SYPHILIS RAPID TEST

INTENDED USE

Nuvision Syphilis Rapid Test is a rapid immunochromatographic assay for the qualitative detection of antibodies against Treponema pallidum (TP) which causes Syphilis in human Serum/Plasma samples. It is intended for professional use as a tool in the diagnosis Syphilis infection.

SUMMARY

Syphilis is a sexually transmitted infection caused by the spirochete bacterium Treponema pallidum (TP). The primary route of transmission is through sexual contact; however, it may also be transmitted from mother to fetus during pregnancy or at birth, resulting in congenital syphilis. Congenital syphilis is a serious but preventable disease which can be eliminated with effective screening and treatment of syphilis in pregnant women. The early detection and treatment of infection in pregnant women is crucial in preventing and controlling maternal and congenital syphilis. Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary syphilis is defined by the presence of a chancre (painless genital ulcer) at the site of inoculation. The antibodies response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.

PRINCIPLE OF THE ASSAY

Nuvision Syphilis test is a rapid immunochromatographic assay, detecting the presence of Syphilis antibodies in serum and plasma samples. Specific TP antigens are conjugated with colloidal gold and deposited on the conjugate pad, and also immobilized on the test line on the nitrocellulose membrane. When serum or plasma sample is added the gold-antigen conjugate is rehydrated and the TP antibodies, if any in the sample, will interact with the gold conjugated antigen. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where they are captured by immobilized antigen, forming a visible pink line. If TP antibodies are absent in the sample, no pink line will appear in the Test Zone (T).To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- **Syphilis Test Pouches**
- **Pouch contents: Test Cassette, Desiccant.**
- **Sample droppers (25 nos./pouch)**
- **1 Test instruction per box**

MATERIALS REQUIRED (BUT NOT PROVIDED)

- **Clean, specimen collection container.**
- **Clock or timer.**

WARNINGS AND PRECAUTIONS

- **For professional *in vitro* diagnostic use only. NOT FOR MEDICINAL USE.**
- **Do not reuse.**
- **Do not use if the product seal or the packaging is compromised.**
- **Do NOT swallow Desiccant pouch, it can cause harm.**
- **Do not use after the expiration date shown on the pouch.**
- **Do not use if the Desiccant pouch's color is changed to pink or colorless when the test pouch is opened.**
- **Do not mix and interchange different specimens.**
- **Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.**
- **Wash hands thoroughly after finishing the test.**
- **Do not eat, drink or smoke in the area where the specimens or kits are handled.**
- **Clean up spills thoroughly with appropriate disinfectants.**
- **Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.**
- **Dispose of all specimens and used devices in a proper bio- hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.**
- **Keep out of children's reach.**

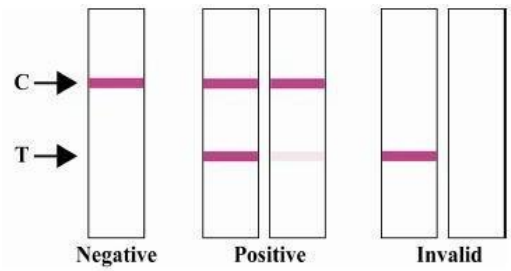
SPECIMEN PREPARATION AND STORAGE

- **For serum samples, collect blood in a tube without anticoagulant and allow it to clot.**
- **For plasma samples, collect blood in a tube containing anticoagulant.**
- **Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.**
- **Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.**
- **It is recommended that Fresh samples should be used for testing. However, the serum/plasma may be stored at 2°C to 8°C for up to three days and at -20°C for upto 2 months, if the tests cannot be performed immediately. Ensure that the samples are allowed to attain room temperature prior to use. Note: Hemolytic samples should not be used!**
- **Mix each specimen thoroughly prior to use. Do not heat or repeatedly freeze/thaw specimen.**

PROCEDURE

- **Bring the kit components to room temperature before testing.**
- **Open the pouch and remove the Test. Once opened, the test must be used immediately.**
- **Label the test card with patient's identity.**
- **Hold the sample dropper vertically. Add two full drops (70-80 µL) of serum/plasma without air bubbles into the sample well that is marked with arrow on the testing device.**
- **Read the results at the end of 20 minutes. Note:**
  1. Some strong positive samples may show positive results before 5 minutes.
  2. DO NOT READ RESULTS AFTER 30 MINUTES. To avoid confusion, discard the test device after interpreting the results.

INTERPRETATION OF RESULTS



Negative

A pink colored band appears only at the control region (C), No band appears in Test region.

Positive

A clear pink control band (C) and a detectable test band (T) appears on their respective regions, indicating a positive result for Syphilis infections.

Invalid

No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

Note:

This test is designed for primary screening test of Syphilis. Although this kit can provide fast and easy way to get a result, the testing can alone be used to diagnose Syphilis and also the testing do not completely exclude the possibility of false positive or false negative result caused by various factors. So refer to the result of this kit and make a final decision with symptoms, other test results, and doctor's view, collectively. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE AND STABILITY

- **Test device in the sealed pouch should be stored at 2°-30°C. Do not freeze the test device.**
- **If stored at 2°-8°C, ensure that the device is brought to room temperature before opening.**
- **The test device should be kept away from direct sunlight, moisture and heat.**
- **Do not expose the kit over 30°C.**

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

Syphilis Samples	Positive	Negative	Total
Positive	48	02	50
Negative	02	108	110
Total	50	110	160

Relative Sensitivity: 96.00%, Relative Specificity: 98.18%, Overall agreement: 97.09%

LIMITATIONS

- **This product is an *in vitro* diagnostic test designed for professional use only.**
- **Humidity and temperature can adversely affect results.**
- **The instructions for the use of the test should be followed during testing procedures.**
- **There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.**
- **Although the test demonstrates superior accuracy in detecting Syphilis, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.**

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