INFECTIONOUS MONONUCLEOSIS TESTING

Method: McKesson Infectious Mononucleosis Test

CLIA Complexity: Waived

Principle: The McKesson Infectious Mononucleosis Test detects infectious mononucleosis (IM) through visual reading of color band formation in the test device which is a membrane solid phase sandwich immunoassay. The device contains a membrane strip which is pre-coated with bovine erythrocyte extracted antigens on the test band region. During the test, a mixture of bovine erythrocyte extracted antigen, patient sample, and developer buffer will migrate to the test band region by capillary action. When the patient IM heterophile antibodies are present, a visible test line appears as the antibody binds with the antigen. If no IM heterophile antibodies are present in the sample, no visible color band will form in the test region. The formation of a colored band in the test region indicates a positive result.

A control band with different antigen / antibody reaction is also added to the membrane strip to indicate that the test has been performed properly and that the test device has worked properly. This control line should always appear regardless if the test region is positive or negative. A negative result will produce one colored band in the control region only; a positive result will produce two colored bands.

Materials:
- Disposable McKesson test device (20 per kit)
- Disposable sample dropper
- Developer Buffer; do not combine reagents from different lots
- Mono Negative Control: normal human plasma or serum diluted; 0.09% sodium azide
- Mono Positive Control: IM heterophile antibody positive human plasma or serum diluted; 0.09% sodium azide
- Finger lancets or blood collection tubes: purple (EDTA), blue (citrate) or green (heparin).

Patient specimen: fingerstick blood or EDTA lavender-top tube.

PRECAUTIONS:
1. For in-vitro diagnostic use only
2. Potential Biohazardous Material capable of transmitting disease
3. Sodium azide may react with lead or copper plumbing to form metal azides that may be explosive. Large quantities of water should be used to flush reagents down the sink.
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Specimen: Whole Blood
1. Collect whole blood into a purple top Vacutainer (with EDTA), blue top (with citrate) or green top (with heparin) collection tube by venipuncture.
2. The whole blood may be used for testing immediately or may be stored at 2 - 8°C up to three days.
3. Do not use grossly hemolyzed samples.

Fingerstick
1. Clean the area to be lanced with an alcohol swab. Allow to dry.
2. Gently squeeze the end of the fingertip and pierce with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Use disposable pipet provided to collect and deliver about 40 µl (two full drops) fresh blood into the sample well.

Procedure:
1. Test device, developer, patient samples and controls should be brought to room temperature (20 - 30°C) prior to testing.
2. Remove the test device from the protective pouch. Use as soon as possible.
3. Label the test device with patient or control identification. When a new kit is opened, positive and negative controls must be run with patient specimen.
4. Add specimen to sample well:
   Whole blood in collection tube: aspirate blood from patient sample (EDTA tube) with the provided transfer pipet and add 2 full drops (about 40 µl) into the sample well, holding the pipet in a vertical position.
   Fingertip blood: touch the end of the capillary tube to the blood until filled to the red line. Place bulb on end of capillary tube and squeeze bulb to dispense whole blood into the sample well.
5. Add 1 drop of Sample Buffer into the sample well.
6. Read the result in 5 minutes. Do not interpret the results after 10 minutes. Strong positive results may be observed sooner.

Interpretation of Results

POSITIVE: Two red colored bands appear - one in test region “T” and one in control region “C”. Any shade of red should be considered positive.

NEGATIVE: Only one red colored band appears in the control region “C”. No colored band appears in the test region “T”.

INVALID: No colored band appears in control region “C”. Improper test procedure may have been used, or reagents may have deteriorated. Read procedure again and repeat test with a new device. Call Technical support if invalid result is obtained again. (866) 288-7653.
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Quality Control:
Internal Procedural Control
1. A procedural control is included in the test. A red band appearing in control region “C” indicates that the test has been performed properly and the device has functioned properly.

2. A clear background in the result window is considered an internal negative control. However, when whole blood samples are tested, the background may appear slightly reddish because of some hemolysis of red blood cells. This is acceptable as long as it does not interfere with the reading of the test. The test is invalid if the background does not clear and obscures the reading of the test result.

External Quality Control
1. For each new test kit, run positive and negative controls and record in testing log.

Limitations
1. This test kit is used for the qualitative detection of IgM antibodies to Infectious Mononucleosis (IM) heterophile antigen. A positive result suggests the presence of IgM antibodies to heterophile antigen.
2. This test kit should be used for patients with symptoms suspicious of Infectious Mononucleosis. Diagnosis of IM should be made by confirmation with other clinical findings.
3. A negative result does not rule out the possibility of IM because the antibodies to heterophile antigen may be absent or may not be present in quantity high enough to be detected.
4. Grossly hemolyzed samples will yield invalid results.

Expected Values:
1. During the acute phase of IM, heterophile antibodies are detectable in 80 – 90% of patients. Heterophile antibodies can be detected in 60 - 70% of patients during the first week of clinical illness.
2. Epstein-Barr virus infection during young adulthood causes infectious mononucleosis 35% to 50% of the time.
3. Some people who contract IM do not produce a measurable level of heterophile antibodies.

Interference: No significant interference from visibly hemolyzed, lipemic and icteric samples. Do not use grossly hemolyzed blood specimens.

References:

Product insert, McKesson Medical-Surgical Richmond, VA 23228 U.S.A. 1-866-288-7653.