Title:	OSOM® POCT Mononucleosis Rapid Procedure					
Department:	**Admin:**		**Medical:**	✔	**Counseling:**	
Written By: T. Rochon			**Responsible Person/Dept:** Medical Services Staff			
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Reviewed By: Medical Services Director		**Approved By:** A. Kimberly, Lab Director				
Guiding Regulatory or Administrative Rules: Synopsis of 42 CFR 493 and OAR 333-024-0005 thru 333-024-0055						

Intended Use:

The OSOM® Mono Test is intended for the qualitative detection of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aid in the diagnosis of infectious mononucleosis.

A Certificate of Waiver is needed in order to run this test.

Summary:

The diagnosis of infectious mononucleosis (IM) is suggested on the basis of clinical symptoms of **fever, sore throat, and swollen lymph glands**. The highest incidence of symptomatic IM occurs during late adolescence (15-24yrs). IM is caused by the Epstein-Barr Virus (EBV). The laboratory dx of IM is based on the detection of IM heterophile antibodies. These antibodies are directed against antigens found in bovine erythrocytes to give the required sensitivity and specificity.

Principle:

The OSOM Mono Test uses color immunochromatographic dipstick technology with bovine erythrocyte extract coated on the membrane. In the test procedure, serum, plasma, or whole blood is mixed with the Diluent. Then the Test Stick is placed in the mixture and migrates along the membrane. If the specific IM heterophile antibody is present in the sample, it will form a complex with the bovine erythrocyte extract conjugated color particles. The complex will then be bound by bovine erythrocyte extract immobilized on the membrane and a visible blue Test Line will appear to indicate a positive result.

Reagents:

This test device contains bovine erythrocyte extracted antigen-coated particles and bovine erythrocyte extracted antigen-coated membrane.

Precautions:

- For in-vitro diagnostic use only
- Follow your laboratory safety guidelines in the collection, handling, storage, and disposal of patient specimens and all items exposed to patient specimens.
- The Diluent and controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. **Do not dispose of Diluent or controls down the sink.**
- **Do not interchange or mix components from different kit lots.**
- Humidity and temperature can adversely affect the test results. Do not reuse the test.
- Discard the test device if the package is torn, ripped, or if the device itself is damaged.

Storage & Stability:

The kit can be stored at room temperature or refrigerated (15℃ - 30℃). The test device is stable through the expiration date printed on the KIT. **DO NOT FREEZE**. Test strips must remain in the original container until use. Do not use beyond the expiration date.

Sample Collection & Preparation (serum, plasma, whole blood):

The IM Test can be performed using whole blood from venipuncture or fingerstick. At Reed College HCC, we perform the test using fingerstick whole blood.

Materials Needed:

Specimen Collection:

- Lancet
- Alcohol swab
- Capillary Pipettes (included in test kit) or
- Gloves/eye protection
- Appropriate PPE per COVID protocols

Running the Test:

- Gloves/eye protection

- OSOM Test Stick (included in test kit)
- Capillary Pipettes with blood sample collected
- Test Tube (Included in test kit)
- Diluent (included in test kit)
- Timer

Collecting the Sample - Fingerstick Method

1. Wash the patient's hands with soap and warm water or clean with an alcohol swab. Allow to dry.

2. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

3. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.

4. Gently rub the hand from the wrist to palm to finger to form a rounded drop of blood over the puncture site.

5. Holding the capillary tube horizontally, touch the end of the capillary tube to the blood until filled to the line; avoid air bubbles.

6. Place the pipette into the test tube and squeeze the bulb. Remove the pipette and discard in the appropriate biohazard container.

7. **Testing should begin immediately after the sample has been collected**. Do not leave the samples at room temperature for prolonged periods. Whole blood collected by fingerstick should be tested immediately. Do not freeze blood samples.

Running the Test:

Allow the test stick, sample, diluent and controls to reach room temperature (15 - 30℃) before testing.

1. Slowly add 1 drop of Diluent to the bottom of the test tube

2. Mix

3. Remove the Test Stick from the container. Re-cap the container immediately.

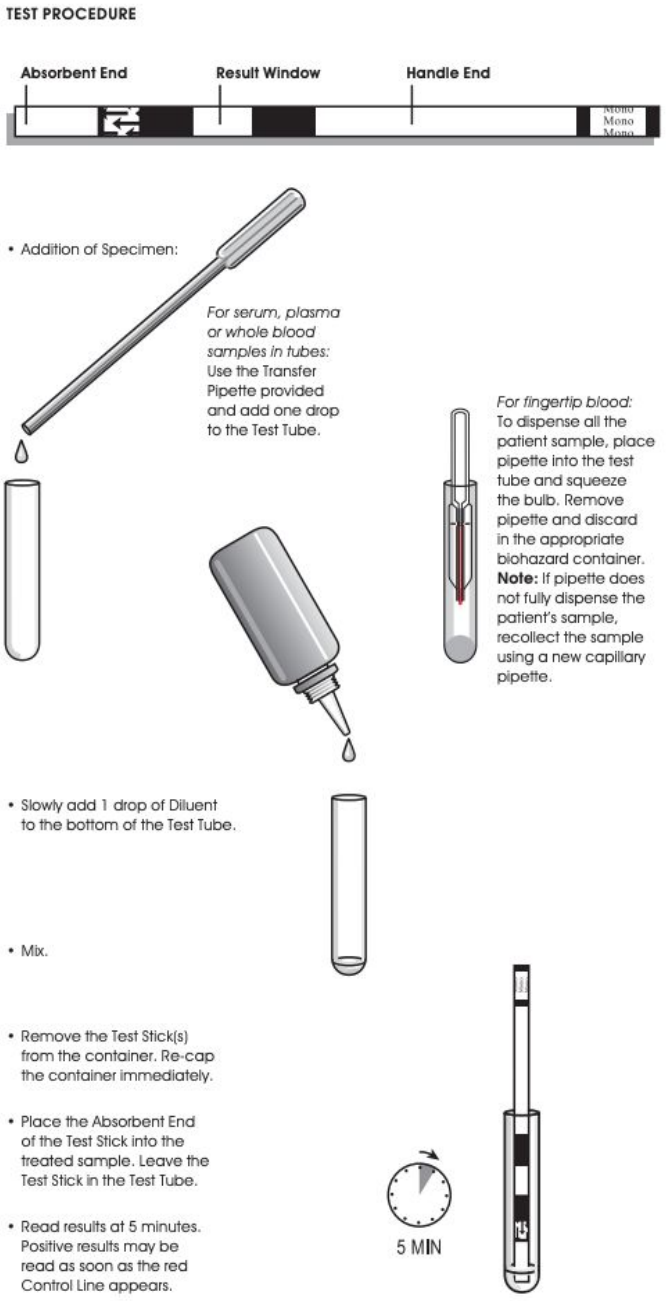
4. Place the Absorbent End of the Test Stick into the treated sample. Leave Test Stick into the treated sample. Leave the Test Stick in the Test Tube.

5. Set the timer for 5 minutes.

6. Read results in 5 minutes. Positive results may be read as soon as the red Control Line appears.

7. Record the result in the lab logbook and add the result to the patient's electronic health record (EHR).

8. Notify the medical provider of the result.



Interpretation of Results:

- **A blue or red line which appears uneven in color density is considered a valid result.**

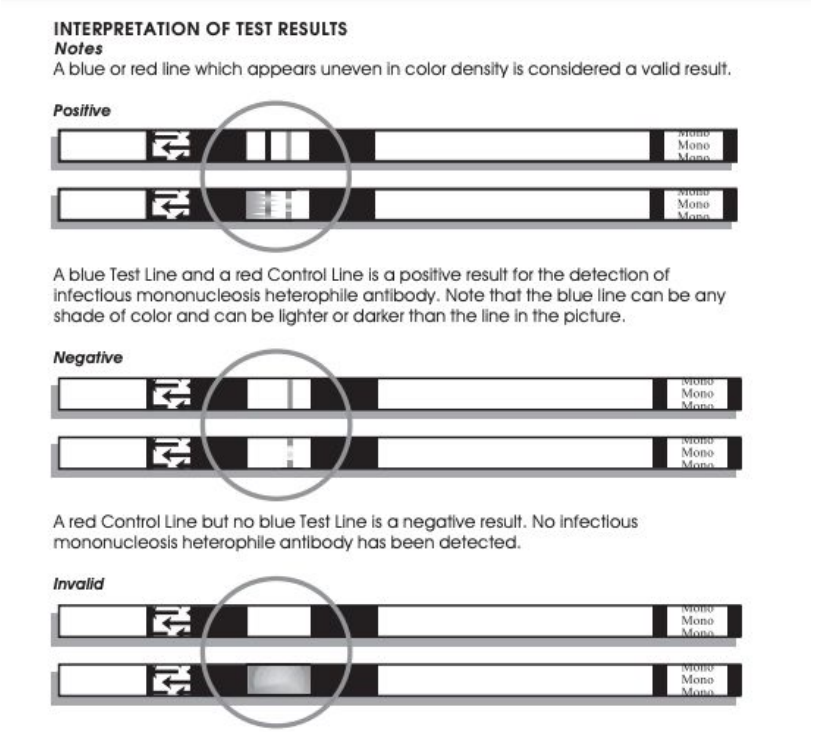
Positive*: A blue Test Line and a red COntrol Line is a positive result for the detection of IM heterophile antibody.

***NOTE:** The blue line can be any shade of color and can be lighter or darker than the line in the picture.

Negative: A red Control Line but no blue Test Line is a negative result. No IM heterophile antibody has been detected.

Invalid: If after 5 minutes, no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, read the directions again and repeat the test with a new Test Stick. If the result is still invalid, stop using the test kit and contact the Medical Services Director/Lab Director. Sekisui Diagnostics Technical Assistance can be reached at (800) 332-1042, if needed.

The appearance of a dry white line located near the Test and/or Control line positions has been observed on some Test Sticks. When present it can remain visible at the read time. The artifact is most seen with plasma or serum and has no impact on the performance of the assay.



Quality Control (QC):

Internal QC: The OSOM IM test provides two levels of internal procedural controls with each test procedure.

- The red Control Line is an internal positive control. The Test Stick must absorb the proper amount of sample and be working properly for the red Control Line to appear.
- A clear background is an internal negative control. If the test has been performed correctly and the Test Stick is working properly, the background will clear to give a discernible result.

If the red Control Line does not appear, the test is invalid. If the background does not clear and interferes with the test result, the test may be invalid. Call Sekisui Diagnostics technical Assistance if you experience either of these problems.

Limitations:

- As with all diagnostic assays, the results obtained by this test yield data that must be used as an adjunct to other information available to the medical provider.
- The OSOM IM Test is a qualitative test for the detection of IM heterophile antibodies.
- A negative result may be obtained from patients at the onset of 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 negative.

Performance Characteristics:

A total of 439 specimens (183 serum, 176 plasma, and 80 whole blood) were evaluated by two clinical labs in a clinical study. Test results of the OSOM IM Test were compared to results obtained with commercially available latex particle agglutination test for the qualitative determination of IM heterophile antibodies. Discrepancies between results were resolved by Epstein-Barr Virus (EBV) specific serological assays. In these assays, the specific antibodies to the EBV capsid antigen (IgM) and EBV nuclear antigen-1 (IgM and IgG) were determined.

When compared to commercially available latex particle agglutination test for IM heterophile antibodies, the OSOM IM test showed a sensitivity of 100% and a specificity of 90.3%. The overall agreement was 94.1%.

15 to 26 discrepant samples were determined to be recent or acute EBV infections by EBV serological testing. In which case the sample was considered positive. Including the samples confirmed positive by EBV serological testing, the overall clinical study specificity of the OSOM IM Test is 95.9% and the overall sensitivity is 100%.

POL Studies:
An evaluation of the OSOM IM Test was conducted at 3 medical providers' offices or clinical laboratories where testing was performed by personnel with diverse educational backgrounds. Each site tested the randomly coded panel consisting of negative, low positive, and moderate positive specimens for three days. The results obtained had 99.1% agreement (107/108) with expected results.

Reorder# 145 OSOM Mono Test (25 Tests)

REVIEW:
Procedure will be reviewed every two years or as indicated by the Medical Services Director/Laboratory Director.

Key Words: Infectious Mononucleosis, POCT, OSOM

References: OSOM Mono Test Documentation

Replaces: *ProAdvantage POCT Infectious Mononucleosis Rapid Procedure*