

**Stool Nucleic Acid Collection and Preservation Devices Dx**

**Product Insert**

**REF** Dx45660



**IVD**



PIDx45660-6

Norgen's Stool Nucleic Acid Collection and Preservation Devices Dx provide a rapid and simple method for the collection and preservation of stool samples at ambient temperatures.

**For *In Vitro* Diagnostic Use**

**Intended Use**

Norgen's Stool Nucleic Acid Collection and Preservation Devices Dx are designed for the collection and preservation of nucleic acids from fresh stool specimens. The Stool Nucleic Acid Collection and Preservation Devices Dx - 50 contains 50 individual Stool Nucleic Acid Collection and Preservation Devices Dx. Each Stool Nucleic Acid Collection and Preservation Device Dx consists of Norgen's Stool Nucleic Acid Collection and Preservation Tube Dx containing Norgen's Stool Preservative in a liquid format. The user simply collects stool into the tubes (fill up to the line indicated on the tube) and mixes gently until the stool is well submerged under the preservative. The Stool Nucleic Acid Collection and Preservation Tube Dx is subsequently sent to the laboratory for DNA and/or RNA isolation and analysis. The stool DNA in preserved samples is stable for more than 2 years at room temperature, and the stool RNA in preserved samples is stable for 7 days at room temperature. DNA can be isolated from the preserved stool samples using Norgen's Stool DNA Isolation Kit Dx (Cat# Dx27600) and RNA can be isolated from the preserved stool samples using Norgen's Stool Total RNA Purification Kit Dx (Cat# 49500). These tubes are ideal for collecting and preserving DNA and RNA samples for *in vitro* diagnostic use for medical purposes.

**Stool Preservative**

Norgen's Stool Preservative is an aqueous storage buffer designed for preservation of DNA and RNA from fresh stool 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 Stool 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 Stool Preservative allow samples to be stored at room temperature for over 2 years for DNA and 7 days for RNA without any detectable degradation. To extend the stool RNA stability in the preservative, storage at -20°C or -70°C is recommended upon arrival at the testing facilities until RNA purification.

**Nucleic Acid Isolation From Preservative**

Stool DNA can be isolated from the preserved stool samples using Norgen's Stool DNA Isolation Kit Dx (Cat# Dx27600) and Stool RNA can be isolated from the preserved stool samples using Norgen's Stool Total RNA Purification Kit Dx (Cat# Dx49500).









**Stool Nucleic Acid Collection and Preservation Devices Dx - 50 Contents:**

Component	Contents
Stool Nucleic Acid Collection and Preservation Devices Dx	50
Product Insert	1

**Individual Stool Nucleic Acid Collection and Preservation Device Dx Contents:**

Component	Contents
Stool Nucleic Acid Collection and Preservation Tube Dx filled with Preservative	1
Insert Card	1

## Label Legend

							
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	
Stool Input	2 g
Stability of Stool Nucleic Acid at Room Temperature	2 years for DNA 7 days for RNA*

\* The RNA stability will vary depending on the samples

## Shelf Life and Handling

- The **Stool Nucleic Acid Collection and Preservation Tube Dx** 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 tube label and the box label).
- The stool DNA in preserved samples is stable for more than 2 years at room temperature, and the stool RNA in preserved samples is stable for 7 days at room temperature.
- To extend the stool RNA stability in the preservative, storage at -20°C or -70°C is recommended at the arrival to testing facilities until the RNA purification.

## Quality Control

In accordance with Norgen's Quality Management System, each lot of Norgen's Stool Nucleic Acid Collection and Preservation Devices Dx – 50 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 Stool Preservative comes into contact with skin or eyes, wash thoroughly with water.
2. Do not ingest the Stool Preservative.
3. Small items may pose a choking hazard (tube lid and collection spoon). Keep away from children.
4. Stool of all human and animal subjects is considered potentially infectious. All necessary precautions recommended by the appropriate authorities in the country of use should be taken when working with stool.
5. Dispose of human specimens according to local, provincial or federal regulations.
6. 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 user is located.

# Procedure

## A. Sample Collection and Preservation Procedures

1. Avoid any contact between the stool sample and urine.
2. Pass stool directly onto plastic wrap (If stool is loose use a large clean container) placed under the seat of the toilet.
3. Scoop stool sample from three sites using the spoon attached in the cap, and place the stool into the tube until the liquid reaches the Fill To This Line (Do not over fill).
4. Tighten the cap and shake gently until the stool is thoroughly mixed with the preservative.
5. Label the stool tube with your full name and date of collection.
6. Submit the specimen to the lab by shipping at room temperature.
7. Nucleic acids can be purified from the preserved stool sample using a number of different methods, including Norgen's stool-based sample preparation kits (please refer to Related Products table below).

## B. Instructions for Storage of Preserved Stool Samples

1. The stool DNA in preserved samples is stable for more than 2 years at room temperature without significant loss of DNA quality
2. The stool RNA in preserved samples is stable for 7 days at room temperature without significant loss of RNA quality.
3. To extend the stool RNA stability in the preservative, storage at -20°C or -70°C is recommended at the arrival to testing facilities until the RNA purification.

## Isolation of Stool DNA and Stool RNA From Preserved Stool Samples

The use of Norgen's Stool DNA Isolation Kit Dx (Cat# Dx27600) is recommended for the fast and simple isolation of genomic DNA from preserved samples. The use of Norgen's Stool Total RNA Purification Kit Dx (Cat# Dx49500) is recommended for the fast and simple isolation of total RNA from preserved samples. In both kits, the purification is based on spin-column chromatography, and the purified DNA and RNA 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
Stool DNA Isolation Kit Dx	Dx27600
Stool Total RNA Purification Kit Dx	Dx49500

## 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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