

Safety Data Sheet		
	Document: SDS-00001 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	FebriDx® is a rapid immunoassay for the visual, qualitative, in vitro detection of elevated levels of both Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) directly from fingerstick whole blood. The test measures an immune response to a suspected bacterial or viral infection in patients 1 year of age or older that present within 7 days of new onset respiratory symptoms consistent with a community-acquired acute respiratory infection. The FebriDx® test aids in the diagnosis and differentiation of bacterial and viral acute respiratory infection. FebriDx® is not intended to diagnose any specific bacteria or virus. The test is intended for professional use and should be used in conjunction with other clinical evidence including laboratory, radiographic, and epidemiological information.
Product Number	CP0003
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: info@lumosdiagnostics.com
		Poison Control: 1-800-876-4766 (US Only)

2. Hazards Identification	
Description of the components	
<ul style="list-style-type: none"> Potential Health Effects: 	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"> Eyes 	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"> Skin 	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.
<ul style="list-style-type: none"> Inhalation 	Allow the victim to rest in a well-ventilated area. Seek immediate

Safety Data Sheet

	Document: SDS-00001 FebriDx™	
	Revision: 2	Page 2 of 6

	medical attention.
<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • Pictogram 	N/A
<ul style="list-style-type: none"> • Signal words 	N/A
<ul style="list-style-type: none"> • Hazard Statements 	N/A
<ul style="list-style-type: none"> • Precautionary Statements 	N/A

3. Composition/Information on Ingredients		
Ingredients/Components:	Classification	Concentration
<ul style="list-style-type: none"> • Sterile Lancet 	N/A	N/A
<ul style="list-style-type: none"> • Blood Collection Tube 	N/A	N/A
<ul style="list-style-type: none"> • Buffer Blister Pack 	N/A	N/A

4. First Aid Measures	
First Aid Procedures:	
<ul style="list-style-type: none"> • General Advice 	Only use for intended use
<ul style="list-style-type: none"> • If Swallowed 	If swallowed, wash mouth out with water provided person is conscious. Call a physician.
<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • Skin Contact 	In case of contact, immediately wash with soap and copious amounts of water.
<ul style="list-style-type: none"> • Symptoms/effects 	N/A
<ul style="list-style-type: none"> • Indication of any immediate medical and special treatment needed 	N/A

5. Fire Fighting Measures	
Extinguishing media:	
<ul style="list-style-type: none"> • Suitable Extinguishing Media 	The kit components will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire.
<ul style="list-style-type: none"> • Unsuitable Extinguishing Media 	N/A

Safety Data Sheet		
	Document: SDS-00001 FebriDx™	
	Revision: 2	Page 3 of 6

• 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	
• Physical State/Appearance	Test card, pipettes and lancet are solid; the Buffer is liquid.
• Color	Clear, colorless
• Odor	None

Safety Data Sheet

	Document: SDS-00001 FebriDx™	
	Revision: 2	Page 4 of 6

• 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
• 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

Safety Data Sheet

	Document: SDS-00001 FebriDx™	
	Revision: 2	Page 5 of 6

<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • Reproductive toxicity 	No data available
<ul style="list-style-type: none"> • Specific target organ toxicity- single exposure 	Occupational exposure routes may include inhalation, skin and eye contact.
<ul style="list-style-type: none"> • Specific target organ toxicity- repeated exposure 	No data available
<ul style="list-style-type: none"> • Aspiration hazard 	No data available
<ul style="list-style-type: none"> • Additional Information 	No data available

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

13. Disposal considerations	
Waste treatment methods	
<ul style="list-style-type: none"> • Product 	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"> • Contaminated packaging 	

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

15. Regulatory information	
<ul style="list-style-type: none"> • SARA 302 Components 	N/A
<ul style="list-style-type: none"> • SARA 313 Components 	N/A
<ul style="list-style-type: none"> • SARA 311/312 Hazards 	N/A
<ul style="list-style-type: none"> • US Federal Regulations 	No
<ul style="list-style-type: none"> • CERCLA (Superfund) Reportable Quality 	No
<ul style="list-style-type: none"> • SARA (Superfund Amendments and Reauthorization Act of 1986) 	No
<ul style="list-style-type: none"> • Further Information 	Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Communication Standard. European Communities

Safety Data Sheet		
	Document: SDS-00001 FebriDx™	
	Revision: 2	Page 6 of 6

	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)).**

16. Disclaimer

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage, and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Rapid Pathogen Screening, Inc. be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential, or exemplary damages, howsoever arising, even if Rapid Pathogen Screening, Inc. has been advised of the possibility of such damages.