

Alere San Diego, Inc.
MATERIAL SAFETY DATA SHEET
MSDS

MSDS-4401
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Alere Cholestech LDX[®] Test Cassette

Section 1 - Chemical Product Identification

MSDS Name: Alere Cholestech LDX[®] Test Cassette

Product Description: See product insert.

Common Name (Used on label)

Alere Cholestech LDX[®] TC
Alere Cholestech LDX[®] TC- HDL
Alere Cholestech LDX[®] TC - GLU
Alere Cholestech LDX[®] Lipid Profile
Alere Cholestech LDX[®] TC – HDL - GLU
Alere Cholestech LDX[®] Lipid Profile - GLU
Alere Cholestech LDX[®] AST - ALT

Chemical Name: Does not apply

Chemical Family: Does not apply

Formula: Does not apply

Trade Name & Synonyms: Alere Cholestech LDX[®] , Trademark of Alere San Diego, Inc.

Company Identification: Alere San Diego, Inc. d/b/a Biosite Incorporated 9975 Summers Ridge Road,
San Diego, CA 92121
Phone: (858) 455-4808 Fax: (858) 455-4815

Emergency Phone Number

**For information or technical assistance please contact the Technical Services Department
at Alere San Diego, Inc. (1-877-308-8289)**

Section 2 - Composition, Information on Ingredients

See product insert sheet for cassette contents.

Section 3- Hazard Identification

HAZARDOUS COMPONENT	CAS #	% (wt)	TLV	PEL
None – Dry Test system				

PEL: Permissible Exposure Limit established by the Occupational Safety and Health Administration (OSHA).

TLV: Threshold Limit Value established by the American Conference of Governmental Industrial Hygienists, 1987-88.

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Section 4- First Aid Measures

PRIMARY ROUTES OF EXPOSURE Skin			
SIGNS AND SYMPTOMS OF EXPOSURE (1) ACUTE OVEREXPOSURE - None			
(2) CHRONIC OVEREXPOSURE - None			
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE None			
CHEMICAL/COMPONENT LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN None	NTP ___ Yes ___ No	IARC ___ Yes ___ No	OSHA ___ Yes ___ No
OTHER EXPOSURE LIMITS None			
EMERGENCY & FIRST AID PROCEDURES None			

Section 5 - Fire Fighting Measures

FLASH POINT Not Applicable	FLAMMABLE LIMITS IN AIR (% by VOLUME) LOWER: Not Applicable UPPER: Not Applicable
EXTINGUISHING MEDIA Use extinguishing media appropriate for surrounding fire	AUTO IGNITION TEMPERATURE Not Applicable
UNUSUAL FIRE AND EXPLOSION HAZARDS Not determined	
SPECIAL FIRE FIGHTING PROCEDURES None	

Section 6 - Accidental Release Measures

STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED Not applicable
WASTE DISPOSAL METHOD <u>Unused cassettes</u> should be disposed of as regular waste in accordance with Federal, State, and Local codes. <u>Used cassettes</u> , i.e. cassettes tested as intended in diagnostic procedures with human biological samples, must be treated as potentially infectious and disposed of as biohazard waste in accordance with Federal, State, and Local codes.

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Section 7 - Handling and Storage

PRECAUTIONS TO BE TAKEN IN HANDLING & STORING

Store and handle according to packaged instructions

See product insert sheet for storage instructions.

Section 8 - Exposure Control, Personal Protective Equipment

RESPIRATORY PROTECTION

Not required under normal and intended uses.

VENTILATION

General room ventilation

PROTECTIVE GLOVES

Not required

EYE PROTECTION

Not required

OTHER PROTECTIVE CLOTHING OR EQUIPMENT

When used for intended diagnostic procedures, i.e. testing human samples treat test samples as potentially biohazardous and exercise universal precautions.

Section 9 - Physical and Chemical Properties

BOILING POINT Not Applicable		SPECIFIC GRAVITY (H ₂ O = 1) Not Applicable	VAPOR PRESSURE (mm Hg) Not Applicable
PERCENT VOLATILE BY VOLUME (%) Not Applicable	VAPOR DENSITY (AIR = 1) Not Applicable	EVAPORATION RATE (Butyl Acetate = 1) Not Applicable	
SOLUBILITY IN WATER Some components are soluble		REACTIVITY IN WATER Not determined	
APPEARANCE AND ODOR Polystyrene with attached white to yellow membranes with no odor			

Section 10 - Stability and Reactivity

STABILITY Unstable ___ Stable <u>X</u>	CONDITIONS TO AVOID Not determined
INCOMPATIBILITY (MATERIALS TO AVOID) Not determined	
HAZARDOUS DECOMPOSITION PRODUCTS Not determined	
HAZARDOUS POLYMERIZATION May Occur ___ Will Not Occur <u>X</u>	CONDITIONS TO AVOID Not determined

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Section 11 - Toxicological Information

RRECS: No information available
LD 50 / LC 50: No information available
Carcinogenicity: None
Epidemiology: No information available
Teratogenicity: No information available
Reproductive: No information available
Mutagenicity: No information available

Section 12 - Ecological Considerations

Ecotoxicology: No information available
Environmental movement and partitioning: No information available
Environmental Fate (Degradation, Transformation and Persistence): No information available
Environmental Investigations: No information available

Section 13 - Disposal Considerations

WASTE DISPOSAL METHOD

Unused cassettes should be disposed of as regular waste in accordance with Federal, State, and Local codes.

Used cassettes, i.e. cassettes tested as intended in diagnostic procedures with human biological samples, must be treated as potentially infectious and disposed of as biohazard waste in accordance with Federal, State, and Local codes.

Section 14 - Transport Information

	US DOT	IMO	IATA	RID / ADR
Shipping Name:	Not regulated as a hazardous material	Not regulated as a hazardous material	Not regulated as a hazardous material	Not regulated as a hazardous material
Hazard Class:	NA			
UN #:	NA			
Packing Group:	NA			
<p>Note: If an Alere Cholestech LDX[®] Test Cassette is used and needs to be shipped to another facility or returned to Alere please contact the Technical Services Department at (1-888-246-7483 option 2)</p>				

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Section 15 - Regulatory Information

US Federal TSCA: This material is not listed on the TSCA Inventory.

TSCA Section 12b: This material is not listed.

CERCLA/SARA Reportable Quantities/TPQ's: This material is not listed.

CERCLA/SARA Section 313: This material is not listed.

Clean Air Act: This material is not recognized as an air contaminant.

Clean Water Act: This material is not on any CWA list.

Section 16 - Other Information

PRECAUTIONS TO BE TAKEN IN HANDLING & STORING

Store and handle according to packaged instructions

Please review product insert prior to using this product.

All individuals using this product should follow general good laboratory safety procedures as established and implemented by your institution in compliance with Federal, State and local requirements.

OTHER PRECAUTIONS: None

Effective Date: 10 November 2011

*The information presented above is believed to be accurate and represents the best information currently available to us. Since the conditions and manner of use are outside our control, we make no warranties, express or implied, and assume no liability in the connection with any use of this information. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential, or exemplary damages howsoever arising, even if the company has been advised of the possibility of such damages. **Additionally, this data sheet is not to be substituted for product literature which may accompany the finished product.***

Signature Manifest

Document Number: MSDS-4401

Revision: D

Title: Cholestech LDX® Test Cassette

All dates and times are in US/Pacific.

DCF-0204 MSDS-4401

Collaboration Step 1

Name/Signature	Title	Date	Meaning/Reason
Ed Brehm (BREHMED)		11 Nov 2011, 12:51:54 PM	Complete
Renee Wiegmann (WIEGMRE)		11 Nov 2011, 01:45:25 PM	Complete

Collaboration Step 2

Name/Signature	Title	Date	Meaning/Reason
Ed Brehm (BREHMED)			
Catherine Cyr (CATHERINE.CYR)			
Renee Wiegmann (WIEGMRE)		22 Nov 2011, 10:12:20 AM	Complete

Approval Step

Name/Signature	Title	Date	Meaning/Reason
Ed Brehm (BREHMED)		29 Nov 2011, 07:34:30 AM	Approved
Matt Rowe (ROWEMA)		29 Nov 2011, 11:00:35 AM	Approved
Eric Ogg (OGGER)		29 Nov 2011, 01:58:38 PM	Approved
Robert Schmidt (SCHMIRO)		29 Nov 2011, 03:44:58 PM	Approved
Susan Moi (MOISU)	Manager, Reagent Optimization	2 Dec 2011, 10:21:36 AM	Approved

Final Release

Name/Signature	Title	Date	Meaning/Reason
Farah Shah (FARAH.SHAH)			
Erica Garcia (GARCIER)			
Deborah Phillips (PHILLDE)			
Renee Wiegmann (WIEGMRE)		2 Dec 2011, 12:06:08 PM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Renee Wiegmann (WIEGMRE)		2 Dec 2011, 12:30:39 PM	Approved