

HOW TO DO THE RAPID TEST FOR SYPHILIS

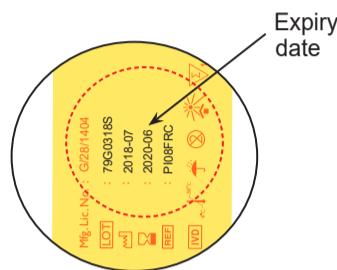
Training in the use of First Response® Syphilis Anti-TP Card Test for the Diagnosis of Syphilis in Human Whole blood/serum/plasma.

- a. New unopened test device pouch
- b. New unopened alcohol swab
- c. New unopened lancet
- d. New pair of disposable gloves
- e. Specimen Transfer Device
- f. Assay Buffer Bottle
- g. Timer
- h. Biohazardous waste container
- i. Non-biohazardous waste container
- j. Permanent Marker



READ THE INSTRUCTIONS CAREFULLY BEFORE PERFORMING THE TEST.

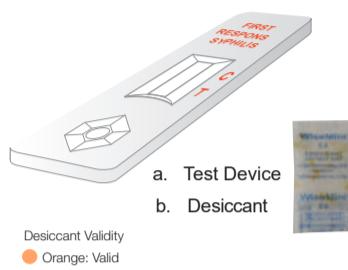
1. Check the expiration date of the test.



2. Wear gloves.
(Use new gloves for each patient)



3. Open the pouch and remove:

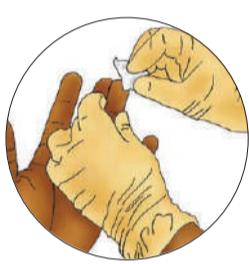


Desiccant Validity
Orange: Valid
Green (Do not use the test device if the desiccant turns green).

4. Label the test device with the patient identification number.



5. Wipe the complete fingertip with the alcohol swab provided and wait until the fingertip is completely dried..



6. Detach the protective cap of the lancet. Squeeze the fingertip then prick the lateral side of the fingertip with auto safety lancet provided.



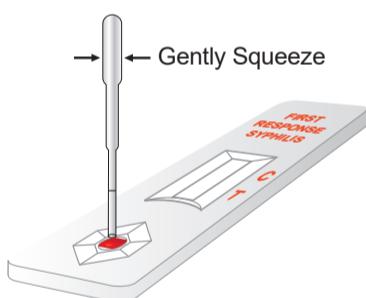
7. Dispose the lancet immediately into the sharps box.



8. Wipe the first drop of the blood using sterile gauze. Gently squeeze your fingertip once again to obtain a large second drop of blood (~40-50 µl). Take the specimen transfer device provided and hold it vertically. Gently squeeze the bulb of specimen transfer device and immerse open end in the center of a blood drop and release the bulb slowly to draw up the blood up to the 20 µl marking line on the specimen transfer device.



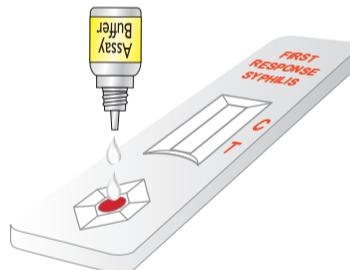
9. Hold the specimen transfer device vertically as shown in above figure and gently squeeze the bulb of specimen transfer device to dispense 20 µl of whole blood/serum/ plasma (Filled up to the marking) to the specimen well (s) by gently touching the tips of the specimen transfer device to the sample pad.



10. Dispose the used specimen transfer device into the biohazardous container.



11. Hold the assay buffer bottle vertically and add two drops of assay buffer to the specimen well.



12. Read the test results at **20 minutes**.



Do not interpret after 25 min.

14. How to read the test results:

POSITIVE

A line in "C" & a line in "T" means the patient **DOES** have Syphilis Infection.



NEGATIVE

A line in "C" and NO LINE in "T" means the patient **DOES NOT** have Syphilis Infection.



INVALID RESULT

No line in "C" & "T" means the test is **INVALID**



ONLY line in "T" means the test is **INVALID**



The Invalid test results should be retested with new test device.

15. Record the test results. Dispose of used test device into biohazardous waste container.



16. Dispose off desiccant and used gloves in a biohazardous waste container. Dispose off the packaging materials in a non-biohazardous waste container.



NOTE:Do not re-use the test device,alcohol swab,lancet and specimen transfer device as are intended for single use only



ISO 13485 & EN ISO 13485
Certified Company

Manufactured by
Premier Medical Corporation Private Limited

A1-302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA
• Customer support email : info@premiermedcorp.com • Tel.: +91 260 2780112/113,
• www.premiermedcorp.com