

CRMLN Frequently Asked Questions

What is CRMLN?

The Cholesterol Reference Method Laboratory Network (CRMLN) certifies manufacturers of clinical diagnostic products that measure total cholesterol (TC) and HDL cholesterol (HDL-C). The CRMLN laboratories use reference methods or designated comparison methods that are rigorously standardized to the Centers for Disease Control and Prevention (CDC) reference methods. The Food and Drug Administration (FDA) has recognized the value of the CRMLN's certification program and encourages manufacturers to certify their products through the CRMLN. Go to this website to see the complete list of CRMLN certified manufacturers of analytical systems for Total Cholesterol:

http://www.cdc.gov/labstandards/pdf/crmln/Web_TC_Report.pdf

And for HDL Cholesterol:

http://www.cdc.gov/labstandards/pdf/crmln/Web_HDL_Report.pdf

What methods constitute the accuracy base for lipids and lipoproteins?

The Abell-Kendall reference method (the AK method) for cholesterol is the basis for quantification of cholesterol in the reference method for HDL cholesterol. The National Cholesterol Education Program (NCEP) has recommended that CDC's reference methods be used as the accuracy base for measurement of cholesterol. The AK method is recognized as an integral part of the National Reference System for Cholesterol.

What is involved in the certification process?

- Manufacturer selects and makes arrangements with CRMLN lab (there are 3 in the US)
- Manufacturer identifies samples meeting protocol requirements
- Manufacturer tests samples (on each method) in duplicate
- Manufacturer aliquots serum and sends to CRMLN lab
- Manufacturer sends results of patient sample testing and imprecision data tested according to NCCLS (CLSI) EP5-A to CRMLN lab
- CRMLN lab analyzes sera and compares CRMLN results with manufacturer
- Certification process takes 4-8 weeks depending upon number of samples, analytes, and methods to be tested

What are the certification criteria?

NCEP Analytical Goals for TC and HDL-C

Analyte	Accuracy	Imprecision	Total Error
TC	bias \leq 3%	CV \leq 3%	\leq 8.9%
HDL-C	bias \leq 5%	CV \leq 4%	\leq 13%

Why has Cholestech obtained CRMLN Certification now?

Cholestech is committed to providing point-of-care testing products of unsurpassed quality to healthcare professionals and the patients they treat. Cholestech's continuous process improvement programs have enabled the Company to deliver CRMLN certification as a demonstration of this commitment. Meeting stringent NCEP performance goals and maintaining tight, proven traceability to CDC reference methods ensures that Cholestech LDX lipid tests can be used with confidence for cardiovascular risk assessment and management.

Why is Cholestech only certified for TC and HDL-C?

The CRMLN certifies manufacturers of clinical diagnostic products that measure TC and HDL-C. It does not certify manufacturers of triglyceride tests. Therefore, it is not possible for Cholestech to be certified by CRMLN for measuring calculated LDL-C.

What does CRMLN certification mean to me?

Cholestech has always had a committed focus on product quality and customer care. With CRMLN certification you now have unsurpassed proof that the cholesterol results you obtain with the Cholestech LDX are always lab accurate. The ultimate benefit of this certification is improved patient care.

CHOLESTECH 

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