CRP Latex

Qualitative determination
by latex agglutination on slide
of C Reactive Protein on Serum

2 x 5 ml **REF 6101**

Also available

CRP latex kit complete with controls and accessories **REF 6001**

PRINCIPLE

The rheumatoid disease is a systemic morbid disease associated with a chronic inflammatory process. From a diagnostic perspective it is characterized by VES, α-2 gamma globulins and CRP increase and by the presence of rheumatoid factors.
In this test the C-Reactive Protein, if present in the serum, agglutinates with latex particles sensitized with anti-CRP antibodies to form an easily visible agglomerate.

REAGENTS

Kit components: **REF 6101**

REAGENT 1 (liquid) **2 x 5 ml**

Latex polystyrene particles in suspension sensitized with monoclonal anti RPC antibodies, ready to use.
WARNING: the reagents contain sodium azide (< 0.1%) as preservative. Handle with caution and avoid ingestion and contact with skin.

SLIDE **5 pieces**

STABILITY: sealed and stored at 2-8°C, reagents are stable up to the expiration date printed on the label.

SAMPLE

Serum. Avoid lipemic and hemolized sera for this test.
STABILITY: 2 days at 2-8°C, 1 month at -20°C.

PREPARATION OF THE REAGENTS

Let the reagents reach the test temperature before use. Shake the Reagent 1 accurately before use. Make sure all latex particles are in suspension and not deposited on the bottom of the vial.

MANUAL PROCEDURE OF THE QUALITATIVE TEST

Pour the reagents in the proper areas of the slide, as the following table:

	Sample	Pos. Control	Neg. Control
Sample Reagent 2 Reagent 3	50 µl	1 drop	1 drop
Reagent 1	1 drop	1 drop	1 drop

Mix to spread the liquid on the whole area of the slide. Shake the slide gently (round movement) for 2 minutes and then evaluate the results.

READING OF THE RESULTS

Any agglutination presence in the sample highlights the PCR concentrations of at least 6 mg/l. On positive sera, it is recommended to perform the title with the semiquantitative test as further on described.

MANUAL PROCEDURE WITH THE SEMIQUANTITATIVE TEST

Dilute the sample with saline solution as it follows:

Dilution	1:2	1:4	1:8	1:16
Sensitivity equal to mg/l	12	24	48	96

Proceed on each dilution as for the qualitative test.

RESULTS

The last dilution which shows any agglutination corresponds to the sample title.

REFERENCE VALUES

SERUM: < 6mg/l.

NOTES

1. Longer reaction times may give false positive results.
2. Always compare the results with the controls.
3. All reagents have been deactivated and tested for HIV, HBsAg and HCV antibodies. However, they should be treated as potentially infectious.
4. After an accurate wash, slides can be reused maximum three times.

REFERENCES

Available upon request.

KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	read instructions for use

IVD CE Ed. 02 - Mar 2015 MS

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