

Lembar Prosedure CRP



CRP-Latex 

CONTENTS		
GD-CRP50 GD-CRP100	CRP-Latex CRP-Latex	50 Tests 100 Tests
For <i>in vitro</i> diagnostic use only		

PRINCIPLE

CRP-Latex Test is a rapid slide agglutination procedure based on a modification of the latex fixation method, developed for the direct detection and semi-quantitation of C-reactive protein (CRP) in serum.

The assay is performed by testing a suspension of latex particles coated with anti-human CRP antibodies against unknown serum. The presence of a visible agglutination indicates an increase of the CRP level above the upper limit of the reference interval in the samples tested.

REAGENT COMPOSITION

R	CRP-Latex Reagent: Suspension of polystyrene latex particles coated with specific anti-human C-reactive protein antibodies in a buffered saline solution. Contains 0.95 g/L of sodium azide.
CONTROL⁺	Human serum with a CRP concentration > 15 mg/L. Contains 0.95 g/L of sodium azide.
CONTROL⁻	Animal serum with a maximum concentration of human CRP of 1 mg/L. 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 contact with skin or mucous membranes.

PACKAGING CONTENTS

REF	2410005, kit 50 tests. 1 vial CRP-Latex Reagent, 1x1 mL. Positive control, 1x1 mL. Negative control, 3 Test cards and 1x50 disposable stirrers.
REF	2410010, kit 100 tests. 2 vials CRP-Latex Reagent, 1x1 mL. Positive control, 1x1 mL. Negative control, 3 Test cards and 2x50 disposable stirrers.

STORAGE AND STABILITY

Store at 2-8°C. 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.

After the clear serum has been separated it may be stored at 2-8°C up to one week or longer periods at -20°C.

CRP-Latex

Determination of C-reactive protein

SLIDE TEST

MATERIAL REQUIRED

- Automatic pipettes.
- Saline solution (0.9% NaCl, only for semi-quantitation 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 Reagent vial gently. Aspirate dropper several times to obtain a thorough mixing.
3. Place 1 drop (50 µL) of the serum under test into one of the circles on the card. Dispense 1 drop of positive control serum and 1 drop of negative control serum into two additional circles.
4. Add 1 drop of CRP-Latex Reagent to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide means of a mechanical rotator (100 r.p.m.) for a period of 2 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 (Note 3).

Reactive: Any degree of agglutination visible macroscopically (Note 4).

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, 1:8, 1:16, 1:32, 1:64.
4. Test each dilution as described in steps 4-7 for the Qualitative Test.

QUALITY SYSTEM CERTIFIED
D 9001 ISO 13485



Glory Diagnostics
Manufactured in the Spain

Hasil pemeriksaan endotoksin



PT. GRAHA MUTU PERSADA
 Jl. Raya Pacing No. 35A, Kec. Bangsal, Mojokerto, Jawa Timur 61381
 Telp. (0321) 5287839
 Email : persadalab@gmail.com Website : www.grahamutupersada.com



REPORT OF ANALYSIS

Nama Pelanggan (Customer Name)	: RSUD KANJURAHAN	Kode Sampel (Sample Code)	: R026-0194
Alamat (Address)	: Jl. Panji No. 100, Krajan, Panggungrejo, Kec. Kepanjen, Malang, Jawa Timur	Metode Sampling (Sampling Method)	: 1) SNI 9063:2022 2) IKP-202
Jenis Sampel (Sample Matrix)	: Reverse Osmosis	Tgl. Sampling (Sampling Date)	: 20 Mei 2026
Lokasi Sampel (Sample Location)	: Ruang RO	Tgl. Penerimaan (Received Date)	: 20 Mei 2026
Titik Koordinat (Coordinate point)	: S. 08° 08' 34.06" E. 112° 34' 12.77"	Tgl. Analisis (Analysis Date)	: 20 Mei 2026
No. Seri (Serial Number)	: 4324/V/2026	Tgl. Laporan (Report Date)	: 02 Juni 2026

No.	Parameter	Hasil	Baku Mutu**)	Satuan	Metode
A. Mikrobiologi					
1	Endotoksin	< 0,25	< 0,25	EU/ml	IKP-141 (Gel Cloth)
2	Angka Kuman	< 1,00	< 100	CFU/mL	IKP-62 (Pour Plate)

Keterangan :

****)** = American National Standards Institute (ANSI) dan Association for the Advancement of Medical Instrumentation (AAMI) 23500:2019-Microbiological Standards for Dialysis Water

- Hasil uji yang ditampilkan hanya berhubungan dengan contoh yang diuji
- Angka <1 pada parameter mikrobiologi menunjukkan tidak ada pertumbuhan koloni
- IKP-202 Metode Pengambilan Contoh Uji Air RO untuk Parameter Endotoksin
- SNI 9063:2022 Metode Pengambilan Contoh Uji air dan air limbah untuk parameter mikrobiologi

Dokumentasi penelitian

Tempat Pengambilan air RO



Proses Pengambilan air RO



Pengambilan sampel darah



Tabung serum



Pemeriksaan Suhu Tubuh



Pengisian Inform Consent



Sampel dan Reagen



Pemeriksaan CRP



Penggunaan alat Rotator



Hasil CRP

