MONO II RAPID TEST (WHOLE BLOOD)

☒ St. Joseph Medical Center, Tacoma, WA	☒ St. Anthony Hospital Gig Harbor, WA	☐ Harrison Medical Center, Bremerton, WA
☒ St. Francis Hospital, Federal Way, WA	☒ St. Elizabeth Hospital Enumclaw, WA	☐ Harrison Medical Center, Silverdale, WA
☒ St. Clare Hospital Lakewood, WA	☒ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To describe the method for performing the CLIA waived MONO II Rapid Test on whole blood samples.

BACKGROUND

The laboratory diagnosis of infectious mononucleosis is based on the detection of infectious mononucleosis (IM) heterophile antibodies.

PRINCIPLE & CLINICAL SIGNIFICANCE

Mono II Rapid Test is a qualitative membrane strip based immunoassay for the detection of IM heterophile antibodies in whole blood. In this test procedure, bovine erythrocyte extracted antigen is coated on the test line region of the strip. The sample reacts with bovine erythroctye 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 coated bovine erythrocyte extracted antigen. If the sample contains IM antibodies, a colored line will appear in the test line region indicating a positive result. If the sample does not contain IM heterophile antibodies, a colored line will not appear in the region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

All results must be interpreted together with other clinical information available to the physician. A heterophile antibody response is observed in approximately 80-90% of adults and children with EBV-caused IM. This percentage drops to approximately 50% for children under four years of age. Epstein-Barr virus infection during adolescence or young adulthood causes infectious mononucleosis 35-50% of the time.

RELATED DOCUMENTS

R-PO-SER-0700	Waived vs Non-Waived Testing Policy – Serology
R-F-SER-0103	Mono Test Kit External QC Log

SPECIMEN REQUIREMENTS

Whole blood EDTA and Heparinized anticoagulant is acceptable.

Sample Storage

Do not leave the samples at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at room temperature (15-30C) and tested within 24 hours of collection.

Unacceptable Specimens

Grossly hemolyzed samples

EQUIPMENT & SUPPLIES

1. Mono II Rapid Test Kit
   - Stored at room temperature or refrigerated (15-30C).
   - The test strips must be remain in the closed canister until use.
   - Test strips in the canister and the other reagents are stable through the expiration date printed on the box.

2. Timer

QUALITY CONTROL

External Controls

Positive and Negative controls are provided in the kit.

- Run external controls on each new lot and new shipment before use. Record results on the Mono Test External QC Log.
- Each new untrained operator must run external controls prior to testing any patients.
- To perform external QC testing, add one free falling drop of control to the test tube and continue in the same manner as with a patient sample.

Internal Controls

The kit provides two levels of internal procedural controls with each test.

- The red control line in the control region (C) is an **internal positive procedural control**. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique. If the Red Line does not appear, the test is invalid.
- A clear background is an **internal negative background control**. If the test is working properly, the background in the result area should be clear and not interfere with the ability to read the test results. If the background does not clear, the test result is invalid.

STEPS

The sample, test strip, diluent, and controls should be room temperature (15-30C).

1. Label a test tube from the kit with patient identifier.

2. Draw whole blood sample into dropper supplied with the kit.

3. Hold the dropper upright, insert the dropper nearly to the bottom of the sample tube and add 1 drop of whole blood to the bottom of the tube. Avoid getting sample on the sides of the tube.

4. Add 1 drop of Diluent to the bottom of the tube.

5. Gently tap bottom of tube and mix with wooden stick.

6. Remove the Test Strip from the canister, and re-cap the container immediately.

7. Place the absorbent end of the Test Strip into the treated sample, leaving the strip standing up in the tube.

8. Start the timer.

9. Wait for the red line to appear. The result should be read at 5 minutes. The background should be clear and red Control Line should be present before the result is read.

INTERPRETATION OF RESULTS

Positive Results:

- A blue test line and a red control line appear. One line should be in the control line region (C) and another line should be in the test line region (T). Positive results may be read as soon as the red Control Line appears and the blue line is present. A positive result indicates the IM heterophile antibodies were detected in the sample.
  Note: The shade of the blue color in the test line region (T) will vary. ~~based.~~ Any shade of blue in the test line region (T) should be considered positive.

Negative Results:

- One red line appears in the control line region (C). No ~~apparent~~ blue line appears in the test line region (T). A negative result means that IM heterophile antibodies were not found in the sample or are below the detection limit of the test.

Invalid Results:

- Control line fails to appear after 5 minutes or background color makes reading of the red Control Line impossible, the result is invalid. Insufficient sample 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 Strip. If the problem persists, discontinue using the test kit immediately and contact Technical Services as 1-800-332-1042.

ORDERING AND RESULTING

Ordering:

The order code for the MONO Rapid Test is MONO.

Resulting:

1. Document the results of the positive internal control (appearance of the red control line) by entering POSITIVE for the Positive Control.

2. Document the results of the negative internal control (presence of a clear background) by entering NEGATIVE for the Negative Control.

3. Enter patient results as POSITIVE or NEGATIVE.

LIMITATIONS

- A negative result may be obtained from patients at the onset on the disease due to heterophile antibody levels below the sensitivity of this test kit. If symptoms persist or intensify, the test should be repeated.
- Some segments of the population with acute IM are heterophile antibody negative.
- This test will only indicate the presence of IM heterophile antibodies in the sample and should not be used as the sole criteria for the diagnosis of mononucleosis infection.

REFERENCE

Mono II Rapid Test package insert, Rev. A 12/15, Cardinal Health, Waukegan, IL 60085 USA