


Safety Data Sheet		
	Document: SDS-00013 FebriDx®	
	Revision: 2	Page 1 of 6


SAFETY DATA SHEET

1. Product and Company Identification of the substance/mixture and of the company/undertaking	
Product name	FebriDx
Chemical Name & Synonyms	N/A
Product Description and Use	The FebriDx Bacterial/Non-Bacterial Point-of-Care Assay is a qualitative visually read rapid immunoassay for the detection of human host response proteins, Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) directly from fingerstick blood. FebriDx is indicated for use in patients aged 12-64 who present to urgent care or emergency care settings for evaluation of acute respiratory infection who have had symptoms for less than 7 days and within 3 days of fever onset. FebriDx test results are intended to be used in conjunction with other clinical and diagnostic findings as an aid in the diagnosis of bacterial acute respiratory infection and differentiation from non-bacterial etiology. The assessment of whether a bacterial infection is present should always be based on consideration of all available information, and not based solely on the FebriDx test results. FebriDx test results are not intended to identify a specific pathogen or the severity of infection.
Product Number	CP0014
Product Brand	FebriDx

Corporate Headquarters	Manufacturer/Distributor	Contact Information
Lumos Diagnostics	Lumos Diagnostics	Phone: +1 855-586-6739
2724 Loker Ave. West Carlsbad, CA 92010 USA	2724 Loker Ave. West Carlsbad, CA 92010 USA	Email: <a href="mailto:info@lumosdiagnostics.com">info@lumosdiagnostics.com</a>
		Poison Control: 1-800-876-4766 (US Only)

2. Hazards Identification	
Description of the components	
<ul style="list-style-type: none"> <li>Potential Health Effects:</li> </ul>	Hazardous in case of skin contact (irritant), of eye contact (irritant). Hazardous in case of ingestion, of inhalation. Slightly hazardous in case of skin contact (permeator). Severe over-exposure can result in death. Eye inflammation is characterized by itching, redness, and watering. Skin inflammation is characterized by itching, scaling, reddening or, occasionally, blistering.
<ul style="list-style-type: none"> <li>Eyes</li> </ul>	Check for and remove any contact lenses. Immediately flush with running water for at least 15 minutes, keeping eyelids open. Cold water may be used. Do not use ointment. Seek medical attention.
<ul style="list-style-type: none"> <li>Skin</li> </ul>	After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases, and groin. Cold water may be used. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

## Safety Data Sheet

	Document: SDS-00013 FebriDx®	
	Revision: 2	Page 2 of 6

• Inhalation	Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.
• Ingestion	Do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.
• Pictogram	N/A
• Signal words	N/A
• Hazard Statements	N/A
• Precautionary Statements	N/A

### 3. Composition/Information on Ingredients

Ingredients/Components:	Classification	Concentration
• Sterile Lancet	N/A	N/A
• Blood Collection Tube	N/A	N/A
• Buffer Blister Pack	N/A	N/A


### 4. First Aid Measures

First Aid Procedures:	
• General Advice	Only use for intended use
• If Swallowed	If swallowed, wash mouth out with water provided person is conscious. Call a physician.
• Inhalation	Inhalation of any kit component is unlikely. If a kit component is inhaled and causes discomfort, move to fresh air. If breathing is difficult, seek medical attention.
• Eye Contact	If any of the kit components enter the eyes, immediately flush with copious amounts of potable water making sure that the eyelids are held open. If pain or irritation persists, seek medical attention.
• Skin Contact	In case of contact, immediately wash with soap and copious amounts of water.
• Symptoms/effects	N/A
• Indication of any immediate medical and special treatment needed	N/A

### 5. Fire Fighting Measures

Extinguishing media:	For small fires, use dry chemical, carbon dioxide or alcohol resistant foam.
• Suitable Extinguishing Media	The kit components will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the

## Safety Data Sheet

	Document: SDS-00013 FebriDx®	
	Revision: 2	Page 3 of 6

	surrounding fire.
• Unsuitable Extinguishing Media	N/A
• Specific Hazards	N/A
• Hazardous Combustion Products	N/A
• Advice for Firefighters	N/A
• Protective for Firefighters	Utilize proper personal protective equipment such as eye protection and protective gear.
• Further Information	N/A

### 6. Accidental Release Measures

Personal Precautions	This kit contains materials of biological origin. Avoid personal contact. Use Universal Precautions during clean-up procedures.
Environmental Precautions	No environmental hazard is anticipated provided the material is handled and disposed with due care.
Protective Equipment's	N/A
Emergency Procedures	N/A
Methods and Materials for containment and cleaning up	Absorb liquid and place in proper disposal containers. Contain spill to prevent migration.
Reference to other sections	N/A

### 7. Handling and Storage


Precautions for Safe Handling	Avoid direct contact with the liquid buffer. Wash exposed areas thoroughly after using this kit. Do not drink or eat while using this kit. Universal Precautions should be followed when using this kit.
Conditions for Safe Storage, including any incompatibilities	To maintain efficacy, store according to the package instructions.
Specific End Use(s)	N/A

### 8. Exposure Controls/Personal Protection

Exposure Guidelines	Use with adequate ventilation and lighting.
Appropriate Engineering Controls	No special engineering controls are required.
Personal Protective Equipment:	
• Respiratory Protection	None needed under normal conditions of use.
• Eye/Face Protection	Safety glasses are recommended to prevent contact with eyes.
• Skin Protection	Laboratory coat or similar outer garment should be worn.
• Body Protection	N/A
• Hand Protection	Impervious gloves should be worn to avoid hand contact.
• Control of environmental exposure	No special environmental controls are required.

### 9. Physical & Chemical Properties

## Safety Data Sheet

	Document: SDS-00013 FebriDx®	
	Revision: 2	Page 4 of 6

• Physical State/Appearance	Test card, pipettes and lancet are solid; the Buffer is liquid.
• Color	Clear, colorless
• Odor	None
• Odor Threshold	Not applicable
• pH	Neutral
• Melting Point	Not applicable
• Freezing Point	Not available
• Initial boiling point and boiling range	Not available
• Flash Point	Not available
• Evaporation rate	Not available
• Flammability (solid, gas)	Not available
• Upper/lower flammability or explosive limits	Not available
• Vapour pressure	Not available
• Vapour density	Not available
• Relative Density	Not available
• Water solubility	Not available
• Partition coefficient: n- otanol/water	Not available
• Auto-ignition temperature	Not available
• Decomposition temperature	Not available
• Viscosity	Not available
• Explosive properties	Not available
• Oxidizing properties	Not available
• Other safety information	Not available


### 10. Chemical Stability & Reactivity Information

• Reactivity	Unknown
• Chemical stability	Stable as indicated in the Package Insert.
• Possibility of Hazardous Reactions	Hazardous polymerization will not occur.
• Conditions to avoid	None known
• Incompatible Materials	Avoid strong oxidizers, strong acids and bases, heavy metals and their salts.
• Hazardous Decomposition Products	None expected under normal conditions.

### 11. Information on Toxicological information

• Acute toxicity	No data available
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## Safety Data Sheet

	Document: SDS-00013 FebriDx®	
	Revision: 2	Page 5 of 6


<ul style="list-style-type: none"> <li>• Skin corrosion/irritation</li> </ul>	Slight irritation is possible
<ul style="list-style-type: none"> <li>• Serious eye damage/ eye irritation</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Respiratory or skin sensitization</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Germ cell mutagenicity</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Carcinogenicity</li> </ul>	No data available. None of the components at concentrations present in this kit are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.
<ul style="list-style-type: none"> <li>• Reproductive toxicity</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Specific target organ toxicity- single exposure</li> </ul>	Occupational exposure routes may include inhalation, skin and eye contact.
<ul style="list-style-type: none"> <li>• Specific target organ toxicity- repeated exposure</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Aspiration hazard</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Additional Information</li> </ul>	No data available

<b>12. Ecological information</b>	
<ul style="list-style-type: none"> <li>• Toxicity</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Persistence and degradability</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Bioaccumulative potential</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Mobility in soil</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Results of PBT and vPvB assessment</li> </ul>	No data available
<ul style="list-style-type: none"> <li>• Other adverse effects</li> </ul>	No data available

<b>13. Disposal considerations</b>	
Waste treatment methods	
<ul style="list-style-type: none"> <li>• Product</li> </ul>	Since the sample matrix is whole blood, dispose of used tests, lancets, pipettes, and alcohol swabs in biohazard waste containers in compliance with federal, state, and local regulations.
<ul style="list-style-type: none"> <li>• Contaminated packaging</li> </ul>	

<b>14. Transport Information</b>	
<ul style="list-style-type: none"> <li>• DOT (US)</li> </ul>	Not regulated as Hazardous Goods.
<ul style="list-style-type: none"> <li>• IMDG</li> </ul>	Not regulated as Hazardous Goods
<ul style="list-style-type: none"> <li>• IATA</li> </ul>	Not regulated, not dangerous, not hazardous, and not restricted for transport by IATA.

<b>15. Regulatory information</b>	
<ul style="list-style-type: none"> <li>• SARA 302 Components</li> </ul>	N/A
<ul style="list-style-type: none"> <li>• SARA 313 Components</li> </ul>	N/A
<ul style="list-style-type: none"> <li>• SARA 311/312 Hazards</li> </ul>	N/A
<ul style="list-style-type: none"> <li>• US Federal Regulations</li> </ul>	No
<ul style="list-style-type: none"> <li>• CERCLA (Superfund) Reportable Quality</li> </ul>	No

Safety Data Sheet		
	Document: SDS-00013 FebriDx®	
	Revision: 2	Page 6 of 6

<ul style="list-style-type: none"> <li>SARA (Superfund Amendments and Reauthorization Act of 1986)</li> </ul>	No
<ul style="list-style-type: none"> <li>Further Information</li> </ul>	Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Communication Standard. European Communities Safety Data Sheets, Canadian Controlled Products Regulations and UN Globally Harmonized System of Classification and Labeling of Chemicals.

\*Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15(29 CFR 1910.1200(g)(2)).

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