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ONE STEP HIGH SENSITIVITY C-REACTIVE PROTEIN TEST

(CRP)

FOR PREDICTING CARDIOVASCULAR RISK

INTENDED USE

The **One Step C-reactive Protein (CRP) Test** is a rapid performing immunoassay designed for the semi-quantitative determination of human CRP in human whole blood, serum or plasma. It is intended for professional use as an aid in predicting cardiovascular risk.

SUMMARY AND BIOLOGICAL PRINCIPLE OF THE ASSAY

Low density lipoprotein (LDL) cholesterol plays a critical role in arterogenesis and as such, is the focus of current guidelines for the determination of risk factors associated with cardiovascular disease. Research has shown that a condition called atherothrombosis often occurs in the absence of hyperlipidemia (hyperlipidemia indicates the presence of elevated or abnormal levels of lipids and/or lipoproteins in the blood) and researchers now believe that inflammation and cholesterol work together to increase the risk of heart disease:

Multiple lines of investigations include 27,979 people, have converges to indicate a prominent role for inflammation in coronary artery disease (CAD) and myocardial infarction disease (AMI). CRP is a substance manufactured by the liver in response to the immune system's alarms. The association of CRP level with active CAD and AMI is well documented. CRP levels were greater in the patient with CAD, AMI, cerebrovascular disease and peripheral arterial disease. CRP level was also an independent predictor for the cardiovascular event in subpopulation with normal levels of low density lipoprotein cholesterol (LDL).

1. How Cholesterol builds: Too much fat in the blood can build up as plaque within heart vessel walls. Its presence triggers the inflammation alarm, attracting immune cells such as monocytes, which seek out and attach to the plaque.

2. Inflammation sets in: The monocytes mature into macrophages, which begin engulfing the fatty plaque. The immune activity alerts the liver to produce CRP, which floods in to attack the growing plaque.

3. A heart attack occurs when immune cells pile onto the plaque causing it to become unstable and eventually ruptures. Debris from the lesion can cause a blood clot or trigger a heart attack.

Principle of the Procedure

The **One-Step C-reactive Protein (CRP) Test** uses a sandwich immunoassay system and the innumochromatographic detection assay, to be performed in one assay. If CRP is present in the test sample in concentrations above the cut-off level, a labeled specific monoclonal antibody-dye complex forms. This complex is then captured by another specific monoclonal antibody immobilized in the Test Zone (T) of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of CRP in the sample. However, a color band will always appear at the control zone (C).

STORAGE AND STABILITY

1. Store the test kit as packaged at 2-30°C until time of use.
2. DO NOT FREEZE.
3. Do not use beyond the expiration date.

PRECAUTIONS

1. For professional *In Vitro* Diagnostic use only.
2. The test kit should remain in the sealed packaging until time of use. Do not use after the expiration date.
3. All serum or plasma specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The test device should be discarded in a proper biohazard container after testing.
5. Avoid cross-contamination of serum samples by using a new specimen pipette for each sample.
6. Avoid splashing or aerosol formation.

INSTRUCTIONS: SPECIMEN COLLECTION

1. Fresh blood samples are preferred when using a Whole Blood test cassette.
2. If Whole Blood is not tested immediately, an anticoagulant such as EDTA or Heparin must be used. Anticoagulated specimen may be stored under refrigeration for up to 18 hours.
3. Plasma and serum stored under refrigeration (5-8°C) for up to 72 hours is also suitable. Do not freeze the specimen

MATERIALS PROVIDED

1. Test device
2. Plastic dropper
3. Package insert

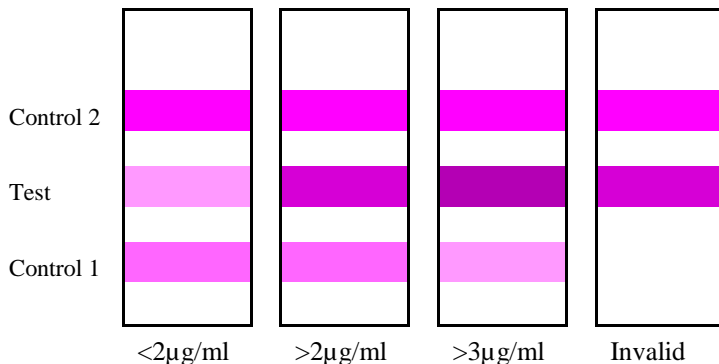
MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer/clock
2. Specimen collection container.

ASSAY PROCEDURE

1. Read package insert carefully before testing. Allow the test devices, whole blood, serum or plasma to equilibrate to room temperature (15-30°C) prior to testing. Do not open packaging until ready to perform the assay.
2. Remove the test device from the foil pouch and use it as soon as possible.
3. Place the test device on a clean and level surface. Hold the dropper provided vertically and transfer 2 drops* of specimen to the specimen well (S) in the test device.
4. Wait 1 minute until the plasma appears in the test window.
5. Read the results at 5 minutes after the serum/plasma appears in the test window.

Note: * Serum or plasma for whole blood, dispense pipette quantity followed by two drops of diluents. Diluent is not included for serum or plasma.



INTERPRETATION OF RESULTS

To determine your result, compare the color intensity, i.e., shade of color, lightness or darkness or color, of the Test band "T" to the Control band "C1" and "C2".

If the test band is of lesser intensity (lighter) than the control band, this means the level of antigen in the sample is less than the value represented by C band. If the test band is of equal or greater intensity (equal or darker) than the Control band, then the concentration of antigen in the sample is above the value represented by C1 and C2 band.

C1 = 2 $\mu\text{g/ml}$ C2 = 3 $\mu\text{g/ml}$ *

* High risk of Coronary Artery Disease (CAD) and Myocardial Infarction Disease (AMI)

The test is invalid if no Control Line or only one Control Line appears with the Test Line

LIMITATIONS OF PROCEDURE

1. The test is for *in vitro* diagnostic use only.
2. The test is limited to the detection of CRP levels in plasma/serum, or fresh whole blood*¹.
3. Although the test is very accurate in detecting elevated CRP, a low incidence of false positive results can occur, especially lysis samples.
4. The test is a qualitative screening assay and is not suggested for use in determining the quantitative levels.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

*¹ Whole Blood or fingerstick samples require a Whole Blood Test cassette.

REFERENCES

1. Paul M. Ridker et.al. N.Enbl. J.Med. Vol. 347, No. 20 1,557-1561, Nov., 2002
2. William L. Roberts, et.al. Clinical Chemistry 47:3 p.418-425, 2001
3. Hans K.Meier-Ewert, et.al. Clinical Chemistry, 47:3 p.426-430, 2001

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