

Quality Control

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	66.2	11.07
SD	4.26	4.64
CV%	6.44	4.19

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	72.7	110.7
SD	4.02	4.64
CV%	5.53	4.44

Accuracy

Results obtained using Spectrum reagents (y) did not show systematic differences when compared with other commercial reagents. (x). The results obtained using 200 samples were the following. Correction coefficient (r): 0.996.

Regression equation: $y = 4.6 + 0.940x$.

The results of the performance characteristics depend on the analyzer used.

Dynamic range:

The measuring range is from 1.0 mg/dl to linearity limit of 250 mg/dl. If the results obtained were greater than linearity limit, dilute the sample 2 times with NaCl 9 g/L and multiply the result by 2.

Sensitivity

When run as recommended, the minimum detection limit of this assay is 1 mg/dL.

Linearity

250 mg/dL

Interfering Substance

No Interferences were observed up to the following

Ascorbic acid 50 mg/dL

Haemoglobin 500 mg/dL

Bilirubin 30 mg/dL.

A list of drugs and other interfering substances with LDL cholesterol determination has been reported by Young et al 8.4.

NOTES

Spectrum has Instrument application sheets for several automatic analyzers. Instructions for many of them are available on request.

Expected Values

Levels of the risk:

Desirable	<100 mg/dL
Medium	100 – 160 mg/dL
High	>160mg/dL

These values are for orientation purpose; each laboratory should establish its own reference range.

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Kaplan A et al. Lipoprotein Clin Chem the C. V. Masby Co. St Louis.
2. Okada M. et al Low- density lipoprotein can be chemically measured J. Lab, Clin. Med., 1996; 132, 195-201.
3. Young DS. Effects of Drugs on Clinical Lab. Tests, 4th ad AACC Press, 1995.
4. Young DS. Effects of diseases on Clinical Lab. Tests 4th ad AACC 2001.
5. Burlis A et al. Teitz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al, Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

ORDERING INFORMATION

CATALOG NO.	QUANTITY
280 001	100 Test
280 002	200 Test

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