HDL3 ASSAY

The HDL3 Assay is a homogeneous enzymatic assay for use in the quantitative determination of HDL3 in human serum. High-density lipoprotein (HDL) is known to be a negative risk factor for coronary heart disease (CHD). HDL can be further divided into two major subclasses, larger, more buoyant HDL2 particles and smaller, more dense HDL3 particles. Several studies suggest that measuring these HDL subclasses better reflects CHD risk than measurement of total HDL.[1-8]

Diazyme's HDL3 Assay is a cost effective, homogenous, direct assay for the fast and easy quantification of HDL3 cholesterol.

DIAZYME HDL3 ASSAY ADVANTAGES

- Allows for quantification of HDL2 by the subtraction of HDL3 from total HDL
- Wide Measuring Range: 7 to 148 mg/dL
- Improves laboratory efficiency and workflow
- Fast test results (10 minutes) for a rapid turnaround time
- Liquid stable format requires no reagent preparation
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

USA: For Research Use Only

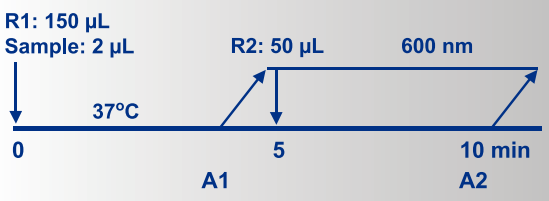
HDL3 ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Homogeneous Enzymatic Assay
Sample Type & Volume	Serum Sample Volume 2 µL
Method Correlation	N = 40 y-intercept = 0.92 Slope = 1.2 R^2 = 0.9045 Sample Range: 20 to 100 mg/dL
LOD ***LOQ***	1.3 mg/dL 4.5 mg/dL
Calibration Levels	3-Point Calibration

*HDL3 Assay Procedure**



***Analyzer Dependent**

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

1. *Stampfer MJ et al. N Engl J Med 1991; 325: 373-81.*
2. *Williams PT. J Lipid Res 2012; 53: 266-72.*
3. *Smuts CM et al. Coron Artery Dis 1994; 5: 331-8.*
4. *Mueller O et al. Clin Chem Lab Med 2008; 46: 490-8.*
5. *Kempen HJ et al. J Lab Clin Med 1987; 109: 19-26.*
6. *Lamarche B et al. Arterioscler Thromn Vasc Biol 1997; 17: 1098-105..*
7. *Chapman MJ et al. J Lipid Res 1981; 22: 339-58.*
8. *Blanche PJ et al. Biochim Biophys Acta 1981; 665: 408-19.*

ASSAY PRECISION

In the study, two serum samples containing 11.8 and 61.5 mg/dL HDL3 respectively, were tested on hitachi 917 in one run with 20 replicates. Within-Run Precision is listed in the table below

	Level 1	Level 2
N	20	20
Mean (mg/dL)	11.8	61.5
SD (mg/dL)	0.58	1.54
CV (%)	4.93	2.51

ASSAY INTERFERENCE

To determine the level of interference from the substances present in serum, the Diazyme HDL3 Assay was used to test two serum samples with 8 mg/dL and 40 mg/dL HDL3 spiked with various concentrations of substances following the CLSI EP7-A2. The following substances do not interfere with this assay at the levels tested (less than 10% bias).

Interferent	Concentration
Bilirubin	40 mg/dL
Bilirubin Conjugated	40 mg/dL
Hemoglobin	500 mg/dL
Ascorbic acid	10 mM
Triglycerides	1000 mg/dL

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