FOUNDATIONONE®LIQUID CDx

Specimen Instructions

Peripheral Whole Blood

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.

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

On the same day of collection ship the sample overnight. Foundation Medicine must receive 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 upon receiving the specimen.

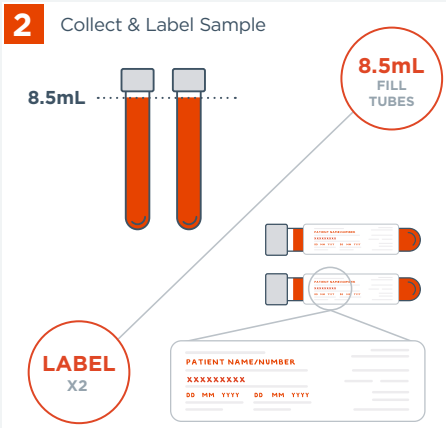
WHAT'S IN THE KIT

- Specimen Instructions
- Test Requisition Form (TRF)
- Two Specimen Collection Tubes
- Pre-Labeled Shipping Bag
- Temperature Stability Gel Pack
- Biohazard Bag
- Kit Background Card
- Kit Tracking Card
- Individual Tube Return Bags
- Return Foam Block
- ABN Letter and Form

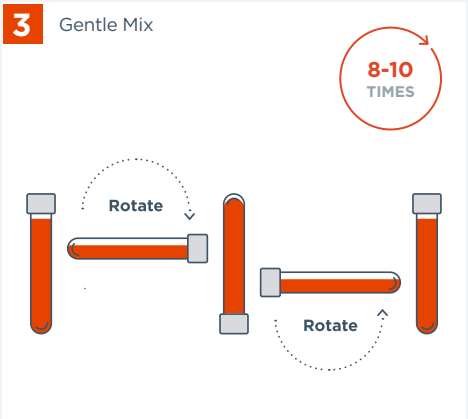
SPECIMEN COLLECTION INSTRUCTIONS

1 Check Expiration

2 Collect & Label Sample



3 Gentle Mix



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 is cloudy or contains foreign matter, please contact your Foundation Medicine representative at 888-988-3639 or client.services@foundationmedicine.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 completely (8.5mL per tube).
- **DO NOT FREEZE OR REFRIGERATE** blood samples or temperature stability gel pack.
- **Temperature is important. Keep at room temperature (39–95°F, 4–35°C).**
- Collection tubes are the primary specimen containers and must be labeled properly. **indicate date of collection** and **two unique patient identifiers**, such as patient date of birth, patient first and last name, or order identification number. **Ensure these two unique identifiers are also labeled on the TRF**. The unique identifiers must be identical on the labels and TRF.

Mix Tubes Via Inversion

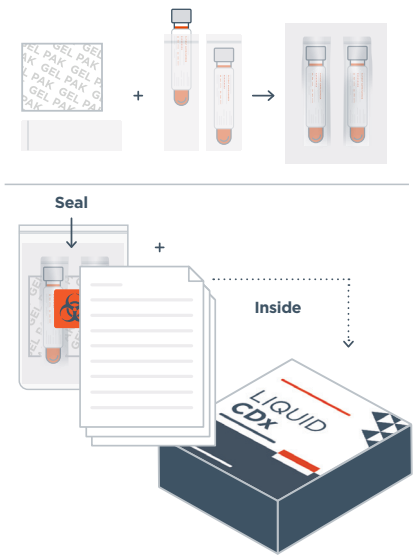
Remove the tube from adapter and immediately **mix by gentle inversion 8 to 10 times.** Inadequate or delayed mixing may result in inaccurate test results. One inversion is a complete turn of the wrist, 180°, and back per the figure above.

Shipping Instructions on Back →

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.

1 Package for Shipping



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**.
- Insurance information*
- **Available reports** (copies of pathology reports and/or other clinical documentation)*

** Mobile Phlebotomists do not need to collect and submit the information above.*

2 Place and Seal

Seal Shipping Pack

Place the specimen kit (including samples and paperwork) into the provided clinical shipping pack, first ensuring that primary specimen containers (e.g. tubes) are labeled with two patient-specific identifiers.

3 Dropoff or Call

Dropoff or Call for Pickup

Call 800.463.3339 to request a pick-up or drop off the package at your site's designated FedEx pick-up location to be shipped back to Foundation Medicine.

FoundationOne®Liquid CDx is for prescription use only and is a qualitative next-generation sequencing based *in vitro* diagnostic test for advanced cancer patients with solid tumors. The test analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes and as a companion diagnostic to identify patients who may benefit from treatment with specific therapies (listed in Table 1 of the Intended Use) in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Patients who are negative for companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if available. For the complete label, including companion diagnostic indications and complete risk information, please visit *www.F1LCDxLabel.com*.

Reference

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

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