

# Cell-Free DNA Collection Tube

## REF

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## IVD

### INTENDED USE

The Roche Cell-Free DNA Collection Tube is a direct draw whole blood collection tube intended for collection, stabilization, and transportation of whole blood specimens, and for the preservation of nucleated cells to enable analysis of cell-free DNA.

### PRINCIPLE OF THE PROCEDURE

The Cell-Free DNA Collection Tube is a sterile, evacuated tube that contains K<sub>3</sub>EDTA plus a cell preservative. The vacuum ensures a correct blood draw volume. The K<sub>3</sub>EDTA chelates calcium ions, and thereby prevents blood coagulation. The cell preservative prevents lysis of nucleated blood cells.

### LIMITATIONS

- For *In vitro* diagnostic use.
- For Professional Use Only.
- The Cell-Free DNA Collection Tube is not intended for pediatric blood draws.
- The Cell-Free DNA Collection Tube is not intended for analytes other than cell-free DNA.

### MATERIALS AND METHODS

#### Materials Provided

The package contains:

Component	Description
Cell-Free DNA Collection Tube	An evacuated plastic single-use blood collection tube with 8.5 mL nominal liquid capacity, designed to be used in conjunction with standard phlebotomy equipment to collect whole blood by venipuncture.

#### Materials Required But Not Provided

- Disposable gloves and personal protective equipment
- Blood collection needles and multi-tube collection devices for 16 mm X 100 mm tubes
- Alcohol swab for cleansing site
- Tourniquet
- Gauze pads
- Bandage
- Sharps disposal container for disposal of used materials

#### Storage, Shipping and Handling

- Prior to blood collection, the Cell-Free DNA Collection Tube is stable through the expiration date when stored between 18-25°C.
- Blood specimens collected in the Cell-Free DNA Collection Tube are stable for 7 days when stored or shipped between 18-25°C, with transient excursions of up to 16 hours to 15-30°C.

#### WARNINGS AND PRECAUTIONS

- Do not use products after their expiration date.
- DO NOT REFRIGERATE OR FREEZE.
- Avoid contact of reagents with skin and mucous membranes. In case of eye contact, rinse thoroughly with plenty of water for at least 15 minutes. In case of skin contact, wash off with soap and plenty of water.
- Treat all biological specimens and materials coming in contact with them as biohazards. Handle with proper caution and dispose of in accordance with the policies and procedures of your facility.
- Practice universal precautions. Use protective personal equipment and other engineering controls to protect from blood splatter, blood leakage, and potential exposure to blood borne pathogens.
- Use caution when handling to avoid dropping or breakage of the Cell-Free DNA Collection Tube.
- Do not use the Cell-Free DNA Collection Tube if the contents are cloudy or if foreign matter is present.
- Do not use the Cell-Free DNA Collection Tube for collection of materials intended for injection.

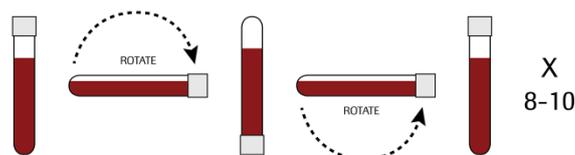
- Do not transfer a collected specimen into the Cell-Free DNA Collection Tube using a needle and syringe. Additional manipulation of sharps increases the risk of injury.
- Check venipuncture collection system before use.
- Do not fill the Cell-Free DNA Collection Tube above the nominal fill line. Over-filling may cause incorrect blood to additive ratio and may lead to inaccurate analysis or poor product performance.
- Ensure that collected specimens are packaged and labeled following all requirements for transportation of biohazardous materials.
- Safety Data Sheets (SDS) are available on request.

### INSTRUCTIONS FOR USE

#### Collecting Specimen

General guidelines for specimen collection can be found in Clinical and Laboratory Standards Institute (CLSI) H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture<sup>1</sup>.

1. Collect specimen (avoid backflow):
  - a. Place the patient's arm in a downward position.
  - b. Hold the tube with the stopper uppermost.
  - c. Release tourniquet once blood starts to flow in the tube.
  - d. Fill tube and confirm that the fill volume is between the minimum fill line and the nominal fill line.
  - e. Ensure the tube contents do not touch the stopper or the end of the needle during collection.
2. Remove tube from adapter.
3. To avoid hemolysis, immediately mix by gentle inversion 8 to 10 times to ensure adequate mixing of the chemical additives with the blood specimen.



#### Extracting DNA

1. Store or transport specimens under recommended conditions.
2. Separate plasma in accordance with assay instructions or standard laboratory protocols. Do not exceed 1600 x g relative centrifugal force for 10-15 minutes.
3. Decap Cell-Free DNA Collection Tube:
  - a. Hold the tube firmly in one hand, using a solid base to support the arm.
  - b. Twist the safety cap with the other hand to loosen.
  - c. Carefully open the tube with a gentle twist and pull motion.
4. Perform DNA extraction from plasma in accordance with assay instructions or standard laboratory protocols.

#### ORDERING INFORMATION

Please contact Roche customer service.

#### REFERENCES

<sup>1</sup>Clinical and Laboratory Standards Institute. H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition.

#### INTELLECTUAL PROPERTY

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## GLOSSARY OF HARMONIZED SYMBOLS

 Manufacturer	 Use-by date	 Batch code	 Catalogue number
 Sterilized using irradiation	 Temperature limit	 Do not re-use	 Consult instructions for use
 <i>In vitro</i> diagnostic medical device	 Contains sufficient for <n> tests		

## CONTACT INFORMATION



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Instructions for Use may be found online at:  
<http://sequencing.roche.com/dna-collection.html>