

Specimen Instructions

Peripheral Whole Blood

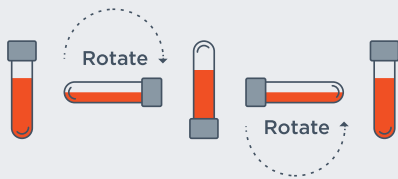
Please only use the blood collection tubes provided inside the FoundationOne® Liquid CDx Shipment Kit and do not cover the tube labels. Other tubes will not be accepted. Foundation Medicine is not liable if the specimen collection kit of blood tubes are found to be tampered with upon receiving the specimen.



Overview of Specimen Handling

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 the cell-free DNA with DNA from white blood cell lysis.

- 1** Check the blood collection tubes provided in FoundationOne® Liquid CDx Shipment Kits to confirm liquid is clear and without cloudiness or crystals. **Check the kit expiry to ensure it is in date.**
- 2** Label each tube with the supplied labels indicating the date of collection and two unique patient identifiers e.g. (Test Requisition form (TRF) Customer Order Number and Date of Birth).
- 3** Collect two tubes of whole blood (8.5mL per tube). Levels of ctDNA may decrease after chemotherapy, and we recommend that blood samples are drawn shortly before chemotherapy or at least two weeks after previous treatment.
 - Prevent backflow: tubes contain chemical additives and it is important to avoid backflow to the patient
 - Collect specimen by venipuncture according to local guidelines¹
 - Fill tubes to marked level (8.5mL per tube).
- 4** Remove the tube from the 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 degrees, and back per the figure below.



- 5** Place specimen, fully completed Test Requisition Form (TRF), and a copy of the most recent redacted pathology report into the FoundationOne® Liquid CDx Shipment Kit.
 - **Confirm each tube is labeled with the supplied labels indicating the date of collection and two unique patient identifiers.** We strongly recommend using the TRF, Customer Order Number and the Patient's Date of Birth.
- 6** Call Customer Care the day before collection to arrange for courier pick-up.

Temperature is important.
Keep at room temperature (4-35 degrees Celsius).

DO NOT FREEZE.

Refer to FoundationOne® Liquid Packing Instructions for details.

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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