Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

# OneStep C-Reactive Protein (CRP) Serum RapiCard™ InstaTest

REF 166770-1

IVD See external Label 2-30°C ∑= 10 Tests

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|---|---|
| **Sensitivity** | **< 5 µg / mL, 5-10 µg/mL and > 10 µg/mL ranges** |

## INTENDED USE

The Cortez Diagnostics OneStep CRP RapiCard™ InstaTest is an immunochromatography based one step in vitro test.

## SUMMARY AND EXPLANATION

Produced by hepatocytes, C- reactive protein (CRP) is a non-specific, acute-phase reactant indicating acute injury, bacterial infection, 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.

Cortez OneStep CRP RapiCard™ InstaTest 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.

## TEST PRINCIPLE

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 can be detected in 10 minutes.

## SPECIMEN COLLECTION AND PREPARATION

1. The serum specimen should be collected under standard laboratory conditions.
2. Patient samples performed best when tested immediately after collection. If the 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.

   Sodium azide can be added as a preservative up to 0.1% without effecting the Immerse the strip into the sample (sample volume should not less than 150 µL) with arrow pointing toward the sample.

## MATERIALS AND COMPONENTS

### Materials provided with the test kit

1. Cortez CRP Test device.
2. Sample buffer ( 1buffer / 10 tests).
3. *Sample tube (supplied upon request).

### Materials required but not provided

1. Serum collection containers.
2. Timer or clock.

## ASSAY PROCEDURE

Bring all materials and specimens to room temperature.

### *Sample preparation*

1. Add 10 drops of 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*

### Test Strip

1. Remove the test strip from the sealed foil pouch.
2. Open the cap of the sample tube.
3. Immerse the strip into the sample (sample volume should not less than 150 µL) with the arrow pointing toward the sample.
4. Leave the strip in the sample or take the strip out after a minimum of 30 seconds in the sample and lay the strip on a flat non-absorptive surface.
5. Result the result at 10 minutes after adding the sample.

### Test Card

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 d rops (150 µL) of sample into the sample well.
3. Read the result at 10 minutes after adding the sample.

## 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.

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***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.

***CRP concentration: > 5 µg/mL***

Two colored bands form. The color intensity of test band is equivalent to or stronger than that of control band. The result indicates that the CRP concentration in the specimen is less than 5 µg/mL.

***Invalid result:***

The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.

## PERFORMANCE CHARACTERISTICS

**Sensitivity:**

Cortez CRP RapiCard™ InstaTest 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:

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| Bilirubin | 10 mg/dL |
| Cholesterol | 800 mg/dL |
| Hemoglobin | 250 mg/dL |
| Triglyceride | 500 mg/dL |

## 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 which is not provided with this kit are commercially available.

## LIMITATIONS OF 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/
Adult serum: 0.07 to 8.0 µg/mL

## PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiration date.
3. Handle all specimens as potentially infectious.
4. Store the test device at 2 to 30°C. Do Not Freeze.

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| ISO 13485<br>ISO 9001<br>Diagnostic Automation/<br>Cortez Diagnostics, Inc.<br>21250 Califa St, Suite 102 and 116,<br>Woodland Hills, California 91367 USA | |
| **Date Adopted** | **2016-01-21** |
| **166770-1** | **CORTEZ- OneStep**<br>**C-Reactive Protein (CRP)**<br>**Serum**<br>**RapiCard™ InstaTest** |
| EC REP | **CEpartner4U,**<br>**Esdoornlaan 13, 3951DB**<br>**Maarn. The Netherlands.**<br>**www.cepartner4u.eu** |
| **Revision Date: 2003-06-12** | |