

Established guidelines for specimen submission and stability

Follow the steps outlined in this document to ensure the accuracy and integrity of the Galleri™ Multi-Cancer Early Detection Test results.

The Galleri test specimen overview

The Galleri specimen collection kit contains the tubes and labels required for sample collection. In some scenarios, the patient will deliver the test kit to the lab instead of being available on-site. The test kit is sealed for quality assurance. Before collecting your specimen, check that the kit is not expired.

Specimen type:

Human whole blood

Container:

Streck Cell-Free DNA® Blood Collection Tubes

Volume:

Two (2) tubes (10 mL each)

Sample storage:

Ambient temperature (not to extend outside the 6–37 degrees Celsius range)

Stability:

Up to seven (7) calendar days

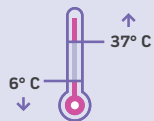
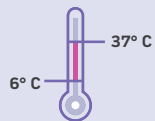
There are two versions of the Galleri test kit: The Standard Kit, which is used when temperatures are mild and samples will remain thermally stable in transit, and the Extreme Temperatures Kit, which is used when samples may be exposed to extreme temperatures in transit.

Standard Temperatures:

between 6 and 37 degrees Celsius

Extreme Temperatures:

below 6 degrees or above 37 degrees Celsius



More information on the contents of the kit are provided in the "Packing + shipping a specimen" instructions.

Instructions

Step 1

Print the patient's identifying information on each label used, including the following:

- Full legal name
- Date of birth (MM/DD/YYYY)
- Biological sex
- Medical record number (if applicable)



Four labels are included on the blood tube label page in the document pouch inside the test kit. The primary blood tube labels are labeled A1 and A2. Extra backup labels are provided if needed and are labeled A3 and A4.

Step 2

To attach the label to the tube, place the tube on its side and align the red dot on the new label over the red owl icon on the existing tube label.



Be sure to label the specimen tubes before you perform the blood draw. Ensure that the patient's identifiers match what is included on the Test Requisition Form (TRF). In order for the sample to be processed, completed labels must be attached to the blood tubes as follows so that the laboratory's automated machinery has a clear view of the sample.

Step 3

Affix the TRF label from the label page to the upper right corner of the TRF in the field labeled "GRAIL ID" to link the TRF to the blood tubes. If using the Provider Portal to submit the test order, record the GRAIL ID on the electronic TRF.

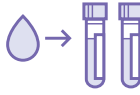


Do NOT attach any other labels to the collection tube.

- The unique identifier on each label, known as the GRAIL ID, is used to identify and link the entire patient experience. Use this identifier to reference the patient's encounter when speaking with GRAIL Customer Service.
- All specimens submitted for testing must be labeled with a minimum of two unique patient identifiers that exactly match the patient information on the Test Requisition Form (TRF).

Step 4

Before collecting the specimen, verify the patient's identity. Draw the patient's blood. For best results, use a 21- or 22-gauge needle to collect the patient's blood sample. If a "butterfly" draw set is used, it is recommended that an EDTA discard tube be partially drawn per standard procedure prior to filling the Streck tube to remove air from the tubing.



- Due to the chemical additives in Streck tubes, it is important to avoid backflow from the tube during blood draw. To prevent backflow:
 - a. Keep the patient's arm in the downward position during the collection procedure.
 - b. Hold the tube with the stopper in the uppermost position so that the tube contents do not touch the stopper or the end of the needle during sample collection. Release the tourniquet once blood starts to flow into the tube or within two minutes of application.
- The Galleri test requires two Streck tubes with 10 mL of blood in each tube. If 10 mL cannot be collected from the patient, there should be no less than 3 mL of blood in each tube.
- The blood collection tubes provided for the Galleri test are designed for direct blood draws. Transferring a blood specimen collected with a syringe and needle into the blood collection tube or transferring from other tubes is not permitted. Follow the order of draw recommendations outlined by the Clinical & Laboratory Standards Institute Collection of Diagnostic Venous Blood Specimens (GP41).
- The only acceptable specimen type for the Galleri test is human whole blood collected in Streck Cell-Free DNA® Blood Collection Tubes. Specimens exposed to tubes other than Streck Cell-Free DNA® Blood Collection Tubes cannot be tested even if transferred into these Streck tubes.

Specimen rejection criteria

If the minimum specimen requirements are not met, the sample submitted may be rejected and the test canceled. GRAIL Customer Service will communicate any rejections or cancellations to the ordering healthcare provider. The rejection criteria are:

- Tubes other than Streck Cell-Free DNA® Blood Collection Tubes
- Less than 3 mL of whole blood per collection tube
- Any specimen type other than human whole blood
- Unlabeled specimens
- Severely damaged or dangerously packaged specimens
- Specimens with grossly hemolyzed plasma
- Specimens submitted or stored at a temperature outside of 6–37 degrees Celsius
- Collection date more than seven days prior to the start of processing

Step 5

Gently mix with 10 complete inversions.
Do NOT refrigerate or freeze.



Step 6

After specimen collection, store at an ambient temperature (between 6 and 37 degrees Celsius). Specimens should never be frozen, refrigerated, or exposed to excessively hot temperatures, and they must be tested within seven days of collection.



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