Syphilis(TP) Antibody Rapid Test Kit
(Colloidal glod method)

【PRODUCT NAME】

Syphilis(TP)Antibody Rapid Test Kit (Colloidal gold method)

【PACKING SPECIFICATIONS】

1 test/bag, 1/5/10/25/50 test(s)/kit

【INTENDED USE】

This product is used for the qualitative detection of Treponema pallidum (TP)antibodies in human whole blood/serum/plasma in vitro.

Treponema pallidum is the causative agent of human syphilis, mainly sexually transmitted. Clinically, it can be manifested as primary syphilis, secondary syphilis, tertiary syphilis, latent syphilis and congenital syphilis (fetal syphilis). The clinical manifestations are extremely complex. In the early stage, it mainly invades the skin and mucous membranes, and in the late stage, it can invade the blood vessels, central nervous system and various organs of the whole body. Clinically, this product is mainly used for the auxiliary diagnosis of Treponema pallidum infection. This product is for medical personnel use only.

The traditional laboratory diagnostic techniques are isolation, culture and identification of viruses. The rapid diagnosis of patients is mainly using chemiluminescence, immunochromatography and latex methods.

【TEST PRINCIPLE】

The product adopts the principle of double antigen sandwich. When the sample contains Treponema pallidum antibody, the Treponema pallidum antibody in the sample reacts with the colloidal gold labeled-syphilis recombinant antigen 1 on the binding pad to form a labeled antigen-antibody complex. The complex is chromatographed forward through capillary action and is captured by the recombinant syphilis antigen 2 coated on detectin area(T line) of the nitrocellulose membrane,and a red band appears. The complex continues to be chromatographed upward, and the chicken lgY colloidal gold marker is captured by the goat anti-chicken lgY antibody coated on the quality control area (C line)of nitrocellulose membrane, and a red band appears. When the content of the analyte in the sample is lower than the minimum detection limit, the detection area(T line) does not develop color.

【MAIN COMPONENT】

1. Test pad, individually packaged in aluminum foil bag(1piece/bag,1/5/10/25/50 piece(s)/kit)

2. Disposable plastic straw(1picce/bag,1/5/10/25/50 piece(s)/kit)

3. Medical waste bag(1picce/bag,1/5/10/25/50 piece(s)/kit)

4. Instruction manual(1copy/bag,1 copy/kit)

Note: The components in the kits of different batch numbers are not interchangeable.

【OPTIONAL COMPONENTS】

☐Sample diluent (1 piece/bag,1/5/10/25/50 piece(s)/kit)

☐Alcohol cotton pad(1piece/bag,1/5/10/25/50 piece(s)/kit)

☐ Blood collection needle(1 piece/bag,1/5/10/25/50 piece(s)/kit)

【STORAGE CONDITIONS AND VALIDITY PERIOD】

Storage conditions: The original packaging should be stored in a dry place at 4-30℃ protected from light, and do not freeze.

Validity period: The kit is stable within the expiration date printed on the labeling.

The test pad should be used within 1 hour under the condition of 4-30℃and humidity <65%after the aluminum foil bag is unpacked. It is recommended to use it immediately under high temperature or high humidity conditions.

See label for production date and expiry date

【SAMPLE REQUIREMENTS】

1. This reagent is suitable for whole blood, serum or plasma.

2. Sample collection

2.1 Whole blood: Use an anticoagulant tube for blood collection or add an anticoagulant to the blood collection tube. Heparin, EDTA,and sodium citrate anticoagulants can be used.

2.2 Serum/plasma; Serum and plasma should be separated as soon as possible after blood collection to avoid hemolysis.

3. Sample storage

3.1 Whole blood; Anticoagulant tubes are used for blood collection, and common anticoagulants can be used; if whole blood samples cannot be used immediately after collection, they can be stored at 2-8℃ for 3 days,and the samples cannot be frozen.

3.2 Serum/plasma: The sample can be stored at 2-8℃ for 7 days, and it should be stored at -20℃ for long-term storage.

4.Only non-hemolyzed samples should be used.Severely hemolyzed samples should be resampled.

5 The refrigerated samples must be retuned to room temperature before the test. The frozen samples should be completely thawed, rewarmed, and mixed evenly before use. Do not freeze and thaw repeatedly.

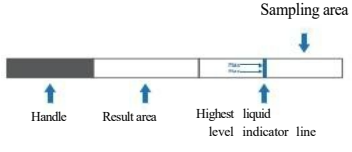
【TEST METHOD】

Please read the instruction manual carefully before the test, check whether the reagent is within the validity period,and check whether the reagent kit is missing or damaged. Reagents and samples should be returned to room temperature before testing, and testing should be performed at room temperature.

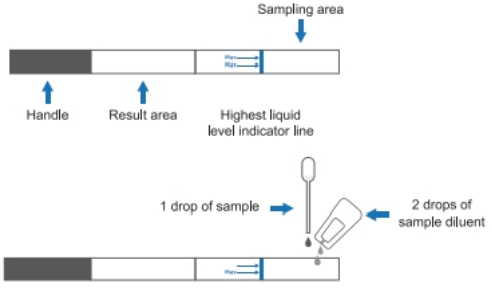
1.Tear the foil bag and take out the test pad (strip/card).

1.1 Strip type

Serum/Plasma: Place the test strip on a clean table and draw the sample with a disposable plastic straw.Slowly add 3 drops(about 75μL)of sample to the sampling area and start timing.

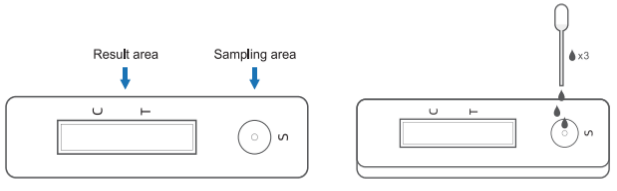


Whole blood: Place the test strip on a clean table and draw the sample with a disposable plastic straw. Vertically add 1 drop(about 25μL)of sample and 2 drops (about 50μL)of sample diluent to the sampling area, then start timing.

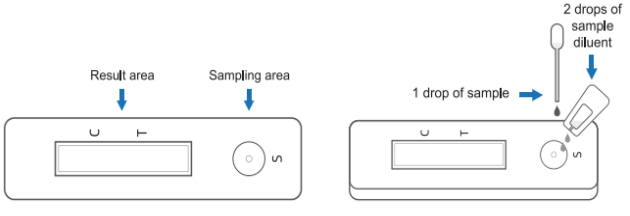


1.2 Card type

Serum/Plasma: Place the test card on a clean table, draw the sample with a disposable plastic straw, slowly add 3 drops(about 75μL)to the sample hole, and start timing.



Whole blood:Place the reagent card on a clean table, draw the sample with a disposable plastic straw, add 1 drop(about 25μL) vertically to the sample hole, and then add 2 drops(about 50μL)of the sample diluent.Start timing after adding the sample.



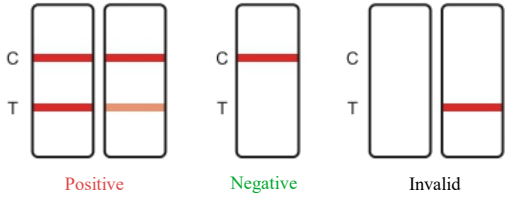
2. The results are read within 10 minutes, and the results are valid within 30 minutes.

3.All used consumables,test strips/cards and other wastes should be placed in medical waste bags and properly disposed of in accordance with relevant national regulations.

4. Wash or sanitize your hands.

Note: Please interpret the results within the specified time, and reading less or more than this time may lead to wrong results.

【INTERPRETATION OF TEST RESULTS】



Positive: Red bands appear in both the detection area(T)and the control area (C). The results show that the sample contains syphilis antibodies.

Negative: There is no red band in the detection area(T),and a red band appears in the control area(C). The results show that syphilis antibodies are not detected in the sample.

Invalid:| No red band appears in the control area(C), regardless of whether there is a red band in the detection area(T), the test pad is judged to be invalid, and it is recommended to perform a retest.

Note: Do not read the results in dimly lit places.

It is recommended not to make any medically related decisions without first consulting a healthcare provider.

【LIMITATIONS OF TEST METHODS】

1.This reagent is for in vitro diagnosis only.

2. The test results of this reagent are for reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.

3.Limited by the methodology of the testing reagents, the testing personnel should pay more attention to the negative results and make a comprehensive judgment based on other testing results. It is suggested that other methods can be used to review the negative results in doubt.

4. Other methods are suggested to confirm the weakly positive results.

5. This kit is a reagent for qualitative screening of Treponema pallidum antibodies, and the specific concentration of Treponema pallidum antibodies in samples cannot be determined.

【PERFORMANCE CHARACTERISTICS】

1.Coincidence rate of negative reference products: Use the enterprise negative reference product for testing, and the coincidence rate(-/-) of the negative reference product should not be lower than 20/20.

2.Coincidence rate of positive reference products: Use the enterprise positive reference product for testing, and the coincidence rate(+/+) of the positive reference product should not be lower than 10/10.

3. Minimum detection limit: Use the enterprise minimum detection limit reference product for testing. The test result of Ll is positive, the result of L2 can be negative or positive, and L3 is negative.

4. Repeatability: Repeat the test 10 times with the enterprise repeatability reference product, and the results should all be positive and the color rendering should be uniform.

【PRECAUTIONS】

1. This product is only used for in vitro qualitative diagnosis, please use it within the validity period.

2. Please read the instruction manual carefully before use, and carry out the test operation in strict accordance with the kit instructions.

3. The product is for one-time use.If the aluminum foil bag is found to be damaged, please do not use it.All samples and used products should be treated as infectious agents. Follow the local regulations on safe disposal of waste and infectious waste. Please handle with caution.

4. If the test reagents stored in the refrigerator are used, it is recommended that they should be taken out of the refrigerator before the test and placed at room temperature before opening for use, otherwise the test results will be affected.

5. This reagent contains animal-derived materials and has potential infectious risks, so try to avoid direct contact with the test pad.

6. Since this product is for visual interpretation, in order to ensure accurate results, please do not interpret in dim light.

7. If there is unknown drug interference or technical reasons for operation, the results will be wrong; if the results are in doubt, please re-test.

8. Containers of serum or plasma must be clean and not reusable to avoid contamination.Samples contaminated with bacteria cannot be used for testing, so as not to affect the test results.

9. There is a desiccant in the aluminum foil bag, which should not be taken orally; the sample diluent should not be taken orally.

10. The transportation of whole blood and plasma should meet the requirements of biosafety referring to local regulations.

【LABEL INTRODUCE FOR USER】

Abbreviation	Explanation	Abbreviation	Explanation
IVD	In vitro diagnostic medical device	LOT	Batch code
	Contains sufficient forcn>tests		Date of manufacture
	Manufacturer		Use-by date
	Keep dry		Temperature limit: 4~30℃

	Do not use if package is damaged		Keep away from sunlight
	Consult instructions for use		Do not re-use
REF	Catalogue number		Biological risks

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