Roche Cell-Free DNA Collection Tube

REF	Σ
07785674001	50
07832397001	1,200

For Research Use Only. Not for use in diagnostic procedures.

PRINCIPLE OF THE PROCEDURE

The Roche Cell-Free DNA Collection Tube is a sterile, evacuated whole blood collection tube that contains K_3EDTA plus a cell preservative. The vacuum ensures an adequate blood draw volume. The K_3EDTA chelates calcium ions, and thereby prevents blood coagulation. The cell preservative prevents lysis of nucleated blood cells.

HAZARD INFORMATION

WARNING

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H373: May cause damage to organs through prolonged or repeated exposure.

P260: Do not breathe mist or vapours.

P280: Wear protective gloves/ eye protection/ face protection.

P314: Get medical advice/ attention if you feel unwell.

P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.

P337 + P313: If eye irritation persists: Get medical advice/ attention.

P362 + P364: Take off contaminated clothing and wash it before reuse.

65501-24-8 Tripotassium hydrogen ethylenediaminetetraacetate

39236-46-9 N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]

Note: Product safety labeling primarily follows EU GHS guidance

LIMITATIONS

- For Research Use Only. Not for use in diagnostic procedures.
- For Professional Use Only.
- The Roche Cell-Free DNA Collection Tube is not intended for analytes other than cell-free DNA.
- Hemolysis may occur and does not impact the function of the tube as long as there is a detectable separation between hematocrit and plasma.

MATERIALS AND METHODS

Materials Provided

The package contains:

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

WARNINGS AND PRECAUTIONS

- NO TUBE SHOULD BE FILLED BELOW THE MINIMUM FILL LINE OF 6.5 ML BLOOD PLUS PRESERVATIVE SOLUTION.
- 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 Roche Cell-Free DNA Collection Tube.
- Do not use the Roche Cell-Free DNA Collection Tube if the contents are cloudy or if foreign matter is present.
- Do not use the Roche Cell-Free DNA Collection Tube for collection of materials intended for injection.
- Because transferring a specimen into a Roche Cell-Free DNA Collection tube with a needle and syringe is not validated on the Roche Cell-Free DNA Collection tube, do not transfer a collected specimen into the Roche Cell-Free DNA Collection Tube using a needle and syringe. Additional manipulation of sharps increases the risk of injury.
- 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

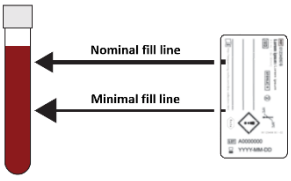
Collecting Specimen

General guidelines for specimen collection can be found in Clinical and Laboratory Standards Institute (CLSI) GP41, Collection of Diagnostic Venous Blood Specimens.[1]

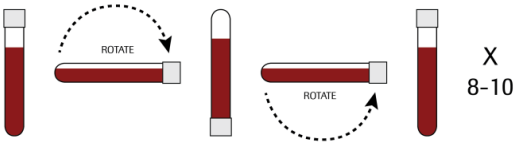
Follow recommendations for the order of blood draw outlined in CLSI GP41:

- Draw the Roche tube after EDTA and before fluoride oxalate tubes.
- Do not draw the Roche tube immediately after a heparin tube. In this situation, draw using an EDTA tube as a waste tube before using the Roche tube.

1. Check venipuncture collection system before use.
2. 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 until flow stops. Blood volumes above the nominal fill line are acceptable.
   e. Remove tube from adapter.
3. If the volume is not at or above the minimum fill line, then discard the tube and repeat the draw with a new tube.



4. To reduce potential hemolysis, immediately mix by gentle inversion 8 to 10 times to ensure adequate mixing of the chemical additives with the blood specimen.



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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. Discard tube if there is no detectable separation between hematocrit and plasma.
3. Decap Roche 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

[1]CLSI Collection of Diagnostic Venous Blood Specimens. 7th ed. CLSI standard GP41. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

INTELLECTUAL PROPERTY

TECHNICAL SUPPORT

For technical support (assistance) please reach out to your local affiliate:
https://www.roche.com/about/business/roche_worldwide.htm

CONTACT INFORMATION

Manufactured for
Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876 USA
www.roche.com

Made in Austria

Distributed by Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim,
Germany

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250-0457 USA
(For Technical Assistance call the Roche Response Center
toll-free: 1-800-526-1247)

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

GLOSSARY OF HARMONIZED SYMBOLS

Manufacturer	Use-by date	LOT Batch code	REF Catalogue number
Date of manufacture	Temperature limit	Do not re-use	Consult instructions for use
IVD In vitro diagnostic medical device	Contains sufficient for <n> tests	CE marking of conformity; this device is in conformity with the applicable requirements for CE marking of an in vitro diagnostic medical device	**Rx Only** US Only: Federal law restricts this device to sale by or on the order of a physician.
This way up	CONTENT Content of kit	Importer	STERILE R Sterilized using irradiation
GTIN Global Trade Item Number	UDI Unique Device Identifier		

DOCUMENT REVISION

Document Revision Information	
Doc Rev. 3.0 02/2024	Updated hazard warning information. Added hemolysis statement to **Limitations** section. Clarified hemolysis information in Step 4 in **Collecting Specimen** section and Step 2 in **Extracting DNA** section. Please contact your local Roche Representative if you have any questions.