

Read ALL the instructions before drawing blood.

GENERAL

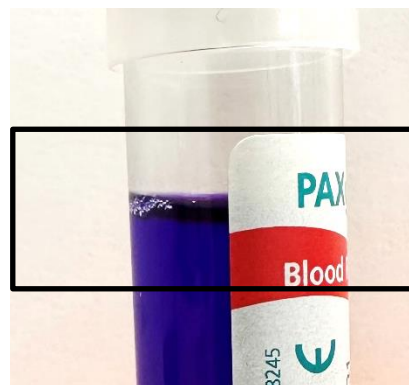
Retain this box and cooler, you will need it to return ship your sample. Each PAXgene tube contains a preservative that will prevent the breakdown of fragile RNA transcripts found in white blood cells, this is what we measure. Please keep tubes at room temperature until blood is drawn. Ship the frozen tubes back to our lab on a Monday, Tuesday or Wednesday and avoid shipping over holidays. Failure to follow this protocol precisely may render the sample unusable. A set of replacement tubes is \$50. A blank FedEx domestic airbill is included although you may use the shipper of your choice. You will be responsible for return shipping costs. Please mail patient history survey separately. Please make sure the tube numbers on your patient history survey form match the tube numbers included with this kit.

KIT CONTENTS – DO NOT THROW OUT

- Cardboard box and styrofoam cooler
- PAXgene tubes - 2
- Plastic bags – 1 small, 1 Large
- Bubble wrap sleeves - 2
- PAXgene Tube Protocol
- Patient History Survey
- Dry Ice and Fed Ex Shipping Label

IMPORTANT

PAX tubes are designed to pull 2.5 mls of blood and will produce best results with this volume. When drawing blood into the PAX vacutainer, please make sure the tubes have a volume somewhere inside the black box outlined here. **Tubes with blood volumes outside this box may be rejected by the lab.** The tube shown has been filled with 2.5 mls of blue dye. 2.5 mls of blood would fill the tube to just over the top of the red banner, which you can identify on your PAX tube. You can order replacement tubes for \$50 if needed.



DRAWING AND FREEZING

Blood MUST be drawn between the hours of 8 am and 12pm (noon). Keep your normal morning routine, you do not need to fast. Drawn blood must sit at room temperature for 4 hours and then be placed in a freezer. Therefore, only draw blood 4 hours (or more) before your office will close. Frost free freezers go through thaw/freeze cycles; this is not good for frozen tubes. If you have a frost-free freezer (if there's no frost, it's frost-free) you can only store the blood samples a few days, so best to draw the blood on a Monday or Tuesday and ship it the next day. If your freezer is not frost free (it has a build up of ice), you can store the frozen samples for several weeks.

Use only the PAXgene tubes that came with the order by matching the Tube# on the tubes with the Tube ID on the Patient History Survey and Order Form. **Record the Tube ID# in your patient's file.** Complete the information requested on each tube label. The other lab tests (see the Patient History Survey pg 2) should be completed the same day as the PAXgene draw for the best results; if the other tests are within a week that is acceptable. DO NOT PLACE EXTRA LABELS ON THESE TUBES.

1. If you are only drawing blood for PAXgene tubes, first run a small amount of blood into a waste tube to clear the line – we do not want any potential skin or vascular cells to be collected. If you are drawing other tubes, there is no need for the waste tube, but draw the others first; do not draw the PAXgene tube first as you will have to stop and invert the tubes.
2. **IMPORTANT** - Fill the 2 PAX tubes with blood drawn from a peripheral vein. Hold the PAX tube vertically below the venipuncture site during draw. The amount of blood drawn into each tube should be 2.5 mls, which can be seen in the picture above. Please try to draw the appropriate amount of

blood into each tube. Volumes below 2 mls and above 3 mls will hamper the RNA extraction process. Remove each tube from the phlebotomy sleeve sequentially. **Immediately invert the tubes at least 10 times to thoroughly mix the whole blood with the preservative to prevent clotting.** One inversion means that you hold the blood in one hand and turn your wrist over 180 degrees, briefly hold, and then back to an upright position. Clotting blood will ruin the sample.

- Place the mixed PAXgene tubes upright at room temperature for **precisely 4 hours**. Please use a timer (± 5 minutes is fine but do not let 4 hrs become 3.5 or 4.5 hrs).
- At 4 hours, place the tubes in a freezer overnight. Do not freeze the tubes on dry ice. Tubes must remain frozen until we receive them.
- Please mail the completed Patient History Survey (match the Tube ID) to Progene DX, 500 Market St., Suite 103, Pocomoke City, MD. 21851

DRY ICE INSTRUCTIONS

CAUTION: Do not touch Dry Ice with your bare hands. You will need a minimum of 6 lbs of dry ice for shipping, we recommend you add 7 lbs. However, your shipping costs will increase if the shipment weighs over 9 lbs. If you buy the Dry Ice early, you will need to start with more than 7 lbs. Its best to ship in the afternoon so the package does not sit all day losing dry ice. Use Dry Ice nuggets if possible as they fit around the tubes better. If you can only find block form dry ice, break it into small pieces but do not touch with your bare hands. Need a dry ice vendor? Try Google or <https://dryicedirectory.com>

SHIPPING WITHIN THE U.S.

Make sure your shipping location will accept packages with dry ice. Re-use the styrofoam cooler and box the PAXgene tubes arrived in. Dry Ice is considered a hazardous material for shipping. As such, you must fill out and affix the enclosed Dry Ice sticker to the outside of the box. 7 lbs is equal to 3.2 kg. This is a “non-infectious clinical sample” if you are asked by FedEx. Do not send patient paperwork with the tubes as the lab only uses the deidentified tube number for tracking due to HIPAA. When you have everything ready to ship:

- Place each frozen tube in a bubble wrap sleeve and seal the sleeve. Place the frozen tubes back into the small plastic bag and then place that bag into the EMPTY larger plastic bag and fold in half so it fits into the cooler.
- Using a minimum of 6 lbs of Dry Ice, put half the Dry Ice in the bottom of the cooler and place the bag/tubes on top. Put the remaining Dry Ice on top of the bag/tubes.
- Secure the styrofoam lid but do not seal cooler with tape. Close and tape the outer cardboard box with packing tape.
- Ship the frozen tubes Priority Overnight ONLY on Monday, Tuesday or Wednesday.** You can use the FedEx airbill included in the kit, or one from a similar shipping vendor, and address to:
Jim Ryan
Progene DX
19A Crosby Dr, Suite 205
Bedford, MA 01730
(410)-957-1550
- After FedEx takes the package, please email info@progenedx.com with your shippers tracking number and the Tube ID#s on the paperwork.
- Please track your package if you would like to know if it arrived safely at the lab, we will only notify you if there was a problem. Results will take approximately 3 weeks, please check www.progenedx.com for current processing times.

Questions or comments: Contact Debbie Waidner at info@progenedx.com, or (410) 957-1550.