SECTION I. IDENTIFICATION AND COMPANY DETAILS

Product Name:

- Name: *CareStart* ™ COVID-19 Antigen

Manufacturer Information:

- Address: Access Bio, Inc.
  65 Clyde Road, Suite A.
  Somerset, NJ 08873, USA
- Telephone Number: +1 (732) 873 4040
- Fax Number: +1 (732) 873 4043
- Web Site: www.accessbio.net

Intended Use:

- *In vitro* Rapid Diagnostic test for qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in an nasopharyngeal or nasal swab specimens directly collected.
- This kit is for *in vitro* diagnostic use only.

SECTION II. HAZARD IDENTIFICATION

Emergency Overview:

- No significant health effects are anticipated from using this product when used under normal operating conditions and in accordance with the kit specific instructions for use.
- Although sodium azide is included as a preservative in the nitrocellulose membrane, it is not considered as hazardous at this concentration (<0.1%) according to the latest edition of Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
- Repeated or prolonged exposure is not known to aggravate any medical condition.

Extraction Solution:

- Eye Contact: Irritation. Tears.
- Skin Contact: Irritation.
- Ingestion: No known significant effect or critical hazard upon ingestion of extraction vial in the kit.
- Inhalation: None known.

SECTION III. COMPOSITION / INFORMATION ON INGREDIENTS

Classification of the Substance or Mixture:

- *In vitro* Rapid Diagnostic test for detection of the nucleocapsid protein antigen from SARS-CoV-2.

Hazardous Substance:

Ingredient(s)	CAS #	Concentration (%)	Hazard Statement
Sodium Azide	26628-22-8	< 0.1 %	Non-hazardous at this concentration

SECTION IV. FIRST-AID MEASURES

If symptoms persist, call physician or poison control center.

Extraction Solution:

- Eyes Contact: Immediately flush eyes under running water for at least 15 minutes. Assure adequate flushing of the eyes by separating the eyelids with fingers. Consult with a physician immediately.
- Skin Contact: Immediately rinse exposed skin area with soap and plenty of water.
- Ingestion: Wash out mouth with water. Consult with a physician immediately.
- Inhalation: Not applicable.

SECTION V. FIRE-FIGHTING MEASURES

This product contains no combustible materials.

Special Exposure Hazards: None.

SECTION VI. ACCIDENTAL RELEASE MEASURES

Personal Precaution: Wear appropriate personal protective clothing (refer to section VIII)

Environmental Precaution:

- Extraction Buffer: Avoid flushing away in drain pipes.

Methods for Containment and Cleaning Up: Clean the extraction buffer spilled surface with liquid-binding material and dispose the waste in accordance with the instructions listed in section XIII.

SECTION VII. HANDLING AND STORAGE

Precautions for Safe Handling: Wear appropriate protective clothing (refer to section VIII). Wash hands and any other exposed area with soap and water before eating, drinking, smoking, and leaving work place.

Conditions for Safe Storage: Store at room temperature, not above 30°C and not below 1°C

Specific End Use: No special measures required if used under normal operating conditions.

SECTION VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupation Exposure Limits: Not applicable

Personal Protective Equipment:

- Respiratory System: No specific requirement when operating in normal condition.
- Skin:
  - Hands: Impervious gloves.
  - Other Skin Area: Laboratory coat and/or protective clothing.
- Eyes: Safety glasses or goggles.
- Other/Special: Not required.

SECTION IX. PHYSICAL AND CHEMICAL PROPERTIES

	Cassette	Extraction buffer
Physical State	Solid	Liquid
Color	White	Clear
Odor	Not applicable	None
Odor Threshold	Not applicable	Not available
pH	Not applicable	10.0
Boiling Point	Not applicable	100 °C

Melting Point	Not available	Not applicable
Flash Point	Not applicable	
Evaporation Rate	Not applicable	
Flammability	Not applicable	
Upper/lower Explosion Limit	Not applicable	
Vapor Pressure/density	Not applicable	
Density	Not available	
Solubility	Not applicable	
Partition Coefficient	Not available	
Auto-ignition	Not applicable	
Decomposition	Not applicable	
Viscosity	Not available	
Explosive Properties	No risk	
Oxidizing Properties	Not applicable	

SECTION X. STABILITY AND REACTIVITY

Reactivity: Not applicable

Chemical Stability: Not applicable

Possibility of Hazardous Reactions: Not available

Conditions to Avoid: None

Incompatible Materials: None

Hazardous Decomposition or By-Products: None

Hazardous Polymerization: None

SECTION XI. TOXICOLOGICAL INFORMATION

Cassette: Non-toxic

Extraction Buffer Solution:

- Acute Toxicity: No effects are known.
- Irritation/Sensitization:
  - Skin: Irritation
  - Eye: Irritation
  - Respiratory: None known

Mutagenicity: No effects are known.

Carcinogenicity: No effects are known.

Reproductive Toxicity: No effects are known.

SECTION XII. ECOLOGICAL INFORMATION

No data found

SECTION XIII. DISPOSAL CONSIDERATIONS

This material is not regarded as hazardous waste.

Disposal Methods: Dispose of this product in accordance with all applicable local and national regulations.

SECTION XIV. TRANSPORT INFORMATION

No known transport restrictions

SECTION XV. REGULATORY INFORMATION

Regulations

- 67/548/EEC – Classification, packaging and labeling of dangerous substances
- 1999/45/EC – Classification, packaging and labeling of dangerous preparations
- 91/155/EC – System of specific information relating to dangerous preparations in implementation
- Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

SECTION XVI. OTHER INFORMATION

This test kit is intended solely for *in vitro* use only and must be handled by authorized personnel in the product specific instructions for use. Information herein is based on the current extent of our knowledge and is believed to be correct but is provided without warranty of any kind. The recipient of our product is responsible for observing all applicable laws and regulations.