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 **C-Reactive Protein (CRP)**

Diagnostic reagent set **(Slide latex tests)** for the in-vitro qualitative screening and semi-quantitative for the detection of CRP present in infected human serum manually.

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| REF: BS.1/CRC1.050.0050 50 tests REF: BS.1/ CR01.050.0050 50 tests | REF: BS.1/CRC1.100.0100 100 testsREF: BS.1/CR01.100.0100 100 tests |

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**CLINICAL SIGNIFICANCE (1-2)**

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 judgment about the disease genesis.

**METHOD PRINCIPLE (2)**

***BioScien*** 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.

**REAGENT COMPOSITION**

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| **Reagents:**  | **Composition** |
| **Latex Reagent**  | A suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.1, coated with anti-human CRP antibodies. |
| **Positive Control \*****\*** Only with REF: BS.1/CRC1.050.0050 BS.1/CRC1.100.0100  | 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.

**PRECAUTIONS AND WARNINGS**

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

* Wearing personnel protective equipment (overall, gloves, glasses,).
* Do not pipette by mouth.
* In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
* Respect country requirement for waste disposal.

***S56:*** dispose of this material and its container at hazardous or
special waste collection point.

***S57:*** use appropriate container to avoid environmental contamination.

***S61:*** avoid release in environment.

For further information, refer to the CRP reagent material safety data sheet.

**REAGENT PREPARATION, STORAGE AND STABILITY**

***BioScien*** CRP reagent is ready-to-use and is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

***Deterioration***

The ***BioScien*** CRP reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive controls.

**SPECIMEN COLLECTION AND PRESERVATION (2)**

Clean and dry glassware free from detergents must be used for sample collection, freshly collected serum is preferable. Specimen should be free of turbidity and hemolysis. Fresh, uncontaminated serum samples may be stored at 2-8ºC in case of delay in testing up to 72 hours.

**EQUIPMENT REQUIRED NOT PROVIDED**

* Sterile Syringe
* Analytical tubes
* Centrifuge
* Stop watch
* Variable Micropipettes
* Physiological saline (as negative control)

**ASSAY PROCEDURE**

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Shake and mix well before dispensing

***Qualitative procedure***

1. Identify each reaction circle of the slide test to make one positive control, one negative control and the desired number of samples respectively.
2. Place one drop of positive control reagents, 50 µl of physiological saline and one drop of patient’s serum to be tested onto each reaction circles.
3. Add one drop of CRP to the reaction circles containing positive controls, physiological saline and patient’s serum.
4. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
5. Rock the slide gently back and forth, and observe for agglutination macroscopically at 2 minute.

***Semi-quantitative method***

1. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc.) in 9 g/L saline solution.

2.Continue with steps 3-5 of the qualitative procedure.

***Note:*** This method is recommended for obtaining quick approximate titers only.

**READING AND INTERPRETATION**

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| *Qualitative procedure* |
| Positive | An agglutination of the latex particles suspension will occur within two minutes, indicating a CRP level of more than 6 mg/L. |
| Negative | No agglutination as indication for the CRP level in the patient’s serum is within the normal range. |
| *Semi-Quantitative procedure* |
| Titer | The titer of the patient serum corresponds to the visible agglutination in the test circle with the smallest amount of serum sample.  |

CRP Titer (mg/L) = Highest dilution with positive reaction x Reagent sensitivity (6 mg/L)

e.g. if the agglutination is present up to a titer 1:8, the approximate serum CRP level is 8 x 6 = 48 mg/L.

**QUALITY CONTROL**

# The positive controls have been included with the test kit to monitor the performance of the reagent. Good physiological saline may be used as a negative control, if the expected results have not been observed, the reagent should not be used. For more information please contact ***BioScien*** technical support.

**PERFORMANCE CHARACTERISTICS**

***Precision (reproducibility and repeatability):*** Precision of CRP suspensions is 100% (+/- one double dilution).

***Analytical sensitivity:*** Accurate titer determination of the reference material, under the described assay conditions.

***Diagnostic sensitivity:*** 100 %.

***Diagnostic specificity:*** 100 %.

**LIMITATIONS OF PROCEDURE**

1. The results of this test ***should not*** be used as a single diagnostic tool to make a clinical diagnosis. Instead, the test results must be evaluated together with other clinical findings and observed symptoms to aid in the final diagnosis.
2. Temperature of the reagents and specimens is critical to test outcome.
3. CRP suspensions are not from human sources hence contamination due to HBsAg and HIV is practically excluded.
4. Accessories provided with the kit only must be used for optimum results.
5. Do not use damaged or leaking reagents.
6. Agglutinins usually appear by the end of the first week of infection, blood sample taken earlier may give a negative result.
7. A rising titer is more significant than a single high titer. It is therefore necessary to evaluate two or more serum samples taken at 4- 6 days intervals after the onset of the disease.
8. False positive results are likely if the test is read more than 2 minute after mixing on the slide test.
9. Use a separate disposable tip for each sample to prevent cross contamination.
10. After usage the antigen suspension should be immediately recapped and replaced at 2-8 ºC.

**REFERENCES**

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

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| **SYMBOLS IN PRODUCT LABELLING** |
| Number of <n> test in the pack |  | For in-vitro diagnostic use |  **IVD** |
| Caution |  | Batch Code/Lot number |  **LOT** |
| Do not use if package is damaged |  | Catalogue Number |  **REF** |
| Consult Instruction for use |  | Temperature Limitation |   |
|  |  |  Expiration Date |   |
|  |  | Manufactured by | **Medical Device Safety Service****MDSS GmbH**Schiffgr aben 41 30175 Hannover, Germany |