

cf-DNA/cf-RNA Preservative Tubes Dx – 50 Tubes

Product Insert

REF Dx63950



IVD



PIDx63950-9

Intended Use

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

Norgen's cf-DNA/cf-RNA Preservation Tubes Dx are intended for use by professional users such as technicians, physicians and biologists experienced and trained in molecular biological techniques.

For *In Vitro* Diagnostic Use







Preservation Summary

- Cell-free DNA in blood samples collected in Norgen's cf-DNA/cf-RNA Preservative Tubes Dx is stable for up to 30 days at room temperature (15-25°C) and for up to 8 days at 37°C.
- Cell-free RNA in blood samples collected in Norgen's cf-DNA/cf-RNA Preservative Tubes Dx is stable for up to 30 days at room temperature (15-25°C).
- Circulating tumor cells (CTCs) in blood samples collected in Norgen's cf-DNA/cf-RNA Preservative Tubes Dx are stable for up to 14 days at room temperature (15-25°C).
- The content of the cf-DNA/cf-RNA 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 and cf-RNA samples for *in vitro* diagnostic use for medical purposes.

cf-DNA/cf-RNA Preservative Tubes Dx (50) Contents:

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

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

Quality Control

In accordance with Norgen's Quality Management System, each lot of Norgen's cf-DNA/cf-RNA 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.

Storage Conditions and Product Stability

1. When stored at 15-30°C, unfilled Norgen cf-DNA/cf-RNA 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/cf-RNA Preservative Tubes Dx.
3. Do not freeze unfilled Norgen cf-DNA/cf-RNA Preservative Tubes Dx for long term storage over 10 days. Freezing unfilled tubes may lead to loss of vacuum and precipitation may occur. If any precipitation is observed, please refer to the note in Section A below.
4. Cell-free DNA in blood samples collected in Norgen's cf-DNA/cf-RNA Preservative Tubes Dx is stable for up to 30 days when stored at room temperature (15-25°C)
5. Cell-free DNA in blood samples collected in Norgen's cf-DNA/cf-RNA Preservative Tubes Dx is stable for up to 8 days when stored at 37°C.
6. Cell-free RNA in blood samples collected in Norgen's cf-DNA/cf-RNA Preservative Tubes Dx is stable for up to 30 days when stored at room temperature (15-25°C).
7. Circulating tumor cells (CTCs) in blood samples collected in Norgen's cf-DNA/cf-RNA Preservative Tubes Dx are stable for up to 14 days at room temperature (15-25°C).

Warnings and Precautions

Do not use Norgen's cf-DNA/cf-RNA Preservative Tube Dx after the expiration date printed on the tube label.

1. Do not freeze specimens collected in Norgen's cf-DNA/cf-RNA Preservative Tubes Dx as breakage or hemolysis could result.
2. These tubes are intended for the use as described above. Do not dilute or add other components to the tubes.
3. Norgen's cf-DNA/cf-RNA Preservative Tubes Dx are for single use only.
4. Do not use tubes for the collection of materials to be injected into patients.
5. Overfilling or underfilling of tubes may lead to incorrect analytical results or poor product performance.
6. 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.
7. Do not transfer a sample from a syringe to the cf-DNA/cf-RNA Preservative Tube Dx.
8. Blood collection sharps should be discarded in biohazard containers approved for their disposal.
9. The cf-DNA/cf-RNA Preservative Solution and blood mixture from Norgen's cf-DNA/cf-RNA Preservative Tubes Dx can be disinfected using 1 volume of commercial bleach solution (5% sodium hypochlorite) per 9 volumes of the cf-DNA/cf-RNA Preservative solution and blood mixture.

Procedure

Notes Prior to Use

- Blood draw should be performed by an individual trained in phlebotomy
- Norgen's cf-DNA/cf-RNA Preservation Tubes Dx utilize a novel method to preserve cf-DNA, cf-RNA and stabilize nucleated blood cells, thus preventing apoptosis and the release of genomic DNA/RNA. 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 5-10 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 5-10 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/cf-RNA 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/cf-RNA 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>)

Note: Norgen's cf-DNA/cf-RNA Preservative Tubes Dx may show some precipitation due to short-term storage at -20°C or due to cold weather during shipping. If any precipitation is observed proceed with blood collection as described below, and gently mix the collected blood with the precipitated preservative until the white precipitates disappear.

1. Ensure that Norgen's cf-DNA/cf-RNA Preservative Tube Dx is at 15-30°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/cf-RNA 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 above.
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/cf-RNA Preservative Tube Dx is filled with blood, stabilize the cf-DNA by gently inverting the contents 5-10 times to ensure that the cf-DNA/cf-RNA 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/cf-RNA Preservative with the blood leads to inadequate stabilization of the cf-DNA and the cf-RNA 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/RNA.

Note: The tube is evacuated to collect 8.4 mL of whole blood. If less than 8.4 mL of blood was collected simply mix the collected blood with the preservative as outlined above in Step 4. However, before Plasma Preparation for cf-DNA/cf-RNA Purification, fill the tube with 1X PBS (pH 7.4) up to the bottom of the blue cap. DO NOT MIX and proceed to Section B.

Please let the tube stand in up right position for at least 30 minutes before shipping.

5. Store Norgen's cf-DNA/cf-RNA Preservative Tubes Dx upright at room temperature (15-25°C) for up to 30 days for cf-DNA preservation, up to 30 days for cf-RNA preservation or up to 14 days for CTCs preservation .
6. Transport tubes within the recommended temperature range.

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

IMPORTANT! DO NOT MIX the contents of the cf-DNA/cf-RNA 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/RNA.

1. To separate plasma, centrifuge the contents of the cf-DNA/cf-RNA 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 or cf-RNA immediately or store at -70°C.

Notes for cf-DNA and cf-RNA Isolation

- For maximum plasma cf-DNA and cf-RNA yield and recovery, process the entire plasma volume recovered from Norgen's cf-DNA/cf-RNA Preservative Tube Dx.
- Isolate plasma cf-DNA according to the instructions provided with Norgen's Plasma/Serum Cell-Free Circulating DNA Purification Kits Dx (Cat. Dx55500, Dx55100, Dx55600 and Dx55800).
- Isolate plasma cf-RNA according to the instructions provided with Norgen's Plasma/Serum RNA Purification Kits (Cat. 55000, 56100 and 56200).
- Frozen plasma recovered from Norgen's cf-DNA/cf-RNA Preservative Tubes Dx may contain some precipitates upon thawing. DO NOT discard any precipitates before cf-DNA or cf-RNA purification. Briefly vortex the plasma and proceed immediately for cf-DNA or cf-RNA purification. Discarding any precipitates may significantly lower cf-DNA or cf-RNA yield.

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.

Norgen's preservation technology is patented and/or patent pending. See www.norgenbiotek.com/patents

Authorized Representative



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