Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep Mononucleosis (Serum, Plasma) RapiCard™ InstaTest

REF 176522-20-44

IVD See external Label 2°C 30°C Σ 25 Tests

Specificity	**98.9%**
Sensitivity	**99.9%**

INTENDED USE

The Cortez Diagnostics Inc. OneStep Mononucleosis Serum, Plasma RapiCard™ is a rapid chromatographic immunoassay for the qualitative detection of Infectious Mononucleosis heterophile antibodies in serum or plasma as an aid in the diagnosis of Infectious Mononucleosis.

SUMMARY AND EXPLANATION

Infectious Mononucleosis (IM) is caused by the Epstein-Barr virus, which is a member of the herpesvirus family. Symptoms of IM are fever, sore throat and swollen lymph glands. In very rare cases, heart or central nervous system problems may occur. Diagnosis of IM is made based on the presence of heterophile antibodies. Infectious Mononucleosis heterophile antibodies belong to the IgM class. They are present in 80-90% of acute IM cases and can be detected in 60-70% of patients during the first week of clinical illness.1,2,3,4

The MONO Rapid Test Cassette (Serum/Plasma) is a simple test that utilizes an extract of bovine erythrocytes to qualitatively and selectively detect Infectious Mononucleosis heterophile antibodies in serum or plasma in minutes.

TEST PRINCIPLE

The MONO Rapid Test Cassette (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IM heterophile antibodies in serum or plasma. In this test, bovine erythrocyte extracted antigen is immobilized in the test line region of the test. During testing, the specimen reacts with bovine erythrocyte extracted antigen coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test and interacts with the immobilized bovine erythrocyte extracted antigen. If the specimen contains IM heterophile antibodies, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain IM heterophile antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains bovine erythrocyte extracted antigen-coated particles and bovine erythrocyte extracted antigen-coated membrane.

SPECIMEN COLLECTION AND PREPARATION

1. The MONO Rapid Test Card (Serum/Plasma) can be performed using 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.
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.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. Test Cassettes
2. Buffer
3. Droppers
4. Negative control (Diluted human plasma, 0.09% sodium azide)
5. Positive control (Diluted human plasma containing IM heterophile antibodies, 0.09% NaN_3
6. Package insert

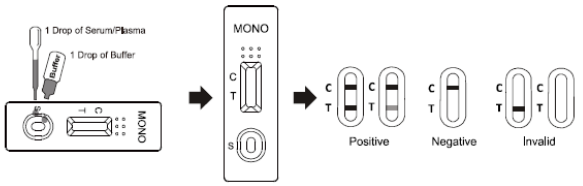
Materials required but not provided

1. Timer
2. Specimen collection containers
3. Centrifuge

ASSAY PROCEDURE

Allow the test, serum or plasma, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to 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.
3. Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the Test Cassette, and **add 1 drop of buffer** (approximately 55µL), then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. **Read results at 5 minutes**. Do not interpret the result after 10 minutes.



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RESULTS

- **Negative: One colored line appears in the control line region (C).** No apparent colored line appears in the test line region (T).
- **Positive**: ***Two distinct colored lines appear.** One line should be in the control line region (C) and another line should be in the test line region (T). *NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of IM heterophile antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
- **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 new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
In addition to your laboratory's standard quality control procedures, it is recommended that a positive and negative external control be tested at least once within each test kit and by each operator performing testing within a kit. This will verify that the reagents and test are working properly and the operator is able to correctly perform the test procedure. External positive and negative controls are supplied in the kit.

PROCEDURE FOR EXTERNAL QUALITY CONTROL TESTING

1. Holding the bottle vertically, add 1 full drop (approximately 40 µL) of positive or negative control solution to the specimen well (S) of the Test Cassette, and add 1 drop of buffer (approximately 55 µL).
2. Continue with Step 3 of Directions For Use.
3. If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

PERFORMANCE CHARACTERISTICS

Sensitivity

The Cortez Diagnostics Inc. MONO RapiCard (Serum/Plasma) has been evaluated with specimens confirmed positive or negative by a leading commercial slide agglutination test. The slide agglutination test served as the reference method for the MONO RapiCard Serum/Plasma). The result shows that the sensitivity of the MONO RapiCard (Serum/Plasma) is >99.9% relative to the slide agglutination test.

Specificity

The MONO RapiCard (Serum/Plasma) uses an antigen that is highly specific for IM antibodies in serum or plasma. The results show that the specificity of the MONO Rapid Test Cassette (Serum/Plasma) is 98.9% relative to the slide agglutination test.

COR MONO RapiCard vs. Slide Agglutination

Method		Slide Agglutination		Total Results
COR MONO RapiCard Test	Results	Positive	Negative	
	Positive	60	1	61
	Negative	0	89	89
Total Results		60	90	150

Relative Sensitivity: >99.9% (95.1%-100.0%)*
Relative Specificity: 98.9% (94.0%- 99.9%)*
Relative Accuracy: 99.3% (96.3%-99.9%)*
* 95% Confidence Intervals

Precision Intra-Assay

Within-run precision has been determined by using 3 replicates of three specimens: a negative, a low positive and a middle positive. The negative, low positive and middle positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive and a middle positive. Three different lots of the MONO Rapid Test Cassette (Serum/Plasma) have been tested using negative, low positive and middle positive specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

RF, HBsAg, HBeAg, HBcAb, HBeAb, HCV, TB, HIV and Syphilis positive specimens were tested with the MONO Rapid Test Cassette (Serum/Plasma). No cross-reactivity was observed, indicating that the MONO Rapid Test Cassette (Serum/Plasma) has a high degree of specificity for human antibodies to IM.

LIMITATIONS OF PROCEDURE

1. The Cortez Diagnostics, Inc. MONO RapiCard (Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of Infectious Mononucleosis antibodies in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Infectious Mononucleosis antibody concentration can be determined by this qualitative test.
2. The MONO Rapid Test Cassette (Serum/Plasma) will only indicate the presence of Infectious Mononucleosis antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Infectious Mononucleosis infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Infectious Mononucleosis infection.

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. The test must remain in the sealed pouch until use.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use test if pouch is damaged.
5. Handle all specimens and controls as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens and controls.

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6. Human plasma used in the Positive and Negative Controls was tested by ELISA for the presence of antibodies to human immunodeficiency virus type HIV-1/HIV-2, as well as Hepatitis B surface antigen (HBsAg) and anti-HCV, and found to be negative. Nevertheless, caution should be used in handling and disposing of these items.
7. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
8. The used test should be discarded according to local regulations.
9. Humidity and temperature can adversely affect results.

STORAGE

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

REFERENCES

1. Hickey SM, Strasburger VC. What Every Pediatrician Should Know About Infectious Mononucleosis In Adolescents.PediatrClin North Am. 1997; 44(6):1541-56
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3. Linde A. Diagnosis of Epstein-Barr virus-related diseases.Scand J Infect Dis Suppl. 1996; 100:83-8
4. Papesch M, Watkins R. Epstein-Barr virus infectious mononucleosis.ClinOtolaryngol. 2001; 26(1):3-8
5. CDC National Center for Infectious Diseases. EBV & IM:

ISO 13485 **ISO 9001** **Diagnostic Automation/ Cortez Diagnostics, Inc.** **21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA**	
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