FOUNDATIONONE® TRACKER
POWERED BY natera

Specimen Instructions

Peripheral Whole Blood

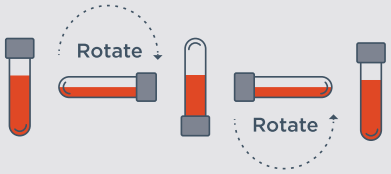
FoundationOne®Tracker is intended to provide ctDNA burden measurements for longitudinal tracking of cfDNA extracted from peripheral blood as a marker for tumor burden in a cancer patient previously tested for specific somatic variants identified through baseline testing of formalin-fixed paraffin-embedded (FFPE) tumor tissue. Baseline tissue testing is performed separately and these specimen instructions are only for the peripheral whole blood sample.

Collecting the Specimen

Please use the sterile Streck Cell-Free DNA BCT® (Blood Collection Tube) provided inside the FoundationOne Tracker Specimen Collection and Shipping Kit and do not cover the tube labels. If any component of the specimen collection kit is found to have been tampered with upon receipt of the sample, Natera will not be held liable.

- ☐ **1** Check the blood collection tubes provided in FoundationOne Tracker kits to confirm liquid is clear and without cloudiness or crystals
- ☐ **2** Label tubes with the supplied labels to indicate date of collection and patient identifiers.
- ☐ **3** Collect two tubes of whole blood (10mL per tube).

  Follow recommendations for order of draw outlined in CLSI GP411. Streck recommends that the Cell-Free DNA BCT should be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Cell-Free DNA BCT tube immediately follows a heparin tube in the draw order, Streck recommends collecting a non-additve or EDTA tube as a waste tube prior to collection in the Cell-Free DNA BCT.*
- ☐ **4** 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 in FoundationOne Tracker Specimen Collection and Shipping Kit
- ☐ **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, 6-37°C).

  DO NOT FREEZE.

Package and mail the specimen(s) to the Natera laboratory address listed on page 2. Use a separate kit for each patient. Do NOT include samples from different patients in the same box.

Shipping Instructions for liquid monitoring samples

1. Remove the kit tracking information and keep for your records.
2. Ensure that the primary specimen containers (i.e. tubes) are labeled with patient name, medical record number, order ID, patient DOB, and collection date. Place the following components into the provided clinical shipping pack: 2 sample tubes, printed TRF from the online order, and temperature stability pack (i.e. gel pack).

   Note: Two unique patient identifiers are required for processing. Samples without 2 unique patient identifiers that match the accompanying requisition may be delayed or rejected.

   Note: Do not freeze or refrigerate blood samples and the temperature stability pack. Samples should be kept at 18°C to 25°C. Samples are stable up to 7 days after collection. Samples received later than 7 days post collection cannot be processed.
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:
5. Ship to Natera™ Inc.

   ATTN: Accessioning,
   Foundation Medicine – Natera Monitoring
   201 Industrial Road, Suite 410
   San Carlos, CA 94070

   Tel: 650-249-9090 x591
   Email: Accession-core@natera.com

FoundationOne®Tracker is a clinical test performed exclusively as a laboratory service. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). FoundationOne Tracker is a personalized assay for oncology that is based on patient-specific somatic variants (substitutions and short insertions/deletions) identified from baseline tumor tissue testing and used to detect and longitudinally measure plasma circulating tumor DNA (ctDNA) abundance as a biomarker for tumor burden. Treatment decisions are the responsibility of the treating physician. ctDNA detection sensitivity may be limited if blood collection occurs within two weeks of surgery or while a patient is on therapy. A negative test result does not definitively indicate the absence of cancer. This test is not designed to detect or report germline variation, nor does it infer hereditary cancer risk for a patient. This test is designed to detect ctDNA from the assayed tumor only; new primary tumors will not be detected. This test is expected to have limited sensitivity in some cancer types due to limited ctDNA shed.

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*Please see Streck instructions below for more detail.

STERILE R

https://www.streck.com/wp-content/uploads/sync/Stabilization/Cell-Free_DNA_BCT/01_Instructions_(IFU)/01_Cell-Free_DNA_BCT_IFU.pdf

FOUNDATION MEDICINE®

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