

Specimen Collection & Shipping Instructions

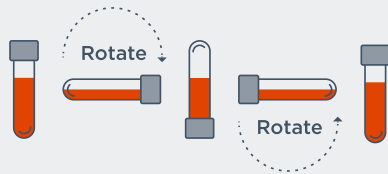
Peripheral Whole Blood

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. In Europe, please include patient date of birth and order identification number. In other countries, please include patient date of birth, first name and surname.
- 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** Place specimen, completed test requisition form (TRF) (remember to include patient's diagnosis), available reports, and accompanying documents into the FoundationOne Liquid CDx Specimen Collection and Shipping Kit.
 - **Confirm each tube is labeled to indicate the date of collection and two unique patient identifiers.** In Europe, please include patient date of birth and order identification number. In other countries, please include patient date of birth, first name and surname.
- 6** Preferably on the same day of collection, ship via courier 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. Place the specimen kit (including samples and paperwork) into the provided courier shipping pack, first ensuring that primary specimen containers (e.g. tubes) are labeled with two patient-specific identifiers. Seal the shipping pack. Ensure export documentation is completed and included in the shipping pack, if needed.
2. Call your country customer care center listed at rochefoundationmedicine.com to request a pick-up or drop the package at your site's designated courier pick-up location and ship sealed shipping pack to:

Foundation Medicine GmbH
Nonnenwald 2, Building 433
82377 Penzberg
Germany

Reference

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

