


Safety Data Sheet (SDS)		
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SAFETY DATA SHEET

1. Product and Company Identification of the substance/mixture and of the company/undertaking	
Product name	FebriDx US External Control Kit
Chemical Name & Synonyms	N/A
Product Description and Use	The FebriDx External Control Set is intended for use as quality control samples to monitor the MxA and CRP assay performance of the FebriDx test. The performance characteristics of the FebriDx external controls have not been established for any other test.
Product Number	CP0007
Product Brand	FebriDx

Corporate Headquarters	Manufacturer/Distributor	Contact Information
Lumos Diagnostics	Lumos Diagnostics	Phone: 855-586-6739
2724 Loker Avenue West Carlsbad, CA 92010	2724 Loker Avenue West Carlsbad, CA 92010	Email: info@lumosdiagnostics.com
		Poison Control: (800) 222-1222

2. Hazards Identification	
• Signal word	None
• Hazard Statements	None
• 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
• Storage	15-25°C
• Disposal	Dispose as medical waste after use
• Hazards not otherwise classified	None

3. Composition/Information on Ingredients		
Ingredients/Components:	Classification	Concentration
• Polystyrene Tubes	N/A	N/A
• Non-hazardous Stabilizer	N/A	>50%
• Sodium Azide	CAS-No-26628-22-8	<1%
• Food Yellow #5	CAS-No 2783-94-0	<1%

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4. First Aid Measures

First Aid Procedures:

- | | |
|--------------------|--|
| • General Advice | Only use the FebriDx External Controls according to their intended use. |
| • If swallowed | If swallowed, wash mouth out with water provided person is conscious. Call a physician. |
| • Inhalation | Inhalation is unlikely. If a kit component is inhaled and causes discomfort, move to fresh air. If breathing is difficult, seek medical attention. |
| • Eye Contact | Immediately flush with water for at least 15 minutes. Seek medical attention if pain or irritation persists. |
| • Skin Contact | Wash with soap and water. |
| • Symptoms/effects | 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 surrounding fire. |
| • Unsuitable Extinguishing Media | Not determined |
| • Specific Hazards | Not Known |
| • Hazardous Combustion Products | N/A |
| • Advice for Firefighters | N/A |
| • Protective Equipment and Precautions 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 |

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7. Handling and Storage

Precautions for Safe Handling	Avoid direct contact with the controls. 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	Store at 5-25°C. No identified incompatibilities
Specific End Use(s)	End use is specifically for FebriDx test assay quality control.

8. Exposure Controls/Personal Protection

Exposure Guidelines	None
Appropriate Engineering Controls	No engineering controls are required.
Personal Protective Equipment:	
• Respiratory Protection	Not required for intended use.
• Eye/Face Protection	Safety glasses are recommended to prevent contact with eyes.
• Skin Protection	Laboratory coats or similar personal protective garments should be worn.
• Body Protection	N/A
• Hand Protection	Impervious gloves should be worn to avoid skin contact on the hands.
• Control of environmental exposure	No environmental controls are required.

9. Physical & Chemical Properties

• Physical State/Appearance	Liquid
• Color	Orange
• Odor	None
• Odor Threshold	N/A
• pH	Neutral
• Melting Point	N/A
• 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

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• 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	There are no known reactivity hazards associated with this product.
• Chemical stability	Stable as indicated in the Instructions for Use
• Possibility of Hazardous Reactions	Not determined.
• Conditions to avoid	None known.
• Incompatible Materials	Avoid strong oxidizers, strong acids and bases, and heavy metals.
• Hazardous Decomposition Products	Not 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.
• 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	N/A

12. Ecological information

• Toxicity	No data available.
• Persistence and degradability	No data available.

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• 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	Follow federal, state, and local regulations.
• Contaminated packaging	N/A

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14. Transport Information

• DOT (US)	Not regulated.
• IMDG	Not regulated.
• IATA	Not regulated.

15. Regulatory information

• SARA 302 Components	N/A
• SARA 313 Components	N/A
• SARA 311/312 Hazards	N/A
• 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 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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