



Alere Cholestech LDX® System:

Cat. No.	Product	CPT Code
10-959	Alere Cholestech LDX® System	-
10-991	Lipid Profile•GLU	80061 QW, 82947 QW
10-989	Lipid Profile	80061 QW
10-990	TC•HDL•GLU	82465 QW, 83718 QW, 82947 QW
10-987	TC•HDL	82465 QW, 83718 QW
10-988	TC•GLU	82465 QW, 82947 QW
10-986	TC	82465 QW
88769	Multianalyte Control Levels 1 and 2 (2 vials Level 1 & 2 vials Level 2, 2 mL each)	-
88773	Multianalyte Control Levels 1 and 2 (1 vial Level 1 & 1 vial Level 2, 0.25 mL each)	-

The Power of Alere

With professional and consumer offerings in over 100 disease categories, Alere delivers the widest range of services and solutions across the widest range of environments—all around the world. Alere is the global leader in near-patient diagnostics for cardiology, infectious disease, and toxicology, with expanding capabilities in diabetes.

Alere provides the solutions needed today by offering a complete range of devices and services that seamlessly integrate real-time data collection, education and health management solutions through each stage of life, from preconception to end of life.

The Alere Cholestech LDX® System offers efficient and economical point of care testing for cholesterol and related lipids, and blood glucose to serve as diagnostic tools that provide information for immediate risk assessment and therapeutic monitoring of heart disease and diabetes.



Accurate actionable results from the leader in point of care lipid testing

Benefits at a Glance

Accurate lipid results are essential for the healthcare provider, wellness participant and patient. For the results to be most effective, diagnostic data should be actionable and readily accessible. With results in 5 minutes, the CLIA waived Alere Cholestech LDX® System has set the standard in point of care lipid and glucose testing and is the #1 choice of healthcare professionals used in thousands of physician offices, hospitals and wellness programs nationwide.



Wellness Program

- Creates an immediate opportunity for awareness and identification of cardiovascular health risk from a fingerstick sample
- Provides accurate results that may have financial implications to both the participant’s and the corporation’s healthcare costs
- A full lipid profile and glucose are available on the same test cassette eliminating multiple fingerstick samples and tests



Physician Office Lab

- Offers the opportunity for immediate intervention and counseling– better patient outcomes
- Improves efficiency for staff– eliminates costly call back to lab and patient
- Reimbursed by Medicare and most private payers

Assured Clinical Decisions

In order for clinical decision points to be valid, lipid testing must be standardized. The National Cholesterol Education Program (NCEP) of the National Institutes of Health (NIH) has established performance goals that the CDC utilizes in their certification programs to standardize testing.

NCEP Performance Goals:

	Bias	CV	Total Error
Total cholesterol	≤ 3%	≤ 3%	≤ 8.9%
HDL cholesterol	≤ 5%	≤ 4%	≤ 13%
Triglycerides	≤ 5%	≤ 5%	≤ 15%

When choosing a point of care lipid profile platform, certification in both programs provides additional assurance that lipid results are standardized



Lipid Standardization Program (LSP) Certification

- **Quarterly** certification for total cholesterol, HDL cholesterol and triglycerides
- Samples provided direct from the CDC to verify traceability to CDC reference methods
- Alere is the first point of care manufacturer invited to participate in the program

Cholesterol Reference Method Laboratory Network (CRMLN) Certification

- **Biannual** certification for total cholesterol and HDL cholesterol
- Samples sent to CRMLN certified laboratories to verify traceability to CDC reference methods

Alere participates in the only two currently available CDC standardization programs that align with the NCEP performance goals.

The Hidden Details Are Crucial to Accuracy

As the market leader for point of care lipid testing, the Alere Cholestech LDX® System has unique safeguards and checks. If the quality checks at each programmed step are not completed correctly, a result will not be reported, **ensuring test accuracy**.

QA Check	Operational Checks	Functions
Self-test Checks	Battery Check	Verifies system contains factory calibration settings
	ADC Converter Check	Checks analog to digital converter is functioning properly
	LED Check	Ensures light source functioning properly
	Configuration Check	Checks integrity of configuration data
	RH Sensor (Humidity) Check	Verifies integrity of humidity sensor
	ROM Check	Checks integrity of ROM pack
Pre-run Checks	Tray Alignment Check	Ensures tray is properly aligned
	Operating Temperature Check	Verifies internal temperature between 20 and 35°C
	Optics Check	Verifies last optics check run passed
	Cassette Expiration Check	Confirms cassette not expired
	RH Sensor Check	Verifies integrity of humidity sensor
Mid-run Checks	Used Cassette Check	Checks initial reflectance reading meets factory specification
	Magnetic Stripe Check	Ensures readability of magnetic stripe on cassette
	Tray Alignment Check	Ensures tray is properly aligned
	Light Sensor Check	Verifies ambient light measurement meets factory specification
	RDNO Check	Checks for sample related issues resulting from insufficient sample volume

Reliable and Accurate

Alere Cholestech LDX® Cassette Quality Assurance

Programming is encoded on the magnetic stripe on each individual cassette ensuring test accuracy.

- **Sample Reliability:** Designed to precisely manage sample flow through timed sequences controlling tray positions to optimize sample variability
- **Result Reliability:** Contains test information including cassette lot numbers and lot specific calibration settings eliminating manual verification or external code chips

Individually foil sealed test cassettes preserves the cassette integrity.

- **Performance Reliability:** Protects each cassette from reagent degradation, contamination or potential spills
- **Test Reliability:** Encoded with important test information including lot number and expiration on each and every foil package

