

APOLIPOPROTEIN A-I APOLIPOPROTEIN B

(Immunoturbidometric)



Reliable and Precise Test Results

- The level of the calibrator for Diazyme apolipoprotein assays are determined using WHO/IFCC reference standards
- Highly precise with low CV's

Adaptable

- Methods are adaptable for use on a wide variety of clinical chemistry analyzers

Extremely Stable

- Twenty one (21) day calibration stability *

Cost Effective

- Low cost per test

Convenient

- Diazyme's is a single source for the full range of lipid testing including Apolipoprotein A-I, Apolipoprotein B, Lp(a), HDL, LDL, Total Cholesterol and Triglycerides

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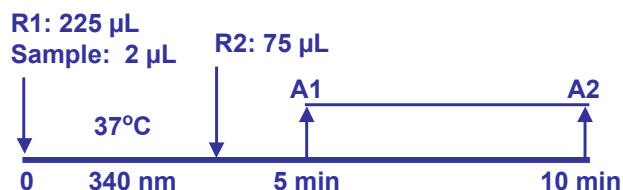
SUMMARY OF PERFORMANCE

Background

Clinical Significance

Lipids are synthesised in the intestine or liver but must be transported to tissues and organs. However, this is not possible without hydrophilic adaptation. Lipids are, therefore, transported by a series of micellar structures. These structures consist of an outer monolayer of protein (an apolipoprotein) and polar lipids (phospholipids and unesterified cholesterol) plus an inner core of neutral lipids (triglycerides and cholesterol esters). The apolipoproteins interact with a series of enzymes and tissue receptors and are therefore responsible for further metabolism and catabolism of the micelle. The A apolipoproteins are the main forms of proteins found in high density lipoproteins (HDL) and the B apolipoproteins are the main form of protein found in low density lipoproteins (LDL). Recently there has been a heightened interest in the specific measurement of the apolipoproteins since. Studies have shown that there is an inverse relationship between APO A-I and coronary artery disease and a direct relationship with APO B such that patients with CAD have generally reduced levels of APO A-I and increased levels of APO B.

Assay Method



Depending on the kit purchased the assay will contain specific antiserum against either Apolipoprotein A-I or Apolipoprotein B. In this method a patient sample containing human apolipoprotein and specific antiserum combine to form an insoluble complex which can be measured turbidimetrically at 340 nm. By constructing a standard curve from the absorbance of standards the concentration of apolipoprotein can be determined.

Performance

Accuracy

The level of the calibrator for Diazyme apolipoprotein assays are determined using WHO/IFCC reference standards.

The performance of the Diazyme Apo A-I assay was assessed on a Roche Hitachi 917. Sixty one (61) serum specimens including fifty eight (58) non-altered samples were used for this comparison to a legally marketed product. To ensure the concentrations of Apo A-I distributed across the reportable dynamic range claimed, additional Apo A-I samples were spiked with Apo A-I or diluted with saline. In this study samples ranged from 45.2 to 250.8 mg/dL Apo A-I, the correlation coefficient between the two methods is 0.9791; the slope is 0.9127; and y intercept is 1.7101.

The performance of the Diazyme Apo B assay was assessed on a Roche Hitachi 917 and compared with the performance of a legally marketed assay using serum samples (Apo B ranging from 10.2 to 242 mg/dL). For the total of sixty five (65) serum samples, the correlation coefficient between the two methods is 0.9874; the slope is 0.9875; and y intercept is -1.8031.

Precision

Diazyme Apo A1 Reagents Assay precision was evaluated according to Clinical Laboratory Standards Institute (formerly NCCLS) EP5-A guideline. In the study, four serum specimens were tested on Hitachi 917 twice daily, in duplicates over 10 days.

Within Run Precision (Sr)

Apo A I	Level 1	Level 2	Level 3
Number of Data Points	40	40	40
Mean	80.18	157.29	212.98
SD	0.47	1.43	1.39
CV%	0.6	0.9	0.7

Within-Laboratory Precision (S_T)

Apo A I	Level 1	Level 2	Level 3
Number of Data Points	40	40	40
Mean	80.18	157.29	212.98
SD	2.65	2.81	4.73
CV%	3.3	1.8	2.2

Diazyme Apo b Reagents Assay precision was evaluated according to Clinical Laboratory Standards Institute (formerly NCCLS) EP5-A guideline. In the study, four serum specimens were tested on Hitachi 917 twice daily, in duplicates over 10 days.

Within Run Precision (S_r)

Apo B	Level 1	Level 2	Level 3
Number of Data Points	40	40	40
Mean	23.81	99.55	154.17
SD	0.34	1.43	1.88
CV%	1.4	1.4	1.2

Within-Laboratory Precision (S_T)

Apo B	Level 1	Level 2	Level 3
Number of Data Points	40	40	40
Mean	23.81	99.55	154.17
SD	1.13	3.89	3.18
CV%	4.8	3.9	2.1

Linearity

The linearity of the Diazyme Apo B assay is from 3.60-240 mg/dL in serum. Results that exceed 240.0 mg/dL should be diluted with saline and retested. The linearity of the Diazyme Apo A assay is from 1.44-250.8 mg/dL in serum. Results that exceed 250.8 mg/dL should be diluted with saline and retested.

Interference

Interference for the Diazyme Apo A I Assay was evaluated on the Roche Hitachi 917. The following substances normally present in serum produced less than 10% deviation at the listed concentrations: Triglyceride at 1000 mg/dL, Ascorbic Acid at 10 mM, Bilirubin at 40 mg/dL, Bilirubin Conjugate at 40 mg/dL, and Hemoglobin at 1000 mg/dL. Interference for the Diazyme Apo B Assay was evaluated on the Roche Hitachi 917. The following substances normally present in serum produced less than 10% deviation at the listed concentrations: Triglyceride at 1000 mg/dL, Ascorbic Acid at 10 mM, Bilirubin at 40 mg/dL, Bilirubin Conjugate at 40 mg/dL, and Hemoglobin at 1000 mg/dL.

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