



<b>Title:</b>	OSOM® Infectious Mononucleosis Quality Control (QC)				
<b>Department:</b>	<b>Admin:</b>		<b>Medical:</b>	✓	<b>Counseling:</b>
<b>Written By:</b> T. Rochon			<b>Responsible Person/Dept:</b> Medical Services Staff		
<b>Origin Date:</b> 10/2020		<b>Review Date:</b> 10/2022		<b>Effective Date:</b> 10/28/2020	
<b>Reviewed By:</b> Medical Services Director			<b>Approved By:</b> A. Kimberly, Lab Director		
<b>Guiding Regulatory or Administrative Rules:</b> <a href="#">Synopsis of 42 CFR 493 and OAR 333-024-0005 thru 333-024-0055</a>					

**Test Type:**

OSOM® Mono Test

**Test Method:**

Qualitative

**Control Reagent (Included in Test Kit):**

- Mono Positive Control
- Mono Negative Control

**Control Viability:**

Viable at room temperature (15°C - 30°C) until expiration date

**Procedure:**

**External QC:**

A positive and a negative control must be evaluated for the following reasons:

- New lot of tests
- Each new box opened
- Monthly to check on appropriate storage conditions
- Each new untrained operator

External positive and negative controls are supplied in the kit. If controls do not perform as expected, assay results are invalid.

During school closures, such winter/summer breaks, Monthly external controls are not required. However, external controls should be run prior to resuming clinical operations.

### Procedure for External Control Testing:

Using the positive or negative external controls in place of a patient sample:

1. Add 1 free falling drop of control to the Test tube and then proceed in the same manner as with a patient sample
2. Slowly add 1 drop of Diluent.
3. Mix
4. Remove the Test Stick(s) from the container, Re-cap the container immediately.
5. Place the Absorbent End of the Test Stick into the treated sample. Leave the Test Stick in the Test Tube.
6. Set the timer for 5 minutes.
7. Read results at 5 minutes. Positive results may be read as soon as the red Control Line appears.
8. Record the result on the control log
9. Repeat steps 1 - 8 for the other control (negative or positive).
10. Dispose of Test Stick(s) and Test Tube in the biohazard container.

**If unexpected results are seen when running the controls, review the directions for use, Interpretation of Results, and Limitations sections and repeat the test with another device. If the problem persists, discontinue use of the test kit immediately and contact the Medical Services Director/Lab Director.**

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Key Words: Infectious Mononucleosis, POCT, Pro Advantage

References:

Replaces: *Pro Advantage Infectious Mononucleosis Quality Control (QC)*