CE
IVD

Leishmania Antibody Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Human Leishmania Antibodyin human serum, plasma or whole blood.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

Leishmania Antibody Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit; 5 tests/kit;1 test/kit

INTENDED USE

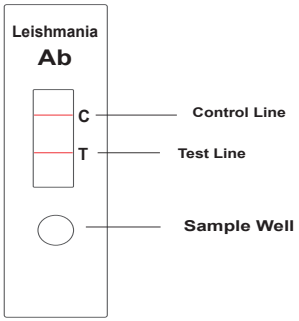
The Leishmania Ab Rapid Test is a lateral flow immunoassay for the qualitative detection of antibodies including IgG, IgM, and IgA to the subspecies of the Leishmania donovani (L. donovani), the Visceral leishmaniasis causative protozoans in human serum, plasma or whole blood. This test is intended to be used as a screening test and as an aid in the diagnosis of the disease of Visceral leishmaniasis. Any reactive specimen with the Leishmania Ab Rapid Test must be confirmed with alternative testing method(s).

SUMMARY AND EXPLANATION THE TEST

Visceral leishmaniasis, or Kala-azar, is a disseminated infection caused by several subspecies of the L. donovani. The disease is estimated by the World Health Organization (WHO) to affect approximately 12 million people in 88 countries. It is transmitted to humans by bites of the Phlebotomus sandflies, which acquire infection from feeding on infected animals. Though it is a disease for poor countries, in Southern Europe, it has become the leading opportunistic infection in AIDS patients.
Identification of L. donovani organism from the blood, bone marrow, liver, lymph nodes or the spleen provides a definite means of diagnosis. However, these test methods are limited by the sampling method and the special instrument requirement. Serological detection of anti-L. donovani Ab is found to be an excellent marker for the infection of Visceral leishmaniasis. Tests used in clinic include: ELISA, fluorescent antibody and direct agglutination tests. Recently, utilization of L. donovani specific protein in the test has improved the sensitivity and specificity dramatically.
The Leishmania Ab Combo Rapid Test is a recombinant protein based serological test, which detects antibodies including IgG, IgM and IgA to the L. Donovani. This test provides a reliable result within 10 minutes without any instrumentation requirements.

PRINCIPLE

The Leishmania Ab Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant L. donovani specific antigen conjugated with colloid gold (Leishmania 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 L. donovani 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- L. donovani Ab if present in the specimen will bind to the Leishmania conjugates. The immunocomplex is then captured on the membrane by the pre-coated antigen, forming a burgundy colored T band, indicating a L. donovani 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	5ml/bottle	1ml/bottle	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

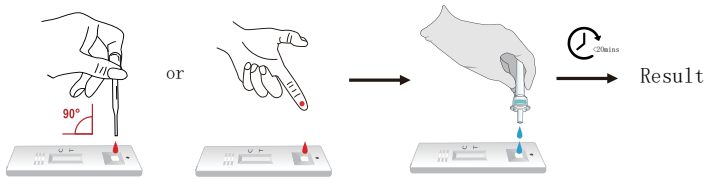
All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date 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.

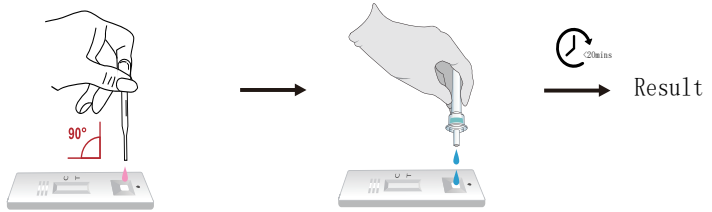
ASSAY PROCEDURE

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 30-35 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 30-35 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.

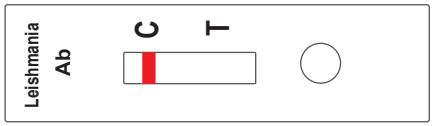
QUALITY CONTROL

Using individual Leishmania Ab 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

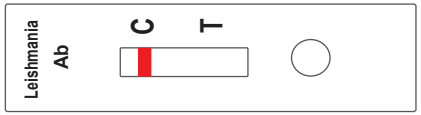
Both C and T bands show color development

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- L. donovani Ab is present in the specimen. The result is negative.



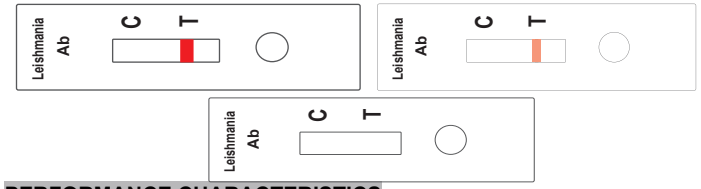
Positive Control

If both C and T bands are developed, the test indicates for the presence of anti- L. donovani 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

A total of 234 patient samples from susceptible subjects were tested by the Leishmania Ab Rapid Test and by a commercial L. donovani Ab ELISA kit. Comparison for all subjects is showed in the following table.

	Leishmania Ab Rapid Test		
EIA	Positive	Negative	Total
Positive	31	3	34
Negative	2	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 L. donovani in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2.The Leishmania Ab Rapid Test is limited to the qualitative detection of antibodies to L. donovani 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-L. donovani antibodies. However, a negative test result does not preclude the possibility of exposure to Visceral leishmaniasis causative species of the L. donovani
4.A negative result can occur if the quantity of the L. donovani 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.

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

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