Syphilis IgM/IgG Field Test Kit

(Whole Blood/Serum/Plasma)

Intend Use

The iCARE Syphilis IgM/IgG Field Test Kit is a rapid, serological, lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in human whole blood, serum, or plasma specimens to aid in the diagnosis of Syphilis. The test only provides preliminary analysis results but not critical diagnosis criteria. Any reactive specimen with the iCARE Syphilis IgM/IgG Field Test Kit must be analyzed and confirmed with alternative testing method(s) and clinical findings. The test is intended for healthcare professional use. Applications of the test including, screening test for sex transmitted diseases (STD's) among high-risk group of people, regular health examinations, and field screen test for blood bank.

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

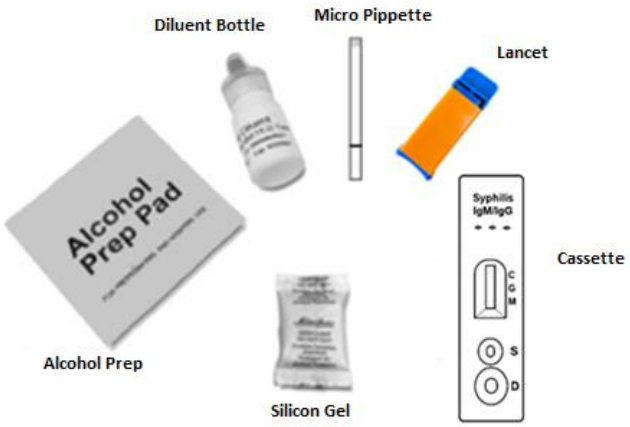
- Test cards individually foil pouched with a desiccant
- Plastic dropper
- Sample diluent
- Safety lancet
- Alcohol swab
- Package insert

Material Required But Not Provided:

Timer

Storage And Stability

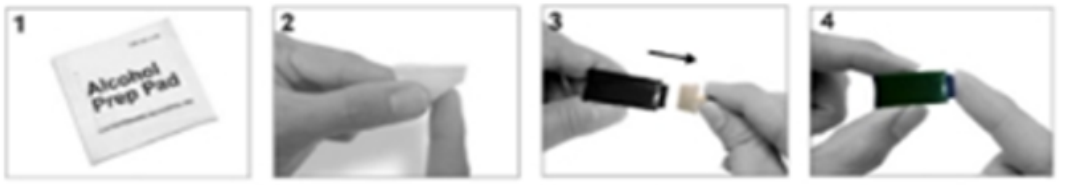
The kit must be stored at 2~30°C.



Do not open pouch until you are ready to test the sample.

Assay Procedures for Finger Blood

1. Bring the Dengue 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).

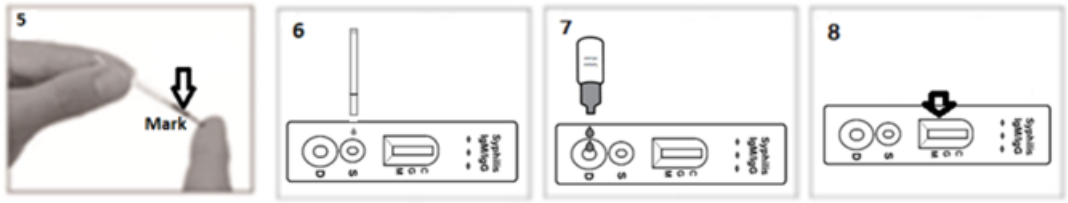


Tear open the Alcohol Prep Pad.

Clean the site area of the finger.

Remove the clear Protective cap of the lancet.

Push gently against test site.



Draw up the blood with plastic pipette until just reaching the black scale mark on the pipette.

Add 1 drop of specimen (20 µL) into the specimen well (S).

Add 2 drops of sample diluent (80-100 µL) into the diluent well (D).

Interpret the result at 15 minutes. Don't interpret after 20 minutes.

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:

   Fill the pipette dropper with the specimen. Hold the dropper vertically and transfer 1 drop of whole blood/serum/plasma specimen (approximately 10 µL) into the specimen well (S) making sure that there are no air bubbles. Then add 2 drops of sample diluent (approximately 80-100 µL) to the diluent well (D) 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**: Two/Three lines appear. One colored line should be in the control line region (C) and other apparent colored line(s) should be in the test line region (G and/or M).

NOTE: The intensity of the color in the test line region (G and/or M) will vary depending on the concentration of anti-TP antibodies present in the specimen. Therefore, the presence of any test line (G and/or M), no matter how faint, within the designated observation time, indicates a positive result.

2. **NEGATIVE**: One colored line appears in the control line region (C). No line appears in the test line region (G and M).

3. **INVALID**: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, stop using the test kit immediately and contact your local distributor.

IgM & IgG Positive

IgM Positive

IgG Positive

Negative

Invalid

1 2 3

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The iCARE Syphilis IgM/IgG Field Test Kit has been correctly identified specimens of a performance panel and has been evaluated with a reference commercial TPPA (Treponema Pallidum Particle Agglutination) test using clinical specimens. Test results are presented in the table below.

Clinical performance compared to TPPA: **Syphilis IgM**

iCARE Syphilis IgM/IgG Field Test Kit	TPPA		
	Positive	Negative	Total
Positive	349	1	350
Negative	1	719	720
Total	350	720	1070

Sensitivity (Positive Percent Agreement): 99.71% = 349/350 (95% CI: 98.40%~99.95%)
Specificity (Negative Percent Agreement): 99.86% = 719/720 (95% CI: 99.22%~99.98%)
Accuracy (Overall Percent Agreement): 99.81% = (349+719)/1070 (95% CI: 99.32%~99.95%)

Clinical performance compared to TPPA: **Syphilis IgG**

iCARE Syphilis IgM/IgG Field Test Kit	TPPA		
	Positive	Negative	Total
Positive	399	1	400
Negative	1	699	700
Total	400	700	1100

Sensitivity (Positive Percent Agreement): 99.75% = 399/400 (95% CI: 98.60%~99.96%)
Specificity (Negative Percent Agreement): 99.85% = 699/700 (95% CI: 99.20%~99.97%)
Accuracy (Overall Percent Agreement): 99.81% = (399+699)/1100 (95% CI: 99.34%~99.95%)

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

1. Centers for disease Control and Prevention. Recommendations and Reports/Vol.64/No.3, MMWR Morb. And Mort. Wkly Rep. June 5, 2015; 34:49.
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4. J.N. Wasserheit. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Diseases 1992; 19:61-77.

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