

cf-DNA Preservative Tubes Dx – 50 Tubes

Product Insert

REF Dx63950



IVD



PIDx63950-3

INTENDED USE

Norgen's Cell-Free DNA (cf-DNA) Preservative Tubes Dx are closed, evacuated plastic tubes for the collection and the preservation of cell-free circulating DNA in human whole blood samples. The cf-DNA Preservative Tubes Dx contain a formaldehyde-free preservative reagent that also stabilizes nucleated blood cells, thus preventing apoptosis and the release of genomic DNA into the plasma.

For *In Vitro* Diagnostic Use

PRESERVATION SUMMARY

Blood samples collected in Norgen's cf-DNA Preservative Tubes Dx are stable for up to 30 days at room temperature (15-25°C) and for up to 8 days at 37°C. The content of the cf-DNA Preservative Tube Dx will not dilute the collected blood sample and therefore no dilution factor correction is required. These tubes are ideal for collecting and preserving cf-DNA samples for *in vitro* diagnostic use for medical purposes.

WARNINGS AND PRECAUTIONS

1. Do not use Norgen's cf-DNA Preservative Tube Dx after the expiration date printed on the tube label.
2. Do not freeze specimens collected in Norgen's cf-DNA Preservative Tubes Dx as breakage or hemolysis could result.
3. These tubes are intended for the use as described above. Do not dilute or add other components to the tubes.
4. Norgen's cf-DNA Preservative Tubes Dx are for single use only.
5. Cloudiness or precipitates present in unused tubes are indications of product defect. Contact Norgen's Technical Service Department if this is observed in unused tubes.
6. Do not use tubes for the collection of materials to be injected into patients.
7. Overfilling or underfilling of tubes may lead to incorrect analytical results or poor product performance.
8. To avoid the risk of infection or injury when working with biological and chemical materials, always wear a suitable lab coat, disposable gloves, and protective goggles.
9. Do not transfer a sample from a syringe to the cf-DNA Preservative Tube Dx.
10. Blood collection sharps should be discarded in biohazard containers approved for their disposal.
11. The cf-DNA Preservative Solution and blood mixture from Norgen's cf-DNA Preservative Tubes Dx can be disinfected using 1 volume of commercial bleach solution (5% sodium hypochlorite) per 9 volumes of the cf-DNA Preservative solution and blood mixture.

STORAGE CONDITIONS AND PRODUCT STABILITY

1. When stored at room temperature (15-25°C), unfilled Norgen cf-DNA Preservative Tubes Dx are stable through the expiration date. See tube label for expiry date.
2. Short-term storage/shipping at -20°C to 37°C for up to 10 days is acceptable for unfilled Norgen cf-DNA Preservative Tubes Dx.
3. Do not freeze unfilled Norgen cf-DNA Preservative Tubes Dx for long term storage over 10 days. Freezing unfilled tubes may lead to loss of vacuum and precipitation may occur.
4. Blood samples collected in Norgen's cf-DNA Preservative Tubes Dx are stable for up to 30 days when stored at room temperature (15-25°C)
5. Blood samples collected in Norgen's cf-DNA Preservative Tubes Dx are stable for up to 8 days when stored at 37°C.

Label Legend

		LOT	REF			IVD		
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

cf-DNA Preservative Tubes Dx (50) Contents:

Component	Contents
cf-DNA Preservative Tube Dx	50
Product Insert	1

INSTRUCTIONS FOR USE

Important Notes Before Use

- Norgen's cf-DNA Preservation Tubes Dx utilize a novel method to preserve cf-DNA and stabilize nucleated blood cells, thus preventing apoptosis and the release of genomic DNA. Collected and preserved blood may appear different than blood collected and preserved in standard EDTA tubes, citrate tubes or other commercially available preservative tubes due to the unique mechanism of preservation.
- It is critical to the preservation and subsequent processing of the blood samples that:
 - Each tube is gently inverted 5 times immediately after blood collection to ensure that the preservative is mixed with the blood.
 - If collecting multiple blood tubes, gently invert after each tube is filled and DO NOT wait until all tubes are collected to mix the samples
 - Failure to invert the tubes gently 5 times immediately after blood collection may result in clotting or other inaccurate results
- DO NOT mix or invert the tubes prior to plasma separation as this may lead to hemolysis

Prevention of Backflow

Since Norgen's cf-DNA Preservative Tube Dx contains a chemical preservative, a blood collection set must be used for blood collection to prevent possible backflow from the tube. To prevent backflow from tube into patient's arm, observe the following precautions:

1. Place patient's arm in a downward position.
2. Hold tube with the cap upright.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube contents do not touch cap or end of the needle during venipuncture.

A. Collecting and Storing Blood in Norgen's cf-DNA Preservative Tubes Dx

Observe the appropriate safety practices when collecting blood. Refer to the product documentation of your blood collection set for specific instructions on venipuncture technique and blood collection. We recommend using the Greiner **VACUETTE**[®] Safety Blood Collection Sets. If using the Greiner **VACUETTE**[®] Safety Blood Collection Set, please refer to the Instructions for Use on the Greiner Bio-One website (<https://www.gbo.com>)

1. Ensure that Norgen's cf-DNA Preservative Tube Dx is at 15-25°C prior to use and properly labeled with patient identification
2. Using a blood collection set and a holder, collect blood into Norgen's cf-DNA Preservative Tube Dx using your institution's recommended procedure for standard venipuncture technique. To prevent possible backflow during blood collection, please refer to the **Prevention of Backflow** section.
3. Fill the tube with blood until the blood flow stops (Note: the tube is evacuated to collect 8.4 mL of whole blood.

4. **IMPORTANT!** Immediately after the cf-DNA Preservative Tube Dx is filled with blood, stabilize the cf-DNA by gently inverting the contents 5 times to ensure that the cf-DNA Preservative makes uniform contact with the sample. One inversion is a complete turn of the wrist 180 degrees and back.

Failure to mix Norgen's cf-DNA Preservative with the blood leads to inadequate stabilization of the cf-DNA and the formation of microclots that can potentially clog the purification spin-columns or cause hemolysis that will lead to the contamination of the plasma with gDNA.

5. Store Norgen's cf-DNA Preservative Tubes Dx upright at room temperature (15-25°C) for up to 30 days.
6. Transport tubes within the recommended temperature range.

B. Plasma Preparation for cf-DNA Purification using Norgen's Plasma/Serum Cell-Free Circulating DNA Purification Kits

IMPORTANT! DO NOT MIX the contents of the cf-DNA Preservative Tube Dx (blood / preservative) prior to plasma preparation. Mixing the tube contents may result in hemolysis and the contamination of the recovered plasma with cellular genomic DNA.

1. To separate plasma, centrifuge the contents of the cf-DNA Preservative Tube Dx at 425 xg for 20 minutes at room temperature.
2. Carefully transfer the upper plasma layer by pipetting to a fresh tube. Avoid the transfer of any cells during the transfer of the plasma
3. Isolate the plasma cf-DNA immediately or store at -70°C.

IMPORTANT! Isolate plasma cf-DNA according to the instructions provided with Norgen's Plasma/Serum Cell-Free Circulating DNA Purification Kits (Cat. 55500, 55100, 55600 and 55800).

IMPORTANT! For maximum plasma cf-DNA yield and recovery, process the entire plasma volume recovered from Norgen's cf-DNA Preservative Tube Dx.

IMPORTANT! Frozen plasma recovered from Norgen's cf-DNA Preservative Tubes Dx may contain some precipitates upon thawing. DO NOT discard any precipitates before cf-DNA purification. Briefly vortex the plasma and proceed immediately for cf-DNA purification. Discarding any precipitates may significantly lower cf-DNA yield.

Quality Control

In accordance with Norgen's Quality Management System, each lot of Norgen's cf-DNA Preservative Tubes Dx is 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.

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 cf-DNA Preservative Tubes Dx, 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

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