

News Release: [June 23, 2004](#)

Cholestech Announces FDA 510(k) Clearance for High Sensitivity CRP, A Test for Arterial Inflammation

First Immunoassay-Based Test for Cholestech LDX(R) Technology Platform

HAYWARD, Calif., June 23 -- Cholestech Corporation (Nasdaq: CTEC) today announced that the Food and Drug Administration ("FDA") has granted 510(k) clearance for the Company's new High Sensitivity C-Reactive Protein ("hs-CRP") test. The new hs-CRP test cassette can be used on the Company's existing Cholestech LDX® System once a simple software upgrade has been completed. This 510(k) clearance will allow the Company to market the product to moderately complex laboratories in the coming months once scale-up of the manufacturing process is completed. Cholestech also plans to seek waived status from the FDA for its hs-CRP test.

In 1999, a state-of-the-art review in the New England Journal of Medicine boldly declared that, "atherosclerosis is an inflammatory disease." Since then, there has been a great deal of research into this area of medicine. At the forefront of much of this research has been blood testing for hs-CRP. In 2003, the American Heart Association and the Centers for Disease Control and Prevention issued a series of evidence-based clinical practice recommendations for use of markers of inflammation. Key among these recommendations was that in individuals determined to be at intermediate risk of coronary heart disease, measurement of hs-CRP, at the discretion of the physician, may help direct further evaluation and therapy in the primary prevention of cardiovascular disease. Experts have estimated that 40% of over 200 million American adults fall into this intermediate risk category.

"We are excited to have our hs-CRP test cleared for marketing by the FDA," said Warren E. Pinckert II, President and Chief Executive Officer. "It is the first immunoassay-based test that we have developed for the LDX System. As a result, it represents an expansion of both our product line and the technological capabilities of the LDX System. The combination of hs-CRP and our cholesterol and liver enzyme tests enhance our market leadership in cardiovascular and diabetes risk assessment and chronic disease management in the physician office."