

# SAFETY DATA SHEET

Revision Date: April 2023

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## 1. PRODUCT AND COMPANY IDENTIFICATION

Product name:	ASI MUMPS IgM TEST
Product number:	860096AM
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:	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. The absence of a specific warning should not be interpreted as an indication of safety.
OSHA hazards:	
Flammable liquid:	None
Target organ effect:	None
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 card, and used reagent container 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. This kit should be handled at Biosafety Level 2, as recommended for any potentially infectious serum or blood specimen in the center for disease control / National Institute of Health Manual. Biosafety in Microbiological and Biomedical Laboratories, 1993 or latest edition.
Irritant:	None
Target organs:	None
Potential health effects:	
Inhalation:	May cause irritation
Skin:	May cause irritation
Eyes:	May cause irritation
Ingestion:	If ingested, seek medical attention

Some of the components in this test kit were derived from materials of human origin. The absence of Hepatitis-B surface antigen, HIV 1 and 2 Antibodies, and Hepatitis-C Antibodies, has been certified by the supplier of these materials. Since 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, as recommended for any potentially infectious serum or blood specimen in the center for disease control / National Institute of Health Manual. Biosafety in Microbiological and Biomedical Laboratories, 1993 or latest edition.

The microwells in this test kit have been coated with mumps virus antigen which has been certified by the supplier to be inactivated. The microwells should however, be handled as though capable of transmitting infection.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Formula:	Reagents contained in kit: Plastic microwells: Coated with inactivated mumps virus antigen Conjugate: Goat anti-human immunoglobulin labeled with calf alkaline phosphatase Negative control*: normal human serum Calibrator 1*: normal human serum Calibrator 2*: normal human serum Positive control*: normal human serum Sample diluent: Phosphatate buffered saline with a protein stabilizer
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Substrate: P-Nitrophenyl phosphate  
Wash concentrate : Tris buffered saline with Tween-20  
Stop solution: Tri-sodium phosphate  
\*Contains 1 mg/ml sodium azide, or less.

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## 4. FIRST AID MEASURES

<b>General Advice:</b>	
If inhaled:	Remove from source to fresh air. If breathing becomes difficult, call a physician.
In case of skin contact:	Exposed skin should be washed with soap and water for three to five minutes
In case of eye contact:	Flush the eyes with water for three to five minutes
If swallowed:	Call for medical assistance.

## 5. FIRE-FIGHTING MEASURES

Flammable properties:	None.
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

<b>Personal precautions:</b>	
Environmental precautions:	No known risk to environment
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 handling the materials in this test kit. The test kits should be stored at 2 to 8° C.
Storage	Store at 2 – 8°C.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal precautions	Wear protective clothing and glasses when working with test kit and test specimens.
Respiratory protection	None required
Hand protection	Surgical gloves
Eye protection	Standard laboratory eye ware
Skin and body protection	Wear protective clothing when working with test kit and test specimens.
Hygiene measures	No special precautions required
Personal precautions	No special precautions required
Respiratory protection	Wear surgical mask if indicated by local procedures

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
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.

## 10. STABILITY AND REACTIVITY

Storage stability	Refrigerate at 2 – 8°C. The materials comprising this test kit are stable inert compounds.
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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. Stop solution is caustic
Inhalation	Flush exposed area with water for three to five minutes.
Skin	Flush exposed area with water for three to five minutes.
Eyes	Flush exposed area with water for three to five minutes.
Ingestion	If ingested seek medical attention
Target organs	None

## 12. ECOLOGICAL INFORMATION

Elimination information	No ecological effects currently identified. When the materials in this test kit are properly disposed of (Please see section 13), They pose no ecological threat.
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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 (50 CFR 261.3) State and local environmental regulations. Certain of the test reagents in this test kit contain sodium azide at a concentration of 1 mg or lower. Azides are reported to react with lead and copper in plumbing to form compounds that may detonate on percussion. When disposing of solutions containing sodium azide, flush drains with large quantities of water to minimize the build-up of metal-azide compounds.
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## 14. TRANSPORTATION INFORMATION

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

	FDA510(k) Class I Exempt
	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. The above information is believed to be correct but is not all inclusive and is intended only as a guide
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