BoatBIO

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Brucella Antibody Rapid Test Kit (Colloidal Gold)

PRODUCT NAME
Brucella Antibody Rapid Test Kit (Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The Brucella Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) anti-Brucella in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Brucella. Any reactive specimen with the Brucella Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION
Brucellosis is a debilitating disease of people caused by infection with one of a number of different Brucella species. In almost all cases, people acquire the infection through exposure to infected animals or contaminated animal products. Human brucellosis is well known for its wide range of symptoms, and is often clinically indistinguishable from other infectious diseases, such as malaria or typhoid. Diagnosing the disease therefore typically relies on laboratory tests. The Brucella Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to Brucella in a whole blood, serum or plasma specimen in 10 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE
The Brucella Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is a one step immunochromatographic lateral flow assay. A lipopolysaccharide antigen (LPS) prepared from a culture of B. abortus is immobilized on the test region of the membrane. During testing, the specimen reacts with Protein A which conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient anti-Brucella antibody in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS
The Brucella Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) containing protein A coated particles and Brucella antigen (LPS) coated on the membrane.

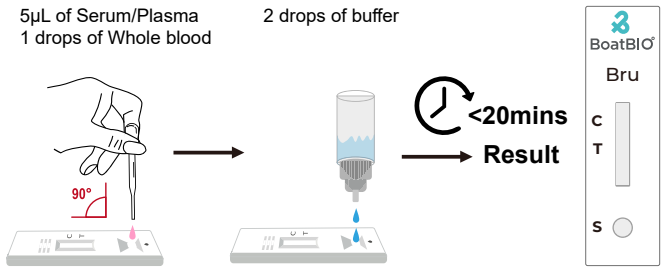
MATERIALS
Materials provided
25 Test cassettes 25 Droppers 1 Buffer 1 Package insert
Materials Required but Not Provided
1. Timer
2. Lancing device for whole blood test

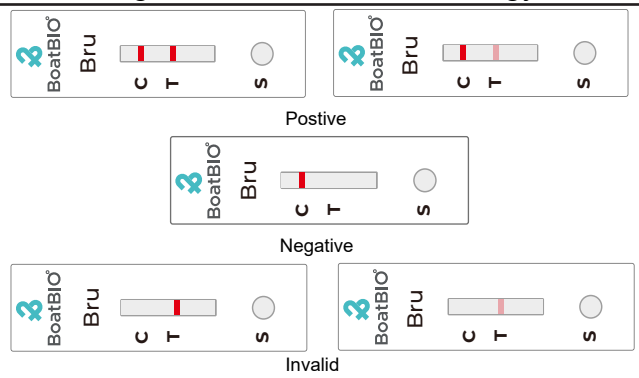
STORAGE AND STABILITY
The kit can be stored at room temperature or refrigerated (2-30°C). The test Cassette is stable through the expiration date printed on the sealed pouch. The test Cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS
1.For professional in vitro diagnostic use only.
2.Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
3.This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
4.Read the entire procedure carefully prior to testing.
5.Do not eat, drink or smoke in any area where specimens and kits are handled.
6.Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7.Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
8.Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION
1.The Brucella Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
2.Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3.Testing should be performed immediately after specimen collection. 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 3 days. For long term storage, 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 fingerstick should be tested immediately.
4. 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.
5.If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE
Bring tests, specimens, reagents and/or controls to room
temperature (15 -30°C) prior to testing testing.
1.Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.
For Whole
Blood Specimen: Hold the 5 µL mini plastic dropper provided vertically and transfer 1 drop of whole blood (approximately 10 µL) to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80 µL) and start the timer. See illust illustra tion below.
For Serum or Plasma Specimen:
With the 5 µL mini plastic dropper provided, draw the serum or plasma specimen to exceed the specimen line as showed in the following image and then transfer drawn serum or plasma into the sample well (S) of the te st device. Then add 2 drops of buffer (approximately 80 µL) and start the timer. See illustration below.
Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer spe cimen by pipette capable t o deliver 5 µL of volume.
3. As the test begins to work, color will migrate across the membrane.
4.Wait for the colored band(s) to appear. The result should be read in 10 minutes. Do not interpret the result after 10 minutes.





INTERPRETATION OF RESULTS
(Pleas e refer to the illustration above)
Positive:
Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in th e test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid:
Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a ne w test Cassette . If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL
A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it i s recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance..

LIMITATIONS
1.The Brucella Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use. This test should be used for the detection of antibodies to Brucella in whole blood, serum or plasma specimen.
2.The Brucella Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to Brucella in the specimen and should not be used as the sole criteria for the diagnosis of Brucella infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4.If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative r esult at any time does not preclude the possibility of Brucella infection.
5.A negative result can occur if the quantity of the antibodies to Brucella 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.
6.Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

PERFORMANCE CHARACTERISTICS
A total of 151 samples from susceptible subjects were tested by the Brucella Antibody Rapid Test (Whole Blood/Serum/Plasma) and by Brucella agglutination test (BAT).

Method		BAT		Total
Brucella Antibody Ra pid Test Cassette	Results	Positive	Negative	Results
	Positive	24	2	26
	Negative	1	124	125
Total Results		25	126	151

Relative Sensitivity: 96.06.0%
Relative Specificity: 98.48.4%
Accuracy: 98.08.0%

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		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		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

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