CORMAY IM Latex

AGGLUTINATION TEST FOR DETECTION OF HETEROPHILE ANTIBODIES (HE) SPECIFIC FOR INFECTIOUS MONONUCLEOSIS

Kit name	Kit size	Cat. No
CORMAY IM Latex 20	20 tests	6-261
CORMAY IM Latex 50	50 tests	6-262

INTRODUCTION

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 heterophile antibodies (HE) 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.

METHOD PRINCIPLE

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

REAGENTS

Package

	CORMAY IM Latex 20	CORMAY IM Latex 50
IM-Latex	1 x 1 ml	1 x 2.5 ml
IM-Control (+) (red cap)	1 x 0.5 ml	1 x 1 ml
IM-Control (-) (blue cap)	1 x 0.5 ml	1 x 1 ml
Stirrers	1 x 25 pcs.	1 x 25 pcs.
Slides (6 circles each)	1 x 4 pcs.	1 x 9 pcs.

Reagent preparation and stability

The reagents are ready to use.

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. Do not freeze.

Concentrations in the test

latex particles coated with antigenic extract of beef erythrocytes membranes	50 mmol/l
human serum solution	150 mmol/l
animal serum solution	150 mmol/l
sodium azide	< 0.1 %

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- 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.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.
- 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.
- Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

ADDITIONAL EQUIPMENT

- mechanical rotator with adjustable speed at 80-100 r.p.m.
- general laboratory equipment.

SPECIMEN

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.
It is recommended to perform the assay with freshly collected samples.

PROCEDURE

The test is recommended for the qualitative and semi-quantitative manual assay.

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. Swirl the IM-Latex reagent gently before using and add one drop (50 µl) next to the sample 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.

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 the specific anti-IM antibodies.

Semi-quantitative method

1. Make serial two fold dilutions of the sample in 0.9% NaCl solution.
2. Proceed for each dilution as in the qualitative method.

Reading and interpretation

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

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.

PERFORMANCE CHARACTERISTICS

- **Analytical sensitivity:** titer equal to 1/28 by the Davidsohn method.
- **Prozone effect:** no prozone effect up to 1/256 titer.
- **Diagnostic sensitivity:** 100%.
- **Diagnostic specificity:** 100%.
- **Interferences:**
  Haemoglobin up to 10 g/l, bilirubin up to 20 mg/dl, triglycerides up to 10 g/l and RF up to 300 IU/ml do not interfere with the test.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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