

FoundationOne® Liquid CDx Specimen Collection 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.

USE ONLY THE TUBES PROVIDED IN THE FOUNDATIONONE® LIQUID CDx SPECIMEN KIT. OTHER TUBES WILL NOT BE ACCEPTED.

STEP 1

Check the blood collection tubes provided in the FoundationOne® Liquid CDx Specimen Kit to confirm liquid is clear and without cloudiness or crystals.

STEP 2

Label tubes to indicate the date of collection and two unique patient identifiers (e.g. patient first and last name, patient date of birth, or order identification number). Labels are included in the FoundationOne® Liquid CDx Specimen Kit.

STEP 3

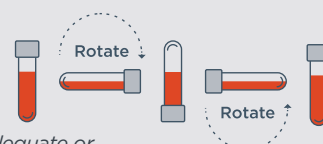
Collect two tubes of whole peripheral blood (8.5mL per tube)

Note: Levels of ctDNA may decrease after chemotherapy. Therefore, we recommend that blood samples be drawn shortly before chemotherapy dosage or at least two weeks after the previous treatment.

- Prevent backflow: as the tubes contain chemical additives which may cause harm, it is important to avoid backflow into the patient
- Collect specimen by venipuncture according to H3-A6¹
- Fill tubes completely (8.5mL per tube)

STEP 4

Remove the tube from the adaptor and immediately mix by gentle inversion 8 to 10 times. *Important: 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.



STEP 5

Confirm each tube is labeled with the supplied labels indicating the date of collection and two unique patient identifiers.

Place the blood samples, the completed (and signed) FoundationOne® Liquid CDx Test Requisition Form, available reports (including patient diagnosis), and any other attachments into the FoundationOne® Liquid CDx Specimen Collection and Shipping Kit. Copies of pathology reports and/or other clinical documentation may be included if available.

STEP 6

On same day as collection, ship via FedEx for priority delivery at ambient temperature.

Do not freeze or refrigerate blood samples. Keep at 4-35°C.

Package and mail the specimen(s) to the Foundation Medicine laboratory. One kit per patient. Do not include different patient samples in the same box.



TEMPERATURE IS IMPORTANT. KEEP AT ROOM TEMPERATURE 4-35°C. DO NOT FREEZE.

✉ SHIPPING INSTRUCTIONS

1. Place the samples, FoundationOne® Liquid CDx Requisition Form, pathology report, and any other attachments into the FoundationOne® Liquid CDx Specimen Kit.
2. Place the specimen kit (including samples and paperwork) into the provided shipping pack and seal the shipping pack. Ensure any export documentation (Commercial Invoice, Air Waybill) is completed and included in the shipping pack. Recording the Kit ID# will allow you to track the specimen.
3. Ship the sealed shipping pack to: **Foundation Medicine, Inc. 150 Second Street, Cambridge, MA 02141, USA**, by calling FedEx to request a pickup. The local FedEx contact number is indicated on the top of the shipping pack.

Mat. code 37567078



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More information can be found at www.foundationmedicine.co.nz.

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