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INFECTIOUS MONONUCLEOSIS

QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION
LATEX AGGLUTINATION SLIDE TEST

IVD CE

Packaging
REF. N° SH070 **50 Tests**

Reaction principle
The INFECTIOUS MONONUCLEOSIS is a slide agglutination test for the qualitative and semiquantitative detection of heterophile antibodies (HE) specific for infectious mononucleosis.
Latex particles coated with antigenic extract of beef erythrocytes membranes are agglutinated when mixed with samples containing IM heterophile antibodies.

Reagents composition, Contents and Safety warnings
1. Latex Reagent 1x2.5 ml
Latex particles coated with bovine erythrocytes extract **-** Phosphate Buffer pH 7.2 - Sodium Azide 0.95 g/l

2. Positive Control * (red cap) 1x0.5 ml
Human serum containing anti - IM Antibodies titer ≥ ¼ - Sodium Azide 0.95 g/l

3. Negative Control (blue cap) 1x 0.5 ml
Animal serum non reactive with the latex

4. Reaction Slides 4

5. Plastic Stirrers 25

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).
Further information on the risks to health and / or the environment are given in the data sheet.

Storage and Stability of Reagents
Store the kit at 2 - 8°C. (do not freeze)

All the components are stable until the stated expiration date if stored tightly closed and refrigerated

Preparation and Stability of working solution
Latex Reagent	**liquid and ready to use**
Positive Control	**liquid and ready to use**
Negative Control	**liquid and ready to use**

Swirl the Latex reagent gently before using

Keep reagents at Room Temperature before use

Samples
Fresh serum (Do not use highly haemolized or lipemic samples)

Samples with presence of fibrin should be centrifuged

Serum may be stored at 2 - 8° C for 7 days, 3 months at - 20°C

Caution

BIOLOGICAL RISK
*** Each unit of source material used in the preparation of the Positive Control has been tested by a licensed method and found non reactive for HbsAg and negative for Antibodies to HCV and HIV 1/2.**
However no known test can offer complete assurance that products derived from human blood will not transmit Hepatitis, AIDS or other infectious diseases. This product, like all materials of human origin,should be handled as potentially infectious biological material

Safety Precautions
For in vitro diagnostic use only
Do not pipette by mouth
Exercise the nornal precautions required for handling laboratory reagents

Qualitative Procedure
Reagents	1ª reactive area Sample	2ª reactive area Positive Control	3ª reactive area Negative Control
Sample	1 drop (~ 50 µl)	-	-
Positive Control	-	1 drop (~ 50 µl)	-
Negative Control	-	-	1 drop (~ 50 µl)
Latex reagent	1 drop (~ 50 µl)	1 drop (~ 50 µl)	1 drop (~ 50 µl)

Mix the two drops with a stirrer, spreading them over the entire surface of the circle. (Use one different stirrer for each reactive area).
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.

Results
The presence of agglutination within 2 minutes indicates an Antibodies concentration ≥ 1/28 (according Davidson method)

Positive samples should be titrated (see semiquantitative procedure)

Semiquantitative Procedure
Prepare serial dilutions of the sample with Saline Solution and proceed, for each dilution, as in the qualitative method.
The titre is defined as the highest dilution showing a positive result

Performance Characteristics
A. ANALYTICAL SENSITIVITY
1/28 (according Davidson method)

B. PROZONE EFFECT
No prozone effect was detected up to titre =1/256

C. DIAGNOSTIC SENSITIVITY
100%

D. DIAGNOSTIC SPECIFICITY
100%

E. INTERFERENCES
1. Haemoglobin till to10 g/l does not interfere
2. Bilirubin till to 20 mg/dl does not interfere
3. Lipids till to10 g/l do not interfere
4. Rheumatoid factors till to 300 IU/ml does not interfere
5. Other substances may interfere [7]

Quality control
Positive and Negative Control Sera should be run with each serie.
Their results should be compared with those of unknown specimen to distinguish possible agglutination

Limitations of the procedure
1. False positive results may be obtained in some geographical areas where the "horse serum" is used as a prophylatic measure (vaccination)
2. Patients suffering from leukemia, Burkitt's lymphoma, pancreatic carcinoma, viral hepatitis, CMV infectious 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.
   In this case, repeat testing samples obtained at intervals of several days.
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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