Leptospira Antibody Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Leptospira Antibody *in human* serum, plasma or whole blood. *For professional medical institutions use only,Not for self testing.*

PRODUCT NAME

Leptospira Antibody Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 tests/kit

INTENDED USE

The Leptospira Antibody Rapid Test kit is a lateral flow immunoassay for the simultaneous detection antibody to Leptospira interrogans (L. interrogans) in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with L. interrogans. Any reactive specimen with the Leptospira Antibody Rapid Test kit must be confirmed with alternative testing method(s).

SUMMARY AND EXPLANATION THE TEST

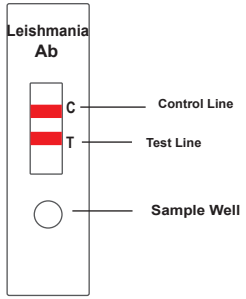
Leptospirosis occurs worldwide and is a common mild to severe health problem for humans and animals, particularly in areas with a hot and humid climate. The natural reservoirs for leptospirosis are rodents as well as a large variety of domesticated mammals. Human infection is caused by L. interrogans, the pathogenic member of the genus of Leptospira. The infection is spread via urine from the host animal.

After infection, leptospires are present in the blood until they are cleared after 4 to 7 days following the production of anti-L. interrogans antibodies, initially of the IgM class. Culture of the blood, urine and cerebrospinal fluid is an effective means of confirming the diagnosis during 1st to 2nd weeks after exposure. Serological detection of anti-L. interrogans antibodies is also a common diagnostic method. Tests are available under this category: 1) The microscopic agglutination test (MAT); 2) ELISA; 3) Indirect fluorescent antibody tests (IFATs). However, all above mentioned methods require a sophisticated facility and well-trained technicians.

The Leptospira antibody is a simple serological test that utilizes antigens from L. interrogans and detects antibodies to these microorganisms simultaneously. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment and the result is available within 15 minutes.

PRINCIPLE

The Leptospira Antibody Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant Leptospira specific antigen conjugated with colloid gold (Leptospira conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with un-conjugated Leptospira antigen, and the C band is pre-coated with goat anti-rabbit IgG antibody.



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. Anti-Leptospira Ab if present in the specimen will bind to the Leptospira conjugates. The immunocomplex is then captured on the membrane by the pre-coated antigen, forming a burgundy colored T band, indicating a Leptospira Ab positive test result.

Absence of the 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-rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

Components	25tests/kit	5tests/kit	1test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution with dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

MATERIALIS REQUIRED BUT NOT PROVIDED

Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2.Do not open the sealed pouch, unless ready to conduct the assay.
3.Do not use expired devices.
4.Bring all reagents to room temperature (15°C-30°C) before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6.Do not use hemolized blood specimen for testing.
7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10.Dispose of all specimens and materials used to perform the test as biohazardous waste.
11.Handle the Negative and Positive Control in the same manner as patient specimens.
12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

1.Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2.Separate the plasma by centrifugation.
3.Carefully withdraw the plasma into new pre-labeled tube.

Serum

1.Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2.Allow the blood to clot.
3.Separate the serum by centrifugation.
4.Carefully withdraw the serum into a new pre-labeled tube.
5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

ASSAY PROCEDURE

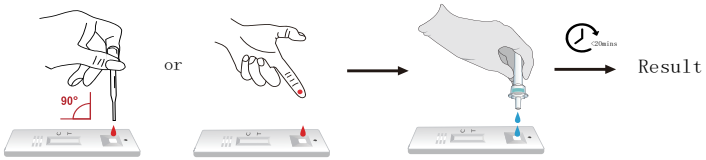
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

Step 4: **For whole blood test**

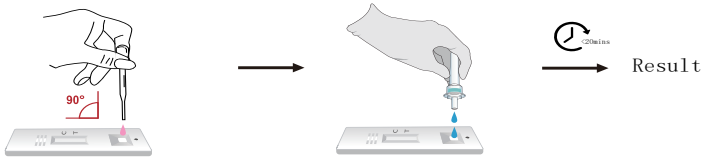
- Apply 1 drop of whole blood (about 20 μL) into the sample well.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of Whole Blood 2 drops of Buffer

For serum or plasma test

- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30 μL-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of serum/plasma 2 drops of Buffer

Step 5:Set up timer.

Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

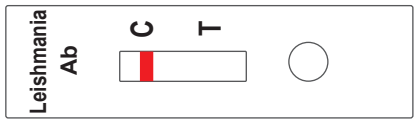
Using individual Leptospira Antibody Rapid Test kit as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:

1.A new operator uses the kit, prior to performing testing of specimens.
2.A new test kit is used.
3.A new shipment of kits is used.
4.The temperature used during storage of the kit falls outside of 2°C-30°C.
5.The temperature of the test area falls outside of 15°C-30°C.

Expected results are as follows:

Negative Control

Only the C band shows color development. The T band shows no color development.

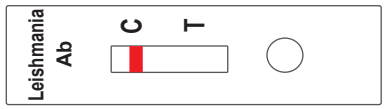


Positive Control
Both C and T bands show color development.

The appearance of any burgundy color in the test bands, regardless of intensity, must be considered as presence of the band.

INTERPRETATION OF ASSAY RESULT

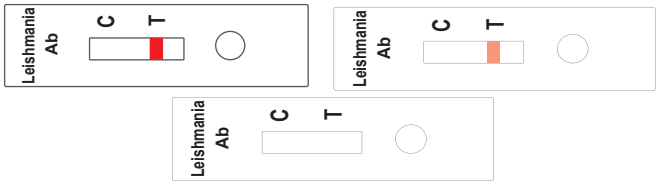
Negative Control
If only the C band is developed, the test indicates that no detectable anti- Leptospira Ab is present in the specimen. The result is negative.



Positive Control:
If both C and T bands are developed, the test indicates for the presence of anti-Leptospira Ab in the specimen. The result is positive.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

INVALID:
If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

Clinical Performance For IgM Test
A total of 234 patient samples from susceptible subjects were tested by the Leptospira Ab Rapid Test and by a commercial Leptospira Ab ELISA kit. Comparison for all subjects is showed in the following table:

	Leptospira Antibody Rapid Test		
EIA	Positive	Negative	Total
Positive	31	3	34
Negative	1	199	200
Total	32	202	234

Relative Sensitivity: 91.2 %, Relative Specificity: 99.5%, Overall Agreement: 98.3%

LMITATIONS OF TEST

1.The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to the Leptospira in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2.The Leptospira Antibody Rapid Test is limited to the qualitative detection of antibodies to Leptospira in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3.A negative result for an individual subject indicates absence of detectable anti-Leptospira antibodies. However, a negative test result does not preclude the possibility of exposure to Visceral Leptospira causative species of the Leptospira
4.A negative result can occur if the quantity of the Leptospira antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5.The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical finding.

CAUTION
1.This product is used for in vitro diagnosis only.
2.Must strictly follow the instructions for operation and interpretation of the results.
3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.
4.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.
5.Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.
6.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
7.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

EC REP **SUNGO Europe B.V.**
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.