CHRONOLAB

CE

IVD

IM-LATEX
Slide agglutination
Quantitative determination of heterophile antibodies.

PACKAGING

Ref.: 101-0600 50 tests	Cont.: 2,5 mL IM-Latex 1 mL Control + / 1 mL Control - 9 x 6 disposable slides

Store at 2 - 8º C.

CLINICAL SIGNIFICANCE

Infectious mononucleosis is a viral disease caused by the Epstein-Barr virus that affects the reticuloendothelial system and has a broad spectrum of clinical presentations, ranging from asymptomatic to severe. The patients usually develop transient IgM heterophile antibodies, have an abnormal white cell picture, and abnormal liver function.
Disease diagnostic is obtained through the detection of HE antibodies or Paul-Burnell antibodies, or antibodies anti- viral structural antigens. The former generally decrease along the disease course, while the later remain along the patient life.

PRINCIPLE OF THE METHOD

The IM-latex is a slide agglutination test for the qualitative and semi-quantitative detection of heterophile antibodies (HE) specific for infectious mononucleosis (IM).

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

REAGENTS

Latex	Latex particles coated with antigenic extract of beef erythrocytes membranes, phosphate buffer, pH 7.2. Preservative
Control + Red cap	Animal serum with an anti-IM antibodies titer ≥1/4. Preservative
Control - Blue cap	Animal serum. Preservative

CALIBRATION

The reagent sensitivity has been standardized against an Internal Control by comparing methods with the Davidsohn method.

STORAGE AND STABILITY

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Mix reagents gently before use.
Do not freeze: frozen reagents could change the functionality of the test.
Reagents deterioration: Presence of particles and turbidity.

SIGNS OF REAGENT DETERIORATION

Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pippetes 50 µL.

SAMPLES

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
Samples with presence of fibrin should be centrifuged.
Do not use highly hemolized or lipemic samples.

PROCEDURE

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the IM-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the samples to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

Chronolab Systems has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
All result different from the negative control result, will be considered as a positive.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
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.

PERFORMANCE CHARACTERISTICS

1. Analytical sensitivity: Titer equal to 1/28 by the Davidsohn method, under the described assay conditions.
2. Prozone effect: No prozone effect was detected up to 1/256 titer.
3. Diagnostic sensitivity: 100 %.
4. Diagnostic specificity: 100 %.

INTERFERENCES

Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (10 g/L) and rheumatoid factors (300 IU/mL), do not interfere. Other substances may interfere[7].

LIMITATIONS OF THE PROCEDURE

- False positive results may be obtained in some geographical areas where the "horse serum" is used as a prophylactic measure (vaccination).
- Patients suffering from leukemia, Burkitt's lymphoma, pancreatic carcinoma, viral hepatitis, CMV infections and others, can result false positive reactions.
- False negative results have been reported in cases of IM which persistently remain seronegative for IM heterophile antibodies or as a consequence of a delay IM heterophile antibodies response. In this case, repeat testing samples obtained at intervals of several days.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

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