Document History:

Title:	**Clearview® IM II Laboratory Procedure**	**Site(s):**	**Shared Health Diagnostic Services WRHA, Westman and Rural RHAs**

Document #:	**120-10-21**	**Version #:**	**07**
Section:	**Clinical Microbiology**	**Subsection:**	**General**

Approved by: *(approval on file)*	Joelle Carlson	**Date:**	07-MAR-2023
		Effective Date:	30-MAR-2023

Details of Recent Revisions:

- Collection Tube section replaced with Sample Requirements section, information added
- Reagents and Equipment, B. Materials Required but not Provided: removed last bullet re: 12x75 plastic aliquot tube

Clearview® IM II Laboratory Procedure

Principle

The Clearview® IM II test is a qualitative, lateral flow immunoassay for the detection of Infectious Mononucleosis (IM) heterophile antibodies in whole blood, serum or plasma to aid in the diagnosis of Infectious Mononucleosis.

In this test, bovine erythrocyte extracted antigen is immobilized in the test line region of the test. During testing, the specimen reacts with bovine erythrocyte extracted antigen coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test and interacts with the immobilized bovine erythrocyte extracted antigen. If the patient sample mixture contains IM heterophile antibodies, a colored line will appear in the test line region, indicting a positive result. If the sample does not contain IM heterophile antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Sample Requirements

- Whole blood
  - Venipuncture: sodium/lithium heparin, potassium/sodium EDTA, sodium oxalate, sodium citrate
  - Fingerstick: heparinized capillary
- Serum or Plasma
  - With or without above mentioned anticoagulants
  - With or without gel

Specimen Sample and Stability for Testing

- Whole Blood
  - EDTA-48hrs @ 2-8°C
  - Fingerstick-test immediately
  - Do not freeze whole blood samples
- Serum/Plasma
  - 72hrs@ 2-8°C
  - Freeze @ -20°C if unable to transport to testing site

Note: Samples transported from distant locations may be accepted up to 96 hours. Samples accepted with a transit time of >48 to ≤96 hours will be tested with the following free text comment to be added to all negative samples. Add REQC in LIS and free text on format: “This specimen was processed but results may be compromised due to prolonged transit time.” If sample has been in transit longer than 96 hours, delete MS and reject the sample. Using REJS format, enter &DELAY (Specimen delayed in transport. Unsuitable for analysis.) and free text “recommend recollection”.

Post testing samples should be retained for 72 hours at 2-8°C before being discarded. See doc# 100-10-05 Lab Records and Materials Retention Policy.

Reagents and Equipment

A. Reagents and Materials Provided

- 20 test devices
- Disposable sample droppers
- Positive control (Goat anti-mono antibody, 0.09% sodium azide)
- Negative control (Diluted human plasma, 0.09% sodium azide)
- R1
- Package insert

B. Materials Required but not Provided

- Sample collection container, see collection tube above, (for venipuncture whole blood)

- Lancet (for finger stick whole blood only)
- Timer
- Centrifuge (for acquiring serum or plasma)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

Storage and Stability

The kit can be stored at room temperature or refrigerated (2-30°C). The test devices must remain in the sealed pouch until use. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Quality Control

Internal Procedural Controls

An internal procedural control is included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique. **If internal controls do not perform as expected, the patient sample results cannot be interpreted.**

External Quality Control Testing

Using the positive or negative external controls in place of a patient sample, add 1 drop of positive or negative control solution to a sample well(s) of the new test device, then add 1 drop of R1. Start the timer. Continue with step 10 in the Test Procedure section.

For waived testing (whole blood) and MANQUAP labs, positive and negative external controls should be run with each new lot number, each new shipment and with each new untrained operator.

For CAP accredited labs performing non-waived testing (i.e. serum or plasma), positive and negative external controls are tested and recorded each day of patient testing. New reagent lots and shipments are checked against old reagent lots or with suitable reference material before or concurrently with being placed in service (parallel testing). This is to ensure the use of new reagent lots and shipments do not affect patient results.

Document on Mono Test Kit QC Log.

If unexpected results are seen when running the controls, review the Procedure, Interpretation of Results and Limitations sections and repeat the test with another device.

Special Safety Precautions

Utilize Routine practices as relates to patient sample manipulation. Wear protective clothing such as laboratory lab coats and disposable gloves when samples are assayed. The positive and negative controls contain sodium azide as a preservative, which may form potentially explosive metal azide if it reacts with lead or copper plumbing. Large quantities of water should be used to flush discarded controls down a sink.

Procedure – Sample Limitations

1. **Note:** Allow serum separator tubes to clot for 30 minutes from time of collection. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Centrifuge tubes for 10 minutes at 2500 rpm.
2. Remove serum/plasma and aliquot into 12x75 plastic tube. Label tube with LIS label.
3. Ideally, testing should be performed immediately after specimen collection.
4. Do not leave the samples at room temperature for prolonged periods.

Test Procedure

1. For Delphic results reporting (Does not apply to WebMicro): Using Delphic Explorer/ Registration, register the sample using test code **MS**.
2. Print worksheet:
   - New Page: type Print in format, click Okay – Type **MS** in worksheet to be printed. Press F12.
3. Allow test cassette, R1 and controls to reach room temperature prior to use.
4. Remove the test device from the foil pouch and use it as soon as possible. For best results, perform the test immediately after opening the foil pouch.
5. Place the test cassette on a clean and level surface.
6. Process External Quality Control (positive and negative) as per Quality Control section of this SOP.
7. For Serum or Plasma samples:
   - Hold the dropper upright and add 1 drop of serum or plasma (about 25 µL) to the sample well (S) of the test device.
   - Then add 1 drop of R1 to the sample well.
   - Start the timer.
   - Avoid trapping air bubbles in the sample well.
8. For Whole Blood (Venipuncture) samples (EDTA):
   - Fill dropper with sample.
   - Hold the dropper upright and add 2 drops of whole blood (about 50 µL) to the sample well (S) of the test device.
   - Then add 1 drop of R1 to the sample well.
   - Start the timer.
   - If sample does not travel through specimen well, spin an aliquot of the sample and follow instructions for plasma samples above.
9. For Fingerstick Whole Blood specimens (EDTA):
   - To use a capillary tube: Fill the capillary tube and transfer approximately 50 µL of fingerstick whole blood specimen to the sample well (S) of the test device.
   - Add 1 drop of R1 (approximately 55 µL).
   - Start the timer.
   - If sample does not travel through the specimen well, spin an aliquot of the sample and follow instructions for plasma samples above.
10. Wait for the colored line(s) to appear. **Read results at 5 minutes**. The background should be clear before the result is read. Do not interpret the result after 10 minutes.

Interpretation of Results

Positive: **Two distinct colored lines appear.** One line should be in the control line region (C) and another line should be in the test line region (T). A positive result indicates that IM heterophile antibodies were detected in the sample.
Note: The intensity of the color in the test line region (T) will vary based on the concentration of IM heterophile antibodies in the sample. Any shade of color in the test line region (T) should be considered positive.

Negative: **One colored line appears in the control line region (C)**. No apparent colored line appears in the test line region (T). A negative result means that IM heterophile antibodies were not found in the sample or are below the detection limit of the test.

Invalid: **Control line fails to appear** (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact the vendor and Microbiology Technical Director.

Result Reporting in Delphic (does not apply to WebMicro)

Result entry in Delphic as follows:

1. Call up **New Page**
2. Enter **MS** in format box
3. Enter **Lab ID#** in starting request box; press **okay**
4. On MS format, enter [**P**] for positive or [**N**] for negative in result box
5. Press **Release**

Using **Enquiry/Results** Search format, call up Lab ID and verify manually entered results in LIS.

Document patient result on worklist and retain worklist in lab as per Retention Policy.
Note: pending/outstanding test can be found on TESTVIEW, enter MS on this format.

Method Limitations

1. The Clearview® IM II Test (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of IM heterophile antibodies in whole blood, serum or plasma samples only. Neither the quantitative value nor the rate of increase in Mononucleosis antibody concentration can be determined by this qualitative test.
2. Grossly hemolyzed samples will yield invalid results. Strictly follow the Package Insert instructions to obtain accurate results.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

Procedure Notes

1. Use only clear, non-hemolyzed samples.
2. Testing should ideally be performed immediately after the samples have been collected.
3. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.
4. Do not read the result after 10 minutes. Low titers of IM heterophile antibodies might result in a weak line appearing in the test line region (T) beyond this time.
5. Do not use kit after expiry date.
6. Humidity and temperature can adversely affect results. If problems occur with kit performance, do not use the kit, document and contact the vendor and the Microbiology Technical Director.

References Clearview® MONO IM II kit insert

Appendix Appendix I Mono Test Kit QC Log Sheet

Appendix I Mono Test Kit QC Log Sheet

Site/Location:_____

Date (dd/mm/yy)	MONO Kit Lot# / Exp Date	Positive Control Lot# / Exp Date	Positive Control Result	Negative Control Lot# / Exp Date	Negative Control Result	Comments	Tech. Initials

Reviewed by:_____ **Date:**_____