IM-Latex CE

CONTENTS

REF	2720005	IM-Latex	50 Tests

For *in vitro* diagnostic use only

IM-Latex
Determination of heterophile antibodies
SLIDE TEST

PRINCIPLE

IM-Latex Test is a rapid slide agglutination procedure, developed for the direct detection of heterophile antibodies (HE) of infectious mononucleosis (IM) in human serum or plasma.

The assay is performed by testing a suspension of latex particles coated with antigenic extract of beef erythrocytes membranes against unknown samples. The presence or absence of a visible agglutination, indicates the presence or absence of HE in the sample tested.

REAGENT COMPOSITION

R — **IM-Latex Reagent**. Suspension of polystyrene latex particles coated with antigenic extract of beef erythrocytes membranes in a buffered saline solution. Contains 0.95 g/L of sodium azide.

CONTROL + — Human serum with an anti-IM antibodies titer ≥1/4. Contains 0.95 g/L of sodium azide.

CONTROL - — Animal serum. Contains 0.95 g/L of sodium azide.

Precautions: Components of different human origin have been tested and found to be negative for the presence of antibodies anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.

Warning: The reagents in this kit contain sodium azide. Do not allow to contact with skin or mucous membranes.

PACKAGING CONTENTS

REF — 2720005 kit 50 tests.
1x 1.4 mL IM-Latex Reagent, 1x 1 mL Positive control, 1x 1 mL Negative control, 9 Test cards and 1 x 50 disposable pipettes.

STORAGE AND STABILITY

Store at 2-8ºC. Do not freeze. Frozen reagents could change the functionality of the test.

Reagent and Controls are stable until the expiry date stated on the label.

REAGENT PREPARATION

Reagent and Controls are ready to use.

SAMPLES

Fresh, clear serum or plasma-EDTA.

Samples should be stored at 2-8ºC up to one week or for longer periods at –20ºC.

Other anticoagulants should be tested before use.

MATERIAL REQUIRED

- Automatic pipettes.
- Saline solution (0.9% NaCl, only for semi-quantitative procedure).
- Mechanical rotator, adjustable at 100 r.p.m.
- Laboratory alarm clock.

PROCEDURE

I. Qualitative Test

1. Bring the test reagents and samples to room temperature (Note 1).
2. Resuspend the antigen vial gently. Aspirate dropper several times to obtain a thorough mixing.
3. Place 1 drop (50 µL) of the sample under test into one of the circles on the card. Dispense 1 drop of positive control and 1 drop of negative control into two additional circles.
4. Add 1 drop of IM-Latex Reagent to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable pipette while spreading over the entire area enclosed by the ring. Use separate pipettes for each mixture.
6. Rotate the slide slowly by means of a mechanical rotator (100 r.p.m.) for a period of **3 minutes** (Note 2).
7. Observe immediately under a suitable light source for any degree of agglutination.

Reading

Nonreactive: Smooth suspension with no visible agglutination, as shown by negative control.

Reactive: Any degree of agglutination visible macroscopically.

II. Semi-quantitative Test

1. For each specimen to be tested place with an automatic pipette 50 µL of 0.9% saline solution into each of the circles of a card. Do not spread diluent.
2. To circle one add 50 µL of specimen to the saline solution and, using the same tip, mix the saline solution with the sample by repeated aspiration and expulsion of the fluid and transfer 50 µL of the mixture to the saline solution in the second circle.
3. Continue with the 2-fold serial dilutions in a similar manner up to the sixth circle, and discard 50 µL from this circle . Final sample dilutions will be: 1:2, 1:4, 1:16, 1:32, 1:64.

Test each dilution as described in steps 4-7 for the Qualitative Test.

Reading

Same as in Qualitative Test. The titer of the specimen is reported as the highest dilution that shows reactivity. The next higher dilution should be negative (Note 3).

If the highest dilution tested is reactive repeat the test starting with a preliminary 1:16 dilution. Use a 1:50 dilution of negative control in 0.9% saline solution to replace the 0.9% saline solution in the new 2-fold dilution series.

QUALITY CONTROL

Positive and negative controls should be run daily following the steps outlined in the Qualitative Test, in order to check the optimal reactivity of the reagent.

The positive control should produce clear agglutination. If the expected result is not obtained, do not use the kit.

EXPECTED VALUES

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

CLINICAL SIGNIFICANCE[1-6]

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 non-symptomatic 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.

ANALYTICAL PERFORMANCES

− The analytical sensitivity corresponds to a 1/28 titer by the Davidsohn method, under the described assay conditions.
− Diagnostic specificity : 100%.
− Prozone effect: No prozone effect was detected up to a titer of 1/256.
− Results obtained with this reagent did not show significant differences when compared with reference reagents. Details of the comparison experiments are available on request.
− The hemoglobin (<10 g/L), bilirubin (<20 mg/L), lipemia (< 10 g/L) and rheumatoid factors (<300 IU/mL), do not interfere. Other substances may interfere[7].

LIMITATIONS OF THE PROCEDURE

− Positive reactions do occur in conditions other that IM such as in some geographical areas where the "horse serum" is used as a prophylactic measure (vaccination), or patients suffering from leukemia, Burkitt's lymphoma, pancreatic carcinoma, viral hepatitis, CMV infections and others.
− 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.

NOTES

1. The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15-25ºC.

2. Delays in reading the results may generate in over-estimation of the antibody present.

SOURCES OF ERROR

− Bacterial contamination of controls and specimens as well as freezing and thawing of the IM-Latex Reagent may lead to false positive results.
− Traces of detergent in the test cards may give false positive results. Wash used cards first under tap water until reactants are removed and then with distilled water. Allow to dry in air, avoiding the use of organic solvents as they may impair the special finish on the slide.
− The IM-Latex Reagent must not be used beyond its expiry date because a prolonged storage can affect the sensitivity of the suspension.

REFERENCES

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