

## AccuTest™ CRP RAPID (1-STEP, FOR BLOOD)

FOR THE SEMI-QUANTITATIVE ASSESSMENT OF  
HUMAN C-REACTIVE PROTEIN  
IN HUMAN SERUM OR WHOLE BLOOD



*For In Vitro Diagnostic Use Only*

### INTENDED USE

The CRP RAPID (1-STEP, FOR BLOOD) test is an immune chromatography based one step in vitro test. It is designed for semi-quantitative determination of C Reactive Protein (CRP) in human serum or whole blood specimens. The range of CRP concentration in serum or whole blood can be detected in 10 minutes.

### SUMMARY AND EXPLANATION

Produced by hepatocytes, C- reactive protein (CRP) is a non-specific, acute-phase reactant indicating acute injury, bacterial infection, and inflammation. Recent studies have found that CRP is also an indicator of myocardial infarction. Elevated levels of CRP are also a good predictor of future cardiac diseases. Although the detection of elevated levels of CRP in the serum is not specific for any particular disease, it is a useful indicator of inflammatory processes. CRP levels rise in serum or plasma within 24 to 48 hours following acute tissue damage, reach a peak during the acute stage (approximately 1000x constitutive level) and decrease with the resolution of inflammation or trauma. The concentration increase of CRP in human serum or plasma may last for several days before decreasing to normal levels. As elevated CRP values are always associated with pathological changes, the CRP assay provides useful information for the diagnosis, therapy and monitoring of inflammatory processes and associated disease. Additionally, measurement of CRP may add to the predictive value of other cardiac markers (myoglobin, creatine-kinase-MB, troponin I and T), which are used to assess the risk of cardiovascular and peripheral vascular disease. As increases in CRP values are non-specific, they should not be interpreted without a complete patient history evaluation, and measurements of CRP should be compared to previous values.

CRP RAPID (1-STEP, FOR BLOOD) test is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human serum specimen. The assay relies on the competition for binding antibody between CRP-dye conjugate and free CRP, which may be present in the specimen being tested. When CRP is present in the specimen, it competes with CRP-dye conjugate for the limited amount of antibody coated on the test band zone. When the amount of CRP is equal or more than the 10 µg/ml, it will prevent the binding of CRP-dye conjugate to the antibody. Therefore, there will be no colored band on the test line zone.

A control line is present in the test window to work as procedural control and as reference. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

### MATERIALS SUPPLIED

- CRP RAPID (1-STEP, FOR BLOOD) Test device
- Sample buffer
- Sample tube

### MATERIALS REQUIRED BUT NOT SUPPLIED:

1. Blood collection containers.
2. Timer or clock

### STORAGE:

Store the kit between 2°C and 30°C. Do not freeze. Do not store the kit in direct sunlight. Be sure to un-pouch only the number of test device that will be immediately used. The test kit may be used until its expiration date, which can be found on the package label.

### PRECAUTIONS:

1. Read instructions carefully before performing the test.
2. Read results under good lighting.
3. Guard the test kit against dampness.
4. Specimens should be handled as being potentially infectious. The Centers for Disease Control (CDC) and the National Institutes of Health (NIH) recommend that all potentially infectious agents be handled at a Biosafety Level.
5. Biological decontamination procedures should be followed for all equipment, containers, surfaces, etc. that come in contact with potentially infectious specimens. All disposables that come in contact with these samples should be disposed of as infectious waste.
6. Do not use the test strips or reagents beyond the stated expiration date marked on the package label, which is generally 12 months from date of manufacture.
7. All test strips and specimens must be brought to room temperature (15-30°C) before running the assay.
8. Do not re-use the test strips.

### SPECIMEN COLLECTION AND PREPARATION

1. The serum or whole blood specimen should be collected under standard laboratory conditions
2. Patient samples performed best when tested immediately after collection. The blood specimen must be tested within 24 hours. If the serum sample cannot be tested within 24 hours, it must be frozen until the test can be performed. Allow sample to reach room temperature before proceeding.
3. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

### QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials that are not provided with this test kit are commercially available.

### PROCEDURE

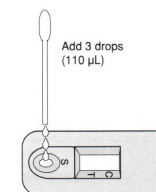
Bring all materials and specimens to room temperature.

#### Sample preparation

1. Add 10 drops or 500 µl of sample buffer to the sample tube.
2. Add 25 µl of specimen to the sample tube.
3. Shake the sample tube gently to mix the specimen and sample buffer well.
4. Put the cap of the sample tube back.

#### Test procedure

1. Remove the test card from the sealed foil pouch.
2. Hold the sample tube in a vertical position over the sample well of the test card and deliver 3 drops (150 µl) of sample into the sample well.



3. Read the result between at 10 minutes after adding the sample

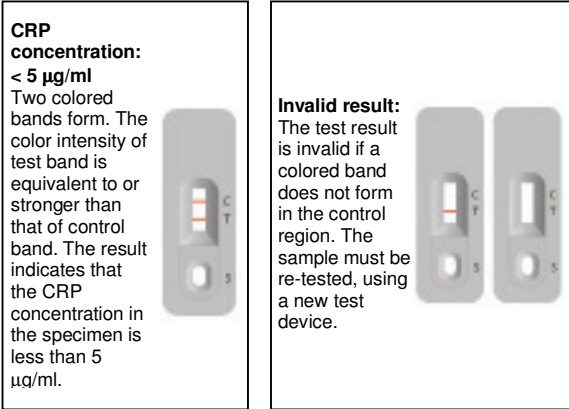
### INTERPRETATION OF RESULTS:

**CRP concentration:**  
**> 10 µg/ml**  
One colored band forms. One colored band appears in control line zone. No colored band is found in test band zone. This is an indication that the CRP level in the specimen is above the 10 µg/ml.



**CRP concentration:**  
**5 – 10 µg/ml**  
Two colored bands form. The color intensity of the test band is less than that of control band. The negative result indicates that the CRP concentration in the specimen is between 5 and 10 µg/ml.





**LIMITATIONS OF THE PROCEDURE**

1. A borderline result could indicate the beginning of an immune response.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

**EXPECTED VALUES**

It is recommended that each laboratory establish its own normal range based on the patient population. However, based on published literature healthy individuals are expected to have CRP values as follows:

Neonatal serum:	0.01 to 0.35 µg/ml
Adult serum:	0.07 to 8.0 µg/ml

**PERFORMANCE CHARACTERISTICS**

**Sensitivity:**

CRP RAPID (1-STEP, FOR BLOOD) test can semi-quantitatively detect CRP in serum or whole blood at: < 5 µg/ml, 5 – 10 µg/ml and > 10 µg/ml ranges.

**Interference testing:**

The following substances were added to CRP negative and 5 µg/ml spiked samples. No interference was found with any of the substances at the following concentrations:

Bilirubin	10 mg/dl
Cholesterol	800 mg/dl
Hemoglobin	250 mg/dl
Triglyceride	500 mg/dl

**REFERENCES**

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It is highly recommended that these tests be performed under the guidance of a registered medical practitioner.

The manufacturer, distributor and/or pharmacy do not accept any liability whatsoever for any consequent actions resulting from the interpretations of the product/s supplied.



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