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| Introduction **Principle** | The clinical diagnosis of infectious mononucleosis (IM) is suggested by symptoms of fever, sore throat and swollen lymph glands. The highest incidence of symptomatic IM occurs during late adolescence (15-24 years of age). Infectious mononucleosis is caused by the Epstein - Barr virus (EBV). The laboratory diagnosis of IM is based on the detection of IM heterophile antibodies. These heterophile antibodies are directed against antigens found in bovine, sheep and horse erythrocytes. The OSOM Mono Test utilizes an extract of bovine erythrocytes to provide optimal sensitivity and specificity for diagnosis.  The OSOM Mono Test uses color immunochromatographic dipstick technology with bovine erythrocyte extract coated on the membrane. In the test procedure, serum or plasma is mixed with the Diluent. Then the Test Stick is placed in the mixture and the mixture 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. |

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| Scope | This procedure is intended for the OSOM Mono Test for the qualitative detection of infectious mononucleosis heterophile antibodies in serum or plasma as an aid in the diagnosis of infectious mononucleosis. CLIA categorizes this test as a moderately complex non-waived test. This procedure is intended for use by Clinical Laboratory Scientists and Medical Laboratory Technologists. |

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| Policy | * Training must be successfully completed and documented before performing this test on clinical specimens. * The laboratory must participate in appropriate proficiency testing survey programs such as those from the CAP and other programs designated by national, state and local policy. * Positive and negative external controls must be run with each new lot number, each new shipment of kits, on each day of use, and with each new untrained operator. * The use of commercial controls is not recommended by the manufacturer. |

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| Specimen sources | * Serum * Plasma |

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| Specimen collection | Serum can be collected using a red (Rd7) or gold top (GLD6) tube.  If plasma is used, ensure the tube contains either EDTA or heparin. Other anticoagulants have not been validated. |  |

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| Specimen transport | * Refrigerated |

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| Specimen storage | Specimens should be tested immediately after collection. However, serum and plasma if refrigerated (2 - 8°C) must be tested within 48 hours. If samples must be held longer, they should be frozen (< -10°C) and tested within 3 months. |

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| Reagents | **Description** | **Vendor** | **Storage** |
| Test Stick | Sekisui | 15 - 30°C |
| Diluent (0.2% sodium azide) | Sekisui | 15 - 30°C |
| **Mono Positive Control**  (contains rabbit anti-beef  stroma in tris buffer with  0.2% sodium azide and  0.05% gentamycin  sulfate preservatives) | Sekisui | 15 - 30°C |
|  | **Mono Negative Control**  (contains goat albumin in  tris buffer with 0.2%  sodium azide) | Sekisui | 15 - 30°C |
| **Note: All items listed in the table are located in the Sekisui Diagnostics OSOM Mono Test Kit Ref# 145** | | |

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| Materials and supplies | * Specimen collection containers * A timer or watch * Test tubes (provided in kit) * Transfer pipettes (provided in kit) |

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| Equipment | * Not applicable |

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| Safety or special safety precautions | * ***Refer to the safety manual for general safety requirements*** |

##### Quality

##### control External Quality Control:

For external QC testing, use the controls provided in the kit. Add one free falling drop of control to the Test Tube and then proceed in the same manner as with a patient sample. Positive and negative external controls should be run once for:

* Each new kit lot #
* Each day of use
* Each new untrained operator
* Each new shipment of test kits
* As required by internal quality control policies

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| Qualitycontrol, **continued** | **Internal Quality Controls:**  The OSOM Mono Test provides two levels of internal controls:   * 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 Services if you experience either of these problems. |

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| Procedure | Follow the steps below: | |
| Title | |
| **Step** | **Action** |
| 1 | Using the transfer pipette provided, add one drop of serum or plasma to the test tube. |
| 2 | Slowly add 1 drop of Diluent (provided in the kit) to the bottom of the Test Tube. |
| 3 | Remove the Test Stick(s) from the container. Re-cap the container immediately. |
| 4 | Place the Absorbent End of the Test Stick into the treated sample. Leave the Test Stick in the Test Tube. |
| 5 | Using a timer or watch, wait 5 minutes before reading the test strip. Results are considered invalid beyond the stated read time.  *Note: Positive results may be read as soon as the red Control Line appears.* |
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| 6 | **Interpretation of Results**   |  |  | | --- | --- | | **If…** | **Then…** | | Mono_Results_POS | Device is showing a **positive result**. The red line is indicating a valid internal control and the blue line is indicating a positive result. | | *Note: There is no red line present* | Device is showing an **invalid result**. Repeat test on a new stick. If problem persists, cancel test and request a new specimen. Additionally, report the issue to Sekisui Diagnostics Technical Service.  Cancellation reason:  *Canceled due to product control failure. Please resubmit if clinically indicated.* |  | | Mono_Results_NEG | Device is showing a **negative result**. | |

**Reference**

**range** Negative

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**Reporting**

**of results**

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| **Step** | **Action** |
| 1 | Click on **ARE** (Accession Result Entry). |
| 2 | Scan the patient’s barcode and click **RETRIEVE**. |
| 3 | Go to the result section. |
| 4 | The first result to enter is **Mono Test**. Click the drop down arrow and choose the correct response (i.e., **Negative or Positive**). |
| 5 | Next, enter the QC result, also **Positive** or **Negative**. |
| 6 | Once all results are entered, click **PERFORM**. |
| 7 | Then go back to the **ACCESSION** box, scan the barcode and click **RETRIEVE** again. |
| 8 | Verify that all results were entered correctly. If yes, click **VERIFY**. |

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| 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 physician. * The OSOM Mono 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 antibody negative. |

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| Non-controlled documents | The following non-controlled documents support this procedure:   * Sekisui Diagnostics OSOM Mono Test Package Insert * Sekisui Diagnostics CLIA Packet * Visual aid summarizing OSOM Mono procedure (**see attachment**) |

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**Attachment**:

