

FoundationOne®Liquid CDx Specimen Collection Kit

Specimen Collection Kit Instructions

Peripheral Whole Blood

IVD INTENDED USE: The FoundationOne®Liquid CDx Specimen Collection Kit is intended to allow for the collection and transport of whole blood, from the specimen collection site to the clinical laboratory, for the purpose of testing with the FoundationOne Liquid CDx assay.

Accurate analysis of cell-free DNA requires proper collection technique and handling of the sample. Failure to adhere to these instructions can compromise results by diluting cell-free DNA with DNA from white blood cell lysis.



USE THE TUBES PROVIDED. OTHER TUBES WILL NOT BE ACCEPTED.

Ship the sample overnight on the same day of collection. Foundation Medicine must receive the sample within 14 days of collection. Foundation Medicine is not liable if the specimen collection kit or blood collection tubes are found to be tampered with upon receiving the specimen.

WHAT'S IN THE KIT

- Two Specimen Collection Tubes
- Return Clinical Shipping Pack
- Temperature Stability Gel Pack
- Biohazard Bag
- Label card with Tube Numbers
- Individual Tube Return Bags
- Return Foam Block

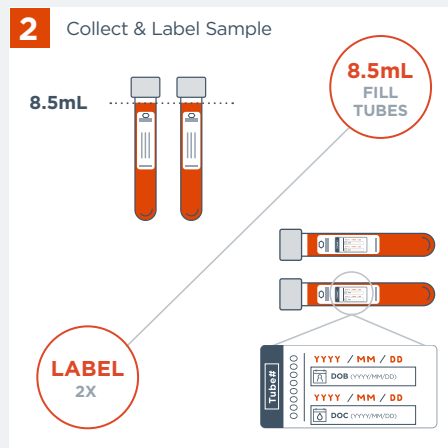
SPECIMEN COLLECTION INSTRUCTIONS



Check Expiration

Check the expiration date on the kit exterior has not expired. Blood collected in expired tubes will be discarded and a new blood specimen will be required. Do not use the provided Collection Tubes if the contents are cloudy or if foreign matter is present.

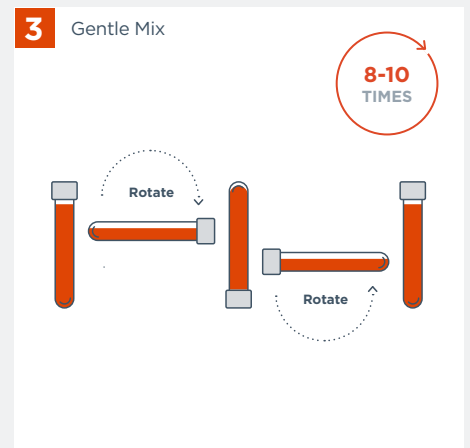
If the kit is expired or the contents of the tubes are cloudy or contain foreign matter, please contact your Roche Foundation Medicine Customer Care team on: 0800 7315711 option3, or UK.Foundation@roche.com



Collect & Label Whole Blood Sample

Collect **two tubes of whole blood (8.5mL per tube)**.

- Prevent backflow: tubes contain chemical additives and it is important to avoid backflow into patient.
- Collect specimen by venipuncture according to CLSI H3-A6.¹
- Fill tubes with 8.5mL per tube.
- **DO NOT FREEZE OR REFRIGERATE** blood samples or gel stability pack.
- **Temperature is important. Keep at ambient temperature (39–95°F, 4–35°C).**
- Collection tubes are the primary specimen containers and must be labeled. Apply the supplied labels as depicted on the label card to ensure the collection tubes and TRF are labeled properly. **Indicate date of collection and date of birth on the specified tube labels.** Both the collection tubes and the TRF must have a provided label applied. **When applying labels, do not cover the expiration date or lot number located on the tubes.**



Mix Tubes Via Inversion

Remove the tube from adapter and immediately **mix by gentle inversion 8 to 10 times**. Inadequate or delayed mixing may result in inaccurate test results. One inversion is a complete turn of the wrist, 180°, and back per the figure above.

TUBE LABEL APPLICATION INSTRUCTIONS AND ASSOCIATED SYMBOLS

Refer to tube label card for complete tube labeling instructions.



Label cards contain an **additional label** to be used either as a replacement for a damaged tube label or for internal record keeping.



Write the Date of Birth and Date of Collection on the tube labels in the requested format: 4-digit year / 2-digit month / 2-digit day



After filling in the patient date of birth and the date of collection on each tube label, **place one tube label on each tube** provided inside the FoundationOne®Liquid CDx kit that was used to collect the specimen. Place labels vertically on top of the existing label seen on the tube. Do not cover the space on the tube where the blood level is visible with any labels. Blood level should be visible for sample processing. Additionally, please place the orange label with the Tube Number provided on the Test Requisition Form in the designated "Tube Number Label" field.



Date of Birth in the format:

4-digit year / 2-digit month / 2-digit day

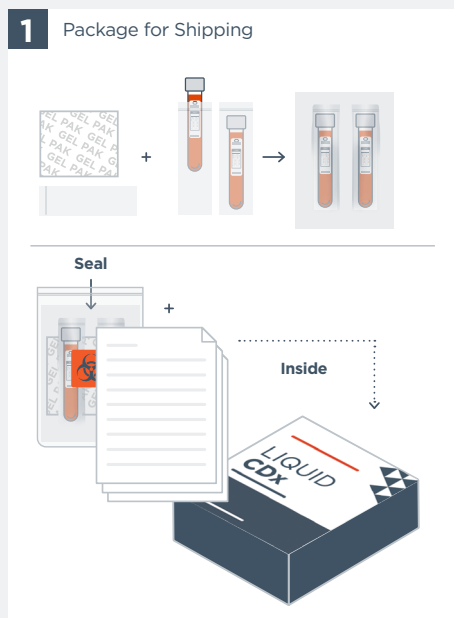


Date of Collection in the format:

4-digit year / 2-digit month / 2-digit day

SHIPPING INSTRUCTIONS

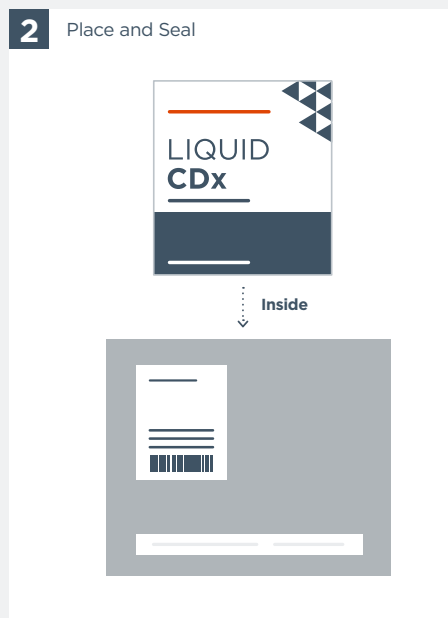
Package and mail the specimen(s) to the appropriate Foundation Medicine Laboratory written on the return label provided by your site location affiliate. Each kit should be utilized for one patient. Do not include different patient samples in the same box.



Package Kit for Shipping

Include the following in the FoundationOne Liquid CDx Specimen Collection and Shipping Kit:

- After collection of the specimen in appropriate **collection tubes** (two total tubes), ensure both tubes are properly **labeled, as described above, and place each individual collection tube into a provided tube bag. One bag per tube.**
- **Place both tubes, each in an individual tube bag, into the foam block.** Place the foam block with both tubes inside into the biohazard bag and seal.
- Place the temperature stability gel pack on top of the biohazard bag. Do not freeze or refrigerate the stability pack at any time.
- Completed test requisition form (TRF) with **date of collection, date of birth, tube number label, and patient's diagnosis.**

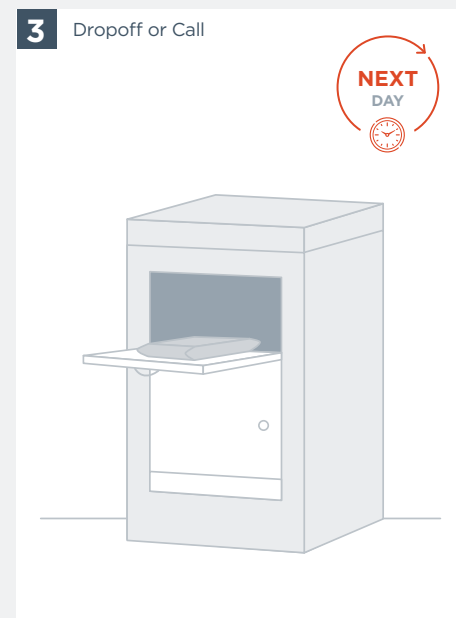


Seal Shipping Pack

Place the repacked specimen collection kit into the provided return clinical shipping pack.

Place return labels on the outside of the return clinical shipping pack.

For questions regarding return labels, return clinical shipping packs, and country specific invoices, please contact your local Roche distributor. A link to the distributor list and contact information is provided below.



Dropoff or Call for Pickup

To return the Specimen Collection Kit back to FMI, either drop the sealed package off at the appropriate courier location or call to arrange a pick-up. Please call your local distributor with any questions about return shipping.

CELL-FREE DNA COLLECTION TUBE SPECIFIC INFORMATION

The following information is provided for the Cell-Free DNA Collection Tube included in the FoundationOne Liquid CDx Specimen Collection Kit. The Cell-Free DNA Collection Tube is CE Marked and manufactured for Roche Molecular Systems, Inc.

Cell-free DNA Collection Tube Intended Use

The Cell-Free DNA Collection Tube, included in the FILCDx collection kit, 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 K3EDTA plus a cell preservative. The vacuum ensures a correct blood draw volume. The K3EDTA chelates calcium ions, and thereby prevents blood coagulation and 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 analytes other than cell-free DNA.

MATERIALS + METHODS

Materials Provided

The package contains:

COMPONENT	DESCRIPTION	SAFETY DATA SHEET
Cell-Free DNA Collection Tube	The FoundationOne®Liquid CDx (FILCDx) Collection Kit contains 2 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.	A Safety Data Sheet is available upon request from your local distributor. See below for local distributor contact information.

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 material

Storage, Shipping and Handling

- Prior to blood collection, the Cell-Free DNA Collection Tube is stable through the expiration date when stored or shipped between 18–25°C.
- When used for FoundationOne® Liquid CDx testing, blood specimens collected in the Cell-Free DNA Collection Tube are stable for up to 14 days when stored or shipped between 4–35°C.

Instructions for Use

- See Pages 1 and 2 of this document for FoundationOne®Liquid CDx specimen collection instructions.

Ordering Information

- Please contact Roche customer service.

WARNING + PRECAUTIONS

- No tube should be filled below the minimum fill line of 6.5mL (small black rectangle on tube label).
- 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 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 (black square on tube label).
- For any serious incident that has occurred in relation to the FoundationOne®Liquid CDx Specimen Collection Kit, please report to Foundation Medicine, Inc., and the competent authority of the Member State in which the user and/or the patient is established.

HAZARD INFORMATION

- H315 : Causes skin irritation.
- H317 : May cause an allergic skin reaction.
- H319 : Causes serious eye irritation.
- H335 : May cause respiratory irritation.
- P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
- P264 Wash skin thoroughly after handling.
- P280 Wear protective gloves/ eye protection/ face protection
- P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor 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.
- Note: Product safety labeling primarily follows EU GHS guidance



Qarad EC-REP BV
Pas 257
2440 Geel
Belgium



www.foundationmedicine.qarad.eifu.online



Foundation Medicine, Inc.
150 Second Street
Cambridge, MA 02141



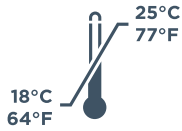
Foundation Medicine GmbH
Nonnenwald 2, Building 433
82377 Penzberg
Germany

DISTRIBUTORS



Please find your country's distributor list at: <https://www.rochefoundationmedicine.com/home/contact-us.html> and search for your desired country.

GLOSSARY OF HARMONIZED SYMBOLS



Temperature Limit



Use-by-date



Do Not Reuse



In-vitro Diagnostic Medical Device



Sterilized Using Radiation



Contains Sufficient for <n> Tests



Country of Manufacture



Batch Code (Lot)



Item Number



Manufacturer



Consult Instructions For Use



Authorized Representative in the European Community



Distributor

Reference

1. Clinical and Laboratory Standards Institute. H3-A6, Procedures for the collection of diagnostic blood specimens by venipuncture; approved standard-sixth edition.