

Lipid Profile (total cholesterol, HDL-cholesterol, triglyceride, calculated LDL)

These assays are run at the Clinical Chemistry Laboratory at Fletcher Allen Health Care, an affiliate of the University of Vermont. The Ortho Vitros Clinical Chemistry System 950IRC instrument (Johnson & Johnson Clinical Diagnostics, Rochester, NY), which uses thin film technology, is used to quantitatively measure lipid levels via a colorimetric reaction.

Cholesterol is measured using a colorimetric reflectance spectrophotometric method. Normal ranges for adults are Desirable : < 200 mg/dL; Borderline: 200 – 239 mg/dL; High: => 240 mg/dL. The reportable range for this assay is 50-325mg/dl. The expected CV of this assay is <2%.

Direct HDL Cholesterol is assayed by colorimetric reflectance spectrophotometry after samples are treated with phosphitungstic acid/magnesium chloride to precipitate HDLs and non-HDLs. Normal ranges for adults are Highly Desirable: > 60 mg/dL; Desirable: 35-60 mg/dL; High Risk: <40 mg/dL. The reportable range for this assay is 5.0-110.0 mg/dL. The expected CV of this assay is approximately 7%.

LDL Cholesterol is calculated: $\text{Total Cholesterol} - \{\text{HDL} + (\text{Triglycerides}/5)\}$. Normal ranges for adults are Desirable: < 130 mg/dL; Borderline: 130-159 mg/dL; High Risk: >= 160 mg/dL.

Triglyceride is measured by colorimetric reflectance spectrophotometry. Normal ranges for adults are Normal:<150 mg/dL; Borderline High: 150-199 mg/dL; High; Very High: >=150mg/dL . The reportable range for this assay is 10.0-525.0 mg/dL. The expected CV of this assay is <2%.

INSTRUCTIONS FOR USE

VITROS Chemistry Products CHOL Slides

CHOL

Cholesterol

REF 166 9829

Intended Use

For *in vitro* diagnostic use only.

VITROS CHOL Slides quantitatively measure cholesterol (CHOL) concentration in serum and plasma.

Summary and Explanation of the Test

Cholesterol is present in tissues and in serum and plasma either as cholesterol or as cholesterol esters bound to proteins. Cholesterol is an essential structural component of cell membranes and the outer layer of plasma lipoproteins and is the precursor of all steroid hormones, including sex and adrenal hormones, bile acids, and vitamin D.

Cholesterol measurements are used to evaluate the risk of developing coronary artery occlusion, atherosclerosis, myocardial infarction, and cerebrovascular disease. Coronary atherosclerosis correlates with a high cholesterol level. Cholesterol concentrations are increased in primary hypercholesterolemia; secondary hyperlipoproteinemia, including nephrotic syndrome; primary biliary cirrhosis; hypothyroidism; and in some cases diabetes mellitus. Low cholesterol concentrations may be found in malnutrition, malabsorption, advanced malignancy, and hyperthyroidism. Serum cholesterol concentration depends on many factors, including age and gender.¹

Principles of the Procedure

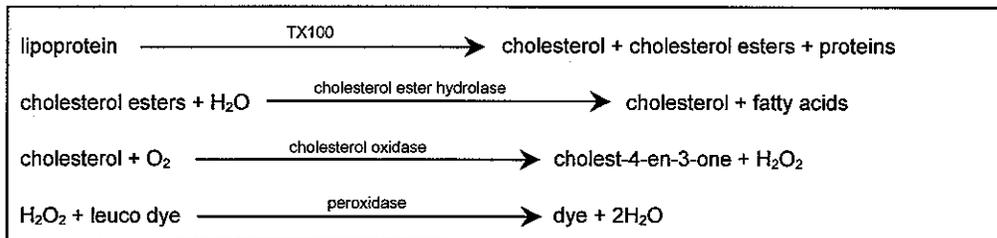
The VITROS CHOL Slide method is performed using the VITROS CHOL Slides and the VITROS Chemistry Products Calibrator Kit 2 on VITROS Chemistry Systems.

The VITROS CHOL Slide is a multilayered, analytical element coated on a polyester support. The method is based on an enzymatic method similar to that proposed by Allain et al.²

A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. The Triton X-100 (TX100) surfactant in the spreading layer aids in dissociating the cholesterol and cholesterol esters from lipoprotein complexes present in the sample. Hydrolysis of the cholesterol esters to cholesterol is catalyzed by cholesterol ester hydrolase. Free cholesterol is then oxidized in the presence of cholesterol oxidase to form cholest-4-en-3-one and hydrogen peroxide. Finally, hydrogen peroxide oxidizes a leuco dye in the presence of peroxidase to generate a colored dye.

The density of dye formed is proportional to the cholesterol concentration present in the sample and is measured by reflectance spectrophotometry.

Reaction Sequence



Test Type and Conditions

Test Type and Conditions for CHOL

Test Type	VITROS System	Approximate Incubation Time	Temperature	Wavelength	Sample Drop Volume*
Colorimetric	5,1 FS, 950, 750, 550, 250	5 minutes	37°C (98.6°F)	540 nm	5.5 µL

* The sample drop volume depends on the format of the slide and is determined automatically by the analyzer. Slides with coating numbers <3201 require a 10 µL sample drop volume.