INSTRUCTIONS FOR USE

MONONUCLEOSI LATEX

LATEX TEST FOR SEROLOGIC DETECTION OF HETEROPHILE ANTIBODIES ASSOCIATED WITH INFECTIOUS MONONUCLEOSIS (I.M.)

1 – CLINICAL SIGNIFICANCE AND INTENDED USE

For ***in Vitro*** diagnostic use only

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 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.
The MONONUCLEOSI LATEX is a slide agglutination test for the qualitative and semiquantitative detection of heterophile antibodies (HE) specific for infectious mononucleosis (IM) from serum samples.

2 - PRINCIPLE OF THE METHOD

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

3 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
MONONUCLEOSI LATEX CND: W0105040402 EDMA: 15.90.90.01; RDM: 1555445/R	Latex agglutination test	**UB80710** (62 tests)	1 glass bottle containing latex for MONONUCLEOSI, Latex particles coated with antigenic extract of beef erythrocytes membranes, phosphate buffer, pH 7.2. Preservative. (3,1 mL = 62 tests) 1 glass bottle containing Positive Control: animal serum with an anti-IM antibodies titer ≥ 1/4 . Preservative. (0.5 mL) 1 glass bottle containing Negative Control: stabilized liquid control, contain Sodium azide <0.1% (0,5 mL) Slide, 6 test areas: plastic waterproof sheets for reaction (11 items) Sticks (1x25): plastic sticks for mixing (3 items) Secondary packaging: cardboard box.
MONONUCLEOSI LATEX CND: W0105040402 EDMA: 15.90.90.01; RDM: 1555455/R	Latex agglutination test	**UB80720** (250 tests)	4 glass bottles containing latex for MONONUCLEOSI, Latex particles coated with antigenic extract of beef erythrocytes membranes, phosphate buffer, pH 7.2. Preservative (4x3,1 mL = 250 tests) 1 glass bottle containing Positive Control: animal serum with an anti-IM antibodies titer ≥ 1/4 . Preservative. (0.5 mL 1 glass bottle containing Negative Control: stabilized liquid control, contain Sodium azide <0.1% (0,5 mL) Slide, 6 test areas: plastic waterproof sheets for reaction (42 items) Sticks (1x25): plastic sticks for mixing (10 items) Secondary packaging: cardboard box.
MONONUCLEOSI CONTROLLI CND: W01050801 EDMA: 15.50.01.90; RDM: 1555460/R	Controls for latex agglutination test	**UD80700** (2x0,5 mL)	1 glass bottle containing Positive Control: animal serum with an anti-IM antibodies titer ≥ 1/4 . Preservative. (0.5 mL) 1 glass bottle containing Negative Control: stabilized liquid control, contain Sodium azide <0.1% (0,5 mL) Secondary packaging: cardboard box.

4 - MATERIALS REQUIRED BUT NOT PROVIDED

Mechanical rotator with adjustable speed at 80-100 r.p.m. Timer or clock. *Pipettes 50 µL*

5 - PRECAUTIONS AND WARNINGS

- MONONUCLEOSI LATEX is a kit for *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel.
- The sensitivity of the test may be reduced at low temperatures. Allow the reagents and samples to reach room temperature (15-30ºC/59-86ºF) before use.
- Do not use after expiration date or if the packaging is damaged. The quality of the reagent cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.
- Normal precautions exercised in handling laboratory reagents should be followed. Dispose of waste observing all local, state, provincial or national regulations. Refer to Material Safety Data Sheet for any updated risk, hazard or safety information.
- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.masciabrunelli.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.
- Notify Mascia Brunelli Spa and the Relevant Authorities of any serious incidents occurring in connection with the in vitro diagnostic device. complaint@masciabrunelli.it

6 - STORAGE CONDITIONS AND SHELF LIFE

All the kit components 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*.
Mix reagents gently before use.
Reagents deterioration: Presence of particles and turbidity

7 – SPECIMENS COLLECTION

Fresh serum. Stable *7 days* at 2-8ºC or *3 months at –20ºC*. Do not use highly hemolysed or lipemic samples. *Samples with presence of fibrin should be centrifuged before testing*.

8 - TEST PROCEDURE

Allow the components of the kit to reach to room temperature (15-30ºC/59-86ºF) prior to testing.

Qualitative test

1. Gently shake the suspension for homogenization of the latex particles.
2. Always use positive and negative controls as references.
3. *Place 50 µL of undiluted serum and one drop or 50 µL of each Positive and Negative control in different area of the slide.*
4. Add 1 drop *or 50 µL* of Latex reagent at the drop of serum.
5. Mix 2 drops of the stretching over the entire surface of the circle with a stick. *Use different stick for each sample*
6. Spinning the slide, either manually or with a mechanical stirrer 80 to 100 rpm for 2 minutes. Read the presence or absence of visible agglutination within 2 minutes. Non-specific agglutination may appear if the test is read after 2 minutes.

Semiquantitative test

Runs in the same way as the qualitative test, but by making a dilution of the serum sample with saline (NaCl 9 g/L):

Dilutions	1:2	1:4	1:8	1:16
Serum / Sample	100 µl	...	...	...
Saline	100 µl	100 µl	100 µl	100 µl
	—	→ 100 µl		
		—	→ 100 µl	
			—	→ 100 µl
Sample Volume	50 µl	50 µl	50 µl	50 µl
Spinning the slide, either manually or with a mechanical stirrer 80 to 100 rpm for 2 minutes. Read the result within 2 minutes.				

9 – READING, INTERPRETATION AND CALCULATION

Qualitative test: The presence of agglutination indicates a titer in the sample ≥ 1/28 of the specific anti-IM antibodies by the Davidsohn method.

Semiquantitative tests: the titer is defined as the highest dilution showing a positive result.

10 – 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. All result different from the negative control result, will be considered as a positive.

11 – CHARACTERISTICS

- **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%
- **Interferences:** the follow substances not interfere: bilirubin (20 mg/L), hemoglobin (10 g/L), and lipemia (10 g/L). Rheumatoid factors (300 IU/mL), interfere. Other substances may interfere[7].

12 – LIMITATIONS OF THE METHOD

- 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.
- As with all diagnostic tests, a final diagnosis cannot rely on the outcome of a single test and must be supported by other clinical and laboratory data.
- The components of this I.v.D. were always tested together without compatibility with components from other manufacturers. While not excluding the possibility that these components can be used with components of the same formulation but produced by other companies, there is no experimental evidence of such compatibility.
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13 – REFERENCES

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

TABLE OF APPLICABLE SYMBOLS

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning	Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (DXXX)		Manufacturer		Keep dry	UDI	Unique device identifier
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 4	Updated layout and content	2022/08
Instructions for Use (IFU) – Revision 5	Update number of slides on REF. UB80710	2022/10

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.