



**2003 AACC ANNUAL MEETING AND CLINICAL LAB EXPOSITION**

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**C-REACTIVE PROTEIN: NEW CDC GUIDELINES ADDRESS WHO SHOULD BE TESTED AND HOW RESULTS ARE BEST MEASURED**

*An elevated C-reactive protein level can greatly increase the risk of many existing cardiovascular risk factors. Should everyone be tested?*

(Philadelphia, PA) -- In the last year, a number of studies have focused on the C-reactive protein (CRP) inflammatory risk factor for heart disease. Using high-sensitivity assays (hsCRP), we are able to measure CRP at lower levels than previously possible. These low levels of CRP (hsCRP) are related to chronic, low grade inflammation, which is associated with heart disease. Many of these studies reported on the relationship of hsCRP to first myocardial or anginal attack, recurrence of coronary heart disease incidents, and increased prognosis of heart disease when elevated hsCRP exists with other risk factors. Other published materials have focused on the laboratory methods used for identifying hsCRP, and have expressed concern about results that stem from using different test methods to identify hsCRP. A Cardiac Risk Survey released earlier this year by the College of American Pathologists (CAP) underscored the need for standardizing the results of five different classes used by labs to identify hsCRP. The Centers for Disease Control and Prevention (CDC) have issued recommendations to address these concerns.

***Presentation at the 55<sup>th</sup> Annual AACC Meeting***

How important is hsCRP as an indicator of cardiovascular disease? What is the role of laboratories and are readings affected by different laboratory methods and a lack of standardization? The CDC has examined these questions and developed recommendations for the public and leaders of the nation's clinical laboratories.

These recommendations will be discussed by Gerald R. Cooper, MD, PhD, of the CDC, Atlanta, GA. Dr. Cooper will deliver his remarks entitled, "C-Reactive Protein: A New Inflammatory Risk Factor for Cardiovascular Disease," during the 55<sup>th</sup> Annual Meeting of the American Association of Clinical Chemistry (AACC) being held July 20-24, 2003 at the Pennsylvania Convention Center, Philadelphia, PA. More than 16,000 attendees are expected.

***Who Should Be Tested?***

Published reports confirm that increased levels of CRP predict an increased risk of cardiovascular disease. A serum CRP level above 5 mg/L is associated with an almost three-fold increased risk of congestive heart failure. Patients with a first myocardial infarction have shown an adjusted 1.3-fold increased risk. Among the elderly, elevated plasma hsCRP levels significantly predict the risk of future first ischemic stroke, and in others, a low grade, chronic hsCRP measurement above 2.91 mg/L predicts a nearly three-times higher risk of developing type 2 diabetes.

The CDC has collaboratively presented two conferences and conducted an evaluation of possible reference materials for the analytic measurements of hsCRP. This has resulted in several recommendations regarding clinical applications of hsCRP testing:

- the entire adult population should not be screened for hsCRP for the purpose of cardiovascular assessment;
- measurement of hsCRP in those judged to be at intermediate risk may help evaluation and indicate a need for therapy;
- in patients with acute coronary syndromes or stable coronary disease, hsCRP measurements may be useful for prognosis.

### **Improving Lab Test Results**

The CDC's recommendations with respect to lab testing and hsCRP include the following:

- measurement of hsCRP be done twice – optimally two weeks apart – and the results averaged;
- when the level is above 10 mg/L, the test should be repeated; and
- the relative risk category and average hsCRP levels be established as: low: <1 mg/L; average: 1.0 to 3.0 mg/L; and high: >3.0 mg/L.

### **Recommendations for Standardizing Test Results**

Because different manufacturers create different types of assays, there is disagreement in test results when different analytical methods are used. To address this issue, the CDC has taken several steps, including plans for an hsCRP reference system that will be used with low-grade inflammation serum values that are associated with high cardiovascular risk. The CDC has also offered a long-term plan for developing a definitive reference method and is working on an immediate plan to develop a candidate hsCRP serum that will be used as the reference material in all diagnostic products.

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*The American Association for Clinical Chemistry (AACC) is the world's most prestigious professional association for clinical laboratorians, clinical and molecular pathologists, and others in related fields. AACC's members are specialists trained in the areas of laboratory testing, including genetic disorders, infectious diseases, tumor markers and DNA. Their primary professional commitment is utilizing tests to detect, treat and monitor disease.*

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**Editor's Note: To schedule an interview with Dr. Cooper, please contact Donna Krupa at 703.527.7357 (direct dial), 703.967.2751 (cell) or [djkrupa1@aol.com](mailto:djkrupa1@aol.com). Or contact the AACC Newsroom at: 215-418-2429 between 8:00 AM and 4:00 PM EST July 20-24, 2003**