

Section 1 – Product and Company Identification

1.1 Manufacturer Information

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1.2 Product Information

Product Name: Solana HSV1+2/VZV Assay (Catalog #: M302)

Intended Use: An *in vitro* diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and differentiation of *herpes simplex virus type 1*, *herpes simplex virus type 2*, and *varicella-zoster virus* DNA isolated and purified from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients suspected of active *herpes simplex virus 1*, *herpes simplex virus 2* and/or *varicella-zoster* infection. Intended for use only with the Solana® instrument.

Components: Process Buffer (1.6 mL), Reaction tubes (Lyophilized cake in 0.2 mL tube)

Section 2 – Hazard Identification

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|--|---------------------------------------|
| 2.1 Classification of the Substance of Mixture(s) | Not a hazardous substance or mixture. |
| 2.2 GHS Label Elements, including Precautionary Statements | Not a hazardous substance or mixture. |
| 2.3 Hazards Not Otherwise Classified (HNOC) or not covered by GHS | None |

Section 3 – Composition / Information on Ingredients

3.1 Mixtures

Contains non-hazardous quantities of proprietary ingredients according to OSHA (29 CFR 1910.1200).
Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

Component	Chemical Name	CAS #	EINECS #	Concentration (%)
Process Buffer	Glycerol	56-81-5	200-289-5	<5.1

Section 4 – First Aid Measures

4.1 Description of First Aid Measures

- If inhaled:** Move the person to fresh air and support breathing as required.
- In case of skin contact:** Wash affected area with soap and water. Seek medical advice if irritation develops.
- In case of eye contact:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical attention.
- If swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

4.2 Most Important Symptoms and Effects (both acute and delayed)

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

No specific measures identified.

Section 5 – Fire Fighting Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

5.1 Suitable Extinguishing Media

For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.

5.2 Special Hazards Arising From the Substance or Mixture

Nature of decomposition products not known.

5.3 General Fire Hazards

The components within this kit will not significantly contribute to the intensity of a fire.

5.4 Fire Fighting Equipment

Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. A large spill of the components contained within this kit is unlikely.

6.1 Personal Precautions

Avoid breathing vapors, mist or gas.

6.2 Environmental Precautions

Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.

6.3 Methods and Materials for Clean-Up

Soak up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.

6.4 Recovery and Neutralization

Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.

Section 7 – Handling and Storage**7.1 Specific Use**

For professional use only – Not for use by the general public.

7.2 Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while working with this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of these controls, reagents, solutions or buffers and who are familiar with the potential hazards. **Universal Precautions should be followed when handling and working with this kit.** Keep out of reach of the general public.

7.3 Conditions for Safe Storage (including any incompatibilities)

To maintain efficacy, store according to the package insert instructions.

7.4 Incompatibilities

To maintain efficacy, store according to the package insert instructions.

Section 8 – Exposure Controls and Personal Protection**8.1 Exposure Limits**

No data available for the components within this kit.

8.2 Exposure Controls

Engineering Measures

Use with adequate ventilation.

Personal Protective Equipment

Respiratory Protection

None needed under normal conditions of use.

Skin Protection

Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.

Section 8 – Exposure Controls and Personal Protection (cont'd)

Eye Protection Wear safety glasses with side shields or goggles to prevent eye contact.
Body Protection Use body protection appropriate for the task. A laboratory coat is recommended.
Hygiene Measures Wash hands before use, after use and at the end of the workday.

8.3 Environmental Exposure Controls No special environmental controls are required.

8.4 Special Notes No data available.

Section 9 – Physical and Chemical Properties

Characteristic	Process Buffer	Reaction Tubes
Boiling Point (°C)	No data available	No data available
Melting Point (°C)	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available
pH	8.0	No data available
Solubility in Water	Soluble	Soluble
Appearance and Odor	Clear, Odorless	White cake, Odorless

Section 10 – Stability and Reactivity

Characteristic	Process Buffer	Reaction Tubes
Component Stability	Stable	Stable
Hazard Reaction Potential	No data available	No data available
Conditions to Avoid	No data available	No data available
Materials to Avoid	No data available	No data available
Hazardous Decomposition Products	No data available	No data available

Section 11 – Toxicological Properties
11.1 Information on Toxicological Effects

Acute Toxicity No data available
Skin Corrosion / Irritation No data available
Respiratory or Skin Sensitization No data available
Generative Cell Mutagenicity No data available
Carcinogenicity No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, IARC, NTP or OSHA.
Reproductive Toxicity No data available
Teratogenicity No data available

Section 11 – Toxicological Properties (cont'd)

Specified Target Organ Toxicity

Single Exposure: No data available Repeated Exposure: No data available

Aspiration Hazard No data available

Potential Health Effects

Inhalation: May cause respiratory tract irritation. *Skin:* May cause skin irritation upon contact.
Ingestion: May be harmful if swallowed. *Eyes:* May cause eye irritation.

11.2 Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

11.3 Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

Kidney – Irregularities – Based on Human Evidence (Glycerol)

Section 12 – Ecological Information

12.1 Toxicity	No data available
12.2 Persistence and Degradability	No data available
12.3 Bioaccumulative Potential	No data available
12.4 Mobility in Soil	No data available
12.5 PBT and vPvB Assessment	Assessment not available as chemical safety assessment not conducted.
12.6 Other Adverse Effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid disposal to the environment.

Section 13 – Disposal Considerations

13.1 Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the controls, buffers, reagents or solutions into drains, water courses or onto the ground.

13.2 Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

Section 14 – Transportation Information

14.1 U.S Department of Transportation (DOT)	This kit is not regulated for transport.
14.2 International Air Transportation Association (IATA)	This kit is not regulated for transport.
14.3 Canada	This kit is not regulated for transport.

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

OSHA Hazards None
SARA 302 The following chemicals are subject to reporting levels established by Sara Title III, Section 302:
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.

