

Specimen Instructions

Peripheral Whole Blood

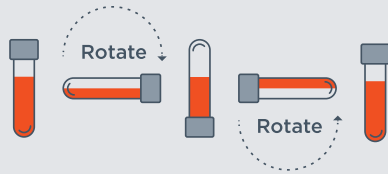
Use only tubes provided inside the FoundationACT® Specimen Collection and Shipping Kit. Other tubes will not be accepted.



Instructions For Use

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.

- 1** Check special tubes provided in FoundationACT kits to confirm liquid is clear and without cloudiness or crystals.
- 2** Label tubes with date of collection and two patient identifiers.
- 3** Collect two tubes of whole blood (8.5mL per tube).
 - 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 requisition form (CRF) (remember to include patient's diagnosis), insurance information, available reports, and accompanying documents into the FoundationACT Specimen Collection and Shipping Kit (copies of pathology reports and/or other clinical documentation).
 - Confirm each tube is labeled with the supplied labels indicating the date of collection and two unique patient identifiers (label included in kit).
- 6** Preferably on the same day of collection, ship via FedEx overnight delivery at ambient temperature. Do not freeze or refrigerate blood samples.

Temperature is important. Keep at room temperature (43-99° F, 6-37° C).

DO NOT FREEZE.

Shipping Instructions

1. Place the samples, FoundationACT requisition form, insurance information, and any other attachments into the FoundationACT Specimen Collection and Shipping Kit.
2. Place the specimen kit (including samples and paperwork) into the provided FedEx shipping pack, first ensuring that primary specimen containers (e.g. tubes) are labeled with two patient-specific identifiers. Seal the shipping pack.
3. Complete the pre-printed shipping labels (if necessary) and apply to shipping pack.
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:

Foundation Medicine, Inc.
150 Second Street
Cambridge, MA 02141
Phone: 888.988.3639

Reference

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