

Guide to **Sample Submission and Shipping**

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.



Table of Contents

Overview	3
Preparing Your Samples	4
Volume, Concentration, and Quality Requirements by Product.....	4
Acceptable Specimen Containers.....	8
Filling a BCL-Provided Nucleic Acid Sample Kit.....	9
Guidelines for Using Non BCL-Supplied Barcode Labels.....	10
Protected Health Information.....	10
Barcode Information.....	11
Additional Label Attributes to Consider.....	12
Label Placement.....	12
Clinical Collection Dates.....	13
Research Sample Metadata Sheet.....	13
Shipping Your Samples to BCL	14
How to Package.....	14
Shipping Requirements for Category B Substances & Dry Ice.....	16
Shipping Manifest Completion.....	17
Shipping Address.....	17
Shipping Options.....	18
Fedex, UPS, or World Courier.....	18
Burlington Walk-in Drop Off at 27 Blue Sky Drive, Burlington, MA.....	18
Central Cambridge Broad Drop Off - Internal Broad Users.....	18
Holiday Schedule & Closures.....	19
Blue Sky Drive Sample Drop Off Instructions	20
Locker Operation Guide.....	21

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Overview

This document should be used as a guide for preparing, packaging, and shipping samples to the Broad Clinical Labs Burlington, MA facility for processing and data generation. The document covers guidelines for samples intended for both research and clinical data generation products, with any differences highlighted.

For BCL to receive and process samples in a timely manner, please follow all of these guidelines, which are detailed in this document:

1. Ensure samples meet the volume, concentration, and quality requirements for the relevant product(s) and are stored in acceptable specimen containers.
2. Follow instructions for completing and submitting the Sample Metadata Sheet.
3. For BCL to receive and process samples in a timely manner please follow all applicable guidelines detailed in this document.
4. Include a [Shipment Manifest](#).
5. Unless delivering samples by [walk-in drop-off](#), local courier, or the [Broad Institute truck](#) (Broad Institute users only), ship samples to the following address:

**Broad Clinical Labs
Receiving Lab 132
27 Blue Sky Drive
Burlington, MA 01803
(617) 714-8952**

Proper packing and shipment of samples to Broad Clinical Laboratories (BCL) LLC is vital to ensure samples are not compromised during transit. Samples that are shipped must adhere to the BCL collection, concentration, volume and quality requirements. Shipments or individual samples that do not adhere to the requirements outlined in this document may be quarantined, issued a "Test Not Performed" (TNP) result, and/or be rejected from further processing.

If you have questions about or are unable to meet any of the guidelines in this document, please reach out to your Project Manager or to bcl-support@broadinstitute.org for assistance.

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Preparing Your Samples

If you are unsure of the product workflow for which the samples you are preparing and sending are destined (this includes understanding whether the workflow is a clinical test or intended for research use only), it is critical that you contact either your project manager or bcl-support@broadinstitute.org for assistance.

Volume, Concentration, and Quality Requirements by Product

Sample volume, concentration, and quality requirements differ by product. The tables below should be used as a guide. They include acceptable volume and concentration ranges for the products offered at Broad Clinical Laboratories, as well as quality specifications where relevant.

If you have questions or are unable to meet the sample requirements specified in the table, please contact your project manager or bcl-support@broadinstitute.org for assistance.

Research Products

Product	Acceptable Input Materials	Research Volume/Concentration/Quality Requirements
Research Blended Genome-Exome (BGE)	<ul style="list-style-type: none"> Whole Blood Saliva Cell Pellet/Cell Suspension Buccal Swab Buffy Coat Genomic DNA (gDNA) extracted from the aforementioned materials 	<p>Whole Blood: 1 – 2 mL</p> <p>Saliva: 2 mL [>1 mL saliva & 1 mL of buffer] – 4 mL [>2 mL saliva & 2 mL of buffer]</p> <p>Cell Pellet: 1 – 2×10^6 cells</p> <p>Buccal Swab: swab in 4 mL of buffer</p> <p>Genomic DNA: 15 ng/μL – 110 ng/μL concentration; 50 μL – 300 μL preferred volume, 30 μL minimum acceptable volume</p>
Research PCR-Free Whole Genome Sequencing (WGS)	<ul style="list-style-type: none"> Whole Blood Saliva Buccal Swab Buffy Coat Fresh Frozen Tissue Cell Pellet Genomic DNA (gDNA) extracted from the aforementioned materials Genomic DNA extracted from Peripheral Blood Mononuclear Cells (PBMC) and Polymorphonuclear Leukocytes (PMN) 	<p>Whole Blood: 1– 2 mL</p> <p>Saliva: 2 mL [>1 mL saliva & 1 mL of buffer] – 4 mL [>2 mL saliva & 2 mL of buffer]</p> <p>Buccal Swab: Swab in 4mL of buffer</p> <p>Buffy Coat: 1 mL</p> <p>Fresh Frozen Tissue: 2 – 30 mg</p> <p>Cell Pellet: 1 – 2×10^6 cells</p> <p>gDNA: ≥ 1 μg total at 10 – 110 ng/μL concentration; 50 – 300 μL preferred volume, 30 μL minimum acceptable volume'</p>
PCR+ Whole Genome Sequencing (WGS)	<ul style="list-style-type: none"> FFPE Scrolls FFPE Slides Genomic DNA (gDNA) derived from the aforementioned materials Genomic DNA (gDNA) derived from Whole Blood, Saliva, Buccal Swab, Buffy Coat, Fresh Frozen Tissue, Peripheral Blood Mononuclear Cells (PBMC), Polymorphonuclear Leukocytes (PMN), or Cell Pellet that does not meet minimum input specifications for PCR-Free WGS 	<p>FFPE Scrolls: 2 – 3 scrolls (30 μm thick, 250 mm² surface area)</p> <p>FFPE Slides: 6 – 8 sections (10 μm thick, 250mm² surface area)</p> <p>gDNA: ≥ 300 ng total in 50 – 300 μL volume; 6 – 110 ng/μL preferred concentration, 3 ng/μL minimum acceptable concentration</p>

Table continues on next page.

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Product	Acceptable Input Materials	Research Volume/Concentration/ Quality Requirements
Long Read Whole Genome Sequencing	<ul style="list-style-type: none"> High Molecular Weight Genomic DNA (HMW gDNA) 	HMW gDNA: ≥4 µg total <i>for single attempt</i> (preferred ≥8 µg total); 50 – 300 µL volume; 37 – 110 ng/µL concentration
Research Somatic Exome	<ul style="list-style-type: none"> Whole Blood Saliva Buccal Swab Buffy Coat FFPE Scrolls FFPE Slides Cell Pellet Fresh Frozen Tissue Genomic DNA (gDNA) derived from the aforementioned materials 	<p>Whole Blood: 1 – 2 mL</p> <p>Saliva: 2 mL [>1 mL saliva & 1 mL of buffer] – 4 mL [>2 mL saliva & 2 mL of buffer]</p> <p>Buccal Swab: Swab in 4mL of buffer</p> <p>Buffy Coat: 1 mL</p> <p>FFPE Scrolls: 2 – 3 scrolls (30µm thick, 250mm² surface area)</p> <p>FFPE Slides: 6 – 8 sections (10 µm thick, 250mm² surface area)</p> <p>Cell Pellet: 1 – 2 x 10⁶ cells</p> <p>Fresh Frozen Tissue: 2 – 30 mg</p> <p>gDNA: ≥500 ng total; 50 – 300 µL volume; 10 – 110 ng/µL concentration preferred, 5 ng/µL minimum acceptable concentration</p>
Plasma Proteomic Profiling	<ul style="list-style-type: none"> Human Plasma (EDTA Plasma, Citrate Plasma, Heparin Plasma) 	Plasma: 40 µL
Microbial Whole Genome Sequencing (WGS)	<ul style="list-style-type: none"> Stool Genomic DNA (gDNA) derived from stool, microbial isolates, or metagenomic samples 	<p>Stool: 75 – 150 mg (100 mg preferred)</p> <p>gDNA: ≥60 ng total; 50 – 300 µL volume; 10 – 110 ng/µL preferred concentration, 2 ng/µL minimum acceptable concentration</p>
Includes the following products		
High, Mid & Low Output Tagmentation-Based Microbial WGS		
Mid Output Non-Tagmentation-Based Microbial WGS		
Cell-free Tumor DNA Profiling via Liquid Biopsy	<ul style="list-style-type: none"> Whole Blood Plasma Urine Cerebrospinal Fluid (CSF) Cell-free DNA (cfDNA) derived from the aforementioned materials 	<p>Whole Blood: 5 – 10 mL</p> <p>Plasma: 4 – 10 mL; 6.3 mL preferred</p> <p>Urine: 4 – 10 mL; 6.3 mL preferred</p> <p>CSF: 4 – 10 mL; 6.3 mL preferred</p> <p>cfDNA: 5 – 50 ng total</p>

Table continues on next page.

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Product	Acceptable Input Materials	Research Volume/Concentration/Quality Requirements
Transcriptome Capture (TCAP)	<ul style="list-style-type: none"> • FFPE Scrolls • FFPE Slides • RNA derived from the aforementioned materials 	<p>FFPE Scrolls: 2 – 3 scrolls (30 µm thick, 250 mm² surface area)</p> <p>FFPE Slides: 6 – 8 sections (10 µm thick, 250 mm² surface area)</p> <p>RNA: ≥1 µg total; 50 – 300 uL volume; 85 – 110 ng/uL concentration; DV 200 score >30%</p>
Whole Transcriptome Sequencing	<ul style="list-style-type: none"> • PAXgene Preserved Whole Blood • Fresh Frozen Tissue • Cell Pellet • RNA derived from the aforementioned materials, or from Whole Blood 	<p>PAXgene Preserved Whole Blood: 10 mL</p> <p>Fresh Frozen Tissue: 2 – 30 mg</p> <p>Cell Pellet: 1 – 2 x 10⁶ cells</p> <p>Total RNA: ≥800 ng total; 50 – 300 µL volume; 10 – 110 ng/µL concentration preferred, 6.5 ng/µL minimum acceptable concentration; RQS > 5.5 required, RQS >7 preferred</p>
Total RNA Sequencing	<ul style="list-style-type: none"> • PAXgene Preserved Whole Blood • RNA derived from PAXgene Preserved Whole Blood or from Whole Blood 	<p>PAXgene Preserved Whole Blood: 10mL</p> <p>RNA: ≥2 µg total; 50 – 300 µL volume; 40 ng/µL concentration; A260/230 >1.5; RQS > 5.5 required, RQS >7 preferred</p>
Long Read RNA Isoform Sequencing (MAS-Seq)	<ul style="list-style-type: none"> • High quality RNA derived from any eukaryotic source 	<p>RNA: 50 – 300 µL preferred volume, 30 µL minimum acceptable volume; 45 – 110 ng/µL concentration; RQS > 7</p>
Sequencing of Customer-Prepared Libraries (Walk-up Sequencing) (all products)	*Please find input requirements and other specifications here	*See link

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Clinical Products

Product	Acceptable Input Materials	Clinical Volume/ Concentration/ Quality Requirements
Clinical Technical Blended Genome-Exome (BGE)	<ul style="list-style-type: none"> • Whole Blood • Saliva • Genomic DNA (gDNA) extracted from the aforementioned materials in a CLIA-certified laboratory. 	<p>Whole Blood: 1 – 2 mL</p> <p>Saliva: 2 mL [≥1 mL saliva + 1 mL of buffer] – 4 mL [2 mL saliva & 2 mL buffer]</p> <p>gDNA: 50 – 300 µL preferred volume, 30 µL minimum acceptable volume; 15 – 110 ng/µL concentration</p>
Clinical Technical PCR-Free Whole Genome Sequencing (WGS), Clinical PCR-Free WGS with Interpretation (Panel or Whole Genome Analysis)	<ul style="list-style-type: none"> • Whole Blood • Saliva/Buccal Swab • Buffy Coat • Genomic DNA (gDNA) extracted from the aforementioned materials* • Genomic DNA (gDNA) extracted from Peripheral Blood Mononuclear Cells (PBMC) and Polymorphonuclear Leukocytes (PMN)* <p>*in a CLIA-certified laboratory.</p>	<p>Whole Blood: 1 – 2 mL</p> <p>Saliva: 2 mL [≥1 mL saliva + 1 mL of buffer] – 4 mL [2 mL saliva & 2 mL buffer]</p> <p>Buccal Swab: Swab in 4mL of Buffer</p> <p>Buffy Coat: 1 mL</p> <p>gDNA: ≥1 µg total at 10 – 110 ng/µL concentration; 50 – 300 µL preferred volume, 30 µL minimum acceptable volume</p>
Clinical Somatic Exome	<ul style="list-style-type: none"> • FFPE Scrolls • FFPE Slides • Whole Blood • Buffy Coat • Saliva • Genomic DNA (gDNA) extracted from the aforementioned materials in a CLIA-certified laboratory. 	<p>FFPE Scrolls: 2 – 3 scrolls (30 µm thick, 250 mm² surface area)</p> <p>FFPE Slides: 6 – 8 sections (10 µm thick, 250 mm² surface area)</p> <p>Whole Blood: 1 – 2 mL</p> <p>Buffy Coat: 1 mL</p> <p>Saliva: 2 mL [≥1 mL saliva & 1 mL of buffer] – 4 mL [2 mL saliva & 2 mL of buffer]</p> <p>gDNA: ≥500 ng total; 50 – 300 µL volume; 10 – 110 ng/µL concentration preferred, 5 ng/µL minimum acceptable concentration</p>

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Acceptable Specimen Containers

*If unable to use the container(s) specified below for research products, please reach out to your project manager.

Please note: all listed specimen containers are not accepted for every product. Should you have questions, reach out to your PM or contact bcl-support@broadinstitute.org.

Material Type	Acceptable Specimen Container(s)*
Whole Blood	10 mL Blood Tubes with Tube Size: 16 mm x 100 mm, e.g. similar to K2EDTA (BDAM367525): VWR EDTA BD Vacutainer 4 mL Blood Tubes with Tube Size: 13 mm x 75 mm, e.g. similar to BD Vacutainer® EDTA Tubes (367861): BD Vacutainer
Whole Blood (RNA)	2.5 mL Blood Tubes with Tube Size: 16 mm x 100 mm, PAXgene Blood RNA Tube (762165): BD Vacutainer
Whole Blood (Cell-Free DNA)	10.0 mL Blood Tube with Tube Size: 16 mm x 100 mm, Cell-Free DNA BCT (218996): Streck
Buffy Coat	2 mL Freestanding Microcentrifuge with Tube Size: 10.45 mm x 44.85 mm, e.g. similar to VWR® Micro Centrifuge Tube (16466-060)
Plasma	2 mL Freestanding Microcentrifuge with Tube Size: 10.45 mm x 44.85 mm, e.g. similar to VWR® Micro Centrifuge Tube (16466-060) 10 mL FluidX Tube Externally Threaded with Tube Size: 77.4 mm x 17.0 mm.
Saliva	Oragene•DNA (OG-500): DNA Genotek OG-500 Oragene•DNA (OG-510): DNA Genotek OG-510 Oragene•DNA (OGD-600): DNA Genotek OGD-600 Oragene•DNA (OGD-610): DNA Genotek: OGD-610 Oragene•DNA (OCD-100): DNA Genotek OCD-100
Saliva (assisted buccal swab collection)	Oragene•DNA (OG-675): DNA Genotek OG-675 Oragene•DNA (OG-575): DNA Genotek: OG-575
Extracted Material (DNA, RNA, etc.)	0.75 mL Thermo Fisher Scientific Matrix Tube (catalog number 3732) Sealed properly with ThermoFisher Scientific SeptraSeal (catalog number 4464)
Formalin Fixed, Paraffin Embedded Tissue Slide	Glass Slide 25 mm x 75 mm
Formalin Fixed, Paraffin Embedded Tissue Scroll	2 mL Round Bottom Safe Lock collection tube 1.5 mL Safe Lock Eppendorf tube

Table continues on next page.

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

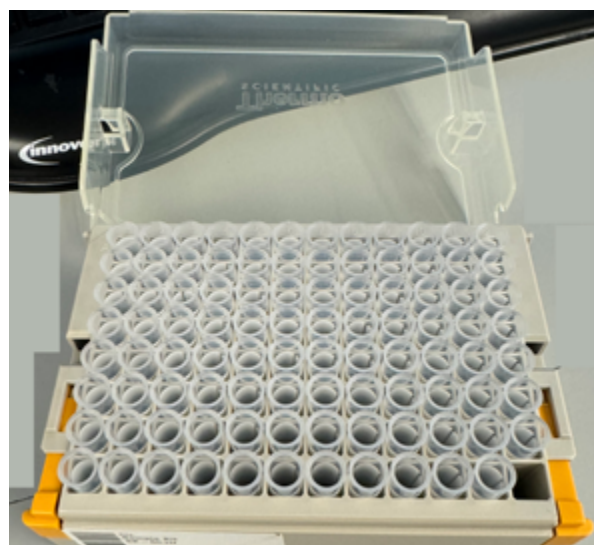
Material Type	Acceptable Specimen Container(s)*
Formalin Fixed, Paraffin Embedded Tissue Core	Paraffin Block 2 mL Self-Standing Cryogenic Vial, similar to Corning 430659 1.5 mL Safe Lock Eppendorf Tube 2 mL Round Bottom Safe Lock Collection Tube
Frozen Tissue	2 mL Self-Standing Cryogenic Vial, similar to Corning 430659
Stool	2 mL Self-Standing Cryogenic Vial, similar to Corning 430659
Cell Pellets	2 mL Round Bottom Safe Lock Collection Tube 1.5 mL Safe Lock Eppendorf Tube

*If unable to use the container(s) specified above for research products, please reach out to your Project Manager for assistance.

Filling a BCL-Provided Nucleic Acid Sample Kit (1 kit = 1 rack of 95 tubes)

Please adhere to the following guidelines when filling pre-labeled 0.75 mL tubes from BCL in order to avoid sample misidentification, and for samples to be processed in a timely manner:

1. All nucleic acid samples should be placed in the 0.75 mL tubes provided (see kit image below).
2. Do not change the positions of tubes within the kit, and do not move tubes into other kits.
3. Do not fill any tubes with water.
4. Remove and discard any tubes in the kit that you will not be filling with a nucleic acid sample. Do not send BCL empty tubes.
5. Position H12 has been intentionally left empty. Do not place a tube in that position.
6. To avoid sample loss and contamination, ensure that tubes are fully sealed with the provided SeptraSeals®.



Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Guidelines for Using Non BCL-Supplied Barcode Labels

The following section includes guidelines for the design and use of a customer’s own barcode labels. If you have received labels or labeled tubes from BCL, disregard this section.

Broad Clinical Laboratories (BCL) requires all tubes to have barcode labels that meet specific requirements enabling automation compatibility and specimen identification. If you are unable to adhere to any of these guidelines, reach out to your Project Manager or bcl-support@broadinstitute.org for assistance.

Protected Health Information

Protected Health Information (PHI) like patient name or date of birth (DOB) is important metadata for *clinical processes only*. We **cannot** accept barcodes containing PHI for research use only samples.

- 2 human readable forms of PHI or unique identifiers must be included on the labels for clinical sample tubes; if this requirement is not met, samples may be quarantined and/or discarded.
- Research sample tubes may be quarantined and/or discarded if tube labels include PHI or other participant identifying information.

	Clinical Samples	Research Samples
DO	Include 2 unique identifiers such as name, DOB, collection date, unique barcode, or other PHI	Use sample identifiers that are alpha-numerical and de-identified (i.e. not an attribute of a participant)
DO NOT	Only have one unique identifier	Use initials, Medical Record Numbers, or other PHI identifiers in your participant or sample naming

*If you are unable to adhere closely to the above specifications, please reach out to your project manager or bcl-support@broadinstitute.org for assistance.

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Barcode Information

All samples must be labeled with a barcode (linear for saliva and blood, QR code for small cryovials/slides) and a customer sample ID. BCL is unable to process tubes received without QR/linear barcodes.

Please ensure that the sample metadata sheet, barcodes as scanned, and any documentation capturing the barcodes submitted to BCL match/align.

Acceptable Barcode Formats:

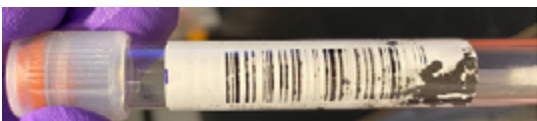
- Letters A through Z, (avoid using the letter O)
- Numerals 0 through 9
 - **Note:** Excel may automatically omit the leading “0” (zero) of a barcode that begins with one or more 0’s. Update the format of the cell(s) to “text” prior to scanning any barcodes into an Excel sheet to ensure any leading zeros will be preserved. **Failing to include leading zeros (if present in your barcode) will create a discrepancy in the physical label scan versus sample manifest metadata, delaying processing of samples.**
- Period, dash, underscore characters (but not as first or last character)

Barcode Formats Not Accepted:

- Special characters (excluding those specified above)
- Spaces
- Barcode cannot end in “0”
- First or last character cannot contain period, dash or underscore

Barcode Rejection Criteria:

- Two conflicting barcodes/labels are found on a single tube
- Tube arrives with no barcode
- Barcode Integrity:
 - Barcode cannot be scanned by either Zebra DS8108-SR7U2100AZW handheld scanners or MS3 laser 11-000077-04 scanners
 - Common Error: Too faded



- Common Error: Too bold (lines of barcode bleed together)



- Common Error: Cut off labels - this is sometimes difficult to tell, but comparing to the length of another label is a good way to confirm the barcode printed fully and is the expected length.



Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Additional Label Attributes to Consider

- Temperature rating of label and collection device
 - Saliva and FFPE samples must have labels and collection devices rated for +4°C
 - DNA must have labels and collection devices rated for -20°C
 - RNA, Frozen blood, cell pellet, fresh frozen tissue or plasma must all have labels and collection devices rated for -80°C long term storage
- If necessary to apply a label onto a tube that has already been stored at -20°C or -80°C, additional steps must be taken to ensure the labels adhere to the tube:
 - Apply ethanol to a paper towel and fully clear off any ice build up from tube
 - Using a hand or towel, cover the area of the tube you intend to place the label onto for 30-60 seconds to warm up the tube, and remove any condensation
 - Place label on warmed area and hold in place for another 30 seconds until label is fully adhered to the tube
 - Return sample to freezer storage
 - Note: prior to shipping samples, please double check tubes to confirm that all labels are still adhering to the tube. **If it has come loose, label must be reprinted (ideal) or re-secured with tape prior to shipment.**
 - Cryotape options currently on the market include:
 - [NitroTAPE™ Cryogenic Tape](#)
 - [Transparent Cryo Tape for Frozen Containers](#)

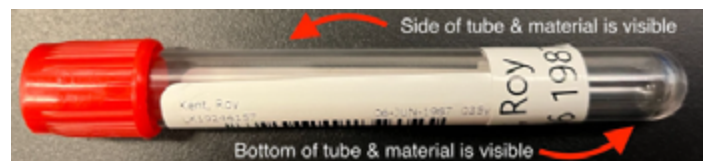
Label Placement

Correct placement of specimen labels is extremely important for sample identification and processing. Poor label placement or barcode quality might prevent sample processing at BCL altogether.

Regardless of sample type, it is important to place a barcode label so that any human readable sample information is still fully visible. If multiple labels are needed, ensure that placement does not obscure or overlap any information or barcodes.

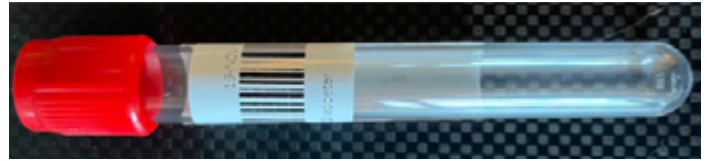
Please note: PHI should only be included on clinical sample submissions.

- Saliva and blood should have linear barcodes with a human readable code placed lengthwise on the tube.
 - Example of correct label placement for blood/saliva tubes:



Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

- Example of incorrect label placement to the right - barcode label placed horizontally



- Cryovials/tissue cassettes and/or FFPE slides should have QR barcodes with a human readable customer sample ID.



Clinical Collection Dates

Collection dates are required for clinical samples on the test requisition form and/or on the inside cover of the box containing the Direct to Patient (DTP) kit. Failing to provide the date the sample was collected could result in delays in sample processing or the test not being performed.

Please reach out to your Project Manager or bcl-support@broadinstitute.org for assistance.

Research Sample Metadata Sheet

Broad Clinical Labs utilizes a software system known as Biological Samples Platform, or BSP, to ship kits for research samples.

The kits for your physical specimens are labeled with a Sample Kit ID (SK-XXXX) and are accompanied by an Excel spreadsheet reflecting the sample IDs (SM-XXXXX) and layout of your sample kit.

Once your sample has been transferred into the tubes in a kit, you must fill out the sample metadata in the corresponding spreadsheet. It is important that this information is filled out correctly so that your data is correct in our systems. Please do not delete or modify any existing header or tab names in the spreadsheet provided by BCL.

Metadata sheets differ by material type, but the following information is required regardless of material:

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

1. Columns A & B [Well Position and Sample ID]

- a. Columns are pre-filled containing the rack position (A1, B4, etc.) and sample ID barcode for each tube in the kit. The SM-ID (SM-XXXXX) can be read on the side of each tube.
- b. NOTE: Rack position can be ignored if you are providing saliva or blood tubes.

2. Column C [Alias Collaborator Participant ID]

- a. Collaborator (i.e. your) Participant ID. This ID must be the same for all samples that come from the same patient. Please use only Alpha-Numeric IDs. DO NOT use only numeric IDs.
- b. Special characters like * and & are not allowed.

3. Column D [Alias Collaborator Sample ID]

- a. Collaborator (i.e. your) Sample ID. This ID should be unique for each sample. Please use Alpha-Numeric IDs. DO NOT use only numeric IDs.
- b. Special characters like * and & are not allowed.
- c. If the sample is another aliquot of a sample already existing in the Broad Clinical Labs Samples repository, please add the suffix “_2, _3, etc. to your Collaborator Sample ID’s (depending on which aliquot is being submitted).

Additional columns are included on the spreadsheet and differ based on the material you are submitting. These columns are optional to fill out and include information such as “Age” and “Primary Disease”. Collaborators are welcome to fill in as many of those additional columns as they’d like or that make sense, depending on the project.

When the spreadsheet(s) are completed, please email them to your Broad Project Manager.

Shipping Your Samples to BCL

How to Package

Triple or quadruple layer packaging is required for shipping biological materials. The layers are defined below:

- **LAYER 1**
 - Primary container securely capped or sealed and wrapped to prevent breakage
 - Examples include:
 - 0.75 mL matrix tube in a matrix rack
 - EDTA blood tube
- **LAYER 2**
 - Secondary container that is leakproof and contains absorbent material.
 - 95 kPA bags must be used as the secondary container if shipping a category B substance.
 - Reach out to your Project Manager if you have questions about how to classify your sample(s).
 - Examples include
 - [Biohazard bag](#) and [absorbent pad](#)
 - 95 kPA bag and paper towels

***Disclaimer:** This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.*

- **LAYER 3 (IF NOT shipping with dry ice)**
 - Tertiary container should be a cardboard box, large enough to hold the primary + secondary container and cold packs if the sample is to be shipped refrigerated.
- **LAYER 3 & 4 (IF shipping with dry ice)**
 - Tertiary container must be an [insulated Styrofoam cooler](#) designed to hold dry ice
 - The insulated cooler contains a Styrofoam box within a cardboard box. This outer cardboard box is the quaternary (4th) layer. Styrofoam alone cannot act as the quaternary layer.
 - Follow International Air Transport Association (IATA) and the [U.S. Department of Transportation \(DOT\) guidelines](#) when shipping dry ice.

The table below includes information on the preferred shipment conditions, depending on material type.

Preferred Shipment Conditions by Material Type

Material Type	Shipment Condition(s)	Packaging Information
Whole Blood (EDTA)	Refrigerated (preferred) or Frozen	Quadruple layer packaging
Whole Blood (PAXgene)	Refrigerated (preferred) or Frozen	Quadruple layer packaging
Blood (Streck)	Refrigerated (preferred) or Room Temperature	Quadruple layer packaging
Saliva (via regular or assisted collection/buccal swab)	Room Temperature	Triple layer packaging
Extracted Material (DNA, cfDNA, etc.)	Frozen (preferred) or Refrigerated (on cold packs) or Room Temperature Dry ice REQUIRED for international shipments	Quadruple layer packaging
Extracted Material (RNA)	Frozen (required)	Quadruple layer packaging
Stool	Frozen (preferred) or Refrigerated (on cold packs) or Room Temperature	Quadruple layer packaging
FFPE Slides	Refrigerated (preferred) or Room Temperature	Triple layer packaging
FFPE Blocks	Refrigerated (preferred) or Room Temperature	Triple layer packaging
Tissue (human or animal)	Frozen (required)	Quadruple layer packaging
Cell Pellets	Frozen (required)	Quadruple layer packaging

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Shipping Requirements for Category B Substances & Dry Ice

It is required to follow federal shipping regulations when shipping dry ice and Category B biological substances. [Category B biological substances](#) are infectious substances that are not likely to cause permanent disability or death in healthy humans or animals. Examples include blood and blood products such as plasma, stool and tissue samples. [Noninfectious extracted material such as DNA or RNA](#) are not considered category B but are required to be shipped on dry ice.

Reach out to your Project Manager if you are unsure of how to categorize your sample.

Consult [International Air Transport Association \(IATA\)](#)'s guidelines as well as the country of origin if shipping from outside of the US. When shipping internationally it is recommended to select a shipping company that will support the addition of dry ice should packages be delayed or held in customs.

Use the table below as a quick reference on the shipping requirements for shipping category B substances and dry ice.

NOTE: The following table includes Federal requirements for shipping within the United States.

Shipping Requirements	Category B	Dry Ice*
IATA Packing Instructions	650	954
Triple Packaging with absorbent; separate fragile primary containers	Yes	No
Pressure capable primary/secondary containment (such as 95 kPA)	Yes	No
4 inch minimum box dimension	Yes	No
Itemized list of contents	Yes	No
Hazard Label	UN3373 Diamond	Class 9 Diamond (must measure at least 4" along one side), "Dry Ice, UN1845, __kg" label
Proper Shipping Name	Biological Substance, Category B	"Dry Ice" or "Carbon Dioxide, Solid"
Orientation of box	Up arrows (↑↑) place on two opposite sides of the box	Up arrows (↑↑) place on two opposite sides of the box


* If package contains dry ice, must follow Category B AND dry ice requirements



Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Shipping Manifest Completion

A completed shipping manifest must be included when shipping any samples to BCL, especially clinical ones. Your shipping manifest should include the information on the picture below. A printed version of that manifest can be found [here](#). It is important to include **one printed copy per box** you are shipping.

		<p>Broad Clinical Labs Receiving Lab 132 27 Blue Sky Drive Burlington, MA 01803 (617) 714-8952</p>	
<p>Broad Clinical Labs Sample Manifest</p> <p><i>Please complete one shipping manifest PER SHIPPING BOX and include in the box with the sample(s).</i></p>			
Shipment Information (*Required):			
Project Name and Info*			
BCL Project Manager*			
Shipping Institution Name*			
Shipper Name*			
Shipper Email*			
Shipper Contact Phone			
Ship Date*			
Description of Contents:			
Number of Individual Samples	Material Type	Test Name	

Shipping Address

Broad Clinical Labs, Receiving Lab 132, 27 Blue Sky Drive, Burlington, MA 01803, (617) 714-8952

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Shipping Options

Domestic (FedEx or UPS)

Our preferred shipping service for shipping samples from anywhere in the United States is FedEx. Please ship the kit overnight Sunday - Thursday using **priority overnight**. "FedEx First Overnight" is not recommended as that service results in delivery prior to our loading dock opening at 9 AM.

International (World Courier or FedEx)

Our preferred shipping method for shipping samples from outside of the United States is World Courier, however FedEx is an option as well. Please ship the kit overnight Sunday - Thursday using **priority overnight**. When shipping internationally it is recommended to select a shipping company, like World Courier, that will support the addition of dry ice should packages be delayed or held in customs. If you require a Customs Declaration please reach out to your Project Manager or bcl-support@broadinstitute.org for assistance.

Local Drop Off

Central Cambridge Broad Drop Off - Internal Broad Institute Users ONLY

The Broad truck will make one trip to 27 Blue Sky Drive daily at 11 AM. There are racks located specifically for Broad truck samples at the loading docks of 415 Main St. and 75 Ames St. Internal samples need to be placed on these racks before 10:30 AM for same day delivery to Burlington. For detailed steps please refer to the [Inter-building Sample Transport](#) standard operating procedure. Contact sgm@broadinstitute.org with any questions.

Burlington Walk-in Drop Off at 27 Blue Sky Drive, Burlington, MA

If you or a courier are planning to bring samples directly to Broad Clinical Labs, drop off hours are between the hours of **9am – 3pm**, Monday through Friday, excluding holidays.

Please refer to the "[Blue Sky Drive Sample Drop Off Instructions](#)" section below for information on where to drop off and how to use our lockers.

Holiday Schedule & Closures

Samples may not be accepted, or receipt might be affected by limited hours of receipt, during Federal holidays.

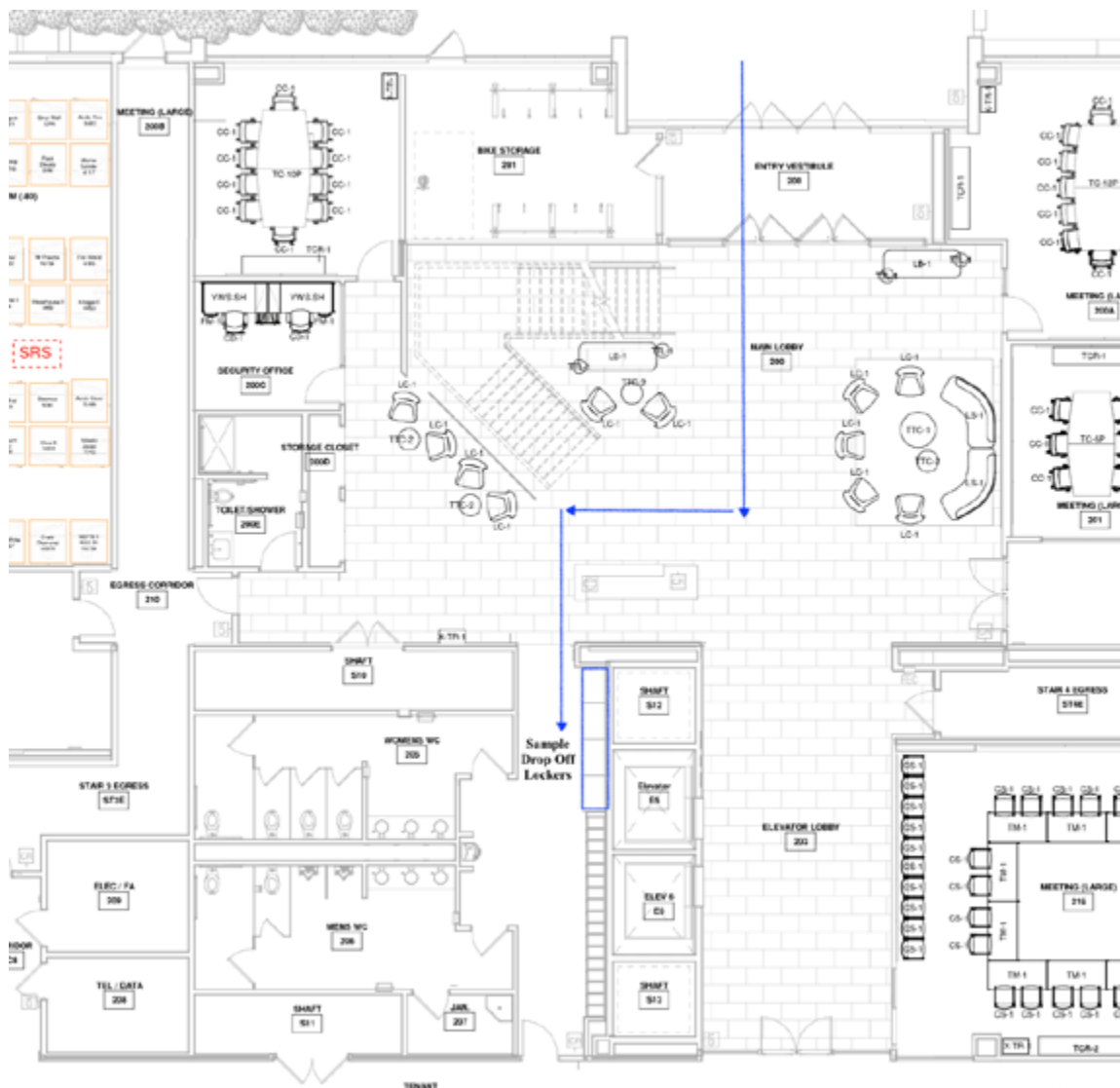
Please reach out to your Project Manager or bcl-support@broadinstitute.org if you have any questions or concerns about shipping near upcoming holidays.

Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Blue Sky Drive Sample Drop Off Instructions

BCL utilizes a locker system for sample drop off (if samples are hand delivered by the customer or a courier rather than shipped). The lockers are located to the right of the security desk (see map below). Security can assist if you have any questions.

Drop off hours are between the hours of 9am – 3pm, Monday through Friday, excluding holidays. These drop-off hours are strictly enforced, and lab personnel are not available for sample drop-off outside of these hours. If your package is too large to fit into the lockers or requires a signature for receipt, it must arrive during drop-off hours.



Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Locker Operation Guide

1. Read guide in its entirety before beginning operation

2. Select "Carriers" on the touch screen
3. Enter the 4-digit code - 1 2 3 4
4. Press "Go"
5. Type "Broad" into the recipient field
6. Select "Broad Institute"
7. Position your drop-off in front of the camera to capture a photo
8. Select a locker size



- a. Note: If you select the wrong size that is okay - the software allows you to reselect the appropriate size

9. A locker will open; place your package inside the locker
10. Close the locker door
11. Select "Exit" on the touch screen

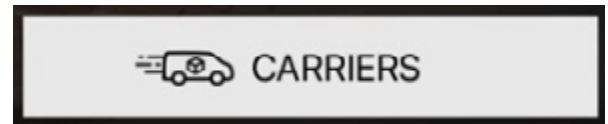


Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.

Guía De Taquillas

1. Lea la guía en su totalidad antes de comenzar la operación

2. Seleccione "Carriers" en la pantalla táctil
3. Ingrese el código de 4 dígitos - 1 2 3 4
4. Presione "Go"
5. Escriba "Broad" en el campo del destinatario
6. Seleccionar "Broad Institute"
7. Coloque su entrega frente a la cámara para capturar una foto
8. Seleccione un tamaño de casillero



a. Nota: si selecciona el tamaño incorrecto, está bien, el software le permite volver a seleccionar el tamaño apropiado

9. Se abrirá un casillero; coloque su paquete dentro del casillero
10. Cierra la puerta del casillero
11. Seleccione "Salir" en la pantalla táctil



Disclaimer: This documentation serves as requirements from BCL. It is the responsibility of the sending Institution to ensure that samples have been or will be properly collected, stored, and shipped with all informed consents, authorizations, approvals and permissions necessary per local, state and regulatory requirements governing human category B samples, as well as any additional institutional policies and contractual obligations. If your sample is destined for a clinical test, the specimen must be extracted in a CLIA-certified laboratory or a laboratory meeting the equivalent quality system requirements.