

Rapid Test for Detection of CRP – Device

A rapid Semiquantitative test for detection of CRP in serum/plasma/whole blood

For Self - Testing & In-Vitro Diagnostic Use Only

Store at 4°C to 30°C

OVERVIEW

CRP is a protein that the liver makes. Normally, the body have low levels of c-reactive protein in the blood. Liver releases more CRP into your bloodstream if having inflammation in the body.

INTENDED USE

Semi Quantitative detection of C-Reactive Protein (CRP) in human serum/plasma/whole blood.

PRINCIPLE

It is an immunoassay for the detection CRP in Plasma/serum/whole blood. The special membrane is placed in front of a reaction pad which contains colloidal gold particles coated with monoclonal anti-CRP antibodies. If a sample is applied, the colloidal gold particles dissolve in the liquid sample. If the sample contains the Higher levels of CRP than normal range, CRP bonded to the monoclonal antibodies marked with colloidal gold particles. The dissolved gold particles are transported through the membrane due to the capillary forces effective in the special membrane. In the area of the T-line, the anti-CRP antibodies immobilized there form the complex of CRP and colloidal gold. A pink-purple line is formed depending on the CRP concentration. The surplus colloidal gold particles are then bonded in the area of the C-line by the control antibodies immobilized there, so that a pink –purple line also becomes visible in this area. This line serves as an internal functional check and must be formed in every test. If no CRP (normal levels of CRP) is present in the sample, the CRP-gold particle complex is not formed or it is formed in insufficient amount to generate a visible pink purple line in the area of the T-line.

CONTENTS OF KIT

1. Test Device with desiccant.
2. Dropper.
3. Assay Buffer.
4. Package Insert.

OPTIONAL MATERIAL REQUIRED

1. Stopwatch

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or consequential arising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

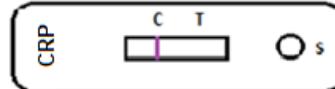
Fresh anti coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants. Fresh serum or plasma can also be used as a test sample. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to three days before testing. Clotted or contaminated blood samples should not be used for performing the test.

TEST PROCEDURE

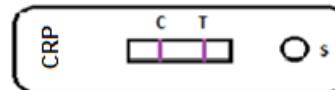
1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
4. Keep the device on plain surface & add one drop (Approx.30µl) serum/plasma or two drops (Approx.60µl) whole blood sample in sample 'S' well by using dropper.
5. Add 1 drop of assay buffer in sample well "S".
6. Start the timer.
7. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

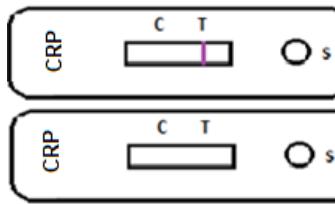
Negative (Normal CRP Value): If only colored line appears at control region 'C', then sample is negative for CRP.



Positive (CRP higher than normal range): A distinct colored line appears at control region 'C' and at the test region 'T', then sample is positive for CRP (1+, 2+, 3+, 4+ as per concentrations low, moderate, high and very high).

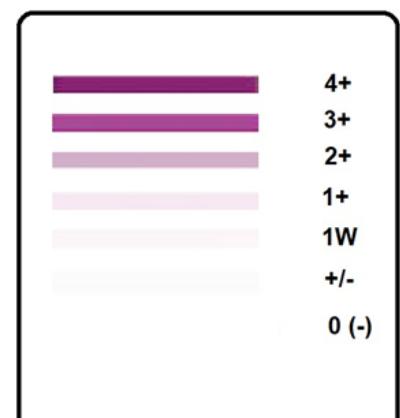


Invalid: Test should be considered invalid and repeat the test using fresh test if No line appears at control side 'C' and line appears only at test side 'T'.
No line appears at control side 'C' and test side 'T'.



NOTE:

intensity of the color in the test line region(T) will vary depending on the levels of the CRP in the specimen. Negative results must be confirmed only at the end of 15 minutes.



LIMITATIONS

- As with all diagnostic tests, the test result must always be correlated with clinical findings.
- The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
- Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.
- The test is limited to the detection of CRP. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Total 168 samples were evaluated for specificity & sensitivity. sensitivity was found to be 100% (50/50) and relative specificity was found 100% (118/118).

The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.

No cross reactivity found with tested samples.

Lowest detection limit: 100 mg/L

Sample	Rapid Test for Detection of CRP - Device & Components		Reference		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
	Positive	Negative	Positive	Negative				
Positive	50	0	50	0	100	-	100	-
Negative	0	100	0	100	-	100	-	100
Cross reactivity	0	18	0	18	No cross reactivity observed			
Total	50	118	50	118	-			

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use



MANUFACTURED BY

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