

SAFETY DATA SHEET

Revision Date: April 2023

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1. PRODUCT AND COMPANY IDENTIFICATION

Product name:	ASI VZV (Varicella Zoster Virus) Test
Product number:	840096AG
Brand:	ASI
Company:	Arlington Scientific Inc. 1840 N Technology Drive Springville, UT 84663 USA
Telephone:	(801) 489-8911
Fax:	(801) 489-5552
Emergency phone #:	(801) 489-8911

2. HAZARDS IDENTIFICATION

Emergency overview:	<p>This test kit should be handled only by qualified personnel, trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use.</p> <p>Some of the components in this test kit were derived from materials of human origin. The components have been certified by the supplier. No test can offer complete assurance that hepatitis B-virus, HIV virus or other infectious agents are absent; this kit should be handled at Biosafety level 2.</p> <p>The microwells in this test kit have been coated with varicella zoster virus antigen which has been certified by the supplier to be inactivated. The microwells should be handled as though capable of transmitting infection.</p>
OSHA hazards:	
Flammable liquid:	None
Target organ effect:	None known
Harmful by ingestion:	Avoid hand-to-mouth contact when handling human serum source materials. Wash hands thoroughly after handling, even when gloves have been worn. Do not eat, drink, or apply cosmetics in the area where human source material is handled. Do not pipet by mouth.
Harmful by skin absorption:	Wear gloves and especially cover any cuts, abrasions, or skin lesions. Dispose of gloves, pipets, stirrers, test cards, and used reagent containers as biohazardous material. Wash hands thoroughly after removing gloves. Use extreme caution with any sharp object to avoid percutaneous exposure to human source material. Wear outer protective garment such as a lab coat or gown.
Irritant:	
Target organs:	None known
Potential health effects:	
Inhalation:	May cause irritation
Skin:	May cause irritation
Eyes:	May cause irritation
Ingestion:	Harmful if swallowed. See physician.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Formula:	<p>Reagents contained in kit:</p> <p>Plastic microwells: Coated with inactivated varicella zoster virus antigen</p> <p>Conjugate*: Goat anti-human immunoglobulin labeled with calf alkaline phosphatase.</p> <p>Negative control*: Normal human serum</p> <p>Calibrator 1*: Normal human serum</p> <p>Calibrator 2*: Normal human serum</p> <p>Positive control*: Normal human serum</p> <p>Sample diluents: phosphatate buffered saline with a protein stabilizer</p> <p>Substrate: P-Nitrophenyl phosphate</p>
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Wash concentrate: Tris buffered saline with TWEEN-20
Stop solution: Tri-Sodium Phosphate
• Contains 1 mg/mL sodium azide, or less

4. FIRST AID MEASURES

General Advice:	The stop solution in this test kit is caustic. If it comes in contact with the skin or eyes, flush the exposed area with water for three to five minutes.
If inhaled:	Remove from source to fresh air. If breathing becomes difficult call a physician.
In case of skin contact:	Wash thoroughly with soap and water. Remove contaminated clothing. Call a physician.
In case of eye contact:	Flush with large amounts of water or sterile eye wash. Call a physician.
If swallowed:	If conscious, wash out mouth with water. Call a physician.

5. FIRE-FIGHTING MEASURES

Flammable properties:	With the exception of the plastic containers and microwells; The materials in this test kit are not capable of supporting combustion.
Suitable extinguishing media:	Use extinguishing media appropriate for surrounding fire conditions.
Special protective equipment for Fire-Fighters	Wear self-contained breathing apparatus and protective clothing to prevent exposure of skin and eyes

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	
Environmental precautions:	Not a risk to environment if disposed of properly.
Methods for cleaning up:	Clean exposed surfaces with a solution of 0.5% sodium hypochlorite (10% bleach).

7. HANDLING AND STORAGE

Handling	THE FDA recommends at least a biosafety level 2 for the handling of materials in this test kit.
Storage	The test kits should be stored at 2 to 8° C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal precautions	Certain components of this test kit are potentially biohazardous materials. Wear suitable protective clothing and glasses when working with the test kit and test specimens.
Respiratory protection	None required
Hand protection	Surgical gloves
Eye protection	Standard laboratory eye ware
Skin and body protection	Typical laboratory coat or gown
Hygiene measures	No special measures required
Personal precautions	No special precautions required
Respiratory protection	Wear surgical mask if indicated by local procedures

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	The materials comprising this test kit are not classified as hazardous chemicals.
Form	Liquid
Color	Varies per component
Odor	None
Safety data	ASI Reagents contain sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large amounts of water to prevent azide build-up.

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10. STABILITY AND REACTIVITY

Storage stability	The materials comprising this test kit are stable inert compounds.
Conditions to avoid	Avoid temperatures outside the range of 2 – 8°C. Avoid freezing.
Materials to avoid	None
Hazardous decomposition products	None
Hazardous reactions	None

11. TOXICOLOGICAL INFORMATION

Potential health effects	Sodium azide is toxic and care should be taken to avoid ingestion.
Inhalation	May cause irritation
Skin	May cause irritation
Eyes	May cause irritation
Ingestion	Harmful if swallowed. See physician.
Target organs	None

12. ECOLOGICAL INFORMATION

Elimination information	No ecological effects currently identified.
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13. DISPOSAL CONSIDERATIONS

Product	Disposal should be done in accordance with existing disposal practices employed for infectious waste at your institution. Observe all federal state and local environmental regulations.
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14. TRANSPORTATION INFORMATION

DOT (US)	Non-hazardous & non-corrosive.
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15. REGULATORY INFORMATION

	FDA 520(k) Premarket notification number K972295
	European information pending.
	CLIA, Moderately complex

16. OTHER

	To the best of our knowledge, the information provided in this Safety Data Sheet is accurate. ASI does not assume any liability for the accuracy or completeness of the information. Final suitability of a material is the responsibility of the user. All materials may present unknown hazards and should always be used with caution. Although hazards are described in this Safety Data Sheet, ASI does not guarantee that these issues are the only hazards that exist.
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