**OnSite Syphilis Ab Rapid Test-Dip Strip (Serum / Plasma)**

**INTENDED USE**

The OnSite Syphilis Ab Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies including IgG, IgM, and IgA to Treponema pallidum (Tp) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Tp. Any reactive specimen with the OnSite Syphilis Ab Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

**SUMMARY AND EXPLANATION OF THE TEST**

Tp, a spirochete bacterium, is the causative agent of the venereal disease syphilis. Although syphilis rates are declining in the United States after an epidemic outbreak between 1986 and 1999, the incidence of syphilis in Europe has increased since 1992, especially in the countries of the Russian Federation, where peaks of 263 cases per 100,000 have been reported. In 1995, WHO reported 12 million new cases of syphilis. Currently, the positive rate of syphilis serological tests in HIV-infected individuals has been rising recently.

SEROLOGICAL DETECTION OF ANTI-Tp ANTIBODY

The OnSite Syphilis Ab Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies including IgG, IgM, and IgA to Treponema pallidum (Tp) in human serum or plasma. The test strip consists of: 1) a burgundy colored conjugate pad containing recombinant Tp antigens conjugated with colloidal gold (Tp conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated recombinant Tp antigens, and the C band is pre-coated with goat anti-rabbit IgG antibody.

When an adequate volume of test specimen is dispensed into the sample pad of the strip, the specimen migrates by capillary action across the strip. Anti-Tp antibody, if present in the specimen, will bind to the Tp conjugates. The immune complex is then captured on the membrane by the pre-coated Tp antigen, forming a burgundy colored T band, indicating a Tp antibody positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/ababbit IgG-gold conjugate regardless of color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

**TEST PRINCIPLE**

The OnSite Syphilis Ab Rapid Test is a lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing recombinant Tp antigens conjugated with colloidal gold (Tp conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated recombinant Tp antigens, and the C band is pre-coated with goat anti-rabbit IgG antibody.

**REAGENTS AND MATERIALS PROVIDED**

1. Each kit contains 50 test devices, each sealed in a foil pouch with two items inside:
   a. One dip strip device.
   b. One desiccant.

2. One package insert (instruction for use).

**MATERIALS REQUIRED AND AVAILABLE FOR PURCHASE**

1. Positive Control (1 vial, red cap, 1 mL, Cat # R0030-P)
2. Negative Control (1 vial, green cap, 1 mL, Cat # R0030-N)

**MATERIALS REQUIRED BUT NOT PROVIDED**

1. Clock or Timer
2. A container for holding test specimen

**WARNINGS AND PRECAUTIONS**

**For In Vitro Diagnostic Use**

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15° C-30° C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as biohazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The testing results should be read within 10 minutes after a specimen is applied to the sample well or sample pad of the device. Reading result after 10 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

**REAGENT PREPARATION AND STORAGE INSTRUCTIONS**

All reagents are ready to use as supplied. Store unused test device unopened at 2° C-30° C. The positive and negative controls should be kept at 2° C-8° C. If stored at 2° C-8° C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30° C.

**SPECIMEN COLLECTION AND HANDLING**

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

**Plasma**

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

**Serum**

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2° C-8° C if not tested immediately.

Store specimens at 2° C-8° C up to 5 days. The specimens should be frozen at -20° C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

**ASSAY PROCEDURE**

**Step 1:** Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

**Step 2:** Collect at least 150-200 µL of serum or plasma in a sample container.

**Step 3:** When ready to test, open the pouch at the notch and remove the test strip.

**Step 4:** Dip the strip into the specimen for at least 10 seconds. Don’t allow the specimen reach above the level indicated by the arrows on the strip. Meanwhile, set up timer.
Step 5: Remove the strip from the specimen, and place it on a flat, dry surface.
Step 6: Read the test result in 10 minutes. Positive result could be visible as short as 1 minute.

Don’t read result after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

Using individual OnSite Syphilis Ab Rapid Test strips as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request if the external quality controls are not available in testing lab) under the following circumstances to monitor test performance:
1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2°C-30°C.
5. The temperature of the test area falls outside of 15°C-30°C.

Expected results are as follows:

Negative Control
Only the C band shows color development. The T band shows no color development.

Positive Control
Both C and T bands show color development.

The appearance of any burgundy color in the T band, regardless of intensity, must be considered as presence of the band.

INTERPRETATION OF ASSAY RESULT

1. NEGATIVE RESULT: If only the C band is developed, the test indicates that no detectable anti-Tp antibody is present in the specimen. The result is negative.

2. POSITIVE RESULT: If both C and T bands are developed, the test indicates for the presence of anti-Tp antibody in the specimen. The result is positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. INVALID: If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

Clinical Performance
A total of 400 samples from susceptible subjects were tested by the OnSite Syphilis Ab Rapid Test and by TPHA test (Serodia TP-PA, Fujirebio Inc., Japan). Comparison for all subjects is showed in the following table.

<table>
<thead>
<tr>
<th>TPPA</th>
<th>OnSite Syphilis Ab Rapid Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>5</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
</tr>
</tbody>
</table>

Relative Sensitivity: 100%, Relative Specificity: 97.5%, Overall Agreement: 97.5%

Precision
Within run and between run precisions have been determined by testing 15 replicates with three of the samples: a negative, a weak positive, and a strong positive sample. The negative,