

PATHFAST D-Dimer

| Section 1 Identification | |
|---------------------------------|--|
| Product name | PATHFAST D-Dimer |
| 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"> a. Well #2: Alkaline phosphatase conjugated anti D-Dimer MoAb b. Well #7: Anti D-Dimer MoAb coated magnetic particles c. Well #13: Chemiluminescent substrate (CDP-Star) d. Well #11: Sample dilution buffer e. 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;">(D-Dimer: Cross linked fibrin degradation product) (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 D-Dimer 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 D-Dimer MoAb coated magnetic particles (Well #7 50 µl)

Suspension of Anti D-Dimer 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 8.7) ⁽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 |
| 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 |

Tris (2-Amino-2-hydroxymethyl-1,3-propanediol) buffer solution containing Bovine serum albumin and so on. (pH: 7.0) ⁽³⁾

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 6.5)

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 |

Tris buffer solution containing Bovine serum albumin and so on. (pH: 7.0) ⁽³⁾

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| Section 3 Composition and Information on Ingredients (cont.) | | | |
|--|-------------------|--------------------------|---|
| 3) CAL-2 (2 vials) Lyophilized preparation containing Human serum, Human fibrinogen and so on ⁽⁴⁾ | | | |
| 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 | |
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| 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 | |
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| 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 D-Dimer MoAb | Anti D-Dimer MoAb coated magnetic particles | CDP-Star | Sample dilution buffer | Washing buffer |
| Appearance | Liquid, Clear | Suspension liquid, Brown – Dark Brown | Liquid, Clear | Liquid, Clear – Slightly yellow | Liquid, Clear – Milky white |
| 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 | 8.7 | 7.0 | 6.5 |
| 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 D-Dimer MoAb | Anti D-Dimer 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, Slightly yellow | Lyophilized solid or powder, Slightly yellow | Liquid, Clear blue |
| Odor | Odorless | Odorless | 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 | |
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| 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 | |
| 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.o. | Human TDLo 710 µg/kg ⁽⁵⁾ |
| p.o. | Rat LD50 27 mg/kg ⁽⁵⁾ |
| ivn | Mouse LD50 19 mg/kg ⁽⁵⁾ |
| par(skin) | Rabbit LD50 20 mg/kg ⁽⁵⁾ |
| 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. | |
| inhl | Human TCLo 4,800 mg/m ³ /30M ⁽⁶⁾ |
| inhl | Rat LCLo 1,960 mg/m ³ /10M ⁽⁶⁾ |
| p.o. | Rat LD50 350 mg/kg ⁽⁶⁾ |
| p.o. | Mouse LD50 329 mg/kg ⁽⁶⁾ |
| 3) Triton X-100 Causes severe eye irritation. May cause skin irritation. Inhalation and ingestion may cause nausea, vomiting and diarrhea. | |
| p.o. | Rat LD50 1,800 mg/kg ⁽⁶⁾ |
| Par(skin) | Rabbit LD50 8,000 mg/kg ⁽⁶⁾ |
| Carcinogenicity | No information available. |

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| Section 12 Ecological Information | |
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| 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 | |
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| 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 | |
| <p>Key literature references and sources for data:</p> <ol style="list-style-type: none"> (1) Lipidure A101-BS safety data sheet from supplier, NOF CORPORATION (2) CDP-Star safety data sheet from supplier, Applied Biosystems, LLC. (3) Bovine serum albumin certificate of analysis from supplier, Seracare Life Sciences, Inc. (4) Normal human serum certificate of analysis from supplier, MIDLAND BIOPRODUCTS CORPORATION (5) Sax's dangerous properties of industrial materials (11th Edition) (6) RTECS (Registry of Toxic Effects of Chemical Substances, NIOSH) <p>Relevant H-statements:</p> <ul style="list-style-type: none"> 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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