PreventID® **Syphilis**

Manual (FOR PROFESSIONAL USE)

REF KSTISY402GP

Intended Use

The **PreventID® Syphilis** is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema pallidum (TP) in whole blood, serum or plasma to aid in the diagnosis of Syphilis.

Introduction

Treponema pallidum (TP) is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane [1]. Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985 [2]. Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users [3]. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis [4]. Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre 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 [5]. The **PreventID® Syphilis** utilises a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilised on membrane to detect TP antibodies (IgG and IgM) qualitatively and selectively in whole blood, serum or plasma.

Test Principle

The **PreventID® Syphilis** a qualitative membrane based immunoassay for the detection of TP antibodies (IgG and IgM) in whole blood, serum or plasma. In this test procedure, recombinant Syphilis antigen is immobilised in the test line region of the test. After specimen is added to the sample application window of the test device, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilised Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains TP antibodies, a coloured line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a coloured line will not appear in this region, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred. The test contains Syphilis antigen coated particles and Syphilis antigen coated on the membrane.

Materials

Materials provided

- test devices (with sample droppers), individually packed TEST
- buffer BUF
- manual

Materials Required but not Provided: timer or stop watch, specimen collection containers, centrifuge, lancets, heparinized capillary tubes and dispensing bulb

Storage and Stability

Store as packaged in the sealed pouch either at room temperature or refrigerated (2–30 °C). The test is stable through the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. **Do not freeze.** Do not use after the expiry date.

Precautions

1. For *in vitro* diagnostic use only. Do not use after expiry date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.
8. Read the instruction carefully before performing the test.
9. Do not mix reagents from different lots.
10. If you have any questions please contact Preventis GmbH.

Sample Collection and Sample Preparation

The **PreventID® Syphilis** can be performed using whole blood (from venipuncture or fingertip), serum or plasma.

Fingertip 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 sterile lancet. 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 Fingertip Whole Blood specimen to the test by using **a capillary tube**:

- Touch the end of the capillary tube to the blood until filled to approximately **80 µL**. Avoid air bubbles.
- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the sample application window of the test device.

→ Add the Fingertip Whole Blood specimen to the test by using **hanging drops:**

- Position the patient's finger so that the drop of blood is just above the sample application window of the test device.
- Allow 2 hanging drops of fingertip whole blood to fall into the center of the sample application window on the test device, or move the patient's finger so that the hanging drop touches the center of the sample application window. Avoid touching the finger directly to the sample application window.

Serum and plasma specimens:

- Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear non-haemolysed specimens.

Testing should be performed immediately after the specimens have been collected. 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 fingertip should be tested immediately.

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.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Test Procedure

Allow the test, specimen, buffer and/or controls to reach room temperature (15–30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface (*Fig. 1*).

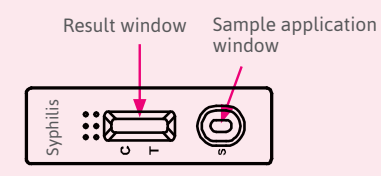

Fig. 1: Test device **PreventID® Syphilis**

For Serum or Plasma specimen: *(Fig. 2a)*
Hold the dropper vertically and transfer **1 drop of serum or plasma** (approximately 40 µL) to the sample application window, then add **1 drop of buffer** (approximately 40 µL), and start the timer.

For Venipuncture Whole Blood specimen: *(Fig. 2b)*
Hold the dropper vertically and transfer **2 drops of whole blood** (approximately 80 µL) to the sample application window, then add **1 drop of buffer** (approximately 40 µL), and start the timer.

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For Fingertip Whole Blood specimen:
To use a capillary tube *(Fig. 2c)*: Fill the capillary tube and transfer approximately **80 µL of fingertip whole blood specimen** to the sample application window of test cassette, then add **1 drop of buffer** (approximately 40 µL) and start the timer.

To use hanging drops *(Fig. 2d)*: Allow **2 hanging drops of fingertip whole blood specimen** (approximately 80 µL) to fall into the sample application window of test cassette, then add **1 drop of buffer** (approximately 40 µL) and start the timer.

3. Wait for the coloured line(s) to appear. Read results at **5 minutes**. Do not interpret the result after 20 minutes.

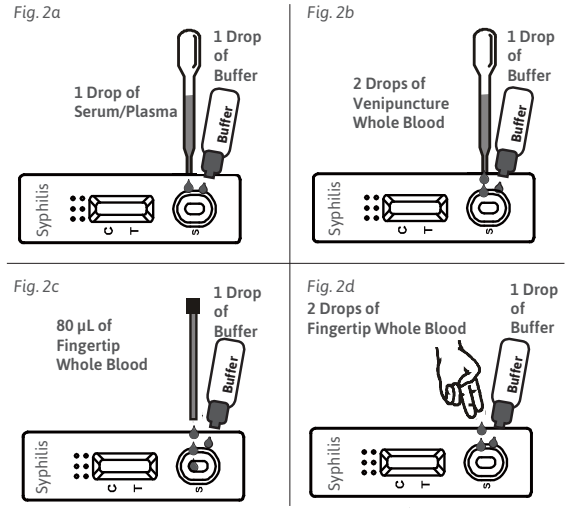
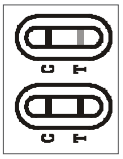


Fig. 2: Sample application

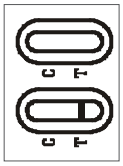
Test Interpretation

Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T). **Note:** The intensity of the colour in the test line region (T) will vary depending on the concentration of TP antibodies present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.



Negative: One coloured line appears in the control line region (C). No line appears in the test line region (T).

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.
If the problem persists, discontinue using the test kit immediately and contact Preventis.



Test Characteristics

Expected Values

The **PreventID® Syphilis** has been compared with a leading commercial TPPA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.8%.

Sensitivity and Specificity

The **PreventID® Syphilis** has correctly identified specimens of a performance panel and has been compared to a leading commercial TPPA Syphilis test using clinical specimens. The results show that the relative sensitivity of **PreventID® Syphilis** is >99.9% and the relative specificity is 99.7%.

		TPPA		
PreventID® Syphilis	Results	Postive	Negative	**Total Result**
	Positive	200	1	201
	Negative	0	319	319
Total Result		200	320	520

Relative sensitivity: >99.9% (95% CI*: 99.4% – 100%)
Relative specificity: 99.7% (95% CI*: 98.3% – 100%)
Accuracy: 99.8% (95%CI*: 98.9% – 100%) *Confidence Intervals

Precision

Intra-Assay: Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.
Inter-Assay: Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the **PreventID® Syphilis** have been tested over a 3-day period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The **PreventID® Syphilis** been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV,HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Syphilis negative and positive specimens.

Acetaminophen: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL
Creatin: 200 mg/dL
Bilirubin: 1g/dL
Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL
Albumin: 2 g/dL
Hemoglobin 1.1 mg/dL
Oxalic Acid: 600mg/dL

None of the substances at the concentration tested interfered in the assay.

Quality Control

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Test Limitations

1. The **PreventID® Syphilis** for in vitro diagnostic use only. The test should be used for the detection of TP antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.
2. The **PreventID® Syphilis** will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of TP infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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 TP infection.

References:
1. Claire M. Fraser. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete, Science 1998; 281 July: 375-381
2. Center for Disease Control. Recommendations for diagnosing and treating Syphilis in HIVinfected patients, MMWR Morb. Mortal Wkly Rep. 1988; 37: 601
3. Aral R. Marx. Crack, sex and STD, Sexually Transmitted Diseases, 1991; 18:92-101
4. J.N. Wasserheit. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Diseases 1992; 19:61-77
5. Johnson Phillip C.Testing for Syphilis, Dermatologic Clinic 1994; 12 Jan: 9-17

US: all products: Research Use Only. Not for use in diagnostic procedures.

Temperature limitation	Manufacturer
In vitro diagnostic device	Lot number
Catalogue number	Expiry date
Keep away from sunlight	Do not reuse
Read user instructions	Contains sufficient for <n> tests

CE Status: 2019-11-07

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