



SPECIMEN COLLECTION AND TRANSPORT MANUAL



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Introduction

The **PrimBio Specimen Collection and Transport Manual** has been developed to provide information about specimen collection, specimen identification, specimen submission, laboratory procedures, and specimen results reporting.

The meaningfulness of clinical laboratory results is directly related to the quality of the specimen submitted for analysis. Proper collection, labeling, storage, and shipment of specimens are the responsibility of the specimen collector.

If you have questions not adequately addressed in this manual, please call the laboratory for further information. Laboratory staff are available to help solve administrative and technical problems and answer questions. In most cases, turn-around time for NGS testing is 14-21 days, excluding weekends and holidays.

"A laboratory test is no better than the specimen
and the specimen no better than the method by
which it was collected."¹

¹Becton Dickinson and Company. Joseph Kleiner and the origins of the Vacutainer™. The Echo. Beckton Dickinson and Company, Franklin Lakes, NJ; 1991 (Spring; 11:3-5, 1991 (September); 11.5-7; 1996 (December); 16:1.

For questions regarding specimen requirements, please contact us at:

PrimBio Research Institute

665 Stockton Dr. 200I

Exton, PA 19341

Email: primbiobiz@primbioresearch.com

Phone: 610-458-1112

Fax: 610-458-1114



Extracted DNA

DNA can be shipped to PrimBio Research Institute for use in our molecular diagnostic tests only if the extraction is performed in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS. This is often the best choice for international samples. If available, please provide information about the concentration of DNA in the sample. The recommended amount is 100 ng of DNA at a concentration of 5-10 ng/ μ l.

Patient Identification and Specimen Labeling:

It is **imperative** that the tube(s) containing patient DNA are labeled with at least two unique identifiers, such as patient name, DOB, social security number, barcode ID #, and/or medical record number. Less than two unique identifiers will result in specimen rejection when the specimen is processed by the laboratory.

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 required
- 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 when possible)

Specimen Storage and Transport:

Extracted DNA is typically stored at -20°C . However, literature shows that DNA is stable for up to 6 months at room temperature if eluted using nuclease-free water. Thus, extracted DNA can be shipped at room temperature.

At intervals decided on by the clinic, specimens should be shipped to the laboratory. Follow the instructions below to properly ship your specimens.

Storage Temperature	Stability
-20°C	Indefinitely
Room temperature	6 months



Shipping Instructions:

1. Tube(s) containing DNA must be tightly sealed, wrapped in parafilm and placed inside sealed plastic bag.
2. Ensure each tube has patients name and date of birth.
3. Place bag containing sample in the provided bubble wrap shipping envelope or similar container.
4. Place completed **Molecular Diagnostic Requisition Form**, including the signed **Consent Document**, **Payment Option**, as well as any other paperwork in another sealed plastic bag or envelope.
5. Ship the sample by an overnight carrier or second-day carrier, to arrive on a weekday (Monday through Friday).
6. Ship sample to the following address:
PrimBio Research Institute, LLC
665 Stockton Drive, STE 200I
Exton, PA 19341 USA

Criteria for Rejection:

1. Specimen is received with no patient identifiers.
2. Patient identifier on tube(s) does not match the requisition.
3. Pathologist report is missing.
4. No requisition form submitted with sample.
5. Quantity of specimen is insufficient for testing.
6. Tube containing specimen is damaged.
7. Specimen quality is compromised beyond ability to complete testing and provide accurate results.

Improperly Identified and Rejected Specimens

Unlabeled or mismatched (name and patient ID number / DOB on specimen does not match name and patient ID number / DOB on requisition) specimens will be held for testing until proper documentation is received by the laboratory. A form will be provided for the clinician to fill out and return to the laboratory.

The laboratory will notify the ordering clinician or requesting client if a specimen is unacceptable by providing a patient report identifying the reason for rejection and recommend that the specimen be recollected. Exceptions may be made based upon client impact and/or for precious specimens. These exceptions are handled on an individual basis by the laboratory.



FFPE Slides

A formalin fixed paraffin embedded (FFPE) block must be sectioned into 2 – 10 consecutive 5 – 15 µm sections and place onto positively charged slides. The first slide should be stained with H&E and given to a pathologist for review. The **pathologist should clearly circle the tumor area in the H&E stained slide** and submit it with 2-10 unstained slides. FFPE slides that do not have an H&E stained slide with tumor regions clearly marked will be rejected unless otherwise directed by the ordering physician.

Patient Identification and Specimen Labeling Steps:

It is **imperative** that the slides are labeled with at least two unique identifiers, such as patient name, DOB, social security number, barcode ID #, and/or medical record number. Less than two unique identifiers will result in specimen rejection when the specimen is processed by the laboratory.

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 required
- 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 when possible)

Specimen Storage and Transport:

Specimens may be stored and shipped at room temperature.

At intervals decided on by the clinic, specimens should be shipped to the laboratory. Follow the instructions below to properly ship your specimens.

Storage Temperature	Stability
Room temperature	14 days



Shipping Instructions:

1. Place slides in a slide case and place case inside a sealed plastic bag.
2. Include patients name and date of birth on each slide case.
3. Place bag containing sample in the provided bubble wrap shipping envelope or similar container.
4. Place completed **Molecular Diagnostic Requisition Form**, including the signed **Consent Document**, **Payment Option**, as well as any other paperwork in another sealed plastic bag or envelope.
5. Ship the sample by an overnight carrier or second-day carrier, to arrive on a weekday (Monday through Friday).
6. Ship sample to the following address:
PrimBio Research Institute, LLC
665 Stockton Drive, STE 200I
Exton, PA 19341 USA

Criteria for Rejection:

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 with sample.
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.

Improperly Identified and Rejected Specimens

Unlabeled or mismatched (name and patient ID number / DOB on specimen does not match name and patient ID number / DOB on requisition) specimens will be held for testing until proper documentation is received by the laboratory. A form will be provided for the clinician to fill out and return to the laboratory.

The laboratory will notify the ordering clinician or requesting client if a specimen is unacceptable by providing a patient report identifying the reason for rejection and recommend that the specimen be recollected. Exceptions may be made based upon client impact and/or for precious specimens. These exceptions are handled on an individual basis by the laboratory.



Blood

Blood must 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). The recommended amount is 1 – 2 cc of blood.

Patient Identification and Specimen Labeling Steps:

It is **imperative** that the collection tube(s) are labeled with at least two unique identifiers, such as patient name, DOB, social security number, barcode ID #, and/or medical record number. Less than two unique identifiers will result in specimen rejection when the specimen is processed by the laboratory.

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 required
- 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 when possible)

Specimen Storage and Transport:

Specimens may be stored at room temperature for up to one week at room temperature. If stored longer, specimens must be kept at 2-8°C (refrigerated temperature). Specimens may be stored refrigerated up to two weeks before being shipped to the laboratory.

At intervals decided on by the clinic, specimens should be shipped to the laboratory. Follow the instructions below to properly ship your specimens.

Storage Temperature	Stability
Refrigerated (2-8°C)	14 days
Room temperature	7 days
Note: Do not ship samples on Fridays. Ship next-day air Monday-Thursday.	



Shipping Instructions:

1. Collect blood in provided lavender (EDTA) or yellow (ACD) tubes.
2. Label each tube with patients name and date of birth.
3. Place collection tube in the provided bubble wrap shipping envelope or similar container.
4. Place completed **Molecular Diagnostic Requisition Form**, including the signed **Consent Document**, **Payment Option**, as well as any other paperwork in another sealed plastic bag or envelope.
5. Ship the sample by an overnight carrier or second-day carrier, to arrive on a weekday (Monday through Friday).
6. Ship sample to the following address:
PrimBio Research Institute, LLC
665 Stockton Drive, STE 2001
Exton, PA 19341 USA

Criteria for Rejection:

1. Specimen is received with no patient identifiers.
2. Patient identifier on vial does not match the requisition.
3. No requisition form submitted with sample.
4. Quantity of specimen is insufficient for testing.
5. Specimen container and/or slides are damaged.
6. Specimen quality is compromised beyond ability to complete testing and provide accurate results.

Improperly Identified and Rejected Specimens

Unlabeled or mismatched (name and patient ID number / DOB on specimen does not match name and patient ID number / DOB on requisition) specimens will be held for testing until proper documentation is received by the laboratory. A form will be provided for the clinician to fill out and return to the laboratory.

The laboratory will notify the ordering clinician or requesting client if a specimen is unacceptable by providing a patient report identifying the reason for rejection and recommend that the specimen be recollected. Exceptions may be made based upon client impact and/or for precious specimens. These exceptions are handled on an individual basis by the laboratory.



Saliva

Saliva is collected using the DNA-Sal collection kit provided by PrimBio. Patients should not eat, drink beverages or coffee, brush their teeth or smoke at least one hour prior to collection. Patients should follow instructions provided in kit or ask physician or nurse for assistance when collecting samples. Recommended amount of saliva, including rinse and cells is approximately 1-2 cc.

Patient Identification and Specimen Labeling Steps:

It is **imperative** that the collection tube(s) are labeled with at least two unique identifiers, such as patient name, DOB, social security number, barcode ID #, and/or medical record number. Less than two unique identifiers will result in specimen rejection when the specimen is processed by the laboratory.

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 required
- 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 when possible)

Specimen Storage and Transport:

Specimens may be stored at room temperature for up to one week at room temperature. If stored longer, specimens must be kept at 2-8°C (refrigerated temperature). Specimens may be stored refrigerated up to two weeks before being shipped to the laboratory.

At intervals decided on by the clinic, specimens should be shipped to the laboratory. Follow the instructions below to properly ship your specimens.

Storage Temperature	Stability
Refrigerated (2-8°C)	14 days
Room temperature	7 days

Note: Do not ship samples on Fridays. Ship next-day air Monday-Thursday.



Shipping Instructions:

7. Collect saliva in the provided collection tube and follow the DNA-Sal collection instructions located inside the collection kit.
8. Label each tube with patients name and date of birth.
9. Place collection tube in back in provided box or similar container.
10. Place completed **Molecular Diagnostic Requisition Form**, including the signed **Consent Document**, **Payment Option**, as well as any other paperwork in the box.
11. Ship the sample by an overnight carrier or second-day carrier, to arrive on a weekday (Monday through Friday).
12. Ship sample to the following address:
PrimBio Research Institute, LLC
665 Stockton Drive, STE 200I
Exton, PA 19341 USA

Criteria for Rejection:

1. Specimen is received with no patient identifiers.
2. Patient identifier on vial does not match the requisition.
3. No requisition form submitted with sample.
4. Quantity of specimen is insufficient for testing.
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The laboratory will notify the ordering clinician or requesting client if a specimen is unacceptable by providing a patient report identifying the reason for rejection and recommend that the specimen be recollected. Exceptions may be made based upon client impact and/or for precious specimens. These exceptions are handled on an individual basis by the laboratory.



Results Reporting

In general, routine clinical lab results will be available within 14-21 days of the time the specimen is received in the laboratory. Any inquiries regarding results can be made by calling the laboratory.

Reports will be either emailed through encrypted email or accessible from our HIPAA compliant Portal as soon as they are reviewed and approved by the medical director or designee. An email will be auto-generated to notify the ordering clinician that their patients' results are ready to view.

Results can also be faxed or mailed via the United States Postal Service, upon request.

Test	Turnaround Time
PrimBio Cancer Hotspot Panel	≤14 business days
PrimBio Colorectal Cancer Panel	14-21 business days
PrimBio Breast Cancer Therapy Panel	14-21 business days

Add-on Test Requests

If additional testing is desired after the specimen has been shipped to the laboratory within the specimen stability guidelines, you may send a test request to the laboratory. Be sure to record the correct date of collection on the requisition so that the specimen can be easily located.

Specimens are retained on site for 14 days after the collection date. Add-on testing can be ordered for any specimen by submitting a requisition for this testing via mail or fax.

Verbal add-on test requests will not be accepted.



Sample Submission Checklist

1. Molecular Diagnostic Requisition Form

- Attached or can be downloaded at <http://www.primbioresearch.com/cancer-hotspot-panel.html>
- Physician Signature required on page 1
- Select appropriate test on page 2
- Patient Consent Signature required on page 3
- Discuss the possible financial responsibility with patient (see next page)
- Fill in the Patient Billing Information, and retain Patient Signature on page 4 for paying the balance after insurance reimbursement or decline

2. Copy of Patient Insurance Card(s)

3. Copy of Patient Credit Card

4. Copy of Patient ID

5. Please send the completed items 1-4 above to the pathology lab.

6. Pathologists:

- Sample Submission Guidelines are attached or can be downloaded at <http://www.primbioresearch.com/cancer-hotspot-panel.html>
- If applicable, please circle the tumor regions on the H&E slide or you can make a paper copy and circle the tumor regions on the paper
- Attach the Patient Pathological Report