

OREGON HEALTH & SCIENCE UNIVERSITY
*Hospitals and Clinics
Point of Care*

Mono II by Acceava

Principle

Epstein-Barr virus infection during adolescence or young adulthood causes infectious mononucleosis 35% to 50% of the time.

The incidence of EBV-associated infectious mononucleosis in the USA has been estimated at 45 per 100,000 and is highest in adolescent and young adults- about 2 out of 1,000. No seasonal pattern of EBV infection exists. The incubation period is 10 to 60 days, though 7 to 14 days is common for children and adolescents.

The BioStar Acceava Mono II test is a qualitative membrane strip based immunoassay for the detection of Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma. In this test procedure, bovine erythrocyte extracted antigen is coated on the test line region of the strip. The sample 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 strip and interacts with the coated bovine erythrocyte extracted antigen. If the sample contains IM antibodies, a colored line will appear in the test line region indicating 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 at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Specimen Requirements

1. Whole blood (from venipuncture or fingerstick). Anti-coagulated blood samples can be from sodium or potassium heparin, sodium or potassium EDTA, sodium or potassium citrate and sodium oxalate.
2. Do not leave the samples at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2°-8°C if the test is to be run within 2 days of collection. Bring samples to room temperature (15-30°C) prior to testing.

Interference

1. No interference was observed in samples containing high levels of hemoglobin (up to 10 mg/mL), bilirubin (up to 1,000 mg/dL) and human serum albumin (up to 100 mg/mL). The test results were also unaffected when the hematocrit was altered ranging from 20% to 60% and when icteric and lipemic samples were tested.
2. The BioStar Acceava Mono II test will only indicate the presence of IM heterophile antibodies in the sample and should not be used as the sole criteria for the diagnosis of Mononucleosis infection.

3. Grossly hemolyzed samples will yield invalid results.

Reference Range

Negative

Quality Control

1. Internal Quality Control is built in to every test strip. If the test flows correctly and the reagents work, a red line will always appear in the control region (C) on the strip. It confirms sufficient sample volume, adequate membrane wicking, and correct procedural technique. It is required that this control be recorded with every test run on the patient's chart.
2. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

3. External Positive and Negative Controls:
A positive and Negative Control is contained in each kit. These controls must be run when a new box is opened.

Running Positive and Negative controls:

Using control material instead of a patient sample, add 1 drop of positive or negative control solution to a sample tube, then add 1 drop of Sample Buffer. Place the test strip into the sample tube and start the timer. Wait for the red line(s) to appear. The result should be read at 5 minutes. The background should be clear before the result is read. **Do not interpret results after 10 minutes.**

4. Document the QC results into the QC log book.

Test Procedure

1. Remove the test strip from the canister and use it as soon as possible. Best results will be obtained if the test is performed immediately. Immediately close the canister tightly after removing the test strip(s). Record initial opening date on the canister. Once opened, the remaining test strips are stable for 12 months. **NOTE: When adding sample, avoid getting sample on the sides of the Sample Tube.**
2. For Whole Blood (Venipuncture) samples:
 - a) Fill dropper with sample.
 - b) Holding the dropper upright, insert the dropper nearly to the bottom of the sample tube and add 2 drops of whole blood (about 50 μ L) to the bottom of the tube
 - c) Add 2 drops of Sample Buffer to the bottom of the sample tube. Tap bottom of tube to mix.

- d) Place the test strip into the sample tube. Start the timer.
3. For Whole Blood (Fingerstick) samples:
 - a) Insert capillary tube nearly to the bottom of the sample tube and add full capillary tube of blood (about 50 μ L) to the bottom of the tube
 - b) Add 2 drops of Sample Buffer to the bottom of the sample tube. Tap bottom of tube to mix.
 - c) Place the test strip into the sample tube. Start the timer.
4. Wait for the red line(s) to appear. The result should be read at 5 minutes. The background should be clear before the result is read. **Do not interpret results after 10 minutes.**

Result Interpretation

POSITIVE: Two distinct red 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 shade of the red color in the test line region (T) will vary based on the amount of IM heterophile antibodies in the sample. Any shade of red in the test line region (T) should be considered positive.

NEGATIVE: One red line appears in the control line region (C). No apparent red or pink 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. Insufficient sample 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 strip. If the problem persists, discontinue using the test kit immediately and contact Inverness Medical Technical Support at (877) 441-7440.

5. Document this result as well as the required internal control result in EPIC.

Storage

The kit can be stored at room temperature or refrigerated (2°-30°C). The test strips must remain in the closed canister until use. The test strips (in their unopened canister) and the reagents are stable through the expiration date printed on the box. Once the canister is opened, the remaining test strips are stable for 12 months.

References

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4. Papesch, M. & Watkins, R. 2001 Clin. Otolaryngol. 26, 3-8
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www.cdc.gov/ncidod/diseases/ebv.htm
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7. Acceava Mono II package insert, 12/2008.

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