todylaboratories®

Latex Reagents

CE **IM-Latex**

Slide agglutination
Qualitative determination of heterophile antibodies

IVD *For in -vitro diagnostic use only*
Store at 2 - 8º C.

PRODUCT CODE: C12LX1005-050 (50 tests)
C12LX1005-100 (100 tests)

INTENDED USE
For the detection of Infectious Mononucleosis (IM) in serum.

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 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.

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.

MATERIALS
MATERIALS PROVIDED:
- IM Latex Reagent: Latex particles coated with antigenic extract of beef erythrocytes membranes, phosphate buffer, pH 7.2. Sodium azide, 0.95 g/L.
- IM Positive Control Serum: Human serum with an anti-IM antibodies titer ≥1/4. Sodium azide, 0.95 g/L.
- IM. Negative Control Serum: Animal serum. Sodium azide, 0.95 g/L.
- Stirring sticks.
- Reaction slide.
- Package Insert.

MATERIAL REQUIRED BUT NOT PROVIDED:
- Timer.
- Serological pipette.

PRECAUTIONS
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.

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. Do not freeze: frozen reagents could change the functionality of the test.
Reagents deterioration: Presence of particles and turbidity.

SAMPLES
Fresh serum: Stable for7 days at 2-8 º C or 3 months at –20 º C.
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 40 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 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. Rock slide gently for two minute with a slight left and right rotation, 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 right rotation.
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.

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
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.

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.

BIBLIOGRAPHY

1. Summaya CV et al. Manual of Clinical Laboratory Immunology, 4th ed, p 568. Wasington DC ASM, 1992.
2. Merlin JR et al. Human Pathol, 1986; 17: 2.
3. Paul JR et al. AM J Med Sci 1932; 183: 90.
4. Andiman WA. Manual of Clinical Laboratory Immunology, 3rd ed, p 509. Wasignton, DC AMS 1986.
5. Henle W et al. Huma Path 1974; 5: 551.
6. Barbara A Levey et al. Journal of Clinical Microbiology 1980: 11: 256-262.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

Rev. aug 2016 lo / amc 30.03.2018

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REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if package is