140mm 140mm

210mm

Syphilis Field Use Rapid Test Kit

(Whole Blood/Serum/Plasma)
Catalog No. WF1003F

Intend Use
iCARE Syphilis Field Use Rapid Test Kit is a screening test for the qualitative detection of the antibodies of Treponema Pallidum (TP) in whole blood/serum/plasma as an aid in the diagnosis of syphilis infection. Syphilis is a curable infection caused by a bacterium called Treponema pallidum that is highly infectious. This infection is sexually transmitted and can also be passed on from a mother to her fetus during pregnancy. The disease is spread primarily through sexual transmission or intimate contact with an individual who has an open, wet syphilitic sore. iCARE Syphilis Field Use Rapid Test Kit can quickly aid in the early diagnoses and treating the disease in time.

Precautions

1. Do not use the test kit beyond the expiration date.
2. Do not use the kit if the pouch is punctured or not well sealed.
3. For in vitro use only. Do not swallow.
4. All specimens from the body should be treated as potentially infectious.
5. Contaminated blood may give incorrect test results.
6. Discard after first use. The test cannot be used more than once.

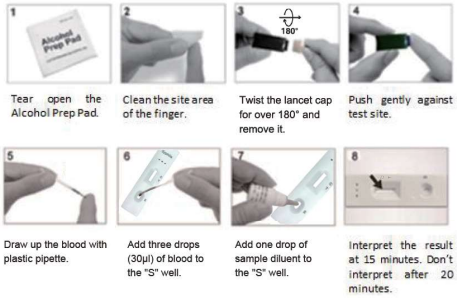
DISPOSAL: The used device has the risk of infection. Please dispose all used contents properly.

Each Kit Contains:
- Test cards individually foil pouched with a desiccant
- Plastic dropper
- Sample diluent
- Safety lancet
- Alcohol swab
- Package insert

Material Required But Not Provided:
Timer

Storage And Stability
The kit must be stored at 2~30°C.

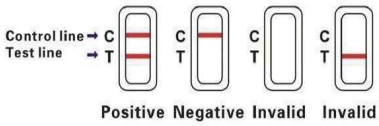
Do not open pouch until you are ready to test the sample.
Assay Procedures for Finger Blood
1. Bring the Syphilis test card, sample diluent, alcohol swab, safety lancet, plastic dropper to room temperature.
2. Take out the test card from the sealed pouch.
3. To perform the test, please follow the steps closely as follow (from picture 1 to picture 8).



Assay Procedures at Clinics
1. Bring all reagents and specimens to room temperature.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. **For whole blood / serum / plasma testing:** Dispense the sample or control (approximately 30 µl) into the well on the card using the plastic dropper provided, then add 1 drop of sample diluent into the well immediately.
5. Interpret test results at 15 minutes. A positive result may be interpreted early, however read any negative at 15 minutes to ensure sample is negative and not a low concentration of syphilis antibodies. Do not interpret the result after 20 minutes.

It is recommended to run a known positive control and negative control in each performance to ensure the assay procedure.

Reading The Test Results
1.**Positive:** Both purplish read test band and purplish read control band appear on the membrane. The lower the antibody concentration, the weaker the test band.
2.**Negative:** Only the purplish red control band appears on the membrane. The absence of a test band indicates a negative result.
3.**Invalid:** There should always be a purplish red control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test device.



Note: *It is normal to have a slightly lightened control band with very strong positive samples as long as it is distinctly visible.*

Performance Characteristics
Sensitivity and Specificity

1000 serum samples were obtained for testing then compared the testing results between iCARE Syphilis Field Use Rapid Test Kit and the TPPA method. The results of sensitivity and specificity between the two methods are shown below.

Reagents		TPPA		Total
		Positive	Negative	
iCARE Syphilis Field Use Rapid Test Kit	Positive	299	1	300
	Negative	1	699	700
Total		300	700	1000

Sensitivity (Positive Percent Agreement): 99.66% = 299/300 (95% CI: 98.74%~100%)
Specificity (Negative Percent Agreement): 99.85% = 699/700 (95% CI: 99.20%~99.97%)

Limitations
1. As it is with any diagnostic procedure, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
2. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of syphilis antibody.

If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of syphilis infection.

Bibliography

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Note: An extra lancet is provided in the package in case that the safety lancet is misused.