

Sample and Shipping Information

Currently PrimBio accepts extracted DNA samples and FFPE sections.

Labeling:

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

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 family history is known for the patient, provide the relationship
- Known family mutations. If the family history is known, provide the mutation(s) of the affected family member(s) if is 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. DNA can be shipped frozen, refrigerated, or at room temperature. If available, please provide information about the concentration of DNA in the sample.

FFPE Slides:

1 H&E and 10-20 unstained 5-10 μm FFPE slides containing adequate amounts of tumor to be analyzed with areas of tumor marked clearly on the H&E section. A copy of the corresponding surgical pathology report must accompany each sample. The FFPE slides can be sent at ambient temperature.

Packing 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. Both DNA and FFPE slides can also be shipped at room temperature during non-summer months.

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:

The criteria listed below shall result in specimen rejection.

1. Specimen received with less than two less than two patient identifiers. Two patient identifiers are required, with the exception of FFPE slides, for which only one acceptable patient identifier is required (per College of American Pathologists specimen identification and labeling standards).
2. Copy of corresponding surgical pathology report not provided if the specimen are FFPE slides.
3. Patient name or other appropriate unique identifiers on the specimen DO NOT match, when compared with the requisition.
4. Specimen is damaged and cannot be used for further processing.
5. Specimen is outside of established stability requirements.
6. Specimen handling has compromised the integrity of the specimen (e.g., not stored, or prepared according to testing requirements; frozen specimens and specimens fixed/processed in alternative fixatives)
7. Specimen quality is compromised at or beyond the ability to complete testing and provide accurate results (e.g., no tumor in tissue, quality not sufficient [QNS]).
8. Specimen contamination (e.g., bacteria, collection, or genome).

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: 1) precious or irreplaceable specimens, such as excision biopsies, 2) specimens which are hard on the patient to collect, such as bone marrow aspirates, or 3) situations in which imminent harm could come to the patient if testing is not performed.