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MONOSPOT® Latex

REF Catalog No. 776150 IVD For *in vitro* diagnostic use only

INTENDED USE

MONOSPOT® Latex is a one step rapid latex particle agglutination test for the qualitative and semiquantitative determination of infectious mononucleosis heterophile antibodies in serum or plasma. MONOSPOT Latex aids in the diagnosis of infectious mononucleosis.

EXPLANATION

Infectious mononucleosis is an acute infectious disease of viral etiology. The most frequent symptoms are fever, sore throat, tender lymphadenopathy, anorexia, malaise, headache and myalgia. Splenomegaly occurs in most patients. A macular, maculopapular or petechial rash occurs in up to 50% of the cases, but such rashes occur most commonly in patients who have been treated with ampicillin.

The complications of infectious mononucleosis include secondary bacterial pharyngitis, rupture of the spleen, autoimmune hemolytic anemia, autoimmune thrombocytopenia, myocarditis, hepatitis and central nervous system involvement with meningoencephalitis or transverse myelitis. Fatal fulminant infectious mononucleosis or acquired hypogammaglobulinemia is rarely seen.

The diagnosis made on clinical history and symptomatology alone is difficult. Numerous cases in which infectious mononucleosis has been misidentified with other non-related viral and bacterial diseases have been cited[1]. For this reason, hematologic and serologic tests are very helpful in diagnosis. In 1932, Paul and Bunnell[2] noted that sera from patients with infectious mononucleosis have heterophile antibodies to sheep erythrocytes. Also described were agglutinins to red blood cells from other mammals[3,4].

The proteins responsible for this agglutination are glycoproteins from red cell membranes called Paul-Bunnell antigen by several authors. Studies made on these glycoproteins show that those purified from bovine red blood cells are the most sensitive to infectious mononucleosis heterophile antibodies. Heterophile antibodies to sheep erythrocytes (which are different from those present during infectious mononucleosis), may also be detected in sera from normal people, from individuals who have received injections of serum, and others[3,5].

Traditionally the infectious mononucleosis heterophile antibodies have been distinguished from other heterophile antibodies by a "differential" absorption test[6,7] with bovine red blood cells and guinea pig kidney tissue.

Now, the use of the purified Paul-Bunnell antigen attached to latex particles provides a simple method with improved sensitivity for the specific detection of heterophile antibodies associated with infectious mononucleosis.

In 1968 the etiologic agent of infectious mononucleosis was described[8]. It was called the Epstein-Barr virus (EBV), a member of the herpes virus group. Subsequently, several serologic techniques involving EBV-related antigens have been developed.

The mode of transmission of infectious mononucleosis appears to be intimate salivary contact, salivary contamination of eating and drinking vessels and airborne dissemination of EBV[9].

BIOLOGICAL PRINCIPLE

The MONOSPOT Latex reagent is a suspension of polystyrene latex particles of uniform size coated with highly purified Paul-Bunnell antigen from bovine red cell membranes. The degree of purity of the antigen is such that MONOSPOT Latex only reacts with infectious mononucleosis heterophile antibodies. For this reason, "differential" absorptions are not necessary. Latex particles allow visual observation of the antigen-antibody reaction. If infectious mononucleosis heterophile antibodies are present in either serum or plasma, the latex suspension changes its uniform appearance and a clear agglutination becomes evident.

MATERIALS PROVIDED

Latex Reagent (1.5ml) - Suspension of polystyrene latex particles coated with Paul-Bunnell antigen in a buffer. Contains sodium azide 0.1%.
Positive Control (1.0ml) - Diluted positive human serum. Contains sodium azide 0.1%.
Negative Control (1.0ml) - Nonreactive diluted human serum. Contains sodium azide 0.1%.
Pipetstirs
Test Slides

MATERIALS REQUIRED BUT NOT PROVIDED

Normal saline (0.9% NaCl, only for semiquantitative technique)
Automatic pipettes
Timer

PRECAUTIONS

MONOSPOT Latex is intended for *in vitro* diagnostic use only.
The reagents in this kit contain sodium azide as a preservative. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
WARNING: POTENTIALLY BIOHAZARDOUS MATERIAL.
Each donor unit used in the preparation of this material was tested by an FDA approved method for the presence of the antibody to HIV as well as for hepatitis B surface antigen and found to be negative.
Because no test method can offer complete assurance that Human Immunodeficiency Virus (HIV), hepatitis B virus, or other infectious agents are absent, the controls of this kit should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual[10].

RISK AND SAFETY PHRASES

CONTROL SERA: HARMFUL – SODIUM AZIDE

RISK PHRASES:
22 Harmful if swallowed.
32 Contact with acids liberates very toxic gas.

STABILITY AND STORAGE

The Latex Reagent and the controls will remain stable through the expiration date shown on the label if stored between 2° and 8°C. Do not freeze. The reagents can be damaged by improper handling,especially temperature extremes. Checking the Latex Reagent with the positive and negative controls provided will permit detection of reagent deterioration. The reagents should not be used after the expiration date shown on the label. The Latex Reagent, once shaken, must be uniform without visible clumping. When stored, a slight sedimentation may occur and should be considered normal. Do not use the Latex Reagent or controls if they become contaminated. The reagent dropper dispenses drops of 28µl ±10%. The dropper must be held perpendicular to the slide surface and a single drop allowed to fall. Do not use another dropper without previously checking the volume of the drop.

SAMPLE COLLECTION

SERUM:

Use fresh serum collected by centrifuging clotted blood. If the test can not be carried out on the same day, serum may be stored between 2° and 8°C for no longer than 48 hours after collection. For longer periods the sample must be frozen (–20°C or below).

PLASMA:

Collect blood into a tube containing anticoagulant (EDTA). Other anticoagulants should be evaluated before use. Centrifuge to separate plasma from cellular elements. Test the specimen within 24 hours of blood collection.
Do not use hemolyzed or contaminated samples.

PROCEDURE

This test should be performed by qualified personnel per local regulatory requirements.

QUALITY CONTROL

Control of the latex reagent:

1. Before performing a set of determinations it is advisable to test the latex reagent with each of the controls, positive and negative, included in the kit.
2. Both controls should be used following the steps outlined in the QUALITATIVE TECHNIQUE.
3. The reaction between the Positive Control and the Latex Reagent should show a clear agglutination, different from the uniform appearance of the negative control. If no agglutination takes place, the test should be repeated, and the kit discarded if there is not positive reaction.

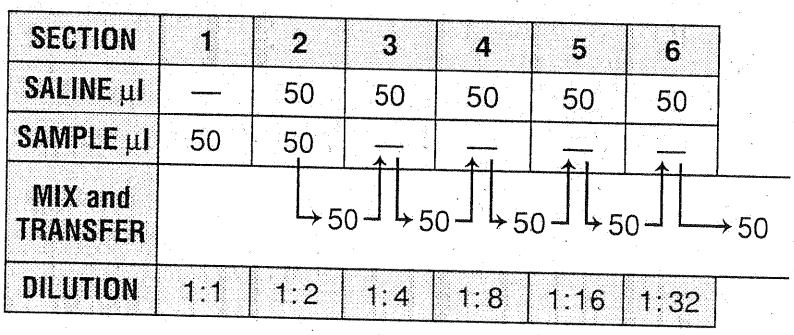
QUALITATIVE TECHNIQUE

1. Allow the Latex Reagent and controls to reach room temperature (20° to 30°C).
2. Gently shake the Latex Reagent vial to disperse and suspend the latex particles in the buffer solution. Vigorous shaking should be avoided.
3. Place 50µl of the sample on one section of the disposable slide.
4. Add a drop of Latex Reagent next to the drop of sample.
5. Mix both drops with a stirrer covering the whole surface of the slide section.
6. Gently rotate the slide for 3 minutes manually or on a rotary shaker set at 60-100 rpm.
7. Look for the presence or absence of agglutination after the aforementioned period of time.

SEMIQUANTITATIVE TECHNIQUE

Allow the Latex Reagent to reach room temperature (20° to 30°C). Prepare the sample dilutions on 2 slides (see descriptive diagram):

1. Place 50µl of normal saline on slide sections 2 through 6.
2. Using an automatic pipette, place 50µl of the sample on slide sections 1 and 2.
3. Using the same pipette, take in and release the sample and the normal saline in section 2 several times until they are well mixed.
4. Take 50µl of the mixture made on section 2 and transfer it to section 3.
5. Repeat the aforementioned operations to obtain a thorough mixing of reagents, transferring 50µl from section 4 and so on, in succession, through section 6, thereafter discarding 50µl.



6. Gently shake the Latex Reagent vial and place a drop on section 1 through 6 of the slides containing the different sample dilution.
7. Mix both drops using a stirrer covering the whole surface of the slide section.
8. Gently rotate the slide for 3 minutes manually or on a rotary shaker set at 60-100 rpm.
9. Look for the presence of agglutination after the aforementioned period of time.

INTERPRETATION OF RESULTS

QUALITATIVE TECHNIQUE

The presence of agglutination indicates a clinically significant concentration of infectious mononucleosis heterophile antibodies in the sample.

SEMIQUANTITATIVE TECHNIQUE

The approximate titer will correspond to the highest sample dilution that still presents a clearly visible agglutination (see diagram).

POSITIVE REACTIONS

3+ Large clumping with clear background.
2+ Moderate clumping with fluid slightly opaque in background.
1+ Small clumping with opaque fluid in background.

NEGATIVE REACTIONS

No visible clumping, uniform suspension.

LIMITATIONS OF THE PROCEDURE

1. As with all diagnostic assays, the results of the MONOSPOT Latex assay should be interpreted in light of the clinical symptoms shown by the patient.
2. Occasionally detectable levels of heterophile antibodies are late in developing in patients symptomatic for infectious mononucleosis. If symptoms persist it is recommended to repeat the assay in several days.
3. Although titers of heterophile antibodies have little relation with the severity of infection, the semiquantitative procedure can be used to follow the evolution of the disease.

EXPECTED VALUES

Studies[11,12] on the presence of infectious mono-nucleosis heterophile antibodies in blood donors show the incidence of the disease in from 0.9 to 1.7% of the population. As the presence of antibodies indicates a relatively recent infection these results suggest that the true incidence of the disease is higher than the diagnosed cases.

PERFORMANCE CHARACTERISTICS

Evaluations comparing MONOSPOT Latex to a commercially available differential hemagglutination test were performed to determine the sensitivity and specificity of the reagent[13]. A differential hemagglutination slide test was used to identify 106 positive and 114 negative sera for the study. Discrepancies between the results given by MONOSPOT Latex and the hemagglutination test were resolved using Epstein-Barr Virus (EBV) specific serological assays. In these assays, the titers of specific antibodies to the EBV capsid antigen (both IgG and IgM), EBV early antigen (both diffused -D- and restricted -R-) and EBV nuclear antigen were determined. The results of these assays specified whether EBV infections were recent or acute, (in which case the sera was considered positive), or if antibodies were absent or relics of an old infection, (in which case the serum was considered negative).

Twelve of the 100 nondiscrepant positive sera and five of the 106 nondiscrepant negative sera were also analyzed using these same EBV specific serological assays. In all cases the EBV specific assay confirmed the positivity or negativity of the samples.

Compared with hemagglutination, MONOSPOT Latex was found to have a sensitivity of 94% and a specificity of 93%. Assuming that the concordant results of the EBV serology performed on nondiscrepant sera applies to all the samples tested, it can be inferred that the sensitivity of MONOSPOT Latex relative to EBV specific tests is 99% and its specificity relative to the same is 93%.

There was only one result negative with MONOSPOT Latex, and positive with EBV serology. It was determined to be a recent infection and not an acute infection due to the absence of anti-VCA IgM and nuclear antigen. For this reason this negative result can not be interpreted as prozone effect.

In a separate study MONOSPOT Latex was compared to a qualitative horse red cell slide test involving a total of 224 EDTA plasma samples. There was complete agreement in test results which included 51 positive and 173 negative samples. Overall, the results of this study indicate clearly that MONOSPOT Latex is highly sensitive and specific for the diagnosis of infectious mononucleosis.

A panel of 10 positive serum samples was tested on three consecutive days using the semiquantitative technique. The results of the study indicate that MONOSPOT Latex has 100% precision. The error of repeated titrations was expected to be only one doubling dilution.

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LOT	Batch Code/Lot Information	CE	CE Symbol

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