INSTRUCTIONS FOR USE

Accurate analysis of cell-free DNA is compromised by improper handling of the sample. It is important to follow the collection procedures to avoid releasing unwanted cellular DNA into the sample.

☐ Step #1: Check special tubes provided in FoundationACT kits to confirm liquid is clear and without cloudiness or crystals

☐ Step #2: Label tubes with date of collection and two patient identifiers

☐ Step #3: Collect two tubes of whole blood (10mL 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
  • Fill tubes completely (10mL per tube)

☐ Step #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

☐ Step #5: Place specimen, completed requisition form (CRF), insurance information, available reports and accompanying documents into the FoundationACT specimen collection 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)

☐ Step #6: Preferably, on the same day of collection ship via FedEx overnight delivery at ambient temperature. Do not freeze or refrigerate blood samples. Keep at 43-99 °F [6-37 °C]

Temperature is important. Keep at room temperature (43-99 °F, 6-37 °C). DO NOT FREEZE.


SHIPPING INSTRUCTIONS:

1. Place the specimen kit (including samples and paperwork) into the provided FedEx shipping pack and seal the shipping pack.

2. Complete the pre-printed shipping labels (if necessary) and apply to shipping pack.

3. Ship the sealed pack to the following address:
   Accessioning, Clinical Laboratory
   Foundation Medicine, Inc.
   150 Second Street, Cambridge, MA 02141
   Phone: 888.988.3639

4. Drop the package at your site’s designated FedEx pick up location or call 1.800.309.0530 to request a pick up.

www.FoundationOne.com
Please call +1.888.988.3639 with questions or to request FoundationACT Specimen Kits,
Client.Services@FoundationMedicine.com