

SAFETY DATA SHEET

1. IDENTIFICATION

Product name	SeraQuest Rubella IgM Test
Product number	800096AM
Brand	SeraQuest
Recommended use/Restrictions on use	For the qualitative detection of human IgM antibodies to rubella virus in human serum by enzyme immunoassay, to aid in the diagnosis of rubella infection. These materials are intended to be acquired, possessed and used only by health professionals.
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

Classification	Classification under 2024 OSHA Hazard Communication Standard (29 CFR 1910.1200)
Hazard Classification	Skin corrosion/irritation Category 2 Serious eye damage/irritation Category 2 Specific target organ toxicity –(single exposure) Category 3 Target organ – respiratory tract
Signal Word	Warning
Hazard Statement	Causes skin irritation Causes severe skin burns and eye damage. May cause respiratory irritation
Label Elements	
Precautionary Statements	Prevention Do not breathe mist/vapors/spray Use in a well-ventilated area. Wash thoroughly after handling Wear protective gloves/protective clothing/eye protection/face protection Response If exposed or concerned – Seek medical attention or advise Storage Store at 2 - 8°C Disposal

SAFETY DATA SHEET

	Dispose of contents/container at an authorized site.
Hazards not otherwise classified (HNOC)	None Identified

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Component: Stop Solution	CAS#	Concentration
Trisodium Phosphate	10101-89-0	0.5M
<u>Non-hazardous Components:</u> The following mixtures do not contain any known hazardous materials at the concentration above OSHA limits according to 2024 OSHA Hazardous Communication Standard.		
Microwell Coated Plate coated with rubella antigen.		
Normal Human Serum		
Conjugate: Goat anti-human IgM labeled with alkaline phosphatase.		
Substrate: p-nitrophenyl phosphate.		
Diluent: Phosphate-buffered saline with protein stabilizer, and absorbents for rheumatoid factor and human IgM		
Wash Concentrate: Tris-buffered saline with Tween 20.		

4. FIRST AID MEASURES

General Advice	Symptoms of mild discomfort may be exhibited after several hours, observe for any medical symptoms for at least 48 hours.
If inhaled	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
In case of skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs, or if more severe symptoms develop, consult a physician.
In case of eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
If swallowed	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Most Important symptoms/effects, acute and delayed	Skin contact may result in irritation or dermatitis. Symptoms of overexposure may include headache and dizziness, generally at concentrations and volumes that greatly exceed that of this kit. The Stop Solution may cause serious eye irritation with possible corneal damage with extended exposure.

5. FIRE-FIGHTING MEASURES

SAFETY DATA SHEET

Flammable properties	Hazardous decomposition products in case of fire. Toxic fumes may be released.
Suitable extinguishing media	Water spray, dry powder, foam, carbon dioxide
Special protective equipment for Fire-Fighters	Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus, complete protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Follow general laboratory practices
Protective Equipment	Do not attempt to take action without suitable protective equipment. For further information refer to section 8: Exposure Control/Personal Protection
Emergency procedures	Ventilate spillage area.
Methods and materials for containment and cleaning up	Take up liquid spill into absorbent material. Dispose of materials or solid residues at an authorized site. Follow established material spill guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. For further information refer to section 13.

7. HANDLING AND STORAGE

Precautions for safe handling	This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper Good Laboratory Practices and safety guidelines for handling chemical, biological, and laboratory hazards. Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent, and eye/face protection. Keep containers tightly closed; avoid splashing, spills, and the generation of aerosols. Handle all human source materials, specimens, and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per <i>Standard and Universal Precautions</i>. All personal protective equipment should be removed before leaving the work area. Refer to section 8 for more specifics.
Conditions for safe storage	Store according to product and label instructions (generally at 2 - 8 °C).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<u>Exposure controls</u>	The following PPE is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes, eyes, or hazardous inhalation, under normal conditions of use for the time during which the protective equipment is utilized.
Ventilation	Adequate lab ventilation is required.

SAFETY DATA SHEET

Eye/Face Protection	Wear ANSI approved safety glasses, goggles, or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.
Protective Gloves	Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves, such as Nitrile, Neoprene, and Vinyl, are recommended because they are sturdy, effective, and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never be reused. Wash hands thoroughly after removing gloves.
Protective Clothing	Wear a lab coat, clinic jacket, gown, apron, and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.
Respiratory Protection	Not required.
Hygiene measures	Do not eat, drink, or apply cosmetics in the area where human source material is handled. Do not pipet by mouth
<u>Engineering controls</u>	Component chemicals with limit values that require monitoring at the workplace: Stop Solution (<i>Trisodium Phosphate</i>) .
OSHA PEL	5 mg/m ³ TWA (Respirable) 15 mgm ³ (Inhalable)
ACGIH TLV	3 mg/m ³ TWA (Respirable) 10 mgm ³ (Inhalable)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Variable, generally aqueous liquids
Color	Varies per component
Odor (odor threshold)	No applicable information is available
Melting point/freezing point	No applicable information is available
Boiling point	No applicable information is available
Flammability	No applicable information is available
Lower and upper explosion limit/flammability limit	No applicable information is available
Flash point	No applicable information is available
Auto-ignition temperature	No applicable information is available
Decomposition temperature	No applicable information is available

SAFETY DATA SHEET

pH	Most of the liquid chemical reagents are between pH 5 and 9, with the exception of the Stop solution at pH ≥ 10 .
Kinematic viscosity	No applicable information is available
Solubility	The liquid chemical components are soluble in water.
Partition coefficient n-octanol/water (log value)	No applicable information is available
Vapor pressure (includes evaporation rate)	No applicable information is available
Density and/or relative density	No applicable information is available
Relative vapor density	No applicable information is available
Particle characteristics	No applicable information is available

10. STABILITY AND REACTIVITY

Reactivity	This product is non-reactive under normal conditions of use, storage and transport
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Do not allow the Stop Reagent to come in contact with strong acids, oxidizing agents, and metals.
Conditions to avoid	Sodium Azide may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.
Incompatible materials	Do not allow the Stop Reagent to come in contact with strong acids, oxidizing agents, and metals.
Hazardous decomposition products	Oxides of carbon or nitrogen may form when heated to decomposition.

11. TOXICOLOGICAL INFORMATION

Inhalation	May cause irritation
Skin	Contact with the Stop Solution can severely irritate skin
Eyes	Contact with the Stop Solution can severely irritate eyes
Ingestion	Harmful if enough is ingested (generally quantities above those found in the kit)
Symptoms related to physical, chemical, and toxicological characteristics	No applicable information is available
Delayed and immediate effects and chronic effects from short-and long-term exposure	No applicable information is available

SAFETY DATA SHEET

Numerical measures of toxicity	No applicable information is available
Interactive effects	No applicable information is available
Listed in National Toxicology Program (NTP) Report on Carcinogens	No applicable information is available
Found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA	No applicable information is available

12. ECOLOGICAL INFORMATION

Elimination information	No applicable information is available
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13. DISPOSAL CONSIDERATIONS

Waste disposal methods	SeraQuest reagents contain sodium azide at $\leq 0.1\%$. Even though the concentration is below what is classified as hazardous according to 2024 OSHA Hazardous Communication Standard 29 CFR 1910.1200, 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. Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.
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14. TRANSPORTATION INFORMATION

DOT (US)	Not regulated
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15. REGULATORY INFORMATION

	FDA 510(k) Premarket notification number K982281
	CLIA, Moderately complex

16. OTHER

Other information	To the best of our knowledge, the information provided in the safety data sheet is accurate. SeraQuest 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 the SDS, SeraQuest does not guarantee that these issues are the only hazards that exist.
Date of preparation/change	June 30, 2026