INFECTIOUS MONONUCLEOSIS

Latex agglutination

REF. 7746 50 tests with controls and accessories

CE IVD

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of heterophile antibodies.

PRINCIPLE

Slide agglutination test for the qualitative and semiquantitative detection of heterophile antibodies specific for infectious mononucleosis.

Latex particles coated with antigenic extract of beef erythrocytes membranes are agglutinated when mixed with samples containing IM heterophile antibodies.

SAMPLE

Fresh Serum. Stable 8 days at 2-8°C or 3 months at -20°C.

Samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolized or lipemic samples.

KIT COMPONENTS

Reagent (A) I.M. Latex Volume = 2.5 ml	Latex particles coated with antigenic extract of beef erythrocytes membranes, phosphate buffer, pH 7.2. Preservative.
Control (+) I.M. Volume = 0.5 ml	Human serum with anti-IM antibodies titer 1/4 . Preservative
Control (-) I.M. Volume = 0.5 ml	Animal serum. Preservative
Stirrers	1 pz
Reaction Slide	1 pz

The Reagents are stable until the expiration date printed on the label, when stored tightly closed at 2-8°C. Once opened, the reagents are stable one month at 2-8°C if contamination is avoided. Do not freeze.

Keep bottles closed when not in use.

REAGENT PREPARATION

All the kit components are ready to use.

PREPARATION REAGENT

Biological risk for Control (+)

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Use the normal precautions required in the laboratory.

Components from human origin have been tested and found to be negative for the presence of HbsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

Dispose of waste according to local laws.

PROCEDURE

Qualitative Method:

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Mix gently the latex.

Dispense 50 µl of serum upon a selected spot of the reaction slide, add one drop of latex and accurately mix with a stirrer paying attention to uniformly distribute the liquid on the selected spot. Rotate the slide and observe within 2 minutes possible agglutination. Evident agglutination indicates positive result. No agglutination indicates negative result.

False positive results could appear if test is read later than 2 minutes.

Semi-quantitative method:

Make serial two fold dilutions of the sample in saline solution.

Proceed for each dilution as in the quantitative method.

READING AND INTERPRETATION

Examine the presence or absence of visible agglutination.

The presence of agglutination indicates a titer ≥ 1/28 of the specific anti-IM antibodies by the Davidsohn method.

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

EXPECTED VALUES

A positive result indicates a specific response to infectious mononucleosis heterophile antibodies, which may be present as early as the fourth day of the disease, thus providing a positive diagnostic result, and last for several months.

QUALITY CONTROL

Positive and Negative Controls are recommended to monitor the performance of the reagent and to have a better results interpretation.

PERFORMANCE

Sensitivity: titer equal to 1/28 by the Davidsohn method.

Prozone effect: No prozone effect was detected up to 1/256 titer

Diagnostic sensitivity: 100 %

Diagnostic specificity: 100 %

Interferences: bilirubin does not interfere up to 20 mg/dl. Hemoglobin and lipemia do not interfere up to 10 g/l, Rheumatoid factors up to 300 U/ml does not interfere.

METHOD LIMITATIONS

Patients suffering from leukemia, Burkitt's lymphoma, pancreatic carcinoma, viral hepatitis, CMV infections and others, can result false positive reactions. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

NOTE

Heterophile antibodies that usually, but not always, appear in sera of patients suffering from Infectious Mononucleosis are IgM immunoglobulins.

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