

Specimen Instructions

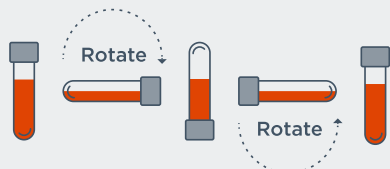
Peripheral Whole Blood

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.

Collecting the Specimen

Please use the blood collection tubes provided inside the FoundationOne®Liquid CDx Specimen Collection and Shipping Kit and do not cover the tube labels. Other tubes will not be accepted. Foundation Medicine is not liable if the specimen collection kit or blood collection tubes are found to be tampered upon receiving the specimen.

- 1** Check the blood collection tubes provided in FoundationOne Liquid CDx kits to confirm liquid is clear and without cloudiness or crystals.
- 2** Label tubes with the supplied labels to indicate date of collection and two unique patient identifiers, such as patient date of birth, patient first and last name, or order identification number.
- 3** Collect two tubes of whole blood (8.5mL per tube). Levels of ctDNA may decrease after chemotherapy, and we recommend that blood samples be drawn shortly before chemotherapy or at least two weeks after the previous treatment.
 - 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).
- 4** 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 below.



- 5** Confirm each tube is labeled with the date of collection and two unique patient identifiers such as patient date of birth, patient first and last name, or order identification number.

Place specimen, completed test requisition form (TRF) (remember to include patient's diagnosis), insurance information, available reports, and accompanying documents into the FoundationOne Liquid CDx Specimen Collection and Shipping Kit (copies of pathology reports and/or other clinical documentation).

- NOTE: Mobile Phlebotomists do not need to collect and submit the information above.

- 6** Preferably on the same day of collection, ship via clinical priority overnight delivery at ambient temperature. **Do not freeze or refrigerate blood samples.**

Temperature is important.
Keep at room temperature (39-95°F, 4-35°C).
DO NOT FREEZE.

Package and mail the specimen(s) to the Foundation Medicine laboratory. Each kit should be utilized for one patient. Do not include different patient samples in the same box.

Shipping Instructions

1. Remove the kit tracking information and keep for your records.
2. 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. **Seal the shipping pack.**
3. If using shipping pack provided in this kit (recommended), recording the Kit ID # will allow you to properly track specimen. If you use a different shipping pack, consider recording that pack's tracking number.
4. Call 800.463.3339 to request a pick-up or drop the package at your site's designated FedEx pick-up location and ship sealed shipping pack to:

Foundation Medicine, Inc.
150 Second Street
Cambridge, MA 02141
Phone: 888.988.3639

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.FILCDxLabel.com.

Reference

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

