Status™ COVID-19 Antigen Rapid Test For Home Use

SDS

Revision Date: June 13, 2024

Section 1 – Identification

1.1 Product Name: *Status*™ COVID-19 Antigen Rapid Test For Home Use

1.2 Intended Use:

***Status*™ COVID-19 Antigen Rapid Test For Home Use** is an *in vitro* rapid qualitative test intended for the qualitative detection of SARS-CoV-2 directly from anterior nasal or nasopharyngeal swab specimens obtained from individuals, who are suspected of respiratory viral infection consistent with COVID-19, by their healthcare provider, within the first five days of onset of symptoms.

1.3 Manufacturer:

Princeton BioMeditech
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

For *in vitro* diagnostic use only. Each test strip/device is for single use only.

2.1 Avoid direct contact with chemical components. Any component containing biological material should be handled as being potentially hazardous.

2.2 All patient specimens and samples used for this test should be handled as potential infectious materials. Follow **Universal Precautions** as necessary.

Section 3 – Composition / Component Information

3.1 Test Kit Components: Test strip/device, Extraction Reagent, Positive Control Swab, Negative Control Swab, Sterile Swabs.

3.2 Hazardous Substances: This product does not contain any hazardous substances above 1% or above 0.1% levels required, depending on the hazard.

Chemical	CAS#	EC#	Kit Component	Concentration	Classification	Risk Phrases
N/A	N/A	N/A	N/A	N/A	N/A	N/A

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.

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.

6.3 Methods and Materials for Clean up: Isolate spill area to prevent further spreading of spilled material. Use absorbent so 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 contents. Wear personal protective equipment (Section 8). Wash thoroughly after handling.

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: Not Available

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	Positive Control Swab	Negative Control Swab
Appearance	White strip in plastic housing	Clear, colorless liquid	White Swab	White Swab
Odor	Odorless	Odorless	Odorless	Odorless
pH	N/A	7.2	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	Swab: Insoluble Control: Soluble	Swab: Insoluble Control: 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 and CO_2.

Section 11 – Toxicological Information

Presently no toxicological data available for this kit or its components.

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: No data available.

12.2 Mobility: No data available.

12.3 Persistence and degradability: No data available.

12.4 Bioaccumalitive 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 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture: This product and its contents are not classified as dangerous under any regulation.

15.2 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 is 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, 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.