algorithm will be used for screening and management of syphilis through Dual RDT. The testing algorithm using Dual RDT kits is provided in the figure 1.

Following are the important operational points for consideration while implementation of Dual RDT Kits for HIV and Syphilis:

- The Dual RDT will be subsequently replacing the Whole Blood Finger Prick (WBFP) test kits for screening of HRG, P&OCS, BP and STI clients. The Whole Blood Finger Prick Test Kits (to be provided by NACO/SACS) will be used primarily for the presumptive TB cases.
- The clients screened reactive for HIV through the Dual RDT Kits for HIV and Syphilis will follow the same referral mechanism to ICTC for confirmation as is used for the WBFP Test Kit.

¹ National AIDS Control Organisation (2023): National Guidelines for Elimination of Vertical Transmission of HIV & Syphilis (EVTHS) 2024, New Delhi, NACO, Ministry of Health and Family Welfare, Government of India. Available at: https://naco.gov.in/sites/default/files/EVTHS%20Guidelines%202024_High%20Res%20shared%20with%20SACS%20dated%203rd%20Dec%202024%20by%20NC.pdf

- When screening is conducted through Dual RDT kits, the Syphilis reactive cases should be referred to ICTC/ general laboratories located at sub-district and district hospitals and medical colleges for confirmatory RPR/VDRL testing.

B.1. Management of Syphilis

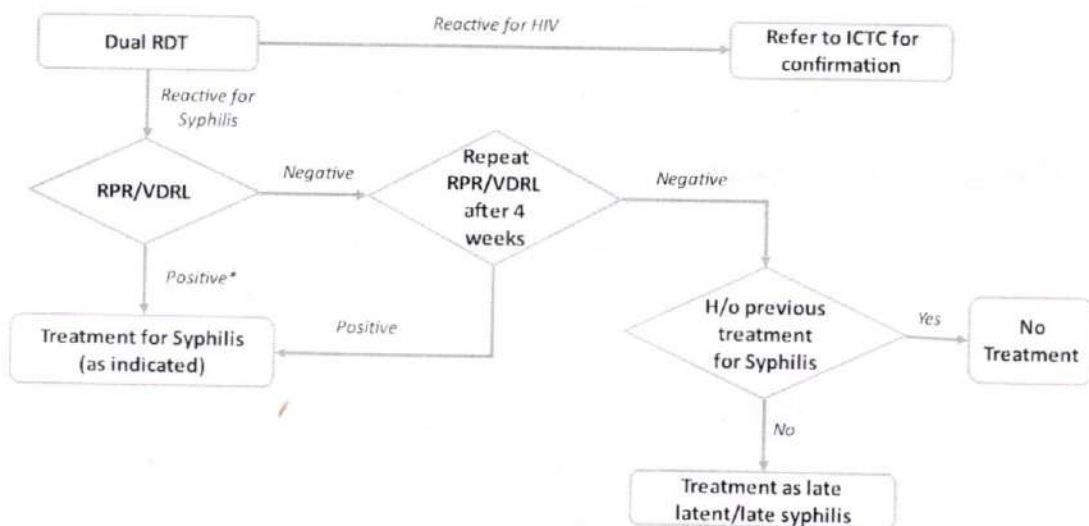
All syphilis confirmed cases can be treated using STI/RTI color-coded kit 3 or 4 under the guidance of trained medical officer. When the treatment cannot be done at TI/LWS/other peripheral sites, the patient should be referred to the nearest DSRC/other identified facility for management. All partners of syphilis-reactive cases should be notified and screened for syphilis and provided with the necessary treatment as per the risk exposure and test results.

When RPR/VDRL testing is not possible for confirmation (e.g., in P&OCS settings etc.), the treatment decision can be taken on the basis of history of potential high-risk exposure, history of syphilis treatment, and clinical discretion of the treating physician.

The detailed diagnostic and management algorithm using Dual RDT for HIV and Syphilis is mentioned in Figure 1. Further National Technical Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections (2024) can be referred for technical details on syphilis screening and management.²



² National Technical Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections (2024). National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India. Available at: https://naco.gov.in/sites/default/files/National%20Technical%20Guidelines%20on%20STI%20and%20RTI_Final.pdf



*RPR/VDRL titres will be conducted for treatment monitoring during follow-up.

Figure 1. Testing and Management Algorithm using Dual RDT kits

B.2. Follow-up

All the screened reactive cases of HIV through the RDT for HIV and Syphilis to be confirmed for the HIV at the nearest ICTC. All HIV confirmed cases to be linked to treatment at the nearest ART Centre as per the standard protocols.

All confirmed cases of Syphilis will be followed up only after 3 months of completion of treatment. In such cases, the RPR/VDRL titers will be tested during the follow up and compared with the baseline RPR/VDRL titer values. If the titers are stagnant or increasing or there is clinical evidence of syphilis, repeat the complete treatment.

The patients once tested reactive with Dual RDT kits for syphilis will be screened with RPR/VDRL in all the follow-up visits.

The details on follow-up screening are mentioned in Table 1.

Table 1. Follow-up and regular screening for syphilis

Result of Dual RDT Screening	Confirmation	Follow-up
HIV & Syphilis non-reactive	-	<ul style="list-style-type: none"> Regular screening using Dual RDT every 6 months for high-risk and at-risk populations
HIV reactive only	HIV Positive ³	<ul style="list-style-type: none"> ARTC referral and linkage Regular screening of at-risk PLHIV for syphilis with RPR/VDRL every 6 months
	HIV Negative ²	<ul style="list-style-type: none"> Regular screening using Dual RDT every 6 months for high-risk and at-risk populations
Syphilis reactive only	Syphilis Positive (using RPR/VDRL)	<ul style="list-style-type: none"> Management at DSRC/ other treatment facility Treatment monitoring after 3 months Regular screening using RPR/VDRL every 6 months
	Syphilis Negative (using RPR/VDRL)	<p>As per the Algorithm, repeat the RPR/VDRL after 4 weeks:</p> <ul style="list-style-type: none"> ✓ RPR/VDRL turns positive → Treatment at DSRC/other treatment facility → Treatment monitoring after 3 months → Regular screening using RPR/VDRL every 6 months ✓ RPR/VDRL remains negative → Treatment at DSRC (if needed as per algorithm) → Treatment monitoring after 3 months (if treated) → Regular screening using RPR/VDRL every 6 months

³ National AIDS Control Organisation (2023); National HIV Counselling and Testing Guidelines 2024, New Delhi, NACO, Ministry of Health and Family Welfare, Government of India. Available at: https://naco.gov.in/sites/default/files/HCTS%20Guideline%202024_High%20Res%20shared%20with%20SACS%20on%203rd%20Dec%202024%20by%20NC.pdf

C. Procedures for Testing

The Dual RDT can be conducted on capillary or venous whole blood, serum, and plasma. The whole blood (capillary or venous) is preferred and can be used for CBS and screening at other sites.

It is essential to read the kit insert carefully and follow the procedure for sample collection, testing and interpretation of results and storage of kits. The general details are mentioned in this section.

C.1. Requisite Material:

- Test kits in cold chain (Please note the TTI indicator and expiry date of the kit.)
- Alcohol swabs
- Pair of gloves
- Soap/hand wash/sanitizer
- Lancets/ needles
- Biohazard bags
- First aid kit

C.2. Steps for collecting blood samples (capillary blood samples)

1. Make the client/ patient to sit or lie down comfortably and lower the arm from which the sample is to be taken. Ensure that the fingers are lower than elbow of the same arm.
2. Choose the fingertip of the middle or ring finger.
3. Clean the fingertip with alcohol swab. Allow the area to air dry. Do not touch the area.
4. Gently squeeze and release the area to be pricked until it is red.
5. Position the hand palm side up. Place the lancet or needle away from the centre of the fingertip. Firmly press the lancet or needle against the skin and puncture the skin. Dispose of the lancet or needle in a puncture proof container
6. Wipe away the first drop of blood with a sterile gauze pad and then discard it as per biomedical waste disposal guidelines.
7. Hold the finger lower than the elbow and apply gentle intermittent pressure to the base of the punctured finger a few times.

8. Using the capillary tube supplied with the test kit, draw up the required amount of whole blood specimen from the fingertip. Do not use any other capillary tube and do not reuse the capillary tube.
9. Once the required amount of whole blood specimen has been collected, gently apply pressure at the puncture site with gauze to ensure that there is no further bleeding from the site. Request the client to continue pressing with the gauze until bleeding stops.

It is important to correctly follow the steps for drawing blood because painful or repeated attempts can cause discomfort and result in collection of a poor quality or quantity of sample.

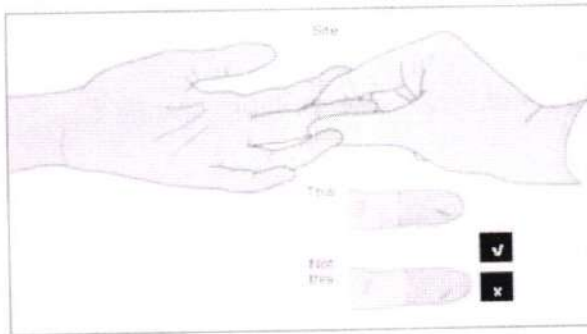


Figure 2.1. Recommended sites for finger puncture



Figure 2.2. Selecting the site for pricking



Figure 2.3. Cleaning the fingertip



Figure 2.4. Pricking the finger

C.2.1. DOs and DON'Ts of using PoC kits

I. DOs

- Store the test kit as per the manufacturer's instructions
- Follow the package insert instructions.
- Use a new disposable pipette and device for testing each new specimen.

- Use the supplied pipette to drop the blood specimen from the finger prick onto the device.
- Use a control specimen at least once after taking the kit from the ICTC.
- Run the test immediately after removing the test cassette from the foil pouch.
- Follow the given instructions while interpreting the test results. The reading may show a reactive result if the sample is checked or read after prescribed time as mentioned in the package insert.
- After reading, confirming and recording the test result, discard the used material, including the used test card, into the discard jar.

C.2.2. DON'Ts

- Do not use the kit or any kit components after the expiry date.
- Do not freeze the kit.
- Do not use the same disposable pipette and device for multiple samples.
- Do not pipette by mouth.
- Do not use any device if the pouches are perforated.
- Do not mix reagents from different kits.
- Do not drop blood droplets directly from the patient's fingertip onto the device of 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.
- **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.

C.3. Steps for Test Procedure

1. **Preparation:** Ensure all components and specimens are at room temperature (15°C to 30°C) before starting the test. Mix the specimen well if thawed after refrigeration (when venous blood/ plasma/ serum is used).
2. **Setup**
 - Open the test pouch carefully at the notch and remove the testing device (kit).
 - Place the test device on a clean, flat surface.

3. Specimen Collection

- For capillary whole blood, collect sample as mentioned in C.2 section
- For venous blood, serum, or plasma, collect the sample using standard laboratory techniques.

4. Sample Application

- Using the capillary tube, add specimen to the sample well on the test device.

5. Buffer Addition

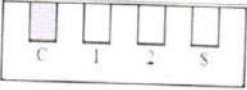
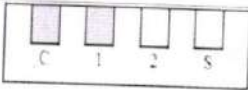
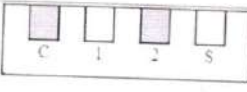
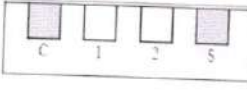
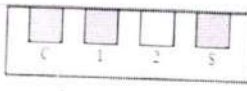
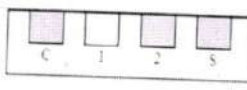
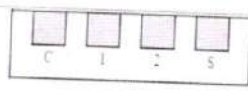
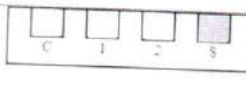
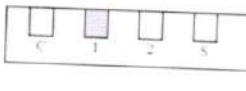
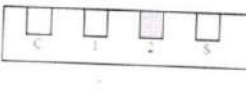
- Add required drops of assay buffer to the sample well using the dropper provided as mentioned in the kit insert.

6. Result Interpretation:

- Interpret the test results within the timeframe specified in kit insert.
- The possible interpretations of the results are mentioned in Table 2.



Table 2. Interpretations of Test Results of Dual RDT

Results	Kit	Interpretations
Only the control line appears, no line on HIV 1&2 and Syphilis band		Non-reactive for HIV and Syphilis
When Control line appears with one or more lines		
Control line + HIV-1		HIV-1 Reactive
Control line + HIV-2		HIV-2 Reactive
Control line + Syphilis		Syphilis Reactive
Control line + HIV-1 + Syphilis		HIV-1 & Syphilis Reactive
Control line + HIV-2 + Syphilis		HIV-2 & Syphilis Reactive
Control line + HIV-1 + HIV-2 + Syphilis		HIV-1&2 Reactive Syphilis Reactive
No control line (C) appears, even if test lines are visible	  	Invalid

7. Disposal:

- Discard the used test device and materials in a biohazard container.
- The availability of color-coded bags/containers should be ensured and the protocols for Bio Medical Waste Management should be followed at all



NACP sites providing screening services as well as during the health camps.⁴

D. Storage of Kits

Store kits at temperature as prescribed in the kit insert. If stored at 2-8°C, the kits have to be brought to room temperature before opening the pouch.

E. Supply Chain Management

- All DSRC/ TI NGOs/SSK/OSC should maintain adequate stocks of Dual RDT kits.
- A record-keeping and storage system should be in place to ensure an adequate stock of supplies.
- A minimum of a 3-month stock of supplies should be maintained at all times. The stock status should be regularly updated in MITR/SOCH.
- SACS is responsible for maintaining adequate availability of testing kits at enlisted facilities.
- The regular supply of kits to all TI /LWS-NGOs/OSC is to be ensured by SACS through direct indenting by these settings to SACS/DAPCU rather than placing the indents to ICTCs/DSRCs.



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⁴ National Guidelines for Infection Prevention and Control in Healthcare Facilities, NCDC, DGHS, MOH&FW, Jan 2020.
Available at: <https://www.mohfw.gov.in/pdf/National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf>