274 mm x 218mm

Insight | CRP

Rapid Immunochromatographic assay for the detection of C - reactive protein in human serum

DEVICE

INTENDED USE
INSIGHT-CRP is a rapid, self-performing, immunochromatograhic assay for the detection of C-reactive protein in human serum.

SUMMARY
C-reactive protein (CRP) is a serum protein, which is synthesized in the liver. Its rate of synthesis and secretion increases within hours of an acute injury or the onset of inflammation and may reach as high as 20 times the normal levels.
Elevated serum concentration of CRP is an unequivocal evidence of an active tissue damage process and CRP measurement thus provides a simple screening test for organic disorders. Apart from indicating inflammatory disorders, CRP measurement helps in differential diagnosis, in the management of neonatal septicaemia and meningitis where standard microbiological investigations are difficult.
Its use in postoperative surveillance is of great importance. CRP levels invariably rise after major surgery but fall to normal within 7-10 days. Absence of this fall is indicative of possible septic or inflammatory post operative complications.
Serum CRP measurement also provides useful information in patients with myocardial infarction there being an excellent correlation between peak levels of CRP and Creatine phosphokinase (CPK).
INSIGHT-CRP detects the presence of C-reactive protein (CRP) in human serum, qualitatively, at concentrations as low as 6 mg/L (0.6 mg/dl).

PRINCIPLE
INSIGHT-CRP is based on the principle of agglutination of antibodies/antisera with respective antigen in immunochromatography format along with use of nano gold particles as agglutination revealing agent. The conjugate pad is impregnated with two components; agglutinating sera for CRP conjugated to colloidal gold and Rabbit globulinconjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the agglutinating sera for CRP colloidal gold conjugate complexes with the CRP in the test specimen and travels on the membrane due to capillary action along with the rabbit globulin colloidal gold conjugate. This complex moves further on the membrane to the test region where it is immobilized by agglutinating sera for CRP coated on the membrane, leading to formation of pink/purple colored band. The absence of this band in the test region indicates a negative test result. The rabbit globulin colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the agglutinating sera for rabbit globulin coated on the membrane at the control region (C) forming a pink / purple coloured band. This control band acts as a procedural control and serves to validate the results.

REAGENTS AND MATERIALS SUPPLIED
A. Each INSIGHT-CRP kit contains individual pouches each containing a
   1. Membrane test assembly impregnated with colloidal gold conjugated to agglutinating sera for CRP and the rabbit globulin, Agglutinating sera for CRP and Agglutinating sera for rabbit globulin at the respective regions.
   2. Desiccant pouch.
   3 Sample applicator.
B. Sample running buffer.
C. Package insert.

OPTIONAL MATERIAL REQUIRED
Stopwatch and Micro pipette.

STORAGE AND STABILITY
The sealed pouches in the test kit and the kit components may be stored between 4-30° C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE
1. For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79- 9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

1. INSIGHT-CRP uses human serum as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 1 week.
4. Refrigerated specimens must be brought to room temperature prior to testing.
5. Repeated freezing and thawing of the specimen should be avoided.
6. Do not use viscous/turbid, lipaemic, hemolysed, clotted and contaminated serum specimens.
8. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE

1. Bring the kit components of INSIGHT-CRP to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample applicator.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. Once opened, the device must be used immediately.
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Using calibrated pipette, pipette out 500µl of sample running buffer and dispense into a test tube. Then pipette 5µl of specimen and dispense into test tube (1:100 dilution), mix well. This is the test specimen.
8. Dispense 2 drops of the test specimen into the specimen port (S).
9. Start the stopwatch. Read the results within 5 minutes. Do not interpret the results beyond 8 minutes.

INTERPRETATION OF RESULTS

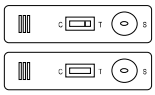
Negative Result:

The appearance of one pink/ purple coloured band at the Control Region (C) indicates absence of CRP in the specimen.

Positive Result:

The appearance of two pink/purple coloured bands at the Control Region (C) and Test Region (T) indicates that the specimen contains detectable levels of CRP.

Invalid Result:



The test result is invalid if no band appears on the device. The test should be considered invalid if only the test band appears and no control band appears. In such cases, verify the test procedure and repeat the test with a new INSIGHT CRP device.

REMARKS

1. Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. CRP is found to be present after the first trimester of pregnancy and persists until delivery.
4. CRP levels increase in women who are on oral contraceptives.
5. CRP response is not affected by the commonly used anti-inflammatory or immunosuppressive drugs, including steroids, unless the disease activity is affected and it covers an exceptionally broad incremental range upto 3000 times.
6. Do not interpret the results beyond 8 minutes.
7. Since CRP production is a non-specific response to tissue injury, it is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.

PERFORMANCE CHARACTERISTICS

The sensitivity of INSIGHT CRP is 6 mg/L (0.6 mg/dl).

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. R.D. Eastham et.al., C-Reactive Protein in Rheumatic Heart Disease, Am. Rheum. Dis. (1958), 17 pgs 314-3182. Ward A.N.
2. Clinical Laboratory Diagnostics, Edited by Lothar Thomas, M.D., 1st Ed., 1998, TH-Books Verlagsgesellschaft mbH, Frankfurt, Germany, pgs 700-706.
3. Data on file: Tulip Diagnostics (P) Ltd.

Manufactured by:

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