

Saliva DNA Collection and Preservation Devices Dx **Product Insert**

REF 49000



IVD



PI49000-10

Norgen's Saliva DNA Collection and Preservation Devices Dx provide a safe and rapid all-in-one procedure for the collection and preservation of saliva DNA at ambient temperatures.

Intended Use

Norgen's Saliva DNA Collection and Preservation Devices Dx are designed for 1) simple and non-invasive saliva collection and 2) preservation of DNA in saliva samples at ambient temperature. Each of the 50 Saliva DNA Collection and Preservation Devices consists of 3 components: (1) Saliva Collection Funnel and Collection Tube, (2) Collection Tube Cap, and (3) Norgen's Saliva DNA Preservative contained within a sealed squeezable ampoule. 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 DNA isolation and analysis. DNA can be isolated from the preserved saliva samples using Norgen's Saliva DNA Isolation Kit Dx (Cat# Dx45400). 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 DNA in preserved samples is stable for more than 2 years at room temperature. This kit is ideal for collecting and preserving DNA samples for *in vitro* diagnostic use for medical purposes.

Saliva DNA Preservative

Norgen's Saliva DNA Preservative is an aqueous storage buffer designed for rapid cellular lysis and subsequent preservation of DNA from fresh specimens. The buffer 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 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 more than 2 years without any detectable DNA degradation.

Nucleic Acid Isolation From Preservative

Prior to saliva DNA isolation, vortex the Collection Tube containing preserved saliva for 10 seconds and incubate at 55°C for one hour. Saliva DNA can now be isolated from the preserved saliva samples using Norgen's spin-column based Saliva DNA Isolation Kit Dx (Cat# Dx45400) or other commercially available methods that have been validated for use with Norgen's Saliva DNA Collection and Preservation Devices.










Saliva DNA Collection and Preservation Devices Dx Kit Contents

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

Individual Saliva DNA Collection and Preservation Device Contents

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

Label Legend

								
Do not reuse	Use by	Batch Code	Catalogue Number	Contains sufficient for <n> tests	Manufacturer	In Vitro Diagnostic Medical Device	Consult instructions for use	Temperature limitation

Specifications

Kit Specifications	
Volume of Saliva Collected	2 mL
Volume of Saliva-Preservative Mix	4 mL
Preservation Temperature	Room temperature
Preservation Time	Over 2 years at room temperature

Shelf Life and Handling

- The **Collection Device** should be kept tightly sealed and stored at room temperature up to the Collect Before Date (indicated on the device label) without any reduction in kit performance.
- Once collected, saliva is stable for more than 2 years when kept tightly sealed and stored at room temperature.
- The Collection Tube, the Collection Funnel and the Device Container of each Individual Saliva DNA Collection and Preservation Device are recyclable.

Quality Control

In accordance with Norgen's Quality Management System, each lot of Norgen's Saliva DNA Collection and Preservation Devices Dx are tested against predetermined specifications to ensure consistent product quality.

Product Warranty 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 DNA Preservative comes into contact with skin or eyes, wash thoroughly with water. Do not ingest the Saliva DNA Preservative.
2. The collection device contains a choking hazard (Collection Tube Cap). Keep away from children.
3. Should any serious incident, such as injury or impairment of the user, occur during the used 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 user is located.

Procedure

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

1. Preserved saliva samples can be stored at room temperature for more than 2 years without significant loss of DNA quality.

Isolation of Saliva DNA From Preserved Saliva Samples

The use of Norgen's Saliva DNA Isolation Kit Dx (Cat# Dx45400) is recommended for the fast and simple isolation of genomic DNA from the preserved samples. Prior to saliva DNA isolation, vortex the Collection Tube containing preserved saliva for 10 seconds and incubate at 55°C for one hour. The purification is based on spin-column chromatography, and the purified DNA is of the highest quality and can be used in a number of downstream applications including PCR, NGS, microarray analysis and *in vitro* diagnostic use.

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


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) or through email at support@norgenbiotek.com.

Authorized Representative



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