

Alere Medical Test Device Control Set / Calibration Verification Controls

Section 1 - Chemical Product Identification

MSDS Name:

Alere Medical Test Device Control Set / Calibration Verification Controls

Product Description:

A set of human source (blood or urine) liquid controls or calibration verification controls used to verify the operation / calibration of the Triage Meter, Triage Meter Plus, Alere Triage MeterPro, Alere™ Heart Check Meter or their associated Test Devices throughout their measurable range.

Product Name	Catalog Numbers				
Alere Heart Check Controls Set	80397	80398	98071EU		
Alere Triage BNP Test / Beckman BNP	98013XR	98014XR	98015XR		
Alere Triage CardioRenal Controls	98423EU	98424EU			
Alere Triage Correlation Sample Set	52133- EDTA	52134- Heparin	52135- Sodium Citrate		
Triage Drugs of Abuse	52229	52230		18002827	
Alere Triage NTproBNP Controls	98713EU	98714EU			
Alere Triage NGAL Controls	98413EU	98414EU			
Alere Triage NGAL Calibration Verification	98415EU				
Alere Triage PLGF Controls	98813EU	98814EU			
Triage Protein C Controls	98513	98514			
Triage Protein C Calibration Verification	98515				
Alere Triage Quantitative hCG Controls	98821EU	98822EU			
Alere Triage Total 3 Controls	88733	88734			
Alere Triage Total 3 Calibration Verification	88735				
Alere Triage Total 5 Controls	88753	88754			
Alere Triage Total 5 Calibration Verification	88755				
Alere Triage Total 5 plus Controls	88753G2EU	88754G2EU			
Alere Triage Total 5 plus Calibration Verification	88755G2EU				
Alere Triage TOX Drug Screen	94413	94414			

Company Identification:

Alere San Diego, Inc. d/b/a Biosite Incorporated
9975 Summers Ridge Rd.
San Diego, CA 92121
phone: (858) 455-4808 fax: (858) 805-8601

Emergency Phone Number:

For Alere Medical Test Device Control Set / Calibration Verification Controls information and technical assistance, please contact the Technical Services Department at 1-888-246-7483 (option 2).

Section 2 - Composition, Information on Ingredients

The Alere Medical Test Device Control Set / Calibration Verification Controls contain human source (blood or urine) material. Alere Inc has determined that this product is not considered to be or to contain hazardous chemicals based on the Code of Federal Regulations, Title 29, Section 1910.1200 and the California Code of Regulations, Title 8, Section 5194, Hazard Communication. No mercury is contained in the products identified by product number in section one.

Section 3 - Hazard Identification

Potential Health Effects:

The Alere Medical Test Device Control Set / Calibration Verification Controls' human source (blood) material used to produce this product has been tested for the following infectious agents and found to be non-reactive by an FDA licensed Reference Testing Laboratory.

- Rapid Plasma Reagin (RPR)
- Hepatitis B surface antigen (HbsAg)
- Hepatitis B virus Antigen (HBV)
- Hepatitis C virus Antigen (HCV)
- antibodies against hepatitis C virus (anti-HCV)
- Human immunodeficiency virus (HIV)
- Antibodies against human immunodeficiency viruses (Anti-HIV-1 and 2)

The Alere Medical Test Device Control Set / Calibration Verification Controls human source (urine) material used to produce this product has been tested for the following infectious agents and found to be non-reactive by an FDA approved method.

- Human Immunodeficiency virus (HIV 1 and 2)
- HIV-AG
- Hbs Ag
- HCV
- RPR

In as much as no known test method can offer complete assurance that infectious agents are not present the reagents should be handled as though they are biohazardous (capable of transmitting disease).

Section 4 - First Aid Measures

In case of contact with:

Eyes: Contact with human source (blood or urine) material may cause irritation or disease. Flush eyes with fresh water for at least 15 minutes. Seek medical attention immediately.

Skin: Contact with human source (blood or urine) material may cause irritation. Wash affected skin with soap and water. Seek medical attention as needed.

Ingestion: Ingestion of human source (blood or urine) material may cause irritation. Rinse mouth out with water. Seek medical advice as needed.

Inhalation: Inhalation of human source (blood or urine) material may cause irritation. Remove to fresh air. Seek medical advice as needed.

Section 5 - Fire Fighting Measures

General Information: Alere Medical Test Device Control Set / Calibration Verification Controls consist of vials of human source (blood or urine) material that when burned will produce carbon monoxide and other toxic gases. Use self contained breathing apparatus (SCBA) when fighting fires with Alere Medical Test Device Control Set / Calibration Verification Controls involved.

Extinguishing Media: In case of fire, use water, dry chemical, chemical foam, or other standard means to extinguish the fire.

Autoignition Temperature: No information available.

Flash Point: None.

NFPA Rating: No information available.

Section 6 - Accidental Release Measures

General Information: Unused Alere Medical Test Device Control Set / Calibration Verification Controls are not chemically hazardous but may be a biohazard.

Spills/Leaks: Alere Medical Test Device Control Set / Calibration Verification Controls spills or leaks should be cleaned up immediately using "Universal Precautions" required by the Bloodborne Pathogen Standard or in accordance with your facility's biological safety program.

Section 7 - Handling and Storage

Handling: See product insert sheet for special temperature requirements and handling instructions for the Alere Medical Test Device Control Set / Calibration Verification Controls. Use "Universal Precautions" in accordance with the Bloodborne Pathogen Standard and/or your facility's biological safety program for handling human source (blood or urine) material.

Storage: See product insert sheet for special temperature storage requirements and instructions before use. Use each tube/vial once and then discard.

Section 8 - Exposure Control, Personal Protective Equipment

Engineering Controls: Not needed.

Exposure Limits:

Chemical Name	ACGIH	NIOSH	OSHA
Not Applicable			

Personal Protective Equipment: Use standard Good Laboratory Practices when handling or using an Alere Medical Test Device Control Set / Calibration Verification Controls. Minimize exposure to human source (blood or urine) materials.

Eyes: Wear safety glasses or chemical goggles if splashing is possible.

Skin: Wear appropriate protective gloves and clothing to prevent skin exposure.

Clothing: Wear appropriate protective clothing to prevent or minimize skin contact.

Respirators: Not needed.

Section 9 - Physical and Chemical Properties

Appearance:	<i>In vitro</i> diagnostic product. Refer to package insert for further description.
pH:	No information available.
Vapor Pressure:	No information available.
Vapor Density:	No information available.
Evaporation Rate:	No information available.
Boiling Point:	No information available.
Freezing/Melting Point:	No information available.
Solubility:	No information available.
Specific Gravity:	No information available.

Section 10 - Stability and Reactivity

Chemical Stability: Stable. No hazardous decomposition products expected.

Conditions to avoid: Temperatures higher than those listed on the product insert sheet may render the Alere Medical Test Device Control Set / Calibration Verification Controls inaccurate due to sensitivity of the human source (blood or urine) material.

Incompatibilities: None known.

Hazardous Polymerization: Has not been reported.

Section 11 - Toxicological Information

RTECS:	No information available.
LD50/LC50:	No information available.
Carcinogenicity:	Not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA, or Prop 65.
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

Used or unused Alere Medical Test Device Control Set / Calibration Verification Controls should be disposed of in accordance with your facility's biological safety program that is consistent with federal, state, and local regulations for human source (blood or urine) material.

RCRA D-Maximum Concentration of Contaminants: Not applicable.

RCRA D Series - Chronic Toxicity Reference Levels: Not applicable.

RCRA F Series Wastes: None of the components are on this list.

RCRA P Series Wastes: None of the components are on this list.

RCRA U Series Wastes: None of the components are on this list.

RCRA Substances Banned from Land Disposal: Not applicable.

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			

Note: If Alere Medical Test Device Control Set / Calibration Verification Controls need to be shipped to another facility or returned to Alere, contact Alere Technical Services at 1-888-246-7483 (option 2) for instructions.

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

All individuals using Alere Medical Test Device Control Set / Calibration Verification Controls should follow "Universal Precautions" as required by the Bloodborne Pathogen Standard and/or general good laboratory safety procedures as established and implemented by your institution's biological safety program in compliance with federal, state, and local requirements.

Effective Date: **October 21, 2010**

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Signature Manifest

Document Number: MSDS-4397

Revision: N

Title: Alere Medical Test Device Control Set / Calibration Verification Controls

All dates and times are in US/Pacific.

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Collaboration

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Approval Step

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Final Release

Name/Signature	Title	Date	Meaning/Reason
Geraldine Ngo (GERALDINE.NGO)		7 Nov 2013, 12:00:09 PM	Approved