

Phlebotomy Instructions

The comprehensive Instructions for Use (IFU) can be found in the FirstLook Blood Collection Kit. Highlighted below are critical steps for a successful blood draw.

If you have any questions or need to request additional Blood Collection Kits, please contact DELFI Diagnostics Client Services at:

FirstLook Lung is a simple blood test designed to be the first step in detecting lung cancer early, when it's most treatable.

1-800-589-2182
clientservices@delfidiagnostics.com

Materials included in blood collection kit:



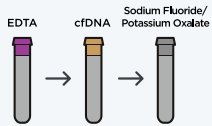
- One 10 mL Streck Cell-Free DNA BCT® Blood Collection Tube (cfDNA BCT)
- Labels for the cfDNA BCT and test requisition form (TRF)
- Foil pouch and biohazard bag with absorbent pad
- 3 oz ambient gel pack
- Cardboard exterior box
- FedEx Clinical Pak with pre-printed return shipping label
- Blood Collection Kit Instructions for Use

What you'll need that's *not* included in the blood collection kit:

- FirstLook Test Requisition Form (TRF) provided by the patient and/or prescribing healthcare provider
- If no TRF is available, contact the prescribing healthcare provider's office.
- 21G Needle, tube adapter, alcohol swab, bandage, gloves, gauze, and tourniquet

1 Blood Collection

- A.** Collect the blood by venipuncture in accordance with **CLSI GP41¹** guidance. If other tubes are being collected, draw blood in the following order:



- The cfDNA BCT tube should be drawn after an EDTA tube and before a sodium fluoride/potassium oxalate tube.



- If the cfDNA BCT immediately follows a heparin tube, collect a non-additive or EDTA tube as a waste tube prior to cfDNA BCT collection.

Note: If the cfDNA BCT is expired or damaged, or if there are missing kit components (e.g. missing label sheet), please discard the tube and its original kit. Use a new blood collection kit to complete the blood draw.

Fasting is not required prior to collecting a blood sample for the FirstLook Lung test.

- !** Below are precautions and instructions critical for ensuring a successful test result. To minimize the chance of test failure and the need for subsequent re-collection:



- Use a 21G needle. If not available, 20G or 22G needles are acceptable.

- Only use the provided labels in the kit to apply to the cfDNA BCT.

- Allow disinfectant to dry completely before initiating the blood draw.



DO NOT use a butterfly apparatus



DO NOT draw blood into a syringe and dispense into the cfDNA BCT.



- B.** Allow the tube to fill completely until the vacuum is exhausted and blood flow ceases. Fill may require **60 to 90** seconds or longer.

Note: In case of vein collapse, a second puncture and new tube may be required. If so, discard the first tube and associated blood collection kit. Use a new kit and tube.



Immediately mix the contents by gently inverting the tube 10 times. A complete **180-degree** turn and back constitutes one inversion. Inadequate or delayed mixing may have a negative effect on test performance.



DO NOT shake the tube vigorously, as this may lead to test failure and the need for subsequent re-collection.

DO NOT centrifuge the blood sample.

2 Sample Labeling



A. Affix the TRF label to the designated spot in the “Phlebotomist to Complete” section of the TRF. Write the date of collection in the adjacent field (MM/DD/YYYY).

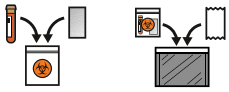


B. On the cfDNA BCT label, write the following:

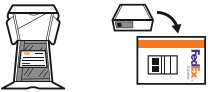
- Patient Name (First and Last)
- Patient Date of Birth (MM/DD/YYYY)

Affix the label to the tube vertically, on top of the existing label.

3 Sample Packing



A. Place the tube and absorbent pad into the biohazard bag and seal closed. Place the sealed biohazard bag and gel pack in the foil pouch and seal closed.



B. Place the foil pouch in the box with the folded TRF. Close the box and place inside the FedEx Clinical Pak, sealing closed.



C. Store blood sample at room temperature (18°–25° C; 59°–86° F).



DO NOT store tube or any part of the blood collection kit in a refrigerator or freezer.

4 Shipping

• Arrange for FedEx to pick up the blood collection kit or drop it at a staffed FedEx location.

• Contact FedEx customer service at 866-393-4585 to arrange pickup or find a staffed FedEx location.



• Ship the sample within 24 hours of collection, Monday through Friday.



DO NOT ship on Saturday or Sunday. Hold any samples collected over the weekend. Ship on Monday or the next business day.



DO NOT place the package in a drop box.

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¹ Clinical and Laboratory Standard Institute. GP41, Procedures for the collection of diagnostic blood specimens by venipuncture. Approved Standard.

The FirstLook Lung test is a laboratory-developed test. It was developed and its performance characteristics determined by DELFI Diagnostics. It has not been cleared or approved by the FDA. The laboratory is regulated under the Clinical Laboratory Improvement Act (CLIA) as qualified to perform high complexity clinical tests. This test is used for clinical purposes. It should not be regarded as investigational or for research.

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Blood collection tube manufactured by Streck, Inc.

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