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innovacon™

MONO

Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) Package Insert

English

A rapid test for the diagnosis of Infectious Mononucleosis (IM) to detect Infectious Mononucleosis heterophile antibodies qualitatively in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma as an aid in the diagnosis of Infectious Mononucleosis.

SUMMARY

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 Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is a simple test that utilizes an extract of bovine erythrocytes to qualitatively and selectively detect Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma in minutes.

PRINCIPLE

The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IM heterophile antibodies in whole blood, 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.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- The test must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- 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.
- Human plasma used in the Control 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

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.

SPECIMEN COLLECTION AND PREPARATION

- The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Venipuncture Whole Blood specimens**: Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test device.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- 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.
- 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 etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Droppers
- Negative control (Diluted human plasma, 0.09% sodium azide)
- Package insert
- Positive control (Goat anti-mono antibody, 0.09% NaN_3)

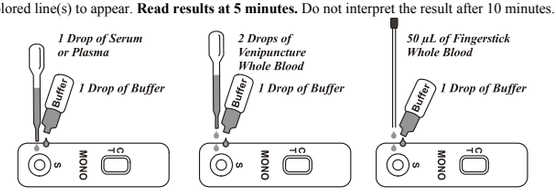
Materials Required but not Provided

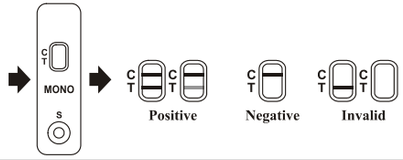
- Timer
- Specimen collection containers (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Centrifuge

DIRECTIONS FOR USE

Allow the test, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device 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 device on a clean and level surface.
   For **Serum or Plasma** specimens:
   Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the test device, and **add 1 drop of buffer** (approximately 55 µL), then start the timer. See illustration below.
   For **Venipuncture Whole Blood** specimens:
   Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, and **add 1 drop of buffer** (approximately 55 µL), then start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimens:
   To use a capillary tube: Fill the capillary tube and **transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 55 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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.

NEGATIVE: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

INVALID: Control line fails (C) 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 CONTROL

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 device, 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.

LIMITATIONS

1. The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of Infectious Mononucleosis antibodies in whole blood, 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 Mononucleosis Rapid Test Device (Whole Blood/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.

EXPECTED VALUES

Epstein-Barr virus (EBV) infection during adolescence or young adulthood causes Infectious Mononucleosis in 35% to 50% of reported cases.[1,5]
The incidence of EBV-associated Infectious Mononucleosis in the USA has been estimated at 45 per 100,000 and is highest in adolescent and young adults - about 2 out of 1,000. No seasonal pattern of EBV infection exists. The incubation period is 10 to 60 days, though 7 to 14 days is common for children and adolescents.

PERFORMANCE CHARACTERISTICS

A total of 611 clinical samples were tested by three independent sites in a clinical study. Slide agglutination served as the reference method for the study. Serum, plasma and whole blood were also collected for the detection of IM heterophile antibodies by the MONO Mononucleosis Rapid Test Device.

Of the 611 clinical samples collected, 185 were considered positive and 426 clinical specimens were considered negative by slide agglutination method. The results for each sample matrix are summarized below.

Serum		Slide agglutination		
		+	-	
MONO Rapid Test Device	+	72	0	Positive Agreement= 72/72 >99% (95%-100%)**
	-	0	168	Negative Agreement= 168/168 >99% (98% -100%)**

Plasma		Slide agglutination		
		+	-	
MONO Rapid Test Device	+	58	1	Positive Agreement = 58/58 > 99% (94%-100%)**
	-	0	181	Negative Agreement = 181/182 > 99% (97%-99%)*

Whole Blood		Slide agglutination		
		+	-	
MONO Rapid Test Device	+	50	0	Positive Agreement= 50/55 =91% (80%-97%)*
	-	5	76	Negative Agreement= 76/76 >99% (95 % -100%)**

ALL SAMPLES		Slide agglutination		
		+	-	
MONO Rapid Test Device	+	180	1	Positive Agreement = 180/185=97% (94%-99%) *
	-	5	425	Negative Agreement =425/426 >99% (99%-99.99%)*

*Denotes 95% Confidence Interval
** Denotes 97.5% Confidence Interval

In addition, the clinical samples were tested with a commercially available rapid diagnostic test kit. 611 serum, plasma and whole blood samples were used to compare the MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) to a comparator test. The results showed a >99% agreement between the two test kits. The results for each sample matrix are summarized below.

Serum		Comparator Test		
		+	-	
MONO Rapid Test Device	+	72	0	Positive Agreement= 72/73 =99% (93%-99%)*
	-	1	167	Negative Agreement= 167/167 >99% (98 %-100%)**

Plasma		Comparator Test		
		+	-	
MONO Rapid Test Device	+	59	0	Positive Agreement=59/60 =98% (91%-99%)*
	-	1	180	Negative Agreement= 180/180 >99% (98 %-100%)**

Whole Blood		Comparator Test		
		+	-	
MONO Rapid Test Device	+	50	0	Positive Agreement=50/51 =98% (90%-99%)*
	-	1	80	Negative Agreement= 80/80 >99% (96 %-100%)**

ALL SAMPLES		Comparator Test		
		+	-	
MONO Rapid Test Device	+	181	0	Positive Agreement = 181/184 =98% (95%-99%)*
	-	3	427	Negative Agreement =427/427 >99% (99%- 100%)**

*Denotes 95% Confidence Interval
** Denotes 97.5% Confidence Interval

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 Mononucleosis Rapid Test Device (Whole Blood/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 Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma). No cross-reactivity was observed, indicating that the MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) has a high degree of specificity for human antibodies to IM.

BIBLIOGRAPHY

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3. Linde A. *Diagnosis of Epstein-Barr virus-related diseases.* Scand J Infect Dis Suppl. 1996; 100:83-8.
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Index of Symbols

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative	Biological risks
IVD	For *in vitro* diagnostic use only		Do not reuse		Use by	
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #	

Manufacturer

Innovacon, Inc.
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CE

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