

PATHFAST cTnI-II

Section 1 Identification	
Product name	PATHFAST cTnI-II
Catalog number	PF1101-K
Recommended use	Reagent for <i>in vitro</i> diagnostic use
Manufactured by	LSI Medience Corporation 13-4, Uchikanda 1-chome, Chiyoda-ku Tokyo 101-8517 JAPAN http://www.medience.co.jp
Distributed by	Polymedco, Inc. 510 Furnace Dock Road Cortlandt Manor, NY 10567 USA www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Product description	1) Reagent cartridge containing: <ol style="list-style-type: none"> Well #2: Alkaline phosphatase conjugated anti cTnI MoAb Well #7: Anti cTnI MoAb coated magnetic particles Well #13: Chemiluminescent substrate (CDP-Star) Well #11: Sample dilution buffer Well #3, 4, 5: Washing buffer 2) Calibrator 1 (CAL-1) (1 bottle) 3) Calibrator 2 (CAL-2) (2 vials) 4) Calibrator diluent (2 bottles) <p style="text-align: right;">(cTnI: Cardiac troponin I) (MoAb : Monoclonal antibody)</p>
Hazard classification	All components are at concentrations that do not meet the criteria for classifying as dangerous or hazardous, respectively, under the regulations.
Signal word	Not applicable.
Pictogram	Not applicable.
Any hazards not otherwise classified	CAL-2 contains human serum and should be handled as though capable of transmitting infectious diseases. No information available for the remaining components of this kit. However, may be harmful by inhalation, in contact with skin and if swallowed and may be irritating to skin and eyes.

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Section 3 Composition and Information on Ingredients
1) Reagent cartridge
a. Alkaline phosphatase conjugated anti cTnI MoAb (Well #2 50 µl)

<u>Chemical name</u>	<u>CAS number</u>	<u>Concentration (%)</u>	<u>GHS Classification (see section 16)</u>
Sodium azide (as preservative)	26628-22-8	0.05	H300 Acute Tox. 2 H400 Aquatic Acute 1 H410 Aquatic Chronic 1
Zinc chloride	7646-85-7	0.0007	H302 Acute Tox. 4 H314 Skin. Corr. 1B H400 Aquatic Acute 1 H410 Aquatic Chronic 1

MES (2-Morpholinoethanesulfonic acid, monohydrate) buffer solution containing Lipidure A101-BS (NOF CORP), sodium chloride and so on (pH 6.0) ⁽¹⁾

b. Anti cTnI MoAb coated magnetic particles (Well #7 50 µl)

Suspension of Anti cTnI MoAb coated polystyrene magnetic latex particles in MOPS (3-Morpholinopropanesulfonic acid) buffer solution containing sodium chloride, gelatin, and so on. (pH 7.0)

c. CDP-Star (Well #13 100 µl)

Aqueous solution containing CDP-Star (Applied Biosystems). (pH 9.2) ⁽²⁾

d. Sample dilution buffer (Well #11 50 µl)

<u>Chemical name</u>	<u>CAS number</u>	<u>Concentration (%)</u>	<u>GHS Classification (see section 16)</u>
Sodium azide (as preservative)	26628-22-8	0.05	H300 Acute Tox. 2 H400 Aquatic Acute 1 H410 Aquatic Chronic 1

Tris 2-Amino-2-hydroxymethyl-1,3-propanediol) buffer solution containing Glycerin and so on. (pH: 8.2)

e. Washing buffer (Well #3,4,5 400 µl respectively)

<u>Chemical name</u>	<u>CAS number</u>	<u>Concentration (%)</u>	<u>GHS Classification (see section 16)</u>
Sodium azide (as preservative)	26628-22-8	0.05	H300 Acute Tox. 2 H400 Aquatic Acute 1 H410 Aquatic Chronic 1
Triton X-100 (p-tertiary-Octylphenoxy polyethyl alcohol)	9002-93-1	0.05	H302 Acute Tox. 4 H319 Eye Irritation 2 H411 Aquatic Chronic 2

MOPS buffer solution (pH 7.5)

2) CAL-1 (1 bottle 2mL)

<u>Chemical name</u>	<u>CAS number</u>	<u>Concentration (%)</u>	<u>GHS Classification (see section 16)</u>
Sodium azide (as preservative)	26628-22-8	0.05	H300 Acute Tox. 2 H400 Aquatic Acute 1 H410 Aquatic Chronic 1

Aqueous solution (pH: Neutrality)

3) CAL-2 (2 vials)

Lyophilized preparation containing Human serum, Lactose, MES, cTnI and so on ⁽³⁾

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Section 3 Composition and Information on Ingredients (cont.)				
4) Calibrator diluent (2 bottles 1 ml respectively)				
<u>Chemical name</u>	<u>CAS number</u>	<u>Concentration (%)</u>	<u>GHS Classification (see section 16)</u>	
Sodium azide (as preservative)	26628-22-8	0.05	H300 Acute Tox. 2 H400 Aquatic Acute 1 H410 Aquatic Chronic 1	
Aqueous solution containing Glycerin and so on. (pH: Neutrality)				
All components are at concentrations that do not meet the criteria for classifying as dangerous or hazardous, respectively, under the regulations.				

Section 4 First Aid Measures	
Eye Contact	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician if necessary.
Skin Contact	In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Ingestion	If swallowed, immediately wash out mouth thoroughly with water, do not induce vomiting. Call a physician and seek medical advice immediately.
Inhalation	If inhaled, immediately move to fresh air. Call a physician if necessary.
Notes to physician	Treat symptomatically.

Section 5 Fire-Fighting Measures	
Flammable properties	Components are nonflammable.
Extinguishing media	In case of fire, use suitable extinguishing media for the fire conditions (water, foam, dry chemical etc.)
Special fire and explosion hazards	No information available.
Hazardous combustion products	No information available.
Protective equipment for firefighters	Wear suitable extinguishing apparatus for the fire conditions. Do not contact the components when extinguishing fire.

Section 6 Accident Release Measures	
Personal precautions, protective equipment, and emergency procedures	Wear appropriate protective equipment. Inform others to keep a safe distance. CAL-2 contains human serum. Blood samples from the donors were tested and found negative for HBs-Ag and antibodies to HIV (HIV-1 and HIV-2) and HCV. The component should be handled as though capable of transmitting infectious diseases.
Containment and cleanup procedures	Land spill: Soak up clearly with paper or cloth. Water spill: Dilute with large quantity of water.

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Section 7 Handling and Storage	
Precautions for safe handling	Use suitable equipment. Do not pipette with mouth. Do not leak, overflow and scatter. Do not fall down and damage. Seal the cap exactly. For components containing Sodium azide, avoid prolonged contact with copper or lead, especially in drainage systems or mercury or other heavy metals which may result in the formation of explosive azides. CAL-2 contains human serum. Blood samples from the donors were tested and found negative for HBs-Ag and antibodies to HIV (HIV-1 and HIV-2) and HCV. The component should be handled as though capable of transmitting infectious diseases.
Conditions for safe storage, incompatibilities	Store in a cool and dark place at 36-47°F (2-8°C). Do not freeze.

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	No information available.
ACGIH	No information available.
Engineering controls	Equip sink and flushing eyes facilities near operating place.
Personal protection	To prevent any contact, wear protective equipment such as safety glasses, rubber gloves, as appropriate.
Respiratory protection	Do not breathe mist.
Hand protection	Wear disposable rubber gloves.
Eye protection	Wear safety glasses with side shields, goggles or eye/face shield.
Skin protection	Wear a laboratory coat and other protective overgarments (e.g., sleeve covers etc.).

Section 9 Physical and Chemical Properties					
	Reagent cartridge				
	Alkaline phosphatase conjugated anti cTnI MoAb	Anti cTnI MoAb coated magnetic particles	CDP-Star	Sample dilution buffer	Washing buffer
Appearance	Liquid, Clear	Suspension liquid, Brown – Dark Brown	Liquid, Clear	Liquid, Clear	Liquid, Clear
Odor	Odorless	Odorless	Odorless	Odorless	Odorless
Odor threshold	No information available	No information available	No information available	No information available	No information available
pH	6.0	7.0	9.2	8.2	7.5
Melting point / Freezing point	No information available	No information available	No information available	No information available	No information available
Initial boiling point and boiling range	No information available	No information available	No information available	No information available	No information available
Flash point	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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Section 9 Physical and Chemical Properties (cont.)					
	Reagent cartridge				
	Alkaline phosphatase conjugated anti cTnI MoAb	Anti cTnI MoAb coated magnetic particles	CDP-Star	Sample dilution buffer	Washing buffer
Evaporation rate	No information available	No information available	No information available	No information available	No information available
Flammability (solid, gas)	Components are nonflammable	Components are nonflammable	Components are nonflammable	Components are nonflammable	Components are nonflammable
Upper/lower flammability or explosive limits	No information available	No information available	No information available	No information available	No information available
Vapor pressure	No information available	No information available	No information available	No information available	No information available
Vapor density	No information available	No information available	No information available	No information available	No information available
Relative density	No information available	No information available	No information available	No information available	No information available
Solubility	Mix free to water	Suspending free to water	Mix free to water	Mix free to water	Mix free to water
Partition coefficient	No information available	No information available	No information available	No information available	No information available
Auto-ignition temperature	No information available	No information available	No information available	No information available	No information available
Decomposition temperature	No information available	No information available	No information available	No information available	No information available
Viscosity	No information available	No information available	No information available	No information available	No information available

	CAL-1	CAL-2	Calibrator diluent
Appearance	Liquid, Clear	Lyophilized solid or powder, Slightly yellow	Liquid, Clear blue
Odor	Odorless	Slightly sulfurous odor	Odorless
Odor threshold	No information available	No information available	No information available
pH	Neutrality	Not applicable	Neutrality
Melting point / Freezing point	No information available	No information available	No information available
Initial boiling point and boiling range	No information available	No information available	No information available
Flash point	Not applicable	Not applicable	Not applicable
Evaporation rate	No information available	No information available	No information available
Flammability (solid, gas)	Components are nonflammable	Components are nonflammable	Components are nonflammable

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Section 9 Physical and Chemical Properties (cont.)			
	CAL-1	CAL-2	Calibrator diluent
Upper/lower flammability or explosive limits	No information available	No information available	No information available
Vapor pressure	No information available	No information available	No information available
Vapor density	No information available	No information available	No information available
Relative density	No information available	No information available	No information available
Solubility	Mix free to water	Mix free to water	Mix free to water
Partition coefficient	No information available	No information available	No information available
Auto-ignition temperature	No information available	No information available	No information available
Decomposition temperature	No information available	No information available	No information available
Viscosity	No information available	No information available	No information available

Section 10 Stability and Reactivity	
Reactivity	No information available.
Stability	Components are stable under normal handling and storage conditions.
Possibility of hazardous reactions	For components containing Sodium azide, Sodium azide may liberate very toxic gas in contact with acids. Forms readily detonatable salts with many metals, particularly heavy metals. No information available for the remaining components.
Conditions to avoid	Do not heat. Do not freeze. For components containing Sodium azide, avoid contact with incompatible materials.
Incompatibilities	For components containing Sodium azide: Strong acids Strong bases Strong oxidizers Metals and metallic compounds
Hazard decomposition products	For components containing Sodium azide, Sodium azide may liberate very toxic gas in contact with acids. Forms readily detonatable salts with many metals, particularly heavy metals. No information available for the remaining components.

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Section 11 Toxicological Information													
Information on likely routes and effects of exposure (short term / long term effects):													
Inhalation	No information available.												
Ingestion	May cause nausea, vomiting, stomachache and diarrhea.												
Skin contact	May cause skin irritation.												
Eye contact	May cause eye irritation.												
Symptoms related to the physical, chemical and toxicological characteristics	No information available.												
Delayed, immediate and chronic effects from short- and long-term exposure	No information available.												
Numerical measures of toxicity	No information available.												
Other information for Sodium azide, Zinc chloride and Triton X-100													
<p>1) Sodium Azide Causes inflammation and irritation of the eyes, nose, throat and bronchus. Inhalation and ingestion cause headache, vomiting, dizziness, low blood pressure, difficulty breathing, sense disorder. In serious case, fatality may occur from acute cardiac collapse, and unconsciousness, systemic convulsion. The symptoms may be delayed.</p> <table border="0"> <tr> <td>p.o.</td> <td>Human</td> <td>TDLo 710 µg/kg ⁽⁴⁾</td> </tr> <tr> <td>p.o.</td> <td>Rat</td> <td>LD50 27 mg/kg ⁽⁴⁾</td> </tr> <tr> <td>ivn</td> <td>Mouse</td> <td>LD50 19 mg/kg ⁽⁴⁾</td> </tr> <tr> <td>par(skin)</td> <td>Rabbit</td> <td>LD50 20 mg/kg ⁽⁴⁾</td> </tr> </table>		p.o.	Human	TDLo 710 µg/kg ⁽⁴⁾	p.o.	Rat	LD50 27 mg/kg ⁽⁴⁾	ivn	Mouse	LD50 19 mg/kg ⁽⁴⁾	par(skin)	Rabbit	LD50 20 mg/kg ⁽⁴⁾
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par(skin)	Rabbit	LD50 20 mg/kg ⁽⁴⁾											
<p>2) Zinc Chloride Causes inflammation and irritation of the eyes, skin and mucous membrane. Inhalation and ingestion may cause nausea, vomiting, diarrhea, fever, sense of fatigue, joint-ache and leucocytosis.</p> <table border="0"> <tr> <td>inhl</td> <td>Human</td> <td>TCLo 4,800 mg/m³/30M ⁽⁵⁾</td> </tr> <tr> <td>inhl</td> <td>Rat</td> <td>LCLo 1,960 mg/m³/10M ⁽⁵⁾</td> </tr> <tr> <td>p.o.</td> <td>Rat</td> <td>LD50 350 mg/kg ⁽⁵⁾</td> </tr> <tr> <td>p.o.</td> <td>Mouse</td> <td>LD50 329 mg/kg ⁽⁵⁾</td> </tr> </table>		inhl	Human	TCLo 4,800 mg/m ³ /30M ⁽⁵⁾	inhl	Rat	LCLo 1,960 mg/m ³ /10M ⁽⁵⁾	p.o.	Rat	LD50 350 mg/kg ⁽⁵⁾	p.o.	Mouse	LD50 329 mg/kg ⁽⁵⁾
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<p>3) Triton X-100 Causes severe eye irritation. May cause skin irritation. Inhalation and ingestion may cause nausea, vomiting and diarrhea.</p> <table border="0"> <tr> <td>p.o.</td> <td>Rat</td> <td>LD50 1,800 mg/kg ⁽⁵⁾</td> </tr> <tr> <td>Par(skin)</td> <td>Rabbit</td> <td>LD50 8,000 mg/kg ⁽⁵⁾</td> </tr> </table>		p.o.	Rat	LD50 1,800 mg/kg ⁽⁵⁾	Par(skin)	Rabbit	LD50 8,000 mg/kg ⁽⁵⁾						
p.o.	Rat	LD50 1,800 mg/kg ⁽⁵⁾											
Par(skin)	Rabbit	LD50 8,000 mg/kg ⁽⁵⁾											
Carcinogenicity	No information available.												

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Section 12 Ecological Information	
Ecotoxicity	For components containing Sodium azide or Triton X-100, Sodium azide and Triton X-100 are toxic for aquatic organisms. No information available for the remaining components.
Persistence / degradability	No information available.
Bioaccumulation potential	No information available.
Mobility in soil (Adsorption / leaching)	No information available.
Other adverse effects (such as hazardous to the ozone layer)	No information available.

Section 13 Disposal Considerations	
Disposal methods	Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	For components containing Sodium azide, Sodium can react with copper or lead used in some plumbing systems to form explosive salts. The quantities used in this kit are small, nevertheless when disposing of azide-containing materials they should be flushed away with relatively large quantities of water. No information available for the remaining components.
Sewage disposal	Do not dispose of product into drains or sewers.
Precautions for landfills or incineration	No information available.

Section 14 Transport Information	
General transport information	Transport at 36-47°F (2-8°C). Confirm no leakage and give no damage when loading. Check loading exactly.
US DOT Hazardous Materials	Not applicable.
UN Number	Not regulated.
UN proper shipping name	Not applicable.
Transport hazard class	Not applicable.
Packing group	Not applicable.
Environmental hazards	No information available.
Guidance on transport in bulk	No information available.
Special precautions on transport	No further information available.

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Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000.
TSCA	All components listed or exempted.
SARA Title III	Not applicable.
CERCLA Reportable Quantity	Not applicable.
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information	
Date of preparation	31 May 2017
Last revision date	31 May 2017
Other information Key literature references and sources for data: (1) Lipidure A101-BS safety data sheet from supplier, NOF CORPORATION (2) CDP-Star safety data sheet from supplier, Applied Biosystems, LLC. (3) Human serum product specification from supplier, Golden West Biologicals, Inc. (4) Sax's dangerous properties of industrial materials (11 th Edition) (5) RTECS (Registry of Toxic Effects of Chemical Substances, NIOSH) Relevant H-statements: H300: Fatal if swallowed H302: Harmful if swallowed H314: Causes severe skin burns and eye damage H319: Causes serious eye irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects H411: Toxic to aquatic life with long lasting effects	
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