

# SAFETY DATA SHEET

Revision Date: April 2023

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## 1. PRODUCT AND COMPANY IDENTIFICATION

Product name:	ASI EB NA IgG
Product number:	870096AG
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

<b>Emergency overview:</b>	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.
<b>OSHA hazards:</b>	NFPA and HMIS ratings: Health = 2; Flammability = 0; Reactivity = 0
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 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:	The stop solution is caustic
<b>Target organs:</b>	None known
<b>Potential health effects:</b>	
Inhalation:	May cause irritation
Skin:	May cause irritation
Eyes:	May cause irritation
Ingestion:	Harmful if ingested. Seek medical care.
	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 measles 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:	Components contained in kit: Plastic microwells: coated with inactivated Epstein-Barr virus nuclear 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
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Sample diluents: Phosphatate buffered saline with a protein stabilizer  
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

## 4. FIRST AID MEASURES

<b>General Advice:</b>	The stop solution in this test kit is caustic.
If inhaled:	If person is conscious remove to fresh air area.
In case of skin contact:	Flush the exposed area with water for three to five minutes.
In case of eye contact:	Flush the exposed area with water for three to five minutes.
If swallowed:	Flush the exposed area with water for three to five minutes.

## 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

<b>Personal precautions:</b>	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.
Environmental precautions:	No known risk to environment.
Methods for cleaning up:	Clean-up with water moistened cloth or mop. After material has been cleaned-up and removed, wash the spilled area site with a disinfectant cleaner.

## 7. HANDLING AND STORAGE

Handling	The FDA recommends at least a Biosafety Level 2 for handling the materials in this test kit.
Storage	The test kits should be stored at 2 to 8° C, and avoid freezing.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal precautions	Certain components of this test kit are potentially biohazardous materials
Respiratory protection	Wear surgical mask if indicated by local procedures
Hand protection	Wear protective clothing when working with test kit and test specimens.
Eye protection	Wear protective glasses when working with test kit and test specimens
Skin and body protection	Wear protective clothing when working with test kit and test specimens.
Hygiene measures	No special measures required
Personal precautions	Wear protective clothing and glasses when working with test kit and test specimens.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	The materials in this kit are not classified as hazardous materials.
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

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Storage stability	Refrigerate at 2 – 8°C. Kit components 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	Not an irritant.
Skin	Stop solution may irritate
Eyes	Stop solution may irritate
Ingestion	Stop solution is caustic and reagents contain sodium azide
Target organs	None

## 12. ECOLOGICAL INFORMATION

Elimination information	No ecological effects currently identified when disposed properly
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## 13. DISPOSAL CONSIDERATIONS

Product	Dispose in accordance with Federal, State and local environmental regulations. Certain reagents may contain sodium azide with a concentration of 1 mg or less. Azides are reported to react with lead and copper in plumbing to form compounds that may detonate on percussion. When disposing flush drains with large quantities of water to minimize build-up of metal-azide compounds.
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## 14. TRANSPORTATION INFORMATION

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

	FDA510(k) Premarket Notification, No K991975
	CLIA, Moderately complex
	European information pending

## 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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