AG-SYPHILIS Ab RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene Syphilis Ab rapid test kit is a rapid and convenient immunochromatographic assay used for the qualitative detection of antibodies against *Treponema pallidum* in human whole blood, serum and plasma sample. It is intended for professional use as an aid in diagnosis of Syphilis. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

PRINCIPLE

AstraGene Syphilis Ab rapid test kit is an antibody-capture immunochromatographic assay, detecting the presence of TP antibodies in blood samples. Specific TP antigens are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) 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 (Test band, indicate positive results). 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

Description	**10 tests**	1 test
Test Cassette and Desiccant	10 Cassette's	1 Cassette
Sample Dropper	10 No's	1 No.
Sample Buffer	1.2 mL per box	0.12mL per box
IFU	1 No.	1 No.

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/SYPAb/24/01	AG/RTK/SYPAb/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE &STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION & PREPARATION

1. AstraGene Syphilis Ab rapid test kit can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect Fingerstick Whole Blood specimens: Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
   - Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
   - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
   - Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
   - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
   - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
   - Add the Fingerstick Whole Blood specimen to the test device by using hanging drops: Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
   - Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

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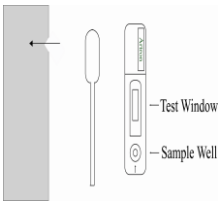
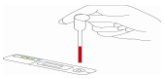
PROCEDURE

1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.



2. For Serum/plasma Sample:
   - Hold the dropper vertically and transfer 2-3 drops of serum or plasma (approximately 60-90 µL) to the specimen well (S) of the test device. See illustration below.



   For Whole Blood Sample:
   - Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer.

3. Read the results in 15-20 minutes. Following instructions under the "Result Interpretation"

   NOTE: Specimens with high concentrations of Syphilis antibodies may produce positive results in as little as 1 minute. Confirm negatives in 10 - 20 minutes.

   DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS

Negative
A colored band appears only at the control region (C), indicating a negative result for Syphilis infections.

Positive
A clear control band (C) and a detectable test band (T) appear, 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.

QUALITY CONTROL

Although the testing device contains an internal control (colored line in the control region), good laboratory practice recommends the use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

SENSITIVITY & SPECIFICITY

AstraGene Syphilis Ab rapid test kit has been compared to a leading commercial Syphilis Ab test using clinical specimens.
The results show that the relative sensitivity of the AstraGene Syphilis Ab rapid test kit is 99.54%, and the relative specificity is 100%; Accuracy: 99.8%

LIMITATION OF THE PROCEDURE

- 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.
- Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
- 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 infections, 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.

WARNING AND PRECAUTION

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.

- 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 tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being 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.

SYMBOLS

 Do not use if package is damaged  Manufacturer  Batch Code

 CE mark of Conformity  Refer to the instructions  ISO  GMP

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