Infectious Mononucleosis IM Cassette Test

RAPU04A830
INTENDED USE
The DIAsource Infectious Mononucleosis Test is a rapid chromatographic immunoassay for the qualitative detection of Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma as an aid in the diagnosis of Infectious Mononucleosis.

SUMMARY
Infectious Mononucleosis (IM) is caused by the Epstein-Barr virus, which is a member of the herpes virus family. Symptoms of IM are fever, sore throat and swollen lymph glands. In very rare cases, heart or central nervous system problems may occur. Diagnosis of IM is made based on the presence of heterophile antibodies. Infectious Mononucleosis heterophile antibodies belong to the IgM class. They are present in 80-90% of acute IM cases and can be detected in 60-70% of patients during the first week of clinical illness. This test is intended for professional use as an aid in the diagnosis of IM. The DIAsource IM Test is a chromatographic immunoassay for the qualitative detection of antibodies against IM in serum, plasma or whole blood.

MATERIALS

MATERIALS PROVIDED

<table>
<thead>
<tr>
<th>CARD</th>
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<tbody>
<tr>
<td>DIAsource Test cassette with sample dropper in foil pouch (20 per kit box)</td>
</tr>
<tr>
<td>CONTROL +</td>
</tr>
<tr>
<td>Positive control (1 per kit box)</td>
</tr>
</tbody>
</table>

| BUF |
| Buffer (1 per kit box) |
| Instructions (1 per kit box) |

MATERIALS REQUIRED BUT NOT PROVIDED

| Stop watch |

PRECAUTIONS
The DIAsource IM Test must be stored at 4-30°C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

SPECIMEN COLLECTION
Whole Blood specimen collection
Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested within 24 hours of drawing. If not tested immediately after drawing, the sample must be kept at 2-8°C.

Plasma/Serum specimen collection:
1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested they should be refrigerated at 2-8°C. For storage periods greater than three days, freezing is recommended.
3. Specimens containing precipitate may yield inconsistent test results. Let the precipitate settle and use the supernatant for testing.

WARNINGS
- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test if the pouch is damaged or the seal is broken.

PROCEDURE
1. Remove the test cassette from the foil pouch, and place it on a flat, clean and dry surface.
2. Holding the sample dropper above the test cassette squeeze 1 drop of specimen (or control) into the sample well.
3. Then add 2 drops of the buffer. As the test begins to work, you will see purple coloured front move across the Result Window in the centre of the test cassette.
4. Interpret test results at 5 minutes. Do not interpret test result after more than 10 minutes.
**Caution:** The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be appropriately increased.

**INTERPRETATION OF RESULTS**

- A coloured line will appear in the section of the result window marked with “C” to show that the test is working properly. This line is the Control Line.
- The section of the result window marked with “T” indicates the test results. If another coloured line appears here, this line is the Test Line.

**Positive Result:** The presence of two coloured lines (“T” line and “C” line) in the result window regardless of which line appears first indicates a positive result (Figure 1). **Note:** Generally, the higher the analyte level in the specimen, the stronger the “T” line colour will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the colour of the “T” line will be very faint.

**Negative Result:** The presence of only one purple coloured line in the result window indicates a negative result (Figure 2).

**Invalid:** If after performing the test no purple coloured line is visible in the Result Window, or only one at “T”, the result is considered invalid (Figure 3 and 4). Causes of invalid results could be not following the directions correctly or using a test, which is beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit. **Note:** A positive result will not change once it has been established at 5 minutes. However, in order to prevent any false positives, the test should not be interpreted after more than 10 minutes.

**USER QUALITY CONTROL**

It is recommended that the positive control is tested as good laboratory testing practice.

**LIMITATIONS OF THE TEST**

Although the DIAsource IM Test is very accurate in detecting anti-IM IgM antibodies, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.

As with all diagnostic tests, a definitive clinical diagnosis must not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

**SPECIFICITY AND INTERFERENCE STUDY**

An in-house study was conducted with 3 separate lots of the DIAsource IM Test. Compounds tested included: Serum with triglyceride concentrations up to 500 mg/ml, Serum with Bilirubin concentrations up to 10 mg/100ml, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml.

All of the above were analyzed and did not show interference or cross reactivity with the test.

**REFERENCES**

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<thead>
<tr>
<th><strong>Consult instructions for use</strong></th>
<th><strong>Manufacturer</strong></th>
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<tbody>
<tr>
<td><strong>Storage temperature</strong></td>
<td><strong>Contains sufficient for n tests</strong></td>
</tr>
<tr>
<td><strong>Use by</strong></td>
<td><strong>IVD</strong> In vitro diagnostic medical device</td>
</tr>
<tr>
<td><strong>LOT Batch code</strong></td>
<td><strong>REF</strong> Catalogue number</td>
</tr>
<tr>
<td><strong>CARD Card Test</strong></td>
<td><strong>BUF</strong> Buffer</td>
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<tr>
<td><strong>CONTROL Positive Control</strong></td>
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