

## Total Nucleic Acid Preservation Tubes Dx

## Product Insert

**REF** Dx69200



**IVD**



PIDx69200-5

### Intended Use

Norgen's Total Nucleic Acid Preservation Tubes Dx are designed for ambient preservation and transport of total nucleic acids (DNA and RNA) from samples collected using a swab (not included). Intended for *in vitro* diagnostic use for medical purposes.

### For *In Vitro* Diagnostic Use

### Product Description

Norgen's Total Nucleic Acid Preservation Tubes Dx are designed for ambient preservation and transport of total nucleic acids (DNA and RNA) from samples collected using a swab. The Total Nucleic Acid Preservation Tubes contain Norgen's Total Nucleic Acid Preservative in a liquid format. The user simply collects the specimen using a sterile nylon flocked swab (not provided), and then transfers the swab into the Total Nucleic Acid Preservative. The Preservative prevents the growth of Gram-negative and Gram-positive bacteria and fungi, and also inactivates viruses allowing the resulting non-infectious samples to be handled and shipped safely. In addition, the Total Nucleic Acid Preservative eliminates the need to immediately process or freeze samples and allows the samples to be shipped to centralized testing facilities at ambient temperatures. The components of the preservative allow DNA samples to be stored at room temperature for over 4 months and RNA samples to be stored at room temperature for over 2 months. This kit is ideal for collecting and preserving nasal and oral swab samples for *in vitro* diagnostic use for medical purposes. This kit can be used to preserve viral RNA, including SARs-CoV-2 RNA for detection of COVID-19.

Norgen's Total Nucleic Acid Preservation Tubes Dx are intended for use by professional users such as technicians, physicians and biologists experienced and trained in molecular biological techniques.

Norgen's Total Nucleic Acid Preservation Tubes Dx do not provide a diagnostic result. It is the sole responsibility of the user to use and validate these devices in conjunction with a downstream *in vitro* diagnostic assay.






### Nucleic Acid Isolation From Preservative

Total RNA can be isolated from the preserved swab samples using Norgen's Total RNA Purification Kit Dx (Cat# Dx17200) and DNA can be isolated from the preserved swab samples using Norgen's Saliva DNA Isolation Kit (Cat# Dx45400). To minimize irregularities in diagnostic results, suitable controls for downstream applications should be used.

### Kit Components

Component	Product # Dx69200
Total Nucleic Acid Preservation Tubes Dx	50
Product Insert	1

### Label Legend

	<b>LOT</b>	<b>REF</b>			<b>IVD</b>		
Use by	Batch Code	Catalogue Number	Contains sufficient for <n> tests	Manufacturer	In Vitro Diagnostic Medical Device	Consult instructions for use	Temperature limitation

### Advantages

- CE-IVD marked in accordance with Regulation (EU) 2017/746
- Fits into *in vitro* diagnostic workflows
- No need to immediately process samples
- Total DNA, including viral DNA, preserved at room temperature over 4 months
- Total RNA, including viral RNA, preserved at room temperature over 2 months
- Inactivate microorganisms including bacteria, fungi, yeast and viruses
- Ship swab samples at room temperature safely
- Compatible with most DNA and RNA isolation methods

### Specifications

Kit Specifications	
Stability of DNA at Room Temperature	4 months
Stability of RNA at Room Temperature	2 months

### Shelf Life and Handling

- The tubes should be kept tightly sealed and stored at room temperature for up to 1 year without any reduction in performance (The collection due date is written on the device label and the kit box label).
- Once collected, RNA is stable for up to 2 months and DNA is stable for up to 4 months when the tubes are kept tightly sealed and stored at room temperature.

### Quality Control

In accordance with Norgen's Quality Management System, each lot of Norgen's Total Nucleic Acid Preservation Tubes Dx are tested against predetermined specifications to ensure consistent product quality.

### Disclaimers and Satisfaction Guarantee

NORGEN BIOTEK CORPORATION guarantees the performance of all products in the manner described in our product manual. The customer must determine the suitability of the product for its particular use. We reserve the right to change, alter, or modify any product to enhance its performance and design.

### Warnings and Precautions

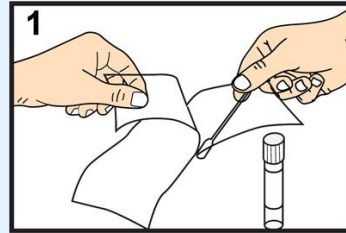
1. If any of the Total Nucleic Acid Preservative comes into contact with skin or eyes, wash thoroughly with water. Do not ingest the Total Nucleic Acid Preservative.
2. The Total Nucleic Acid Collection Tube contains a choking hazard (Collection Tube Cap). Keep away from children.
3. Samples obtained from human and animal subjects are considered potentially infectious. All necessary precautions recommended by the appropriate authorities in the country of use should be taken when working with human specimens. Dispose of human specimens according to local, provincial or federal regulations.
4. The Total Nucleic Acid Preservative will form reactive compounds when combined with bleach, thus care must be taken to properly dispose of any spilled preservative or remaining samples.
5. Should any serious incident, such as injury or impairment of the user, occur during the use of this device, or because of the use of this device, please contact Norgen Biotek to report the incident. Additionally, report the incident to the competent authority in the country in which the incident occurred.

### Customer-Supplied Reagents and Equipment

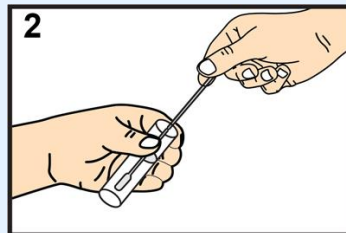
- Sterile nylon flocked swabs
- Scissors (if swabs do not have an appropriate break point)

## Procedure

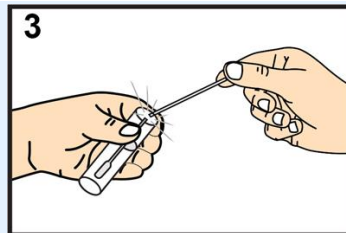
1. Obtain a swab. Peel open the swab wrapper and remove the swab. **Do not touch the swab tip.** Collect the specimen using the swab.



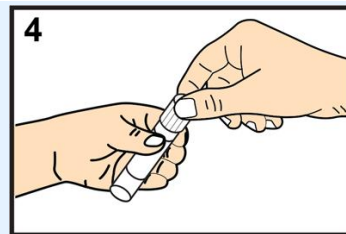
2. Using the appropriate aseptic technique, open the collection tube and insert the swab tip into the vial. **Make sure that the swab is in contact with the Total Nucleic Acid Preservative solution.**



3. Break the swab shaft at the indicated score mark (or cut the swab handle), leaving the swab tip in the collection tube. Discard swab shaft and wrapper.



4. **Replace the tube cap, securing tightly.** Label tube accordingly. The sample is now stable for transport and/or storage prior to DNA and/or RNA purification.



**Note:** Ensure that the swab is present in the Total Nucleic Acid Preservative Tube Dx and that the tip of the swab is fully immersed in the Total Nucleic Acid Preservative prior to starting isolation. Any tubes that do not contain swabs or an insufficient volume of preservative should be discarded and not processed for nucleic acid isolation.

### Disposal of Remaining Preservative

The Total Nucleic Acid Preservative will form reactive compounds when combined with bleach, thus care must be taken to properly dispose of any of any remaining samples. Dispose of any remaining preserved samples as per your institutions hazardous chemical waste procedures.

### Isolation of Nucleic Acids From Preserved Swab Samples

Nucleic acids can be purified from the preserved swab sample using a number of different methods, including Norgen's various sample preparation kits (please refer to Related Products table below). The purified nucleic acids are of the highest quality and can be used in a number of downstream applications including PCR, NGS and microarray analysis.

Related Products	Product #
Shipping Accessories – 50 Mailers	38300
Total RNA Purification Kit Dx	Dx17200
Saliva DNA Isolation Kit Dx	Dx45400

### Product Use Restriction

Norgen's Total Nucleic Acid Preservation Tubes Dx are designed for ambient preservation and transport of total nucleic acids (DNA and RNA) from samples collected using a swab. Intended for *in vitro* diagnostic use for medical purposes.

Any diagnostic results generated using RNA or DNA isolated from Norgen's Total Nucleic Acid Preservation Tubes Dx in conjunction with an *in vitro* diagnostic assay should be interpreted with regard to other clinical or laboratory findings.

To minimize irregularities in diagnostic results, suitable controls for downstream applications should be used.

Norgen's Total Nucleic Acid Preservation Tubes Dx are intended for use by professional users such as technicians, physicians and biologists experienced and trained in molecular biological techniques.

Norgen's Total Nucleic Acid Preservation Tubes Dx do not provide a diagnostic result. It is the sole responsibility of the user to use and validate these tubes in conjunction with a downstream *in vitro* diagnostic assay.

The respective user is liable for any and all damages resulting from application of Norgen's Total Nucleic Acid Preservation Tubes Dx for use deviating from the intended use as specified in the user manual.

All products sold by Norgen Biotek are subjected to extensive quality control procedures and are warranted to perform as described when used correctly. Any problems should be reported immediately. The kit contents are unfit for consumption.


### Technical Support

Contact our Technical Support Team between the hours of 9:00 and 5:30 (Eastern Standard Time) at (905) 227-8848 or Toll Free at 1-866-667-4362.

Technical support can also be obtained from our website ([www.norgenbiotek.com](http://www.norgenbiotek.com)) or through email at [support@norgenbiotek.com](mailto:support@norgenbiotek.com).

### Authorized Representative



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