SAMPLE PROCEDURE

This “Sample Procedure” is not intended as a substitute for your facility’s Procedure Manual or reagent labeling, but rather as a model for your use in customizing for your laboratory’s needs.

Space has been provided within the document to allow you to update this template with information specific to your facility. It is suggested that a current version of the manufacturer’s directional insert be maintained as a supplement.

PROCEDURE

Title: Sekisui Diagnostics OSOM® Mono Test

Procedure #:

Institution: _____

Prepared by: _____ Date:_____

Title: _____

Accepted by: _____ Date adopted: _____

Title: _____

Reviewed by:_____ Date:_____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

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_____ _____

_____ _____

_____ _____

_____ _____

Discontinued by:_____ Date:_____

I. TEST NAME

OSOM® Mono Test
Waived for Whole Blood; Non-waived for Serum or Plasma

II. 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.

III. SUMMARY AND EXPLANATION OF TEST

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). 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.

IV. PRINCIPLES OF TEST

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 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.

V. KIT CONTENTS AND STORAGE

25 Test Sticks in a container
25 Test Tubes
25 Transfer pipettes
25 Capillary Pipettes (50µl)
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)
1 Work Station
1 Directional insert
2 Additional test sticks have been included in the kit for external QC testing

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

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

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

At this facility, kits are stored: _____.

VI. MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection containers
A timer or watch

VII. 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. For sites permitted to dispose of material down a sink: Large quantities of water must be used to flush discarded control material down a sink.
- Do not interchange or mix components from different kit lots.

VIII. PATIENT PREPARATION & SPECIMEN COLLECTION

This facility's procedure for patient preparation is: _____.

This facility's procedure for sample labeling is _____.

Specimen Collection and Handling:

Serum, Plasma or Whole Blood Sample

Obtain specimens by acceptable medical technique. Collect whole blood samples using a tube containing EDTA or heparin as an anticoagulant. Other anticoagulants have not been tested. Serum and plasma specimens may be refrigerated (2° - 8°C, 36 - 46°F) and tested within 48 hours; serum and plasma specimens may be held for longer times should be frozen (below-10°C, 14°F) and tested within 3 months. Test whole blood specimens within 24 hours. Specimens must be at room temperature (15 º – 30 º C; 59 º – 86 º F) when tested.

Fingertip Whole Blood

Hold the capillary pipette horizontally, and touch the tip of the pipette to the drop of blood on the patient's finger until it fills completely to the line. **NOTE:** Filling is automatic; never squeeze the pipette bulb while collecting the sample.

This facility's procedure for transporting specimens is: _____.
_____.

This facility's procedure for rejected specimens is: _____.
_____.

IX. QUALITY CONTROL & ASSURANCE

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. Minimally, Sekisui Diagnostics recommends that positive and negative external controls be run with each new lot and with each new untrained operator. 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.

QC Testing Frequency and Documentation

For this facility, external QC is run: _____.
_____.

Results of External QC and action(s) taken when control results are unacceptable are documented: _____.
_____.

X. TEST PROCEDURE

Addition of Specimen:

For serum, plasma or whole blood samples in tubes:
Use the Transfer Pipette provided and add one drop to the Test Tube.

For fingertip blood:
To dispense all the patient sample, place pipette into the test tube and squeeze the bulb. Remove pipette and discard in the appropriate biohazard container. **NOTE:** If pipette does not fully dispense the patient sample, recollect the sample using a new capillary pipette.

- 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.

For this facility, used test tubes and Test Sticks are disposed: _____.
_____.

XI. INTERPRETATION OF RESULTS

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.

In the event this test becomes inoperable, this facility's course of action for patient samples is: _____.

XII. RESULT REPORTING

This facility's procedure for patient result reporting is: _____.
_____.
_____.
_____.

XIII. 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 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 negative.

XIV. 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).

XV. PERFORMANCE CHARACTERSITICS & POL STUDIES

Refer to Directional Insert

XVI. REFERENCES

Refer to Directional Insert

XVII. ASSISTANCE

For technical assistance, call Sekisui Diagnostics Technical Service at (800)-332-1042.

OSOM® is a registered trademark of Sekisui Diagnostics, LLC.