

REF

07785666001
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1,200

IVD Rx Only

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 Roche Cell-Free DNA Collection Tube is a sterile, evacuated whole blood collection tube that contains K₃EDTA plus a cell preservative. The vacuum ensures an adequate blood draw volume. The K₃EDTA 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 the 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-dioximidazolidin-4-yl)]urea]

Note: Product safety labeling primarily follows EU GHS guidance

LIMITATIONS

- For in vitro diagnostic use with non-invasive prenatal testing and liquid biopsy testing only.
- 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.
- Inform your local competent authority and manufacturer about any serious incidents which may occur when using this device.

INSTRUCTIONS FOR USE

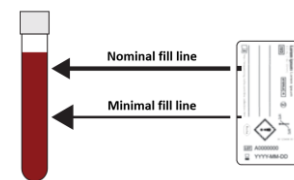
Collecting Specimen

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

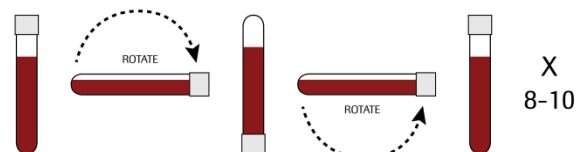
Follow recommendations for the order of blood draw outlined in CLSI GP41:

- 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 the tube until the 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.



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

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

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DOCUMENT REVISION

Document Revision Information	
Doc Rev. 3.0 09/2023	<p>Update to comply with IVDR requirements. Add NB number [2797]. Added serious incident statement to Warnings and Precautions section. Removed H317. Replaced “assay” with “Device” and added “and manufacturer” text in the statement “Inform your local competent authority about any serious incidents which may occur when using this assay.” Updated the harmonized symbol page. Updated to current economic operators. Please contact your local Roche Representative if you have any questions.</p>
Doc Rev. 4.0 02/2024	<p>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.</p>

GLOSSARY OF HARMONIZED SYMBOLS

Age/DOB Age or Date of Birth

SW Ancillary Software

Assigned Range [copies/mL] Assigned Range (copies/mL)

Assigned Range [IU/mL] Assigned Range (IU/mL)

EC REP Authorized representative in the European Community

BARCODE Barcode Data Sheet

LOT Batch code

Bio Biological risks

REF Catalogue number

CE CE marking of conformity; this device is in conformity with the applicable requirements for CE marking of an in vitro diagnostic medical device

Collect Date Collect date

i Consult instructions for use

Σ Contains sufficient for <n> tests

CONTENT Content of kit

CONTROL Control

Factory Date of manufacture

NP Device for near-patient testing

SP Device for self-testing

NP Device not for near-patient testing

SP Device not for self-testing

Distributor
(Note: The applicable country/region may be designated beneath the symbol)

⊘ Do not re-use

♀ Female

IVD For IVD performance evaluation only

GTIN Global Trade Item Number

Importer

IVD In vitro diagnostic medical device

LLR Lower Limit of Assigned Range

♂ Male

Factory Manufacturer

CONTROL - Negative control

NON STERILE Non-sterile

Person ? Patient Name

Person # Patient number

Peel Peel here

CONTROL + Positive control

QS copies / PCR QS copies per PCR reaction, use the QS copies per PCR reaction in calculation of the results.

QS IU/PCR QS IU per PCR reaction, use the QS International Units (IU) per PCR reaction in calculation of the results.

SN Serial number

Site Site

Procedure Standard Standard Procedure

STERILE EO Sterilized using ethylene oxide

Light Store in dark

Temp Temperature limit

TDF Test Definition File

↑↑ This way up

Procedure UltraSensitive Ultrasensitive Procedure

UDI Unique Device Identifier

ULR Upper Limit of Assigned Range

Urine Fill Line Urine Fill Line

Rx Only US Only: Federal law restricts this device to sale by or on the order of a physician.

Hourglass Use-by date