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 chromogenic 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 IgG 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. 2,3 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.

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. The test is performed by combining whole blood, serum or plasma with a latex reagent containing extract of bovine erythrocytes to immobilize heterophile antibodies present in the specimen. The test is not performed on hemolyzed specimens. The presence of IM heterophile antibodies will bind to the immobilized latex reagent and precipitate in the test line region of the test device. If there is no binding of heterophile antibodies to the immobilized latex reagent, the control line region (C) will react with the control reagent in the test device and a colored line will appear indicating that IM heterophile antibodies are not present in the specimen.

TEST MATERIALS

• Whole blood (from venipuncture or fingerstick), serum or plasma.
• Bovine erythrocyte extracted antigen.
• Latex reagent.

TEST PROCEDURE

1. Place the test device on a clean and level surface.
2. Mix the specimen and buffer by gently inverting the capillary tube at least 30 times. The whole blood specimen should be clearly hemolysed.
3. For Fingerstick Whole Blood specimens:
   • Fill the capillary tube and transfer approximately 50 µL of fingerstick whole blood.
   • Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (C) of the test device.
   • Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimen at room temperature longer than 30 minutes. Serum and plasma specimens may be stored at 2–8°C (40°F) 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.
5. Place the capillary tube next to the test device and allow excess specimen to drain away. Specimen should be completely thawed and mixed well prior to testing. Specimens should not be shipped. They should be packed in compliance with local regulations covering the transportation of diagnostic agents.

INTERPRETATION OF RESULTS

For Fingerstick Whole Blood, serum or plasma specimens:

- Place the test device in the sealed pouch and unpack it. This test device is stable through the expiration date printed on the sealed pouch. The test device must be used immediately after opening. DO NOT FREEZE. Do not use beyond the expiration date.
- Place the test device on a clean and level surface.
- Mix the specimen and buffer by gently inverting the capillary tube at least 30 times. The whole blood specimen should be clearly hemolysed.
- For Fingerstick Whole Blood specimens:
   • Fill the capillary tube and transfer approximately 50 µL of fingerstick whole blood.
   • Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (C) 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 specimen at room temperature longer than 30 minutes. Serum and plasma specimens may be stored at 2–8°C (40°F) 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.
   • Place the capillary tube next to the test device and allow excess specimen to drain away. Specimen should be completely thawed and mixed well prior to testing. Specimens should not be shipped. They should be packed in compliance with local regulations covering the transportation of diagnostic agents.

MATERIALS

- Test devices
- Buffer + Droppers
- Dispos. buffer:
  - 1 drop buffer
- Control:
  - Positive control (Diluted human plasma, 0.1% sodium azide)
  - Negative control (Diluted human plasma, 0.1% sodium azide)
- Negative control
- Positive control
- Timers
- Specimen collection containers

USES

- Test devices, specimen, buffer, and/or controls to equilibrate to room temperature (15–30°C) prior to testing.
- To use a capillary tube: Fill the capillary tube and transfer approximately 50 µL of fingerstick whole blood.
- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (C) of the test device.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis.
- Testing should be performed immediately after specimen collection. Do not leave the specimen at room temperature longer than 30 minutes. Serum and plasma specimens may be stored at 2–8°C (40°F) 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.
- Place the capillary tube next to the test device and allow excess specimen to drain away. Specimen should be completely thawed and mixed well prior to testing. Specimens should not be shipped. They should be packed in compliance with local regulations covering the transportation of diagnostic agents.

CONTROL STANDARDS

Control standards are not supplied with this kit; however, 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

1. The Mono Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used as a diagnostic tool. Review the procedure and repeat the test with a new test device if the problem persists. Do not use the test kit more than once.
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 criterion 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 indicate that there is no disease present.