

Collection instructions

Accurate analysis of circulating cell-free (ccf) DNA and RNA requires proper collection technique and handling of the blood sample. Levels of circulating tumor DNA and RNA may decrease after cancer therapy. Biofidelity recommends blood samples be drawn at least two weeks after the previous treatment. Failure to follow these instructions may compromise results.

Please Note: Prior to sample collection, store the Biofidelity Collection Kit at 39°F – 77°F (4°C – 25°C).

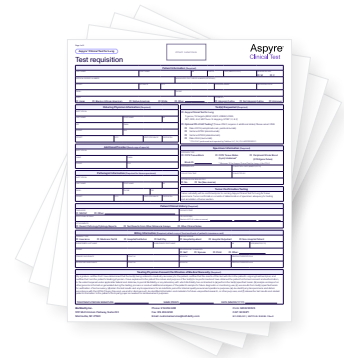
Kit Contents

- Aspyre® Clinical Test requisition form
- Sample collection instructions
- 2 x PAXgene® Blood ccfDNA tubes
- 6 x identification labels
- Biohazard bag with absorbent material
- Return shipping label
- FedEx UN 3373 Pak

Step A – Complete Aspyre Clinical Test Requisition Form, Affix Barcodes, and Copy Patient Documents

Please Note: Incomplete or absent Aspyre Clinical Test requisition form will delay testing.

1. Complete all required and applicable fields on the test requisition form.
2. On each of the provided labels, write the patient's full name and date of birth.
3. Affix one of the labels to the top of the test requisition form. Reserve two labels for the PAXgene® tubes. Additional labels can be used for patient records.
4. Print copies of the following documents to submit with the blood sample:
 - Patient's **insurance card** (front and back)
 - Patient's relevant past **pathology diagnosis report**
 - Patient's relevant **clinical notes**



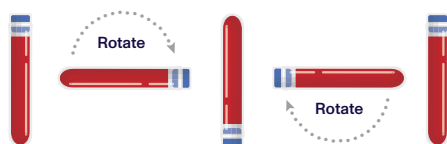
Step B – Collect Blood Sample

Please Note: Use only the PAXgene® tubes provided by Biofidelity for sample collection. Other blood tubes will not be accepted.

Under-filled tubes may delay or prevent testing. Samples **MUST** be labeled with patient name and date of birth.

Inadequately labeled samples will delay or prevent testing.

1. Ensure the PAXgene® tubes are at room temperature prior to use.
2. Collect blood from the patient, ensuring that **both** PAXgene® tubes are completely filled (10 mL total volume per tube). If simultaneously collecting samples for other testing, collect PAXgene® tubes last to prevent potential additive carryover.
 - Venipuncture: Follow your institution's guidelines for a standard venipuncture.
 - Central Line Draw: Line draws are acceptable if 5 mL of blood are drawn and discarded prior to filling the PAXgene® tubes. Follow your institution's guidelines.
3. After filling, immediately mix tubes by **gently** inverting 10 times.
4. Write the collection date and time on two labels (along with patient name and DOB). Affix one label to each PAXgene® tube.



FIRST NAME	LAST NAME	DOB (MM/DD/YYYY)
COLLECTION DATE (MM/DD/YYYY)		HR : MM AM/PM



5. After collection, store the PAXgene® tubes at room temperature 59°F – 77°F (15°C – 25°C). Do not refrigerate or freeze.

Step C – Package the Sample

Please Note: Each Collection Kit is intended for one patient only. Do not combine material from multiple patients inside the same box. It is recommended that samples are packaged and shipped on the same day as sample collection.

Samples MUST be received within 5 days of drawing the blood or the sample will be rejected. Two filled PAXgene[®] tubes are required.

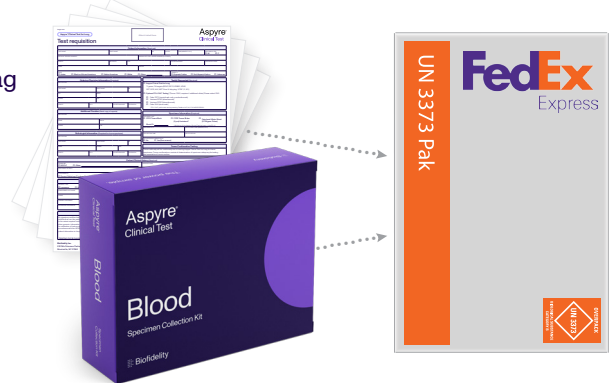
1. Place the **two** filled PAXgene[®] tubes inside the biohazard bag with absorbent material that is provided in the collection kit. Seal the bag.



2. Place the biohazard bag inside the Biofidelity Collection Kit box. Securely close the box.



3. Place the following contents inside the FedEx UN 3373 Pak:
 - Biofidelity Specimen Collection Box containing two filled and labeled PAXgene[®] tubes and absorbent material, sealed inside the biohazard bag
 - Completed **Aspyre Clinical Test requisition form**
 - Copy of patient **insurance card**
 - Copy of patient **pathology diagnosis report**
 - Copies of patient **clinical notes**
4. Securely seal the FedEx UN 3373 Pak.



Step D – Ship Sample

1. Affix the Biofidelity return shipping label to the front of the sealed FedEx UN 3373 Pak.
 - Make note of the tracking number for your tracking purposes.
2. Ship package the same day as the sample is collected for ideal sample integrity. Provide package to FedEx following your standard practice for sending clinical samples. If FedEx does not have a daily pick-up, please call FedEx Customer Service at **+1 (800) 463-3339**. If necessary, email Biofidelity Customer Service at customerservice@biofidelity.com to assist in scheduling a pick-up or drop-off of the package at your designated FedEx location.
 - All collection kits are either shipped to Biofidelity at the following address or held for pickup at a local FedEx location.

Biofidelity Inc.
5151 McCrimmon Parkway
Suite 230
Morrisville, NC 27560

Please call Customer Service at **+1 (919) 659-3285** if you have any questions.