

Safety Data Sheet



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1. Product and Company Identification of the substance/mixture and of the company/undertaking	
Product name	FebriDx Bacterial / Non-bacterial Assay
Chemical Name & Synonyms	N/A
Product Description and Use	The FebriDx Bacterial/Non-Bacterial 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 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, Inc.	Lumos Diagnostics, Inc	Phone: +1 855-586-6739
2724 Loker Ave. West Carlsbad, CA 92010 USA	2724 Loker Ave. West Carlsbad, CA 92010 USA	Email: info@lumosdiagnostics.com
		Poison Control: 1-800-876-4766 (US Only)

2. Hazards Identification	
Signal word	None
Hazard Statements	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.
• Eyes	Potential eye irritant.
• Skin	Potential skin irritant.
• Inhalation	May cause mild irritation.
• Ingestion	Harmful if swallowed.
• Pictogram	N/A
Precautionary Statements	
• Prevention	N/A

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• Storage	4-25°C
• Disposal	Dispose as medical waste after use

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 the FebriDx assay according to its 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	No adverse symptoms or effects have been identified.

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 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

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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)	Refer to Intended Use.

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	N/A
• 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

• Physical State/Appearance	Test card, pipettes and lancet are solid; the Buffer is liquid.
• Color	Clear, colorless
• Odor	None
• Odor Threshold	N/A
• pH	Neutral
• Melting Point	N/A
• Freezing Point	Not available
• Initial boiling point and boiling	Not available

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range	
• 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-octanol/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
• Skin corrosion/irritation	Slight irritation is possible
• Serious eye damage/ eye irritation	No data available
• Respiratory or skin sensitization	No data available
• Germ cell mutagenicity	No data available
• Carcinogenicity	No data available. None of the components at concentrations present in this kit are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

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• Reproductive toxicity	No data available
• Specific target organ toxicity- single exposure	Occupational exposure routes may include inhalation, skin and eye contact.
• Specific target organ toxicity- repeated exposure	No data available
• Aspiration hazard	No data available
• Additional Information	No data available

12. Ecological information

• Toxicity	No data available
• Persistence and degradability	No data available
• Bioaccumulative potential	No data available
• Mobility in soil	No data available
• Results of PBT and vPvB assessment	No data available
• Other adverse effects	No data available

13. Disposal considerations

Waste treatment methods	
• Product	Since the sample matrix is whole blood, dispose of used tests and integrated lancets and alcohol swabs in biohazard waste containers in compliance with federal, state, and local regulations.
• Contaminated packaging	If packaging gets contaminated, dispose of in biohazard waste containers in compliance with federal, state, and local regulations.

14. Transport Information

• DOT (US)	Not regulated as Hazardous Goods.
• IMDG	Not regulated as Hazardous Goods
• IATA	Not regulated, not dangerous, not hazardous, and not restricted for transport by IATA.

15. Regulatory information

• SARA 302 Components	N/A
• SARA 313 Components	N/A
• SARA 311/312 Hazards	N/A
• US Federal Regulations	No
• CERCLA (Superfund) Reportable Quality	No
• SARA (Superfund Amendments and Reauthorization Act of 1986)	No
• Further Information	Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA

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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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