

EZER™ Treponema Pallidum Antibody Rapid Test

INTENDED USE

The **EZER™** Treponema Pallidum Antibody Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to *Treponema Pallidum* in human Whole Blood/Serum/Plasma. It provides an aid in the diagnosis of syphilis. It's an *in vitro* diagnostic test for professional use only.

BACKGROUND

Treponema Pallidum is the causative agent of syphilis, a contagious and infectious systemic disease characterized by periods of active florid manifestations and by years of symptomless latency. Syphilis is traditionally classified as acquired or congenital, each being further subdivided on the basis of the natural course of the disease. In acquired syphilis, infection is usually transmitted by sexual intercourse. The incubation period of syphilis can vary from 1–13 weeks, but usually from 3–4 weeks. Untreated patients with primary or secondary syphilis having active lesions are the most infectious, and the risks of contagion are greatest during the first 2 years of infection. Virtually every organ and tissue of the body is affected, including most body fluids. Over 80% of patients have mucocutaneous lesions, 50% have generalized enlargement of the lymph nodes, and about 10% have lesions of the eyes, bones and joints, meninges, liver, and spleen. Mild constitutional symptoms of malaise, headache, anorexia, nausea, aching pains in the bones, and fatigability are often present. Congenital syphilis is the result of passage of *T. pallidum* across the placenta. Clinical manifestations may be present at birth but are more often seen at 3 weeks to 6 months of age. Two types of antibodies are produced by *T. pallidum*: nontreponemal antibodies (reagin) and treponemal antibodies.

PRINCIPLE

The Treponema Pallidum Antibody Rapid Test (Whole Blood/Serum/Plasma) is a qualitative lateral flow immunochromatographic assay for the detection of total antibodies to *Treponema Pallidum* in whole blood, serum or plasma specimen.

The test uses *Treponema Pallidum* antigen 1 (test line T) and goat anti-mouse IgG (control line C) immobilized on a nitrocellulose strip. During testing, the specimen reacts with *Treponema Pallidum* antigen 2-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with *Treponema Pallidum* antigen 1 in T test line region, if the specimen contains antibodies to *Treponema Pallidum*, a colored line will appear in T test

line region as a result of this.

Therefore, if the specimen does not contain *Treponema Pallidum* antibodies, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

CONTENTS

EZER™ Treponema Pallidum Antibody 40 test devices

The test contains *Treponema Pallidum* antigen 1 as the capture reagent, *Treponema Pallidum* antigen 2 as the detection reagent. A goat anti-mouse IgG is employed in the control line system.

Sample buffer: 1 vial

Plastic dropper: 40 Pcs

Package Insert: 1 Pc

WARNINGS AND PRECAUTIONS

1. For *in vitro* Diagnostic Use.
2. Do not use kit components beyond the expiration date.
3. Pathogenic microorganisms may be present in clinical specimens. All specimen and the related contaminated items need to be handled, stored and disposed following "Standard Precautions" and institutional guidelines.
4. Wear protective clothing such as laboratory coats, masks, disposable gloves and eye protection when specimens are handled.
5. Ensure foil pouch containing test device is not damaged before opening for use.
6. The test plate should be used immediately after opening the packaging. When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
7. Please do not touch the sample drop and the judgment part of the test board directly by hand.
8. Do not reuse the device.
9. Use a clean, sterile pipette tip or dropper for each sample.
10. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
11. If the test is invalid, one should consider the possible improper handling, inaccurate operation procedure, or device quality. Repeat the test with a new device ensuring that the test procedure has been followed accurately.
12. Read the result at 15 min, or up to 30 min. Do not read

the result longer than 30 min, because the result might be altered if the device is dry out.

13. All samples and used accessories should be treated as infectious and discarded according to local regulations.

STORAGE CONDITIONS

Test devices must be stored at 2~30°C. **DO NOT FREEZE.** Devices must be at ambient room temperature at time of testing.

SAMPLE COLLECTION AND PREPARATION

- Applicable samples: Whole Blood/Serum/Plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolysis 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 7 days, for long term storage, serum/plasma 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 finger stick 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 etiological agents.
- K2-EDTA, Sodium Heparin, Sodium Citrate and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

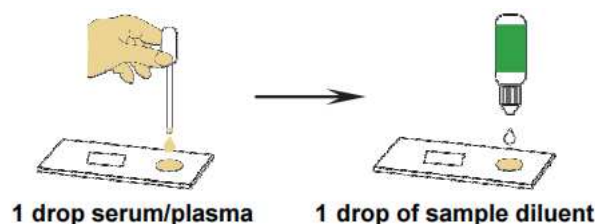
PROCEDURE

Allow the EZER™ Treponema Pallidum Antibody Rapid Test and collected samples to equilibrate to room temperature (15~30°C) prior to testing. Refer to testing procedures printed inside the kit.

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. Open the foil pouch and take out the test device. Once opened, test immediately. Write down the patient's name or number on the test device. (One patient per test device)
3. **For Serum or Plasma Specimen :**
 - To use a dropper : Hold the dropper vertically, dispense 1 drop (approximately 30 µL) of serum/plasma, then add 1 drop of buffer (approximately 40µL), and start the timer.
 - To use a pipette: To transfer 30uL of specimen to

the specimen well, then add 1 drops of buffer (approximately 40µL), and start the timer. See illustration below.

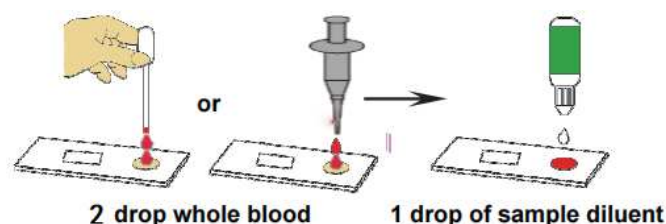
Serum or Plasma Specimen :



4. **For Whole Blood Specimen :**

- To use a dropper: Hold the dropper vertically, dispense 2 drops (approximately 60 µL) of whole blood, then add 1 drop of buffer (approximately 40µL), and start the timer.
- To use a pipette: To transfer 60 µL of whole blood to the specimen well, then add 1 drop of buffer (approximately 40µL), and start the timer. See illustration below.

Whole Blood Specimen :

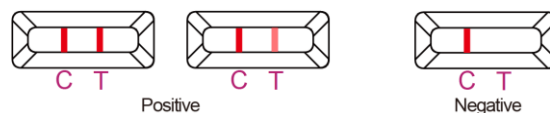


5. **Read the results after 15 minutes. If more than 30 minutes, please retest with another test.**

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.

INTERPRETATION OF RESULTS

Allow the samples to react according to the procedure and read the red purple lines that appear in the reading area.



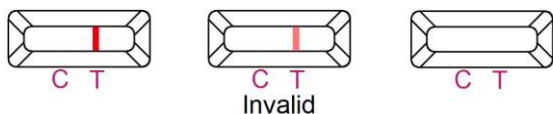
Positive:

The colored line in the control line region (C) appears and a colored line appears in test line region (T). The result is positive for *Treponema Pallidum* specific antibodies.

※NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of *Treponema Pallidum* antibodies in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

Negative Result:

The colored line in the control line region (C) appears. No line appears in test line region (T).



Invalid:

Control band fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PRECAUTIONS FOR ASSESSMENT

1. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the measurement (immunochromatography), the reaction and color development may slightly continue and progress even after 15 minutes.
2. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present. Occasionally, broken lines may appear, but the test result is valid as long as a red line is present.
3. If the line is not red at all (e.g. black), the test result is invalid and another test should be performed.
4. If the specimen is dark-colored, it may stain the membrane and affect the assessment.
5. A highly viscous specimen may affect sample migration and/or the reaction, resulting in weak coloration, delayed or no formation of the line, or a nonspecific reaction because of specimen retention.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume 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.

PERFORMANCE CHARACTERISTICS

Limit of Detection

The limit of detection (LOD) for the EZER™ Treponema Pallidum Antibody Rapid Test was 1:128 for the high antibody titer samples.

Sensitivity and specificity

The EZER™ Treponema Pallidum Antibody Rapid Test was compared with a leading commercial PCR; the results show that EZER™ Treponema Pallidum Antibody Rapid Test has a high sensitivity and specificity.

Result :

		PCR		Total
		+	-	
The EZER™	+	330	1	331
Treponema	-	49	630	679
Pallidum Antibody	Total	379	631	1010

Sensitivity: 87.1%

Specificity: 99.8%

Overall Percent Agreement: 95.0%

Cross-reactivity evaluation

The EZER™ Treponema Pallidum Antibody Rapid Test has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the EZER™ Treponema Pallidum Antibody Rapid Test and no interference was observed.

Triglyceride: 50 mg/dL Ascorbic Acid: 20mg/dL

Hemoglobin 1000mg/dL Bilirubin: 60mg/dL

Total cholesterol: 6mmol/L

LIMITATIONS OF THE PROCEDURE

1. The EZER™ Treponema Pallidum Antibody Rapid Test is for *in vitro* diagnostic use only. This test should be used for detection of antibodies to *Treponema Pallidum* in whole blood, serum or plasma specimens.
2. Neither the quantitative value nor the rate of increase in the concentration of antibodies to *Treponema Pallidum* can be determined by this qualitative test.
3. The *Treponema Pallidum* Total Antibodies Rapid Test (Whole blood/Serum/Plasma) will only indicate the presence of antibodies to *Treponema Pallidum* in the specimen and should not be used as the sole criteria for the diagnosis of *Treponema Pallidum* infections.
4. A negative result can occur if the quantity of *Treponema Pallidum* antibodies present in the specimen is below the detection limits of the assay.
5. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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4. Luger A F H. Serological diagnosis of syphilis: current methods[J]. Immunological diagnosis of sexually transmitted diseases. New York: Marcel Decker, 1988: 249-274.

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6. Norgard M V, Chamberlain N R, Swancutt M A, et al. Cloning and expression of the major 47-kilodalton surface immunogen of *Treponema pallidum* in *Escherichia coli*[J]. Infection and immunity, 1986, 54(2): 500-506.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog #

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