

SARS-CoV-2 & Flu A/B Quality Controls Kit - CE MDXP0010

Document #: MDX-MM-SDS-030 Revision No: 000 Effective Date: Captured Electronically

1. IDENTIFICATION

- 1.1. **Product Name:** SARS-CoV-2 & Flu A/B Quality Controls Kit - CE
- 1.2. Product Part Number: MRN Part #: MDXP0010 Supplier Part #: L019080101002
- 1.3. **GHS Product Identifier:** No data available.
- 1.4. **Recommended Uses:** To be sold as Quality Control Kit for LumiraDx SARS-CoV-2 & Flu A/B
- 1.5. Supplier Information: Company: MRN Diagnostics 101 Constitution Blvd Franklin, MA 02038 United States Telephone: 1-508-384-0033 Website: www.mrndx.com

1.6. Emergency Contact:

1-508-384-0033 Monday - Friday 8am-5pm EST

2. HAZARD IDENTIFICATION

2.1. Classification of the substance or mixture:

This material has the potential to transmit infectious agents and should be handled according to Biosafety Level 2. This product has SARS-CoV-2, Influenza A, and Influenza B viral strains that have been chemically inactivated and lysed to render them noninfectious.

- 2.2. Signal Word: Warning.
- 2.3. Hazard Statements:

Use of universal precautions.

- 2.4. Hazard Pictogram: N/A
- 2.5. **Precautionary Statement(s):**

Biohazard: handle as if capable of transmitting infectious agents.

2.6. Other Hazards:

Contains chemically inactivated and lysed SARS CoV-2 virus, Influenza A virus, and Influenza B virus: exercise universal precautions.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Composition:

Buffered and stabilized formulation containing the hazardous ingredients listed below.



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Component/Chemical Name	Common Name / EC-No.	CAS-No.	Concentration
ProClin 950	Not Applicable	2682-20-4	<0.1%
Sodium Azide	Not Applicable	26628-22-8	<0.1%

4. FIRST-AID MEASURES

4.1. Description of First-Aid Measures:

4.1.1. If Inhaled:

Proceed to an area containing fresh air and keep at rest in a position comfortable for breathing.

4.1.2. In Case of Skin Contact:

Immediately wash thoroughly with warm water and antibacterial soap. Flush with water and seek medical attention.

4.1.3. In Case of Eye Contact:

Rinse immediately with copious amounts of water for several minutes. Use of an eye wash station preferable. Remove contact lenses is applicable and continue to rinse. Seek medical attention.

4.1.4. **If Ingested:** Do not induce vomiting. Rinse mouth with water provided the person is conscious. Never give anything by mouth to an unconscious person. Seek medical attention.

4.2. Most Important Symptoms and Effect, Both Acute and Delayed: No data available. 4.3 Decommon detions for Immediate Mediael Core and Special Treatment

4.3. Recommendations for Immediate Medical Care and Special Treatment Needed: Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1. Suitable Extinguishing Media:

Use extinguishing measures and methods that are appropriate to local circumstances and the surrounding environment.

- 5.2. Specific Hazards Arising from the Chemical or Mixture: Use water spray to cool fire-exposed containers.
- 5.3. Special Protective Actions for Fire-Fighters: Wear self-contained breathing apparatus and protective suit.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures:

6.1.1. For Non-Emergency Personnel:

Avoid contact with skin and eyes. The use of laboratory coat, gloves and safety glasses is required.

6.1.2. For Emergency Responders:

Avoid contact with skin and eyes. The use of protective equipment is required.

6.2. Environmental Precautions:

Do not allow discharge into the environment. Prevent leakage or spillage.

6.3. Methods and Materials for Containment and Cleaning Up:

Clean in accordance with applicable effective procedures and in compliance with state and federal regulations.



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7. HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Avoid contact with skin and eyes. Wear personal protective equipment. Wash hands thoroughly after handling. Do not eat or drink while handling product.

7.2. Conditions for Safe Storage, Including any Incompatibilities

- 7.2.1. Storage Conditions:
 - Store in accordance to labeled or recommended storage temperature. Keep containers properly labeled.
- 7.2.2. Incompatible Products: No data available.
- 7.2.3. **Incompatible Materials:** No data available.
- 7.2.4. **Recommended Storage:** Refer to product label, Certificate of Analysis or recommendation in relation to use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters:

To the best of our knowledge this product does not contain substances with occupational or national exposure limit values.

8.2. Appropriate Engineering Controls:

Ensure adequate ventilation or other engineering controls to reduce airborne levels.

8.3. Personal Protective Equipment:

8.3.1. **Eye/Face Protection:**

Use of equipment for eye protection is required. Avoid exposure to liquid splashes.

8.3.2. Skin/Body Protection:

Use of personal protective equipment is required, which includes the use of a laboratory coat and gloves. **Respiratory Protection:**

In the case of insufficient ventilation wear suitable respiratory equipment.

8.3.3. Hand Protection:

Use of gloves is required. Inspect gloves prior to use to ensure adequate protection. Dispose of contaminate gloves after use in accordance with state/federal regulations and good laboratory practices. Wash hands thoroughly after handling.

8.3.4. Control of Environmental Exposure:

- Prevent product from entering drains.
- 8.3.5. Pictograms



9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (Physical State, Color, etc.):

Color, etc.): Viscous Liquid, Transparent. CONFIDENTIAL – CONTROLLED DOCUMENT



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Upper/lower flammability or explosive limits: Odor: Odor Threshold:	No data available. No data available. No data available.
Vapor Pressure:	No data available.
Vapor density:	No data available.
рН:	No data available.
Relative density:	No data available.
Melting point/freezing point:	No data available.
Solubility(ies):	No data available.
Initial boiling point and boiling range:	No data available.
Flash point:	No data available.
Evaporation rate:	No data available.
Flammability:	No data available.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available

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10. STABILITY AND REACTIVITY

10.1. Reactivity:

No data available.

- 10.2. Chemical Stability: Stable under recommended storage conditions.
- 10.3. Possibility of Hazardous Reactions: No data available.
- 10.4. Conditions to Avoid: No data available.
- 10.5. **Incompatible Materials:** No data available.
- 10.6. Hazardous Decomposition Products: No data available.

11. TOXICOLOGICAL INFORMATION

- 11.1. Acute Toxicity: No data available.
- 11.2. Skin Corrosion/Irritation: No data available.
- 11.3. Serious Eye Damage/Irritation: No data available.
- 11.4. **Respiratory or Skin Sensitization** No data available.
- 11.5. Germ Cell Mutagenicity: No data available.
- 11.6. Carcinogenicity: No data available.
- 11.7. Reproductive Toxicity:



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No data available.

- 11.8. **STOT-Single Exposure:** No data available.
- 11.9. Aspiration Hazard: No data available.

12. ECOLOGICAL INFORMATION

12.1. **Toxicity:**

No data available.

- 12.2. Persistence and Degradability: No data available.
- 12.3. Bioaccumulative Potential: Adverse ecological effects cannot be excluded in the event of improper handling or disposal.
- 12.4. **Mobility in Soil:** No data available.
- 12.5. Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste Disposal Recommendations:

Material has undergone chemical inactivation and lysis. All human derived materials should be handled as if the material is infectious. The use of universal precautions is required by trained personnel. Dispose of in accordance with state and federal regulations.

14. TRANSPORT INFORMATION

14.1. UN Number:

Not applicable.

- 14.2. UN Proper Shipping Name: Not applicable.
- 14.3. Transport Hazard Class(es): Not applicable.
- 14.4. **Packing Group:** Not applicable.
- 14.5. Environmental Hazards: Not applicable.

14.6. Bulk Transport:

Labels Required: Exempt Human Specimen Label, per Classification section 3.6.2.2.3.8 of IATA DGR. IATA Packaging Requirements: Packed in accordance with Classification section 3.6.2.2.3.8 of IATA DGR.

15. REGULATORY INFORMATION

Not Applicable



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16. OTHER INFORMATION

- 16.1. **SDS Prepared by:** Nicole C. Butts, MRN Diagnostics, LLC
- 16.2. **Date of Preparation:** 12/16/2021

16.3. Company Policy or Disclaimer:

The information herein is provided in good faith and is correct to the best of our knowledge and information currently available to us but makes no representation as to its completeness or accuracy. This safety data sheet is intended for use only as a guide for the appropriate precautionary handling of material by suitably trained personnel. Medical Research Networx, LLC – MRN Diagnostics shall not be held liable for any damage, injury or loss resulting from handling or from contact with the above product. Users should make their own investigations to determine the suitability of information for their purposes.