Reactivos GPL

Barcelona, España

CE

-IM LATEX-

I.M. LATEX

Slide agglutination.

Store at: +2+8ºC.

Presentatión:
Cod. SE023 50 Test.

Procedure

Diagnostic reagent for qualitative measurement of Infectious Mononucleosis antibodies.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY

The IM-latex agglutination 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 COMPOSITION

Latex	Latex particles coated with antigenic extract of beef erythrocytes membranes, phosphate buffer, ph 7.2. Sodium azide, 0.95 g/l.
Control (+) 1 mL	Human serum with an anti-im antibodies titer ≥1/4. Sodium azide, 0.95 g/l.
Control (-) 1 mL	Animal serum. Sodium azide 0.95 g/L.

PRECAUTIONS

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

Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY

All the components are ready to use.
Do not use reagents over the expiration date.
Do not freeze; frozen reagents could change the functionality of the test.
If appear particles and turbidity do not use.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8ºC. Do not use reagents over the expiration date.

CALIBRATION

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

SPECIMEN

Fresh serum. Stable 8 days at 2-8ºC or 3 months at –20ºC.
The samples with particles or fibrin should be centrifuged to eliminate them.
Do not use haemolized or lipemic samples.

Discard contaminated specimen.

MATERIAL REQUIRED BUT NOT PROVIDED

Mechanical rotator with adjustable speed at 80-100 r.p.m.

General laboratory equipment

TEST PROCEDURE

Qualitative method

1. Allow the reagents and sample 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 control into separate circles on the slide test.
3. Shake the IM-latex reagent gently before using and add a drop of this reagent next to the sample to be tested.
4. Mix both drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Rotate the slide with 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.

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.

CALCULATIONS

The approximate ASO concentration in the patient sample is calculated as follows: 200 x ASO Titer = IU/mL

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.

Serum controls ASO are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

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 have abnormal liver function.
Disease diagnostic is obtained through the detection of HE antibodies or Paul-Bunnell antibodies, or antibodies anti- viral structural antigens. The former generally decrease along the disease course, while the later remain along the patient life.

REAGENT PERFORMANCE

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

INTERFERING SUBSTANCES

Interferences:
- Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (10 g/L), rheumatoid factors (300 IU/mL) do not interfere.
- Other substances may interfere7.

LIMITATIONS OF THE PROCEDURE

1. False positive results may be obtained in some geographical areas where the "horse serum" is used as a prophylactic measure (vaccination).
2. Patients suffering from leukemia, Burkitt's lymphoma, pancreatic carcinoma, viral hepatitis, CMV infections and others, can result false positive reactions.
3. 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.
4. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

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