MONONUCLEOSIS TEST
004A810

A rapid test for the diagnosis of Infectious Mononucleosis to detect infectious mononucleosis heterophile antibodies qualitatively in whole blood, serum or plasma.

For professional in vitro diagnostic use only.

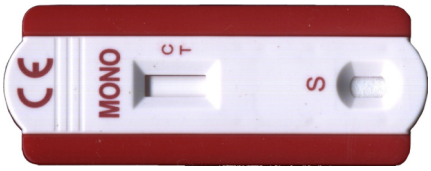
INTENDED USE

The **Mononucleosis Test** 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 herpes virus 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 **Mononucleosis Test** 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 just minutes.

PRINCIPLE



The **Mononucleosis Test** is a qualitative membrane strip based immunoassay for the detection of IM heterophile antibodies in whole blood, serum or plasma. In this test procedure, bovine erythrocyte extracted antigen is immobilized in the test line region of the device. 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 strip 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 the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The **Mononucleosis Test** contains bovine erythrocyte extracted antigen-coated particles and bovine erythrocyte extracted antigen-coated membrane.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Humidity and temperature can adversely affect results.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The **Mononucleosis Test** is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use.

- Do not freeze.
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The **Mononucleosis Test** 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 device 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.

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MATERIALS

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- **Mononucleosis Test** devices
- Disposable specimen droppers
- Disposable capillary tubes and dispensing bulb
- Positive control (Diluted human plasma containing IM heterophile antibodies, 0.1% NaN_3)
- Negative control (Diluted human plasma, 0.1% NaN_3)
- Buffer
- Package insert

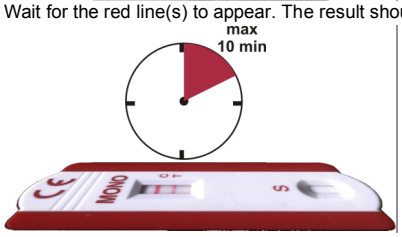
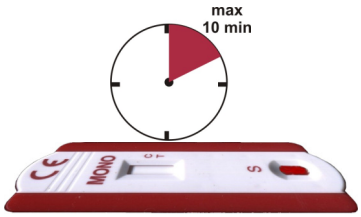
MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers (for venipuncture whole blood)
- Timer
- Lancet (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

1 Allow the **Mononucleosis Test** device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

2 Place the **Mononucleosis Test** device on a clean and level surface. .

	Serum or Plasma	Whole Blood	Control
3	Transfer **1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the **Mononucleosis Test** device.	Transfer **2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test **Mononucleosis Test** device.	Transfer **1 drop of control** (approximately 25 µL) to the specimen well (S) of the **Mononucleosis Test** device.
			
4	Add **1 drop of buffer** (approximately 50 µL) and start the timer.		
			
4	Wait for the red line(s) to appear. The result should be **read at max 10 minutes**.		
			

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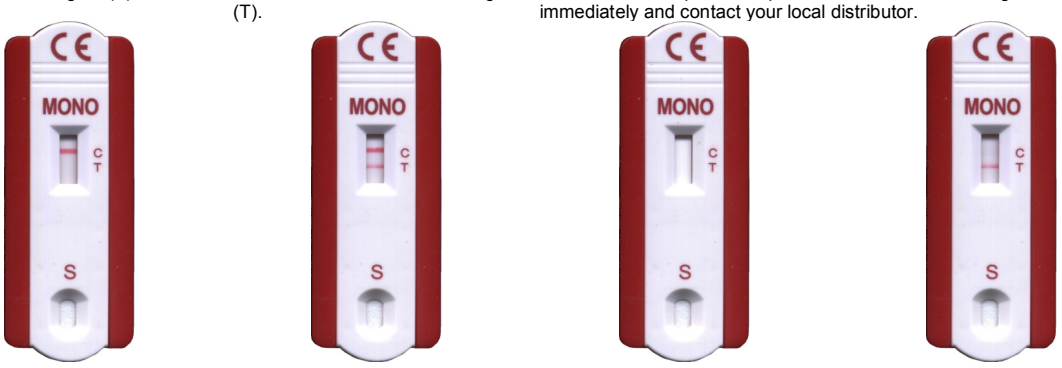
INTERPRETATION OF RESULTS

Negative	Positive *	Invalid
One red line appears in the control line region (C). No apparent red or pink line appears in the test line region (T).	**Two distinct red lines appear**. One line should be in the control line region (C) and another line should be in the test line region (T).	**Lines or control line fail 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



***NOTE:** The intensity of the red 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 red in the test line region (T) should be considered positive.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are supplied with this kit; it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The **Mononucleosis Test** 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.
- The **Mononucleosis Test** 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.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- 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 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

Sensitivity

The **Mononucleosis Test** has been evaluated with specimens confirmed by a leading commercial latex agglutination test. The latex agglutination test served as the reference method for the Inf. Mononucleosis IgM. The result shows that the sensitivity of the Inf. Mononucleosis IgM is >99.9% relative to the latex agglutination test.

Specificity

The **Mononucleosis Test** uses an antigen that is highly specific for IM antibodies in whole blood, serum or plasma. The results show that the specificity of the **Mononucleosis Test** is 98.6% relative to the latex agglutination test.

Mononucleosis Test vs. **Latex Agglutination**

Method	Results	Latex Agglutination		Total Results
		Positive	Negative	
Infectious Mononucleosis Test	Positive	52	1	53
	Negative	0	69	69
Total Results		52	70	122

Relative Sensitivity: >99.9% (93.2%-100.0%)* Relative Specificity: 98.6% (92.3%-100.0%)* Accuracy: 99.2% (95.5%-100.0%)*
* 95% Confidence Intervals

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Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the **Mononucleosis Test** have been tested using negative, low positive and high positive specimens. The specimens were correctly identified > 99% of the time.

BIBLIOGRAPHY

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