

Section 1 – Identification**1.1 Product Name: BioSign® Strep A****1.2 Intended Use:**

BioSign® Strep A-Direct Group A Streptococcus Antigen test is a rapid immunochromatographic assay for the qualitative detection of group A streptococcal antigen directly from throat swab specimens. The test is intended for use as an aid in the early diagnosis of group A streptococcal infection.

1.3 Manufacturer:

Princeton BioMeditech Corp.
 4242 US Highway 1
 Monmouth Junction, NJ 08852
 Tel: 732-274-1000 Fax: 732-274-1010


1.4 Emergency No.:

Poison Control (US): 1-800-222-1222

Section 2 – Hazard Identification

Hazards identified in this product relate to Extraction Reagents A and B. Each reagent bottle contains approximately 6.5 mL of solution for multiple uses.

Emergency Overview

<p>Extraction Reagent A (6.5 mL) <i>2.0 M Sodium Nitrite (13.8%)</i></p> <p>OSHA Hazards Target Organ Effect, Toxic by ingestion, Irritant</p> <p>GHS Classification and Label Elements Oxidizing liquids (Category 3) Acute toxicity, Oral (Category 3) Acute aquatic toxicity (Category 1) Signal Word(s): Danger, Warning</p>	<div style="text-align: center;">  </div> <p>Hazard statement(s) H272: May intensify fire; oxidiser H301: Toxic if swallowed H400: Very Toxic to aquatic organisms</p> <p>Precautionary statement(s) P220- Keep/Store away from clothing/ other combustible materials P201 - Obtain special instructions before use P280 - Wear protective gloves/protective clothing/eye protection/face protection P302+ P352 - IF ON SKIN: Wash with plenty of soap and water P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P309 + P311 - If exposed or you feel unwell: Call a POISON CENTRE or doctor/physician P391 - Collect spillage</p>
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<p>Extraction Reagent B (6.5 mL) <i>0.2 M Phosphoric Acid (1.96%)</i></p> <p>OSHA Hazards Target Organ Effect, Corrosive, Irritant</p> <p>GHS Classification and Label Elements Acute toxicity, Oral (Category 5) Acute toxicity, Dermal (Category 5) Acute toxicity, Inhalation (Category 5) Serious eye damage/eye irritation (Category 2B) Signal Word(s): Warning</p>	<p>Hazard statement(s) H303+H313+H333: May be harmful if swallowed, in contact with skin or inhaled H320: Causes eye irritation</p> <p>Precautionary Statements P304+P312 - Call Poison Center or Doctor if feeling unwell after exposure or INHALATION P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do Continue rinsing. P337+P313 - If eye irritation persists: Get medical advice/attention</p>
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Section 3 – Composition / Component Information

3.1 Test Kit Components: Test strip/device, Extraction Reagent A, Extraction Reagent B, Positive Control, Rayon Throat Swabs, Extraction Tubes, Transfer pipettes.

3.2 Hazardous Substances:

Chemical	CAS#	EC#	Kit Component	Concentration	Classification
Sodium Nitrite	7632-00-0	231-555-9	Extraction Reagent A	2.0 M (13.8%)	Ox. Sol. 3; Acute Tox. 3; Aquatic Acute 1 H400, H272, H301
Phosphoric Acid	7664-38-2	231-633-2	Extraction Reagent B	0.2 M (1.96%)	Skin Corr. 1B; H314

Section 4 – First Aid Measures

- 4.1 Skin Contact:** Immediately wash affected area with soap and water for 15 minutes. Remove and wash any contaminated clothing. If pain, irritation, or a rash occur, seek medical attention.
- 4.2 Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If pain or irritation occur, seek medical attention.
- 4.3 Ingestion:** If swallowed, rinse mouth with copious amount of water. Do not induce vomiting. If irritation or discomfort occur, seek medical attention.
- 4.4 Inhalation:** Move to fresh air if inhaled. If breathing becomes difficult or stops, seek medical attention immediately.

Section 5 – Fire Fighting Measures

- 5.1 Suitable Extinguishing Media:** Dry chemical, carbon dioxide, water, or foam.
- 5.2 Specific Hazards:** Fire may cause material to produce noxious fumes or gases. Potential decomposition products. – nitrogen oxides, sodium oxides, phosphorus oxides.
- 5.3 Fire Fighting Procedure:** Wear self-contained breathing apparatus and protective equipment. Remove containers from fire area if possible. Cool fire-exposed containers with water.

Section 6 – Accidental Release Measures

- 6.1 Personal Precautions:** Kit contains material of biological origin, avoid direct contact with material. Wear protective clothing as outlined in Section 8.
- 6.2 Environmental Precaution:** Keep away from drains, surface and ground water, and soil. Collect spilled and contaminated material in appropriate containers and dispose according to waste regulations. Prevent further leakage if possible, avoid release to the environment.
- 6.3 Methods and Materials for Clean up:** Isolate spill area to prevent further spreading of spilled material. Use absorbent to soak up spilled material. Use 10% sodium hypochlorite, 70% ethanol, or equivalent solution to clean contaminated surfaces when spilled material is of biological origin

Section 7 – Handling and Storage

- 7.1 Handling:** Avoid direct contact with or inhalation of contents. Wear personal protective equipment (Section 8). Wash thoroughly after handling. Keep away from heat and sources of ignition.
- 7.2 Storage:** Store according to directions listed in the package insert. Keep away from combustible materials and ignition sources.

Section 8 – Exposure Controls / Personal Protection

8.1 Exposure Limits:

Components	CAS-No.	Exposure Limit	Limit Values	Health Factors and Target Organs
Phosphoric Acid	7664-38-2	OSHA (PEL) – General Industry 29 CFR 1910.1000 Table Z-1	1 mg/m ³ TWA	Throat Irritation
		National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL)	1 mg/m ³ TWA	Eye and skin burns
			3 mg/m ³ STEL	Eye, nose, skin and throat irritation
		American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) (2001)	1 mg/m ³ TWA 3 mg/m ³ STEL	Eye, skin and respiratory irritation
		CAL/OSHA PELs	1 mg/m ³ TWA 3 mg/m ³ STEL	Eye, skin and respiratory irritation

Sodium Nitrite	7632-00-0	No established exposure limits	N/A	N/A
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8.2 Occupational Exposure Controls:

8.2.1 Engineering Controls: No special engineering controls are required.

8.2.2 Personal Protective Equipment:

Respiratory Protection: None needed under normal circumstances.

Hand Protection: Medical gloves (latex, nitrile, or equivalent), should be worn to avoid direct contact

Eye Protection: Wear suitable lab safety glasses.

Skin Protection: Wear lab coat or other protective clothing.

8.2.3 Environmental Controls: No special environmental controls required.

Section 9 – Physical and Chemical Properties

9.1 General Information and Important health, safety and environmental information:

Properties:	Test Strip	Extraction Reagent A	Extraction Reagent B	Positive Control
Appearance	White strip in plastic housing	Clear, yellow liquid	Clear, colorless liquid	Clear, colorless liquid
Odor	Odorless	Odorless	Odorless	Odorless
pH	N/A	8.8	N/A	N/A
Boiling Point (°C)	N/A	N/A	N/A	N/A
Flash Point	N/A	N/A	N/A	N/A
Flammability	N/A	N/A	N/A	N/A
Explosive Properties	N/A	N/A	N/A	N/A
Oxidizing Properties	N/A	N/A	N/A	N/A
Vapor Pressure	N/A	N/A	N/A	N/A
Relative Density	N/A	N/A	N/A	N/A
Solubilit(ies)	Insoluble	Soluble	Soluble	Soluble
Partition coefficient: n-octanol/water	N/A	N/A	N/A	N/A
Viscosity	N/A	N/A	N/A	N/A
Vapor Density	N/A	N/A	N/A	N/A
Evaporation Rate	N/A	N/A	N/A	N/A

Section 10 – Stability and Reactivity

Stability: Stable under normal conditions. Hazardous reactions are not expected to occur.

10.1 Conditions to Avoid: None identified.

10.2 Materials to avoid: None Identified.

10.3 Hazardous decomposition products: Decomposition as a result of high heat/fire may result in noxious fumes, CO, CO₂, nitrogen oxides, sodium oxides, and phosphorus oxides.

Section 11 – Toxicological Information

Toxicological data:

Sodium Nitrite (CAS# 7632-00-0)

Acute Toxicity

Oral LD50

Rat – 85 mg/kg

Inhalation LC50

Rat – 5.5 mg/L 4 h

No other toxicity data available.

Phosphoric Acid (CAS# 7664-38-2)

Acute Toxicity

Oral LD50

Rat – 1530 mg/kg

Dermal LD50

Rabbit – 2730 mg/kg

Inhalation LC50

Rat – 850 mg/m³ 1 h

No other toxicity data available.

Routes of Exposure:

Inhalation: May cause irritation of the respiratory tract.

Ingestion: May cause irritation of mouth, throat, and gastrointestinal system.

Skin Contact: May cause irritation of the skin.

Eye Contact: May cause irritation of the eyes.

Effects of Short and Long Term Exposure: No data available.

Section 12 – Ecological Information

12.1 Ecotoxicity:

Chemical Name	CAS#	Toxicity to Fish	Daphnia magna (Water Flea)
Phosphoric Acid	7664-38-2	LC50 3-3.5 mg/L Gambusia affinis 96 h	EC50 = 4.6 mg/L 12 h
Sodium Nitrite	7632-00-0	LC50 = 2.3 mg/L Pimephales promelas 96 h LC50 = 20 mg/L Pimephales promelas 96 h LC50 0.092-0.13 mg/L Oncorhynchus mykiss 96 h LC50 0.4-0.6 mg/L Oncorhynchus mykiss 96 h LC50 0.65-1 mg/L Oncorhynchus mykiss 96 h LC50= 0.19 mg/L Oncorhynchus mykiss 96 h	

12.2 Mobility: No data available.

12.3 Persistence and degradability: No data available.

12.4 Bioaccumulative potential: No data available.

Section 13 – Disposal Considerations

Dispose according to local, state, and national regulations.

Section 14 – Transportation Information

This product is not regulated for transport.

UN Number: N/A

Class: N/A

Proper Shipping Name: N/A

Packing Group: N/A

Environmental Hazards: N/A

Section 15 – Regulatory Information

15.1 US Federal Regulations

15.1.1 SARA 313 Components – The following components contain chemicals that are subject to reporting required by SARA Title III, Section 313:

Component	Chemical	CAS#	Section 302	Section 304	CERC LA	Section 313	RCRA Code	CAA 112
Extraction Reagent A	Sodium Nitrite	7632-00-0	N/A	N/A	100 lbs	313	N/A	N/A

15.1.2 SARA 311/312 Hazard Categories

Hazard	Sodium Nitrite	Phosphoric Acid
Acute Health Hazard	Yes	Yes
Chronic Health Hazard	No	No
Fire Hazard	No	No
Sudden Release of Pressure Hazard	No	No
Reactive Hazard	Yes	No

15.2 US State Regulations

15.2.1 California Proposition 65 Components: This product does not contain any products known to the State of California to cause cancer, birth defects, or any other reproductive harm.

15.2.2 US Right-to-Know State Regulations

Chemical Name	CAS	IL	MA	NJ	PA	RI
Sodium Nitrite	7632-00-0		X	X	X	
Phosphoric Acid	7664-38-2		X	X	X	X

15.3 Chemical Safety Assessment: No Chemical Safety Assessment has been carried out on the components of this product.

Section 16 – Other Information

This product is intended for *in vitro* medical diagnostic use. The tests should only be used according to the instructions provided within the kit.

The information provided in this SDS is based on data available to Princeton BioMeditech Corp. and believed to be accurate. This information is based on the conditions and normal use outlined in the instructions of the package insert. As conditions/use can occur beyond the control or knowledge of Princeton BioMeditech Corp., we do not assume any responsibility for the use of this product. It is up to the user to make their own determinations regarding the use of this product under their particular conditions. As such, the user assumes all risk in their use of this material.

No warranty or guarantee, warranty of fitness or merchantability, express or implied, is made with respect to the material, the accuracy of this information, the results obtained from use of this material, or the hazards connected to use of this material. Caution should be used in handling/use of material.