**TITLE:** Sekisui Diagnostics OSOM® Mono Test

**Principle:**

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.

**Clinical Significance:**

The diagnosis of infectious mononucleosis (IM) is suggested on the basis of the clinical 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)1,2. 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 give the required sensitivity and specificity.

**Personnel:**

Medical Technologist

**Reagent preparation:**

Osmo Mono Kit Containing:

25 Test Sticks in a container

25 Test Tubes

25 Transfer Pipettes

1 Diluent (contains buffer with 0.2% sodium azide)

1 Mono Positive Control (contains rabbit anti-beef stroma in tris buffer with 0.2% sodium azide and 0.05% gentamycin sulfate preservatives)

1 Mono Negative Control (contains goat albumin in tris buffer with 0.2% sodium azide)

2 Additional test sticks have been included in the kit for external QC testing

**Note:** Extra components (tubes, pipettes) have been provided for your convenience.

Store the Test Sticks and reagents tightly capped at 15°-30°C (59°-86°F).

Do not use the Test Sticks or reagents after their expiration dates.

Materials Required but Not Provided:

Specimen collection containers

Timer

**Sample Collection:**

Serum and Plasma

Obtain specimens by acceptable medical technique. Collect plasma using a tube containing EDTA or heparin as an anticoagulant. Other anticoagulants have not been tested. Serum and plasma may be refrigerated (2°-8°C; 36°-46°F) and tested within 48 hours; serum and plasma specimens held for longer times should be frozen (below -10°C; 14°F) and tested within 3 months.

**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. Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements.

Positive and negative external controls are to be run with each new lot, new untrained operator and with each day that patient testing is performed.

Record these control results in the Laboratory Information System. Refer to the Procedure IM-107, Quality control for Serology Kits and Reagents for complete instructions on result entry.

Some commercial controls may contain interfering additives. The use of these controls is not recommended.

Internal Quality Controls

The OSOM Mono 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.

**Stepwise procedure:**

For serum and plasma use the Transfer Pipette provided and add one drop to the Test Tube.

* Slowly add 1 drop of Diluent to the bottom of the Test Tube.
* Mix
* Remove the Test Stick(s) from the container. Re-cap the container immediately.
* Place the Absorbent End of the Test Stick into the treated sample. Leave the Test Stick

in the Test Tube.

* Read results at 5 minutes. Positive results may be read as soon as the red Control Line

appears.

Discard used test tubes and Test Sticks in the suitable biohazardous waste container.

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**Reporting Results:**

Report all results through the Laboratory Information System. Refer to the LIS Procedure Manual for complete instructions on the result entry.

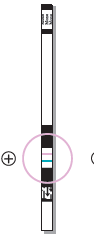
**Notes**

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 infectious

mononucleosis heterophile antibody. Note that the blue line can be any shade of blue.





**Negative**

A red Control Line but no blue Test Line is a negative result. No infectious mononucleosis

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, repeat the test on a new Test Stick

or call Sekisui Diagnostics Technical Assistance at 800-332-1042.



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. This

artifact is most often seen with plasma or serum specimens and has no impact on the

performance of the assay.

**Expected Values:**

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.

While the incidence of IM reflects wide seasonal, ethnic and geographical variation, a large

epidemiological study noted that the highest incidence of symptomatic IM occurred during late

adolescence (15-24 years of age).

**Notes:**

• 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 antibody.

• 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 negative1.

**References:**

Sekisui Diagnostics OSMO Mono Package Insert 2019