

Saliva RNA Collection and Preservation Devices Dx (50) Product Insert

REF 53800



IVD



P153800-2

INTENDED USE

Norgen's Saliva RNA Collection and Preservation Devices Dx are designed for 1) safe and non-invasive supervised self-collection of saliva specimens and 2) preservation of RNA in saliva specimens at ambient temperature. Intended for *in vitro* diagnostic use for medical purposes.

For In Vitro Diagnostic Use

PRODUCT DESCRIPTION

Norgen's Saliva RNA Collection and Preservation Devices Dx are designed for 1) safe and non-invasive supervised self-collection of saliva specimens and 2) preservation of RNA in saliva specimens at ambient temperature. Each of the 50 Saliva RNA Collection and Preservation Devices Dx consists of 3 components: (1) Saliva Collection Funnel and Collection Tube, (2) Collection Tube Cap, and (3) Norgen's Saliva RNA Preservative contained within a sealed squeezable ampoule. Saliva collection is performed through supervised self-collection. Saliva samples are collected by spitting inside the Collection Funnel which has been assembled with the Collection Tube. After collecting the required volume of saliva the Collection Funnel is removed and the contents of the Preservative Ampoule are then added and mixed with the collected saliva. The Saliva Collection Tube is subsequently sent to the laboratory for RNA isolation and analysis. RNA can be isolated from the preserved saliva samples using Norgen's Saliva/Swab RNA Purification Kits Dx (Cat# Dx69100, Dx69300). Each of Norgen's Collection Tubes is labeled with a unique serial number that can be used for secure and anonymous tracking of the sample. The saliva RNA in preserved samples is stable for up to 2 months at room temperature. This kit is ideal for collecting and preserving RNA samples for *in vitro* diagnostic use for medical purposes. This kit can be used to collect and preserve viral RNA, including SARs-CoV-2 RNA for detection of COVID-19.

Norgen's Saliva RNA Collection and Preservation Devices 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.






SALIVA RNA PRESERVATIVE

Norgen's Saliva RNA Preservative is an aqueous storage buffer designed for rapid cellular lysis and subsequent preservation of RNA from fresh saliva specimens. The buffer eliminates the need to immediately process or freeze samples and allows the samples to be shipped to centralized testing facilities at ambient temperature. The components of the buffer allow samples to be stored for up to 2 months at room temperature. The Saliva RNA Preservative also inactivates all bacteria, yeast and viruses present in the saliva sample.

NUCLEIC ACID ISOLATION FROM PRESERVATIVE

Saliva RNA can be isolated from the preserved saliva samples using Norgen's Saliva/Swab RNA Purification Kits Dx (Cat# Dx69100, Dx69300). To minimize irregularities in diagnostic results, suitable controls for downstream applications should be used.

Label Legend

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

Saliva RNA Collection, Preservation and Isolation Kit Dx Contents:

Component	Contents
Individual Saliva RNA Collection and Preservation Device Dx	50
Product Insert	1
Donor Procedure Flowchart	1

Individual Saliva RNA Collection and Preservation Device Dx Contents:

Component	Contents
Saliva Collection Funnel and Collection Tube	1
Collection Tube Cap	1
Preservative Ampoule	1
Donor Instructions	1

Kit Specifications	
Volume of Saliva Collected	2 mL
Volume of Saliva-Preservative Mix	4 mL
Preservation Temperature	Room temperature
RNA Preservation Time	Up to 2 months at room temperature

SHELF LIFE AND HANDLING

- The **Collection Device** should be kept tightly sealed and stored at room temperature for up to 2 years without any reduction in kit performance (The collection due date is written on the device label).
- Once collected, saliva RNA is stable for up to 2 months when kept tightly sealed and stored at room temperature.
- The Collection Tube, the Collection Funnel and the Device Container of each Individual Saliva RNA Collection and Preservation Device Dx are recyclable.

QUALITY CONTROL

In accordance with Norgen's Quality Management System, each lot of Norgen's Saliva RNA Collection and Preservation Devices 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 Saliva RNA Preservative comes into contact with skin or eyes, wash thoroughly with water. Do not ingest the Saliva RNA Preservative.
2. The collection device contains a choking hazard (Collection Tube Cap). Keep away from children.
3. Collection of saliva from children must be supervised by an adult.
4. The Saliva RNA Preservative and preserved saliva samples will form reactive compounds when combined with bleach, thus care must be taken to properly dispose of any spilled preservative or remaining samples.

Procedures

A. SAMPLE COLLECTION AND PRESERVATION PROCEDURES

1. Do not eat, chew gum, drink or smoke for 30 minutes prior to saliva collection.
2. Rinse your mouth with water and wait for 10 minutes.
3. Spit into the **Collection Funnel** until the amount of liquid saliva (not including bubbles) in the **Collection Tube** reaches the 2 mL line. Discard / recycle the Collection Funnel.
4. Twist and remove the tip of the **Preservative Ampoule**.
5. Squeeze the **Preservative Ampoule** to empty the contents into the **Collection Tube**. Screw on the cap of the **Collection Tube** to close it tightly.
6. Shake the **Collection Tube** well for 10 seconds to mix saliva and preservative.
7. The saliva sample is now preserved and ready for storage, shipping or processing.

Note: Each of Norgen's Collection Tubes is labeled with a unique serial number that can be used for secure and anonymous tracking of the sample.

8. Dispose of the **Preservation Ampoule** and tip in the garbage. The plastic device container can be recycled.

B. INSTRUCTIONS FOR STORAGE OF PRESERVED SALIVA SAMPLES

Preserved saliva samples can be stored at room temperature for up to 2 months without significant loss of RNA quality.

ISOLATION OF SALIVA RNA FROM PRESERVED SALIVA SAMPLES

Norgen's Saliva/Swab RNA Purification Kits Dx (Cat# Dx69100, Dx69300) are recommended for the isolation of RNA from the preserved samples. Purification is based on spin column chromatography using Norgen's proprietary resin as the separation matrix. The purified RNA is of the highest integrity, and can be used in a number of downstream applications including PCR, NGS, microarray analysis and *in vitro* diagnostic use.

Norgen's Saliva RNA Collection and Preservation Devices Dx are also compatible with other RNA isolation methods including Qiagen's RNeasy Micro Kit (50) (Cat#74004), Zymo's Quick-DNA/RNA Viral MagBead (Cat# R2140) and ThermoFisher Scientific's MagMAX™ mirVana™ Total RNA Isolation Kit (Cat# A27828). Additionally, Norgen's Total RNA Purification Kit Dx (Cat# Dx17200) can also be used to isolate RNA from the preserved samples using a supplementary protocol. The user must validate these devices in conjunction with a downstream *in vitro* diagnostic assay. To minimize irregularities in diagnostic results, suitable controls for downstream applications should be used.

Disposal of Preserved Saliva Samples

Preserved saliva samples 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 saliva samples as per your institutions hazardous chemical waste procedures.

Related Products	Product #
Shipping Accessories – 50 Mailers	38300
Saliva/Swab RNA Purification Kit Dx	Dx69100
Saliva/Swab RNA Purification 96-Well Kit Dx	Dx69300
Total RNA Purification Kit Dx	Dx17200

Technical Assistance

NORGEN's Technical Service Department is staffed by experienced scientists with extensive practical and theoretical expertise in sample and assay technologies and the use of NORGEN products. If you have any questions or experience any difficulties regarding Norgen's Saliva RNA Collection and Preservation Devices Dx or NORGEN products in general, please do not hesitate to contact us.

NORGEN customers are a valuable source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at NORGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance and more information, please contact our Technical Support Team between the hours of 8:30 and 5:30 (Eastern Standard Time) at (905) 227-8848 or Toll Free at 1-866-667-4362 or call one of the NORGEN local distributors (www.norgenbiotek.com) or through email at techsupport@norgenbiotek.com

Product Use Restriction

Norgen's Saliva RNA Collection and Preservation Devices Dx are designed for 1) safe and non-invasive supervised self-collection of saliva specimens and 2) preservation of RNA in saliva specimens at ambient temperature. These devices are ideal for collecting and preserving RNA samples for *in vitro* diagnostic use for medical purposes.

Any diagnostic results generated using RNA isolated from Norgen's Saliva RNA Collection and Preservation Devices 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 Saliva RNA Collection and Preservation Devices Dx do not provide a diagnostic result. It is the sole responsibility of the user to use and validate the kit 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 Saliva RNA Collection and Preservation Devices 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.

Authorized Representative



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

 Norgen Biotek Corp.
3430 Schmon Parkway, Thorold, ON Canada L2V 4Y6
Phone: (905) 227-8848
Fax: (905) 227-1061
Toll Free in North America: 1-866-667-4362