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510(k) Summary of Safety and Effectiveness

The Wako Direct HDL-C test is an in vitro diagnostic assay for the quantitative determination of high density lipoprotein cholesterol in serum.

Blood total cholesterol levels have long been known to be related to coronary heart disease (CHD). In recent years, in addition to total cholesterol, high density lipoprotein cholesterol (HDL-C) has become an important tool used to assess an individual risk of developing CHD since a strong negative relationship between HDL-C concentration and the incidence of CHD was reported.¹ Thus, there has been substantial interest in HDL-C measurements, and most clinical laboratories routinely perform HDL-C analysis. Selective chemical precipitation techniques are widely used for the determination of HDL-C such as heparin-manganese, dextran-magnesium, and phosphotungstate-magnesium.² However, these techniques require physical separation via centrifugation, which is not suited to large scale lab use. The Wako Direct HDL-C test eliminates the precipitation procedure by employing a specific antibody, and thus, can be applied on automated analyzers.

Anti human β -lipoprotein antibody Reagent 1 binds to lipoproteins (LDL, VLDL, and chylomicrons) other than HDL. The antigen-antibody complexes formed block enzyme reactions when Reagent 2 is added. Cholesterol esterase (CHE) and cholesterol oxidase (CO) in Reagent 2 react only with HDL-C. Hydrogen peroxide produced by enzyme reactions with HDL-C yields a blue color complex upon oxidase condensation with FDAOS [N-ethyl-N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxy-4-fluoroaniline, sodium salt] and 4-aminoantipyrine (4AA) in the presence of peroxidase (POD). By measuring the absorbance of the blue color complex produced, at approximately 600 nm, the HDL-C concentration in the sample can be calculated when compared with the absorbance of the HDL-C Calibrator.

The safety and effectiveness of the Wako Direct HDL-C assay is demonstrated by its substantial equivalency to our previous HDL-Cholesterol assay (510(k)# K801834). Both test systems are used to measure high density lipoprotein cholesterol in serum. In comparison studies against the predicate assay, a correlation coefficient of 0.972 and a regression equation $Y=1.08x - 2.91$ was obtained with serum samples. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is estimated to be 1 mg/dL. The Wako Direct HDL-C assay has been determined to be linear to 120 mg/dL.

References

1. Rifai, N. and Warnick, G.R., Ed. Laboratory Measurement of Lipids, Lipoproteins and Apolipoproteins. AACC Press, Washington, DC, USA, 1994.
2. Burtis, C.A. and Ashwood, E.R. Ed. Tietz Textbook of Clinical Chemistry, 2nd Ed., Saunders, Philadelphia, 1994.
3. The Expert Panel. Summary of the second report of the National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel II). JAMA 1993;269: 3015-23.

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