INSTRUCTIONS FOR USE

PCR LATEX

LATEX AGGLUTINATION TEST ON SLIDE FOR QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP)

1 – CLINICAL SIGNIFICANCE AND INTENDED USE

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

CRP is a protein produced primarily in the liver in response to stimuli such as bacterial and fungal antigens and immune complexes, but also following trauma. PCR levels increase significantly following the presence of malignant neoplasms. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours. *The PCR LATEX is a slide agglutination test for the qualitative and semiquantitative detection of C- Reactive Protein (CRP) in human serum.*

2 - PRINCIPLE OF THE METHOD

Latex particles coated with goat IgG anti-human CRP are agglutinated when mixed with samples containing CRP. When CRP is present in the sample, the presence of agglutination indicates a content equal to or higher than CRP 6 mg/L, without dilution of the sample.

3 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
PCR LATEX CND: W0102160601 EDMA: 12.11.01.09; RDM: 1555471/R	Latex agglutination test	**UA80100** (62 tests)	1 glass bottle containing latex for CRP, with preservative. pH 8.2 (3,1 mL = 62 tests) 1 glass bottle containing Positive Control: human serum with a CRP concentration > 20 mg/L. (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.
PCR LATEX CND: W0102160601 EDMA: 12.11.01.09; RDM: 1555475/R	Latex agglutination test	**UA80110** (250 tests)	4 glass bottles containing latex for CRP, with preservative. pH 8.2 (4x3,1 mL = 250 tests) 1 glass bottle containing Positive Control: human serum with a CRP concentration > 20 mg/L. (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.
PCR CONTROLLI CND: W0102160601 EDMA: 12.11.01.09; RDM: 1555478/R	Controls for latex agglutination test	**UD80120** (2x0,5 mL)	1 glass bottle containing Positive Control: human serum with a CRP concentration > 20 mg/L. 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.

Latex
Danger
H360
P201; P202; P501
(Boric acid H_3BO_3)

Positive control
Warning
H317
P261; P2872; P501
(2-methyl-2H-isothiazol-3-one (Proclin 950))

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

- PCR LATEX is a kit for *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel.
- 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 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.
- This product is classified as dangerous according to current European legislation (view above table and consulting the MSDS).
- 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

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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 (Note 1) 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 content of CRP in the sample equal to or greater than 6 mg/L. *(Note 2)*The absence of agglutination indicates a level of CRP of less than 6 mg/L in the sample.

Semiquantitative tests: the titer is defined as the highest dilution showing a positive result. The approximate CRP concentration in the patient sample is calculated as follows

6 x CPR titer = mg/L

10 – Expected Values

≤ 6 mg/dL.. Each laboratory should establish its own reference range.

11 – Characteristics

- **Analytical sensitivity:** 6 (5-10) mg/L, under the described assay conditions.
- **Prozone effect:** no prozone effect was detected up to 1600 mg/L (Note 1).
- **Diagnostic sensitivity:** 95.6%
- **Diagnostic specificity:** 96.2%
- **Interferences:** the follow substances not interfere: bilirubin (20 mg/L), hemoglobin (10 g/L), and lipemia (10 g/L). Rheumatoid factors (100 IU/mL), interfere. Other substances may interfere[7].

12 – Notes

1. High CRP concentration samples may give negative results (prozone effect). Re-test the sample again using a drop of *20 µL*.
2. The strength of agglutination is not indicative of the CRP concentration in the samples tested.

13 – Limitations of the Method

- As with all diagnostic tests, a final diagnosis cannot rely on the outcome of a single test and must be supported by other clinical parameters.
- 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.

14 – References

1. Lars-Olof Hanson et al. Current Opinion in Infectious diseases 1997; 10: 196-201.
2. M.M. Pepys. The Lancet 1981; March 21: 653 – 656.
3. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 – 144.
4. Yoshitsugy Hokama et al. Journal of Clinical Laboratory Status 1987; 1: 15 – 27.
5. Yamamoto S et al. Veterinary Immunology and Immunopathology 1993; 36: 257 – 264.
6. Charles Wadsworth et al. Clinica Chimica Acta; 1984: 138: 309 – 318.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

TABLE OF APPLICABLE SYMBOLS

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 5	Updated layout and content	2022/03
Instructions for Use (IFU) – Revision 6	Update number of slides on REF. UA80100	2022/10

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

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