Guidelines for Sample Collection and Shipping

Labeling:

In addition to general information required, please complete the **Molecular Diagnostic Requisition Form**. The pre-analytical diagnostic information is important for reporting results with accurate interpretations.

The information required is as follows:

- Ethnic background
- Specific test requested
- Indication of testing/study (diagnostic, carrier or prenatal)
- Family history of the disease tested for
- If the family history is known for the patient, provide the relationship
- Known family mutations. If the family history is known, provide the mutation of the affected family member if possible.

Extracted DNA Samples:

DNA can be shipped to PrimBio Research Institute LLC for use in our genetic tests, and this is often the best choice for international samples. If available, please provide information about the concentration of DNA in the sample. DNA can be shipped frozen, refrigerated, or at room temperature. 1ug of DNA at a concentration of 50 ng/ul is recommended.

FFPE Slides:

1 H&E and 2-7 unstained 5-10 µm FFPE slides containing adequate amounts of tumor to be analyzed with areas of tumor marked on the H&E. A copy of the corresponding surgical pathology report must accompany the sample(s). FFPE slides can be sent at ambient temperature.

Blood:

Blood can be collected in Lavender top tube (EDTA) or Yellow top tube (ACD). If there is a copy of the corresponding surgical pathology report, please send it with the sample(s). Blood can be sent at ambient temperature. 1-2 cc of blood is recommended.

Fresh frozen Tissue:

Primbio accepts fresh frozen tissue snap frozen in liquid nitrogen and stored at -80˚C. 100-200 mg of tissue is recommend. Tissues must be transported on dry ice overnight.

Packaging and Shipping:

1. Wrap the tube or slides in bubble wrap or other protective material and place inside a sealed plastic bag.

2. Place bag containing sample in a Styrofoam shipping box with a cool pack for DNA in the summer months. DNA, blood and FFPE slides can also be shipped at room temperature in weather permitting conditions.
3. Place the completed **Molecular Diagnostic Requisition Form**, including the signed **Consent Document**, and **Payment Option**, as well as any other paperwork in another sealed plastic bag or envelope.
4. Ship the sample by an overnight or second-day carrier, to arrive on a weekday (Monday through Friday).

Ship samples to the following address:

PrimBio Research Institute, LLC
665 Stockton Dr, STE 200-I
Exton, PA 19341 USA

If you have any questions, please call PrimBio at (610)-458-1112.

Criteria for Rejection:

FFPE Slides:

1. Specimen is received with no patient identifiers.
2. Patient identifier on slides DOES NOT match the requisition.
3. H&E slide is missing, or tumor areas are not marked.
4. Pathologist report is missing.
5. No requisition form submitted.
6. Quantity of specimen is insufficient for testing.
7. Specimen container and/or slides are damaged.
8. Specimen quality is compromised beyond ability to complete testing and provide accurate results.

Extracted DNA Samples and Blood Specimens:

1. Specimen container is received with less than two patient identifiers.
2. Patient identifiers on the specimen container DO NOT match the requisition.
3. No requisition form submitted.
4. Quantity of specimen is insufficient for testing.
5. Specimen has leaked or spilled.
6. Incorrect tube, container, or shipping conditions.
7. Specimen is outside of established stability requirements (too long in transit or at high temperature).

8. Specimen quality is compromised at or beyond ability to complete testing and provide accurate results.
9. Specimen contamination suspected.

Exceptions

It must be understood that the aforementioned criteria for rejection are appropriate in order to assure quality laboratory testing. However, it is also understood that there may be circumstances in which outright rejection of certain specimens would be harmful to the patient. Each situation must be considered on a case by case basis. Laboratory Director or designee approval is required in order to process specimens as exceptions. In situations involving specimen identification which have been deemed qualified for exception, written documentation must be obtained from the clinician, attesting to the veracity of the identifying information.

Examples of such situations in which exceptions to the rejection criteria may be applied, with approval, include precious or irreplaceable specimens, such as excision biopsies, specimens which are hard on the patient to collect, such as bone marrow aspirates, or situations in which imminent harm could come to the patient if testing is not performed.