

## C Reactive Protein (CRP)

### A rapid latex slide test for the detection of CRP in serum

REF: 514 001 50 test (Complete Kit)  
 REF: 514 002 100 test (Complete Kit)  
 REF: 514 003 50 test (latex with positive control)  
 REF: 514 004 100 test (latex with positive control)

REF: 514 005 50 test (latex only)  
 REF: 514 006 100 test (latex only)  
 REF: 514 007 200 test (latex only)

#### Intended Use

Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of C Reactive Protein (CRP) in human serum.

#### Background

Tissue-damaging associated with inflammatory diseases, infection and neoplasms are associated with a major acute phase response of the C-reactive protein (CRP) and other acute phase reactants. The CRP response frequently precedes clinical symptoms, including fever. Measuring changes in the concentration of CRP provides useful diagnostic information about how acute and how serious a disease is. It also allows the assessment of complications during the disease and judgement about the disease genesis.

#### Test Principle

Spectrum CRP latex reagent is a suspension of polystyrene particles sensitized with anti-human CRP. When the latex reagent is mixed with a serum containing C-reactive protein, visible agglutination occurs. The latex reagent has been produced so that agglutination will take place only when the level of CRP is greater than 6 mg/L.

#### Reagents

Spectrum CRP latex kit contains the following reagents:

##### Latex Reagent :

A suspension of polystyrene latex particles in glycine-saline buffer pH:  $8.6 \pm 0.1$ , coated with anti-human CRP antibodies.

##### Positive Control Serum (bottle with red cap):

Is prepared from a stabilized human serum pool containing CRP as an antigen.  
 Both reagents contain 0.9 g/L Sodium azide as a preservative.

##### Negative Control Serum (bottle with white cap):

Reagent contain 0.9 g/L Na azide as a preservative.

#### Slides

**NOTE:** Negative Control Serum, Slides are only included in Complete Kits REF: 514 001 (50 test) & REF: 514 002 (100 test)

#### Storage & Stability

The reagents are stable up to the expiration date specified when stored at  $2 - 8^{\circ}\text{C}$ .

#### Precautions and Warnings

All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HBsAg) and HTLV-III antibodies by FDA approved procedure and found to be non-reactive. No known test method for HBsAg or HTLV-III antibodies offers total assurance that a human derived product will not transmit hepatitis or HTLV-III virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.

#### SYMBOLS IN PRODUCT LABELLING

|   |                              |   |                                       |
|---|------------------------------|---|---------------------------------------|
|  | Authorised Representative    |  | Temperature Limitation                |
|  | For in-vitro diagnostic use  |  | Use by/Expiration Date                |
|  | Batch Code/Lot number        |  | CAUTION. Consult instructions for use |
|  | Catalogue Number             |  | Manufactured by                       |
|  | Consult instructions for use |   |                                       |

#### Specimen Collection and Preservation

Use only serum specimens, plasma samples are not suitable for the test. Serum samples can be stored for 24 hrs at  $2 - 8^{\circ}\text{C}$ , for longer storage it is recommended to store the samples at  $-20^{\circ}\text{C}$ .

#### Procedure

##### Qualitative Test (Screening)

1. Bring all reagents and specimens to room temperature.
2. Place one drop (50  $\mu\text{l}$ ) of the positive control and 50  $\mu\text{l}$  of the patient serum into separate circles on the glass slide.
3. Shake the CRP latex reagent gently and add one drop (45  $\mu\text{l}$ ) on each circle next to the sample to be tested and control.
4. Mix well using disposable stirrer spreading the mixture over the whole test area and tilt the slide gently. Agitate for about 2 minutes with rotator or by hand and observe for the presence or absence of agglutination.

#### Results and Interpretation

**Negative result:** No agglutination of the latex particles suspension within two minutes.

**Positive result:** An agglutination of the latex particles suspension will occur within two minutes, indicating a CRP level of more than 6 mg/L.

#### Semi-Quantitative Test

1. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc) in 0.9 g/L saline solution.
2. Place one drop of positive control on slide. Do not attempt to dilute the CRP positive control serum for comparative or other purposes as no correlation exists between actual titre of the control and titre of unknown sera.
3. Place 50  $\mu\text{l}$  of each serum dilution individually in successive circles on the slide and proceed as in screening methodology.

#### Results and Interpretation

The serum CRP titre can be defined as the highest dilution showing a positive result. The approximate CRP level ( mg/L) present in the sample can be obtained by the following formula:

$$\text{CRP Titre ( mg/L)} = \frac{\text{Highest dilution with positive reaction} \times \text{Reagent sensitivity ( 6 mg/L)}}{1}$$

e.g. if the agglutination is present up to a titre 1:8, the approximate serum CRP level is  $8 \times 6 = 48 \text{ mg/L}$ .

#### Expected Value

Up to 6 – 8 mg/L.

#### Limitations of the Procedure

Occasional agglutinations observed after 4 minutes have no diagnostic significance.

Highly haemolyzed and lipemic serum as well as plasma interfere with the test.

## References

1. Bowman BH. In:Hepatic Plasma Protein. San Diego: Academic Press;1993:47-95.
2. Halbert, SP. Ann. N.Y. Acad. Sci., 103, 1027:1051; 1963.
3. Klein GL, Applied Microbiology, 21:999, 1971.
4. Klein GC: Manual of Clinical Immunology ASM 264-273: 1976.
5. Pepys MB et al. Lancet 1961 ; 1 : 653-660.
6. Rantz LD, DiCapri JM, Randall E. Am. J. Med. Sci., 24, 1952.

| ORDERING INFORMATION |          |
|----------------------|----------|
| CATALOG NO.          | QUANTITY |
| 514 001              | 50 test  |
| 514 002              | 100 test |
| 514 003              | 50 test  |
| 514 004              | 100 test |
| 514 005              | 50 test  |
| 514 006              | 100 test |
| 514 007              | 200 test |



### Egyptian Company for Biotechnology (S.A.E)

Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.

Tel: +202 4489 2248 - Fax: +202 4489 2247

[www.spectrum-diagnostics.com](http://www.spectrum-diagnostics.com)

E-mail:[info@spectrum-diagnostics.com](mailto:info@spectrum-diagnostics.com)



**MDSS GmbH**  
Schiffgraben 41  
30175 Hannover, Germany



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