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 Clarity 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 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.\(^1\)\(^2\)\(^3\)

The Clarity 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 just minutes.

PRINCIPLE
The Clarity MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) 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 test device 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.
- 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 as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- 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 at room temperature or refrigerated 35-86°F (2-30°C). The test device 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 Clarity 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.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

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 using the dropper to collect the blood, fill the blood to the first line of the tip end. For detailed information, please refer to the whole blood (fingerstick) sample collection and operating instructions guide provided along with the droppers.
- Squeeze the bulb to dispense the entire contents of the dropper into the specimen well (S) of the test device.

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 35-46°F (2-8°C) for up to 3 days. For long-term storage, specimens should be kept below -4°F (-20°C). Whole blood collected by venipuncture should be stored at 35-46°F (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
- Test devices
- Buffers
- Dippers – for fingerstick whole blood & for venipuncture whole blood/serum/plasma
- Negative control (Diluted human plasma, 0.09% sodium azide)
- Positive control (Diluted human plasma containing IM heterophile antibodies, 0.09% NaNO₃)
- Workstation
- Package Insert

Materials Required But Not Provided
- Specimen collection containers (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Centrifuge
- Timer

DIRECTIONS FOR USE
Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature 59-86°F (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: Fill the blood to the first line of the dropper tip end. Dispense the entire contents of the dropper (approximately 50 μL) into 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. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.
**METHOD**

**Latex Agglutination**

**RESULTS**

**Positive**

52

69

**Total**

70

122

**LIMITATIONS**

1. The Clarity 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 Clarity 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 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 Clarity MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) has been evaluated with specimens confirmed by a leading commercial latex agglutination test. The latex agglutination test served as the reference method for the Clarity MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma). The result shows that the sensitivity of the Clarity MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is >99.9% relative to the latex agglutination test.

**Specificity**

The Clarity MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) uses an antigen that is highly specific for IM antibodies in whole blood, serum or plasma. The results show that the specificity of the Clarity MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is 98.6% relative to the latex agglutination test.

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**INTERPRETATION OF RESULTS (Please refer to the illustration)**

**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 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.

**QUALITY CONTROL**

**Internal Quality Control**

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

**External 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. 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.

**DIAGNOSTIC TEST GROUP**

**Boca Raton, Florida**

1-877-722-6339

**Technical Service:** 1-888-266-9798

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**BIBLIOGRAPHY**

5. CDC National Center for Infectious Diseases. EBV & IM: [http://www.cdc.gov/ncidod/diseases/ebv.htm](http://www.cdc.gov/ncidod/diseases/ebv.htm)

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**Table 1: Clarity MONO Rapid Test Device vs. Latex Agglutination**

<table>
<thead>
<tr>
<th>Clarity MONO Test Device</th>
<th>Results</th>
<th>Latex Agglutination</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>52</td>
<td>1</td>
<td>53</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>69</td>
<td>69</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>52</td>
<td>70</td>
<td>122</td>
</tr>
</tbody>
</table>

**Relative Sensitivity:** >99.9% (93.2%-100.0%)*

**Relative Specificity:** 98.6% (92.3%-100.0%)*

**Relative Accuracy:** 99.2% (95.5%-100.0%)*

*95% Confidence Intervals

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**BCLIA Category**

Whole Blood: Waived
Serum/Plasma: Moderate

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**Technical Service**

1-888-266-9798