Treponema Pallidum Rapid Test Kit

PRODUCT NAME

Treponema Pallidum Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

The kit is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM to Treponema Pallidum (TP) in serum, plasma and whole blood to aid in the diagnosis of syphilis.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

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. 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. Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users. One study reported that a large number of HIV-infected females exhibited reactive syphilis serological test results. Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of syphilis. Primary syphilis infection is defined by the presence of a chancre at the site of inoculation. The antibody 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.

The kit utilizes a double antigen combination of a syphilis antigen coated particle and syphilis antigen to detect TP IgG/IgM (IgG and IgM) qualitatively and selectively in Whole Blood /Serum / Plasma.The test device consists of: 1) a burgundy colored conjugate pad containing SYPHILIS recombinant envelope antigens conjugated with Colloid gold (SYPHILIS conjugates) ,2) a nitrocellulose membrane strip containing a test band and a control band (C band).

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG/IgM anti-SYPHILIS, if present in the specimen, will bind to the SYPHILIS conjugates. The immunocomplex is then captured by the reagent pre-coated on the T band, forming a burgundy colored T band, indicating a SYPHILIS IgG/IgM positive test result and suggesting a recent or repeat infection. Absence of 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 chicken IgY/chicken IgY-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched.
2. Wash Buffer Solution: 1.5 ml in dropper bottle.
3. Droppers: 20 pieces droppers of 25 ul
4. Instructions For Use: 1 copy attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micropipette
- Lancets(for fingertip whole blood only)

WARNINGS

1. Read the Instructions For Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The Instructions For Use must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of wash buffer, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date.The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples:Whole Blood/Serum/Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2~8℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Whole blood collected by finger stick should be tested immediately.
7. 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.
8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
9. EDTA K2,Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

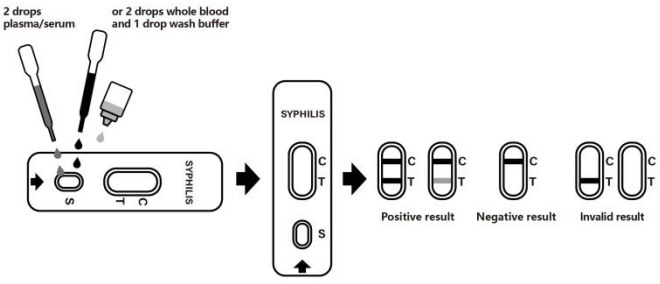
QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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 PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. For Serum or Plasma Specimens
   Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul), Avoid trapping air bubbles in the sample well and start the timer.
   For Whole Blood Specimens
   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul), then add one drop of buffer(approximately 30ul)to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that Syphilis IgG/IgM has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the Syphilis IgG/IgM has been detected and the result is positive for antigen.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure above), and the test shall be conducted again.

LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of Syphilis IgG/IgM in serum, plasma or whole blood specimens only. Neither the quantitative value nor the rate of increase in Syphilis IgG/IgM concentration can be determined by this qualitative test.
2. The kit(Whole Blood/ Serum/ Plasma) will only indicate the presence of Syphilis IgG/IgM in the specimen and should not be used as the sole criteria for the diagnosis of HP infection.
3. The continued presence or absence of IgG/IgM cannot be used to determine the success or failure of therapy
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The serum and plasma samples of patients with or without symptoms were detected with The kit and ELISA were used as reference. If the specimen is positive by Elisa, it is regarded as positive; if it is negative by Elisa, it is regarded as negative. The results indicated that The kit(Whole Blood/ Serum/ Plasma)has a high sensitivity and specificity as summarized below:

Syphilis clinical study		Biological methods		
Treponema Pallidum rapid test kit	Results	Positive	Negative	Total Results
	Positive	200	5	205
	Negative	3	370	373
Total Results		203	375	578

Accuracy Results:

Clinical sensitivity =98.52% (95%CI* 95.74% to 99.69%)
Clinical specificity = 98.67% (95%CI*96.92% to 99.57%)
Accuracy= 98.62% (95%CI*97.29% to 99.40%)

Interference Substances

The following potential interfering substances have been tested using The kit(Whole Blood/ Serum/ Plasma)and no interference was observed:

Substance	Tested Concentration
Ascorbic	20 mg/dL
Hemoglobin	1000 mg/dL
Bilirubin	60 mg/dL
Oxalic acid	1000 mg/dL
Human serum albumin	2000 mg/dL
Triglyceride	500 mg/dL

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use,Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
CE	CE mark		Biological risks

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INSTRUCTION APPROVAL AND REVISION DATE

Revision Date:
Date of Issue: