



CORTEZ DIAGNOSTICS, INC.

23961 Craftsman Road, Suite D/E/F,
Calabasas, CA 91302 USA
Tel: (818) 591-3030 Fax: (818) 591-8383
E-mail: onestep@rapidtest.com
Web site: www.rapidtest.com

IVD



See external label



15°C-30°C



$\Sigma=25$ or 50 tests

REF

Cat. #166800-1

OneStep R-Reactive Protein (CRP) Serum/Whole Blood RapiCard™ InstaTest

Cat # 166800-1

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

For in vitro Diagnostic Use

INTENDED USE

The Cortez Diagnostics Inc. OneStep CRP RapiCard™ InstaTest is an immunochromatography 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, 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.

MATERIAL PROVIDED

1. Cortez CRP Test device
2. Sample buffer
3. Sample tube

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Blood collection containers.
2. Timer or clock

STORAGE

Store the test device at 2 to 30°C. Do Not Freeze.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

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 effecting 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 which is 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: $> 10 \mu\text{g/mL}$

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 $10 \mu\text{g/mL}$.

CRP concentration: $5 - 10 \mu\text{g/mL}$

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 $10 \mu\text{g/mL}$.

CRP concentration: $< 5 \mu\text{g/mL}$

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 $5 \mu\text{g/mL}$.

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.

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:

Cortez OneStep 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:

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

REFERENCES

1. Van Lontе F. "The Diagnostic Utility of C-Reactive Protein", *Hum Pathol*, 1982. 13 (12): 1061-3
2. Thimsen D.A., Tong GK and Gruenberg JC, "Prospective Evaluation of C-Reactive Protein in Patients suspected to have Acute Appendicitis", *Am J Surg*, 1989, 55(7): 466-8.
3. Downton S.R. and Colten H.R., "Acute Reactants in Inflammation and Infection", *Semin Hematol*, 1988, 25(2): 84-90.
4. Shaw A.C., "Serum C-Reactive Protein and Neopterin Concentrations in Patients with Viral or Bacterial Infection". *J Clin Pathol*, 1991, 44(7): 596-9.
5. Wu T.T., Lee Y.H., Tzeng W.S. et al, "The Role of C-Reactive Protein and Erythrocyte Sedimentation Rate in the Diagnosis of Infected Hydronephrosis and Pyonephrosis", *J Urol*, 1994, 152(1): 26-8.
6. Gambino R, "C-Reactive Protein (CRP) – How much Proof do we need?" *Lab Rep*. 1994, 16(11): 83-5.
7. Ridker, P.M., et al., Plasma concentration of C-reactive protein and the risk of developing peripheral vascular disease. *Circulation*, 97:425-428, 1998.
8. Ridker, P.M., et al., Propective study of C-reactive protein and the risks of future cardiovascular events among apparently healthy women. *Circulation*, 98:731-733, 1998.
9. Ridker, P.M., Glynn, R.J., and Hennekens, C.H., C-reactive protein adds to the predictive value of total and HDL cholesterol in determining risk of first myocardial infarction. *Circulation*, 97:2007-2011, 1998.
10. Ridker, P.M., et al., Inflammation, Pravastatin, and the risk of coronary events after myocardial infarction in patients with average cholesterol levels. *Circulation*, 98:839-844, 1998.
11. Tracy, R.P., et al., Relationship of C-reactive protein to risk of cardiovascular disease in the elderly: results from the Cardiovascular Health Study and the Rural Health Promotion Project.. *Arter. Thromb. Vasc. Biol.* 17:1121-1127, 1997.

12. Macy, E. M., Hayes, T.E.and Tracy, R.P.,Variability in the measurement of C-reactive protein in healthy subjects: implications for reference interval and epidemiological applications. *Clin. Chem.* 43(1):52-58, 1997.
13. Ridker, P.M., et al., Inflammation, aspirin, and the risk of cardiovascular disease in apparently healthy men. *N. ENGL. J. MED.*, 336:973-979, 1997.
14. "Clinical Guide to Laboratory Tests". Edited by N.W. Tietz, 3rd Edition. W.B.

Date Adopted	Reference No.
2003-06-12	DA-CRP-2008



CORTEZ DIAGNOSTICS, INC.

23961 Craftsman Road, Suite D/E/F, Calabasas, CA 91302

Tel: (818) 591-3030 Fax: (818) 591-8383

ISO 13485-2003



Revision Date: 10-7-08