



CORTEZ DIAGNOSTICS, INC.

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INTRODUCTION TO InstaTest Mono

InstaTest Mono is an immunochromatographic *in vitro* assay for detection of heterophile antibodies associated with infectious mononucleosis infection.

Infectious mononucleosis (IM) is caused by the Epstein-Barr virus. Serologic diagnosis of IM is based on detection of serum antibodies associated with the infection, such as the heterophile antibodies present in the sera of IM patients.

InstaTest Mono is a rapid and convenient immunochromatographic method of detection of IM-associated heterophile antibodies in human serum. The test kit allows performing 50 tests. It contains 50 sealed foil pouches, with one immuno-chromatographic Testing Device and one disposable Sample Dropper in each pouch. A Testing Device is a test membrane with heterophile antigen and antibody conjugates in a stabilizing matrix containing proteins and sodium azide, enclosed in plastic casing. Other kit components are Extraction Buffer (two dropper vials) and Extraction Tube (optional).

The result is read visually by observing the symbols developing in the test ("T") and control ("C") zones of the result window. Distinctive control line also serves as an indicator of proper performance of the test device.

InstaTest Mono is for *in vitro* diagnostic use only.

Storage conditions

Store the test below 28°C; do not freeze.

TEST PROCEDURE AND INTERPRETATION OF RESULTS

Sample collection

Collect blood using a proper aseptic technique. Allow the blood to clot completely. Centrifuge to obtain clear serum. If necessary, the sample may be stored in a refrigerator for up to 48 hours, or frozen for prolonged storage.

Alternatively, patient plasma can be used. For each test, approximately 0.15 ml of serum or plasma is required.

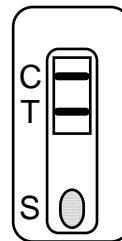
NOTES Do not open the foil pouch until you are ready to perform the test. If a sample or a test kit was refrigerated, bring unopened pouch and test sample to room temperature before performing the test.

Test procedure

1. Open a foil pouch by tearing along the "notch", and remove a Sample Dropper and a testing Device.
2. Using a Sample Dropper, place three drops of serum or plasma into an Extraction Tube.
3. Add nine drops of Extraction Buffer to the Extraction Tube containing the specimen. Close the Extraction Tube and shake gently to mix contents.
4. Place a Testing Device on a flat surface. Invert the Extraction Tube. Holding it vertically, squeeze it to dispense four drops of liquid into the sample ("S") well of the Testing Device.
5. Read the test results at five minutes.

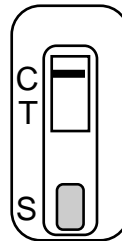
Interpretation of the test results

The result is indicated by the two color lines (bands): the control line in the control ("C") region of the test membrane, and the test line in the test ("T") region of the membrane.



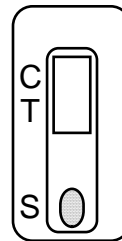
POSITIVE

Two pink-rose lines (bands) are visible in the control ("C") and test ("T") areas of the test window. The intensity of the test line may be less than that of the control line; this still means positive result. The sample should be considered to be IM positive.



NEGATIVE

The control line appears in the test window, but the test line is not visible. IM-associated antibody is not detected.



INVALID

The test is invalid if the control line is not visible at five minutes. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new testing device.

NOTE Do not interpret **InstaTest Mono** results after more than five minutes. To avoid confusion, discard the Testing Device after registering the test result at five minutes.

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