SAFETY DATA SHEET

Revision Date: April 2023

1. PRODUCT AND COMPANY IDENTIFICATION	
Product name:	**ASI Rubella IgG Test**
Product number:	800096AG
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 product is not classified according to the Global Harmonized System (GHS).
OSHA hazards:	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:	None
Target organs:	None
Potential health effects:	
Inhalation:	May cause irritation
Skin:	May cause irritation
Eyes:	May cause irritation
Ingestion:	May cause irritation

3. COMPOSITION/INFORMATION ON INGREDIENTS	
Formula:	Reagents contained in kit: Plastic microwells: coated with inactivated rubella 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: Phosphahate buffered saline with a protein stabilizer Substrate: P-Nitrophenyl trophenyl phosphate Wash concentrate: Tris buffered saline with Tween-20 Stop solution: Tri-sodium phosphate *Contains 1 mg/ml sodium azide, or less All components derived from human source materials have been tested and found to be nonreactive for hepatitis B surface antigen (HBsAg) and antibodies to HIV and HCV. Given that no known test offers complete assurance that infectious agents are absent, all materials derived from human blood should be handled as if capable of transmitting infection.

4. FIRST AID MEASURES	
General Advice:	Stop solution is caustic.

If inhaled:	Remove from source to fresh air. If breathing becomes difficult, call a physician.
In case of skin contact:	Exposed skin should be flushed with large amounts of water.
In case of eye contact:	Flush the eyes with large amounts of water.
If swallowed:	Call for medical assistance.

5. FIRE-FIGHTING MEASURES	
Flammable properties:	None
Suitable extinguishing media:	CO2, or multiple dry chemical or water spray.
Special protective equipment: for Fire-Fighters	No special measures required.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions:	Personal precautions, protective equipment, and emergency procedures are not required.
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	Ensure adequate ventilation and fresh air supply in HVAC
Storage	Store at 2 – 8° C and avoid freezing

8. EXPOSURE CONTROLS/PERSONAL PROTECTION	
Personal precautions	Certain components are potentially biohazardious 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. Wash hand s following removal of gloves.
Personal precautions	No special precautions required
Respiratory protection	Wear surgical mask if indicated by local procedures

9. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance	Not classified as hazardous.
Form	Liquid
Color	Control reagents are transparent; latex is colored.
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	Stable inert compounds.
Conditions to avoid	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. Seek medical attention.
Target organs	None known

12. ECOLOGICAL INFORMATION

Elimination information	No ecological effects currently identified when disposed properly..

13. DISPOSAL CONSIDERATIONS

Product	Some 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. Smaller quantities can be disposed of with solid waste. This product is not considered an RCRA hazardous waste. Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.

14. TRANSPORTATION INFORMATION

DOT (US)	Classified non-corrosive.

15. REGULATORY INFORMATION

	FDA 510(k) Premarket notification no. K961053
	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 of 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.