FOUNDATIONONE® LIQUID CDx

Specimen Collection & Shipping Instructions

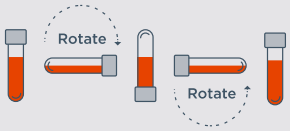
Peripheral Whole Blood

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.
- ☐ 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 filled blood collection tubes into the absorbent sleeve, then into the biohazard bag and seal. Fold the gel pack over the biohazard bag. Place all contents into the silver pouch and seal.
- ☐ 6 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.**
- ☐ 7 Preferably on the same day of collection, ship via courier priority overnight delivery at ambient temperature. Do not freeze or refrigerate blood samples. See additional details below.

Temperature is important.
Keep at room temperature (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 commercial invoice in triplicate is initialed and included in the shipping pack.
2. On the same day as collection ship via FedEx overnight delivery at ambient temperature. Drop the package at your site's designated FedEx pick-up location or call FedEx at 1-800-463-3339 to request a pick-up. Address the sealed shipping pack to:

Foundation Medicine, Inc.
150 Second Street
Cambridge, MA, USA 02141
Phone: 888-988-3639

Reference:
1. Clinical and Laboratory Standards Institute (CLSI). Collection of Diagnostic Venous Blood Specimens. 7th ed. CLSI standard GP41, ISBN 1-56238-813-4; 2017.

If you require this information in an accessible format, please contact Roche at 1-800-561-1759.

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