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

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. Do not use after expiration date. Do not use test if pouch is damaged. Handle all specimens and controls as if they contain infectious agents. Observe established handling and disposing of these items.

INTENDED USE

The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid, lateral flow immunomagnetic assay for the detection of heterophile antibodies in whole blood, serum, or plasma. In this test, bovine erythrocytes are coated with the heterophile antibodies 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. 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/inking working has occurred.

PRINCIPLE

The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunomagnetic assay for the detection of IM heterophile antibodies in whole blood, serum or plasma. In this test, bovine erythrocytes are coated with the heterophile antibodies 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. 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/inking working has occurred.

SUMMARY

Infectious Mononucleosis (IM) is caused by the Epstein-Barr virus, which is a member of the herpesvirus family, found in 15% to 25% of healthy adults. 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. The MONO Mononucleosis Rapid Test Device (Whole Blood/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.

MATERIALS

- Mononucleosis Rapid Test Device
- Buffer
- Negative control (Diluted human plasma, 0.09% sodium azide)

INTENDED USE

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.

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.

STEP 1: SPECIMEN COLLECTION AND PREPARATION

Collect anti-coagulated blood specimen

1. For professional in vitro diagnostic use only. Do not use after expiration date. Do not use test if pouch is damaged. Handle all specimens and controls as if they contain infectious agents. Observe established handling and disposing of these items.
2. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when collecting and preparing specimens.
3. The used test should be discarded according to local regulations.
4. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION

- The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) can be performed on whole blood specimens.
- To collect Venipuncture Whole blood specimens: Collect anticoagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard clinical practice.
- To collect Fingerstick Whole blood specimens:
  - Wash the site free of dirt and debris with alcohol or water or clean with an alcohol swab. Allow to dry.
  - Hold the site minus the touch the puncture site by rubbing down the hands towards the fingertips of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first drop of blood.
  - Gently rub the hand from 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 tip of the capillary tube to the blood until filled approximately 50-75 µL.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood specimen to the test well (S) of the test device.
- Separate serum or plasma from blood by centrifugation. Use only clear, non-hemolyzed sera.
- Specimens should be transported in a refrigerated state and avoid hemolysis. Use only clear, non-hemolyzed sera.
- Specimens should be stored 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.
- Whole blood specimens should be refrigerated until frozen. Freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing a 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) to start the timer. See illustration below.
- For Fingerstick 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) to 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.

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 control be run at least once each week and by each operator performing testing within a kit. This will verify that the reagents and test are working properly and the operator is correctly performing 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 drop of buffer (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) to start the timer. See illustration below.
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.

INTERPRETATION OF RESULTS

- **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). See illustration below.
- **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 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.

RESULTS

- **Positive**
  - Interpretation: Positive
  - Symbol: Positive
  - Meaning: The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is positive for the presence of Infectious Mononucleosis antibodies. This result indicates that the patient is infected with the Epstein-Barr virus. The test result may indicate the presence of Infectious Mononucleosis antibodies in the specimen.
- **Negative**
  - Interpretation: Negative
  - Symbol: Negative
  - Meaning: The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is negative for the presence of Infectious Mononucleosis antibodies. This result indicates that the patient is not infected with the Epstein-Barr virus. The test result may indicate the absence of Infectious Mononucleosis antibodies in the specimen.
- **INVALID**
  - Interpretation: Invalid
  - Symbol: Invalid
  - Meaning: The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is invalid due to procedural errors. The test result may indicate the absence of Infectious Mononucleosis antibodies in the specimen.