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|  | **WORK INSTRUCTION** |
| **R-W-SER-0102-00**  |
| Poly stat Mono test – whole blood |
| **[x]  St. Joseph Medical Center Tacoma, WA** **[x]  St. Clare Hospital Lakewood, WA** **[x]  St. Elizabeth Hospital Enumclaw, WA****[x]  St. Francis Hospital Federal Way, WA** **[x]  St. Anthony Hospital Gig Harbor, WA** **[ ]  PSC** |

**PURPOSE**

To provide instruction for the performance of the Poly stat Mono Test used for the qualitative detection of infectious mononucleosis (IM) heterophile antibodies in human whole blood. This method qualifies as a waived test.

**BACKGROUND**

Infectious mononucleosis (IM) is an acute, self-limited, lymphoproliferative disease caused by the Epstein-Barr virus (EBV). Infection with EBV usually occurs early in life with no recognizable disease. When primary infection is delayed until young adulthood and adolescence, however, there is about a 50% chance that it will occur with the classic clinical manifestations associated with IM. Most individuals exposed to EBV develop a heterophile antibody response and react with surface antigens present on the red cells of different mammalian species. It is not known which specific antigen stimulates their production.

**RELATED DOCUMENTS**

R-F-SER-0103 Mono Test Kit External QC Log

**PRINCIPLE**

Direct solid-phase immunoassay technology is used for the qualitative detection of IM heterophile antibodies.

**SPECIMEN REQUIREMENTS**

5 ml EDTA or heparinized sample

Whole blood may be stored at 2o – 8o C for 24 hours

**REAGENTS AND EQUIPMENT**

1. Poly stat Mono Test kit which contains:

* Poly stat Mono 20 test devices
* Developer Buffer: Phosphate saline buffer
* Negative Control: diluted serum
* Positive Control: diluted in serum
* Sample transfer tube for whole blood (25µL)

 **Note**: Reagents contain 0.1% sodium azide. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Please dispose of cartridges and buffer in biohazard trash.

2. 25 µL pipette

**STORAGE AND STABILITY**

Poly stat Mono test kits should be stored at 2°-30°C in its sealed pouch and is stable for the stability dating given.

**QUALITY CONTROL**

**Internal Quality Control**

There are two internal control features in the Poly stat Mono test. Record results in Cerner with each patient result, using TSA and work center/test site. The positive internal control indicates the test has been performed correctly and the device is working properly when a colored control band appears at the Control position (C). A clear background in the result window is considered an internal negative procedural control. If the test has been performed correctly and the device is working properly, the background in the result window will be clear, providing a distinct result.

**External Quality Control**

Good laboratory practice recommends the periodic use of external control materials to ensure proper kit performance. The kit includes positive and negative controls that can be run in place of serum or plasma. Run external controls on each new lot and shipment before use. Record results on Mono Test Kit External QC Log.

**Note:** To test the kit positive and negative controls, add one (1) drop of control to the upper end of the sample well of the upper end of the test device and two to three (2-3) DROPs of developer buffer to the lower end of the sample well. Test according to PROCEDURE, below.

**STEPS**

1. Whole blood specimens and Poly stat test devices and reagents must be at room temperature before testing.
2. Remove a device from pouch and place on flat surface.
3. Label device with a patient identifier.
4. Using a tube from the bag labeled “Sample Transfer Tube for Whole Blood,” draw the sample into the Sample Transfer.

**Notes:**

1. Capillary action will draw the sample into the fill line and stop. Never squeeze tube while sampling.

2. A 25 µL pipette may instead be used to draw up and expel the blood, if desired.

1. If using the bulb, squeeze it to dispense sample into the UPPER END of the Sample Well (S) of the device. If a sample will not expel, place a finger to cover the pinhole located at the stem of the tube and squeeze the bulb again. If using the 25 µL, expel the blood into the same location.



Developer Solution

Sample – at top

of well by “S”

1. Holding the dropper bottle in a vertical position, add 2 to 3 drops of Developer Buffer onto the LOWER AREA of the Sample Well (S).

**Note:** Do not touch the tip of the Developer Buffer to skin or Poly stat Mono test device to avoid contamination.

1. Read results at 8 minutes. (Do not read after 15 minutes.)

**Note:** Mildly hemolyzed whole blood specimens do not affect the test result, but may create an undesirable reddish background in the result window.

**INTERPRETATION OF RESULTS**

**Positive Results:**

One pink-purple color horizontal band each at the Test position (T) and at the Control position (C) indicates that IM-specific heterophile antibodies have been detected. A positive test result may be read as soon as a distinct pink-purple colored band appears at the Test position (T) and at the Control position (C). Any shade of pink-purple colored horizontal band at the Test position (T) should be reported as a positive. Note: The intensity of the colored band at the Test Position (T) may be different from the intensity of the Control position (C) band.

**Negative Results:**

One pink-purple band at the Control position (C) with no distinct colored horizontal band at the Test position (T) other than the normal faint background color indicates the IM-specific heterophile antibodies have not been detected.

**Invalid Results:**

A distinct colored horizontal band should always appear at the Control position. The test is invalid if no band forms in this position.

If this occurs repeat testing, and contact Polymedco, Inc. Technical Services at 1-800-431-2123.

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| **Positive** | **Negative** | **Invalid** |
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**CERNER ORDERING AND RESULTING**

The order code for the Poly stat Mono Test is MONO.

**Resulting**

1. At the SELECT prompt, enter [TSB], WORKCENTER, enter [500], TESTSITE [500]. SEH results in either TSA or ACC and the workcenter/test site is 7500/500. You may just enter through the test site.
2. The Positive and Negative controls and any outstanding patients will load.
3. Document the results of the positive internal control (appearance of the pink-purple line at the Control position) by entering POSITIVE for the Positive Control.
4. Document the results of the negative internal control (presence of a clear background) by entering NEGATIVE for the Negative Control.
5. Enter patient results as POSITIVE or NEGATIVE.

**PROCEDURAL NOTES**

Occasionally, 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.

Some segments of the population who contract acute IM do not produce measurable levels of heterophile antibody and may test IM heterophile antibody negative.

**REFERENCES**

Poly stat Mono Test package insert (51908-02 P-5265-A, 2009), Polymedco, Inc., 510 Furnace Dock Rd., Cortlandt, Manor, NY.

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| **DOCUMENT APPROVAL Purpose of Document / Reason for Change:** |
| 1. To provide a document that describes the mono testing procedure for the Poly stat Mono Test kit. |
| **[ ]**  *No significant change to process in above revision.  Per CAP, this revision does not require further Medical Director approval.* |
| **CommitteeApproval Date** | **[x]** Date: 3/13/2014**[ ]**  N/A – revision of department-specific document which is used at only one facility  | **Medical Director Approval***(Electronic Signature)* | H:\Katie\Signature - KEW.jpg3/13/14 |