

Cholesterol 1,2,3™

Cholesterol 1,2,3, a Novel Point-of-Care Diagnostic Test for Skin Cholesterol.
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Cholesterol levels in the skin have been reported to be elevated in individuals with atherosclerotic disease, however the invasive nature of skin cholesterol (SC) testing has limited its utility in a clinical environment. Cholesterol 1,2,3, is a novel, non-invasive, point-of-care test for the determination of SC. To determine SC levels an applicator pad was applied to the palmar surface of the skin and a digitonin-peroxidase conjugate was added to a well in the pad with a dropper bottle. After a 1-minute incubation the hand was rinsed briefly with tap water, blotted dry, and peroxidase substrate solution was added to the well and incubated for 2 minutes. The substrate solution was then transferred to a microwell and absorbance at 450nm was determined. A negative control well in the pad remained colourless in a valid assay. The assay was standardized *in vitro* using cholesterol-coated microwells. *In vitro* testing showed that the detector was inhibited from binding to the microwells by soluble cholesterol and that this inhibition was concentration dependent. The detector had a linear range of 0.02 to 2.0mg/mL cholesterol *in vitro*. Intra-assay precision was 8.7-17.6% and interassay precision was 7.2%. We determined SC levels in consecutive individuals presenting to a cardiac outpatient clinic for diagnostic exercise stress testing or transesophageal echocardiography. Results from 111 patients showed that SC levels were correlated with the presence of cardiovascular disease (Pearson correlation 0.262, P<0.023). In addition SC was found to be independent of serum lipids. These data suggest that the non-invasive determination of SC levels may have value in assessing cardiovascular disease risk.

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