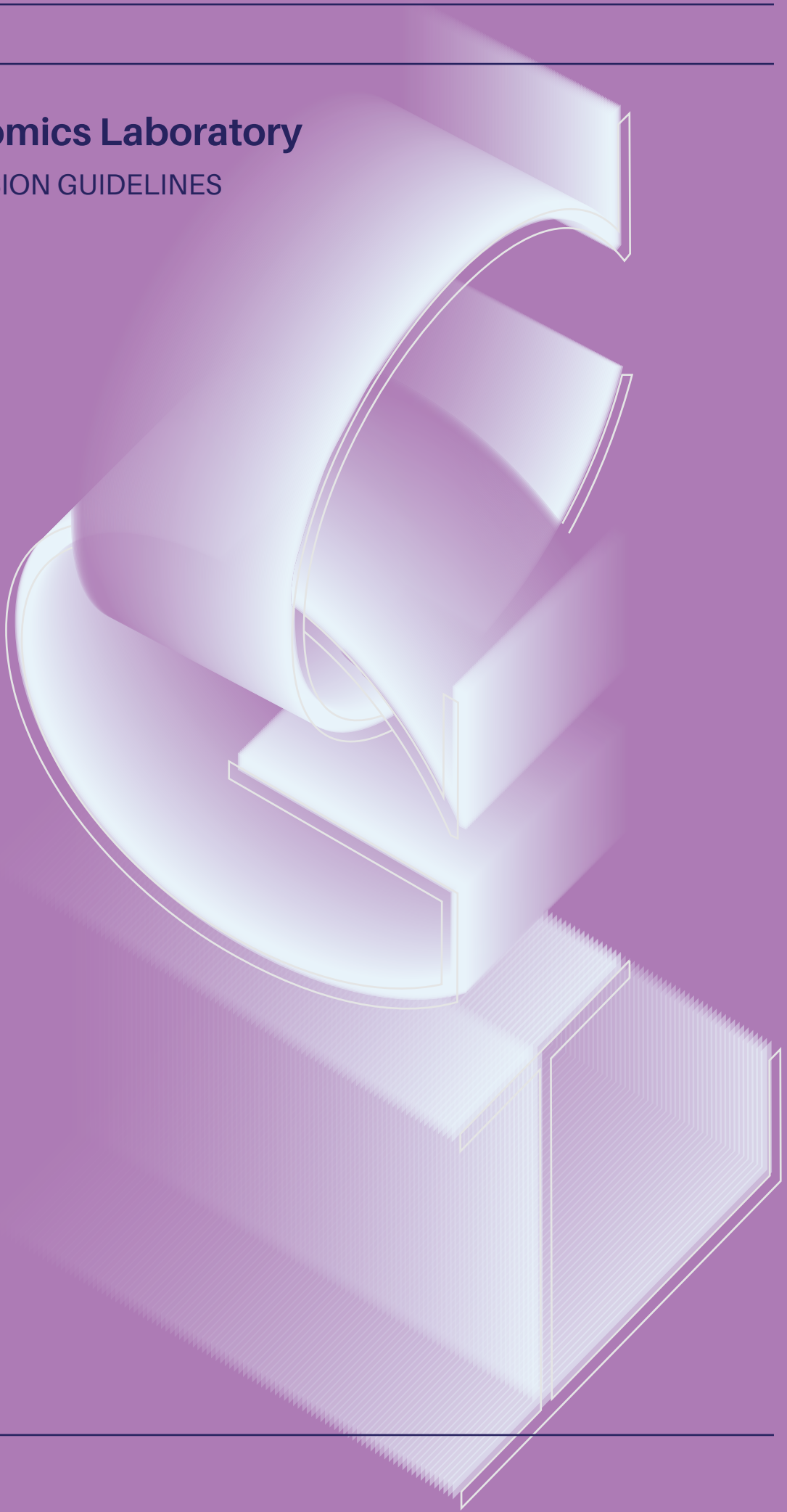
UNIVERSITY OF THE PHILIPPINES
PHILIPPINE GENOME CENTER

Clinical Genomics Laboratory

SAMPLE SUBMISSION GUIDELINES



PGC
PHILIPPINE GENOME CENTER

Clinical Genomics Laboratory

SAMPLE SUBMISSION GUIDELINES

+ Objective

Sample collection is a critical step in NGS testing and must be performed following established standard operating procedures. The collection method and container must be appropriate for the type of sample being collected to ensure the integrity of the genetic material. Proper labeling of the container with patient information and other relevant data is crucial to avoid errors during sample processing. Samples must be transported to the laboratory in accordance with biosafety protocols and general guidelines for NGS testing. Upon arrival at the laboratory, samples will be vetted to ensure they meet the minimum standards for transport.

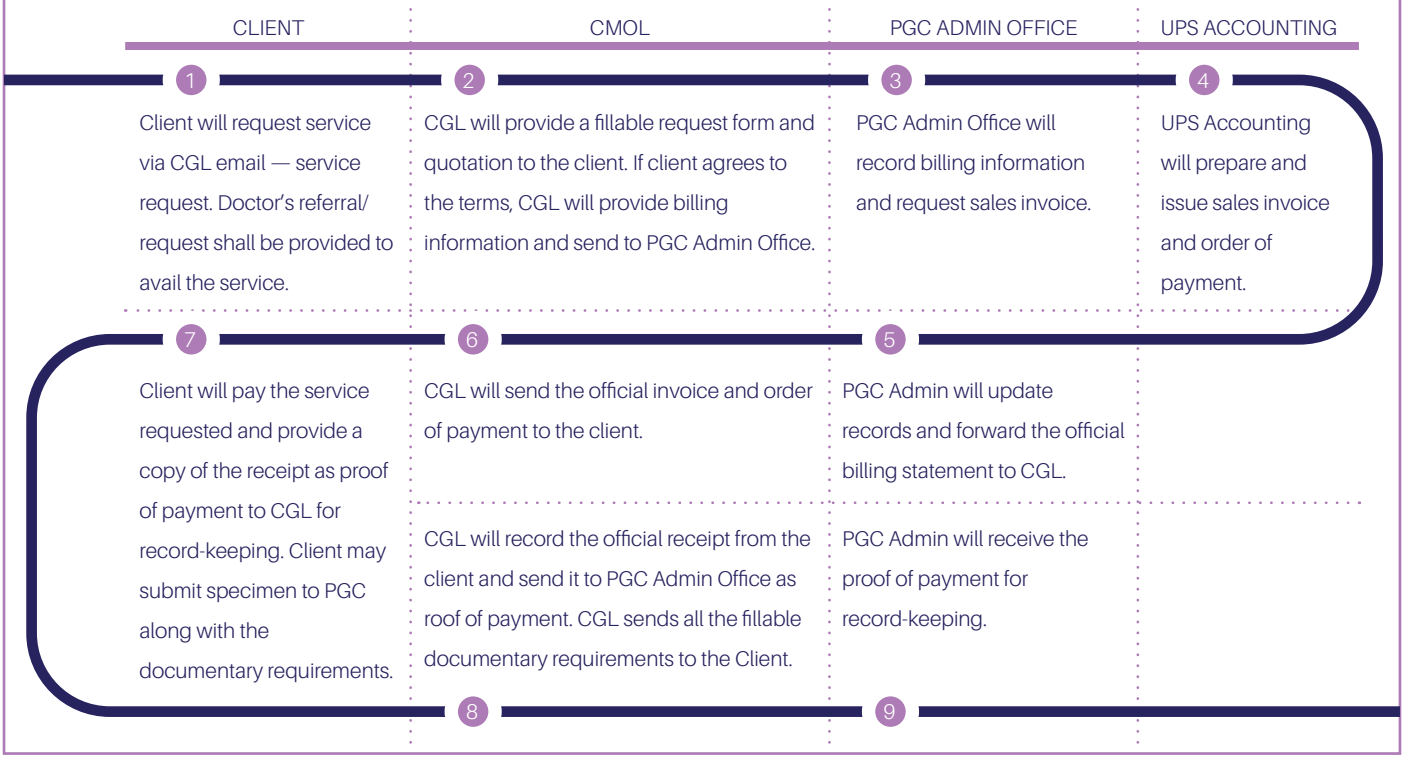
+ Scope

The instructions outlined below are a set of benchmarks for the collection of samples intended for NGS testing that we provide to our partner institutions.

Sample collecting facility should observe first universal precautions and don the appropriate PPE which includes but is not limited to:

- Gowns or full-body suits
- Gloves
- Respirator (e.g., N95 mask)
- Face mask
- Face shield
- Eye protection (e.g., goggles or visor)
- Shoe covers
- Hairnets or caps

+ Workflow



SAMPLE SUBMISSION GUIDELINES

+ Detailed Workflow

A. SERVICE REQUEST

- Clients may inquire for pricing of the available services offered by the CMOL via the PGC website (https://pgc.up.edu.ph/services/) and view for the corresponding documents needed for their service request.
- Clients may request a service by sending an email to clinicalgenomicslaboratory@up.edu.ph with the subject "Request for Quotation: [Test Code i.e BRC-001.1, BRC-001.2] ". Clients should refer to the CMOL sample submission requirements mentioned in Annex 5, which are summarized in Table 1 Below.
- Test Code Description:
  - **BRC-001.1** – Germline testing utilizing NGS technology using whole blood as the sample type. 6 genes are provided with 500x coverage.
  - **BRC-002.2** – Somatic testing utilizing NGS technology using FFPE as the sample type. 6 genes are provided with 7200x coverage at 5% VAF.
- CMOL staff will send quotation to the client. The quotation shall be valid within 60 days.
- Once clients agree to the pricing of the services, they can proceed with payment. They may choose to submit the specimen and hard copy documentary requirements after payment is confirmed. The payment workflow can be found in Appendix xxx. Additionally, clients must send soft copy documentary requirements to the email thread with CMOL at clinicalgenomicslaboratory@up.edu.ph.

TESTING TYPE	DOCUMENTS NEEDED
BRC-001.1	Physician referral form, clinical abstract, general request form, patient information sheet, informed consent form
BRC-001.2	Histopathology report, physician referral form, clinical abstract, general request form, patient information sheet and informed consent form

Table 1. Documentary Requirements for Cancer Testing

B. SAMPLE SUBMISSION REQUIREMENTS

The submission requirements for various types of samples for NGS testing are detailed below and vary accordingly.

- **For whole blood samples**
  - The volume required for submitting blood samples for molecular testing varies depending on the age of the patient.
  - For adults, a minimum of two 3 mL whole blood samples is required. For pediatric cases, it is preferred to submit 3 mL of whole blood but, if necessary, 1.5 mL of whole blood can be accepted.
  - For newborns and infants, at least three small volume microtubes (0.5 mL capacity) of capillary blood collection is required. It is important to note that the volume requirements are necessary to ensure that enough of the blood sample are available for molecular testing, which will improve the accuracy and reliability of the results.

SAMPLE SUBMISSION GUIDELINES

+ Detailed Workflow

B. SAMPLE SUBMISSION REQUIREMENTS

- The acceptable condition for submitting blood samples for molecular testing includes whole blood in lavender blood top tubes. Either K2 EDTA or K3 EDTA are acceptable. The blood shall be stored at refrigerated temperatures within 24 hours.
- Frozen or partially frozen blood samples are also accepted, although the analysis for deletions/duplications cannot be guaranteed for these specimens. These specimens will be thawed upon receipt. However, hemolyzed or clotted blood, archived blood samples that were not stored properly, and poor-quality specimens that fail quality control (QC) upon DNA extraction will be rejected.
- It is important to ensure that the blood samples meet the specified conditions to ensure the accuracy and reliability of the molecular testing results.
- When submitting blood samples for molecular testing, proper labeling and documentation is essential. The labels on the samples should include the patient's full name and one additional unique identifier such as the date of birth, age, or sex. The specimen collection date should also be included on the label. Additionally, a printed copy of the informed consent and patient information sheet must be submitted along with the blood samples.
- A clinical report, doctor's findings, or diagnosis report should also be included in the documentation. This information will help ensure that the correct patient and their corresponding samples are used in the molecular testing process, and that all necessary information is available to accurately interpret and report the results. – Sample outline of clinical abstract may be viewed in Appendix xxx.
- Blood samples are suitable only for germline mutation testing and familial testing.

- **For Formalin fixed paraffin embedded samples (FFPE)**. For submitting formalin-fixed, paraffin embedded tissue samples for molecular testing, the following guidelines should be followed:
  - The tissue should be fixed in 10% neutral-buffered formalin using standard fixation methods that preserve nucleic acid integrity.
  - The submitted specimens should include 1 H&E slide and 10-15 unstained slides that are 5-7 microns thick, or a FFPE tissue block (standard size) and 1 H&E slide.
  - The tissue must contain sufficient tumor that can be macro-dissected to a concentration of more than 20% tumor cells in a normal cell background.
  - Samples that have been decalcified in strong acid decalcification or fixed in Zinc fixatives, Bouins, B5, AZF, or Holland's are not acceptable and will be rejected.
  - Poor quality specimens that fail QC upon DNA extraction will also not be accepted.
  - A printed copy of the informed consent and patient information sheet must be included, as well as a histopathology report. The labels on the samples should include the patient's full name and one additional unique identifier such as the date of birth, age, or sex, and the specimen collection date.
  - Optional if submitting slides only: To avoid cross-contamination during microtomy for molecular testing, it is recommended to use a separate microtome blade for each case. This will help ensure that the molecular testing results are accurate and reliable.
  - FFPE samples are suitable only for somatic mutation testing.

SAMPLE SUBMISSION GUIDELINES

+ Detailed Workflow

C. GUIDELINES FOR PACKING AND SHIPPING OF SAMPLES

To ensure the safe transport of samples, it is important to adhere to the IATA regulations. If you are using PGC-CMOL sample collection kits, it is recommended to follow the instructions provided within the package, as these kits are specifically designed to safeguard samples during transportation. However, if you choose to use alternative packaging, it is imperative to comply with the "three layers of packaging" rule to prevent potential damage by the courier: A primary sample receptacle sealed (collection tube), A leak-proof specimen bag containing absorbent material, An outer packaging that meets the local postal regulations and is labeled as "Exempt Human Specimen." For more information, please refer to IATA Dangerous Goods Regulation.

- **For Blood**
  - Blood should be shipped within 24 hours at refrigerated temperature or within 12 hours at room temperature. We recommend including cold packs if shipping is expected to take longer than overnight to keep the specimen at 2 to 8 degrees Celsius (35.6 to 46.6 degrees Fahrenheit). Frozen blood is not acceptable.
  - For blood samples, sample packaging is shown below:

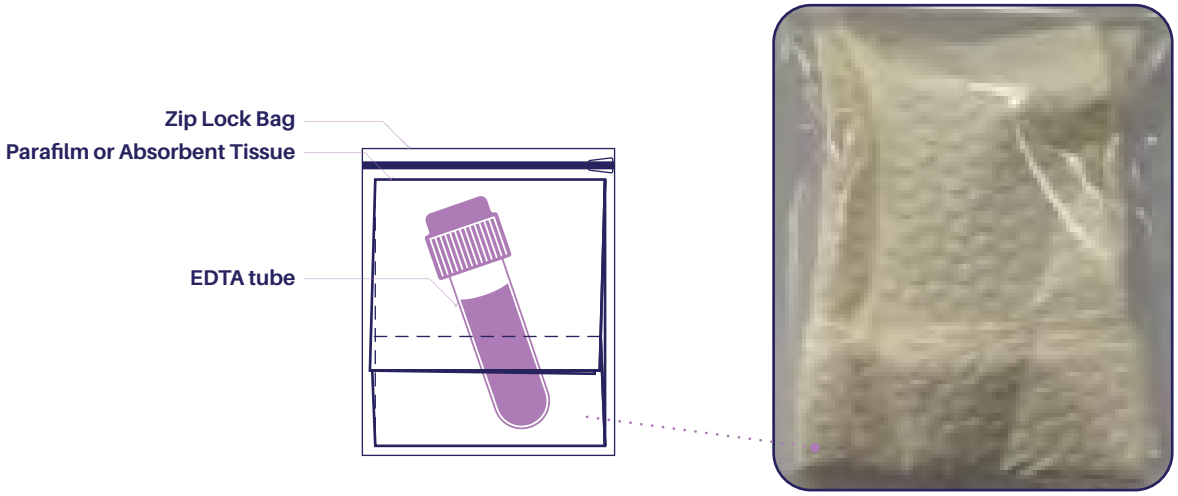


Figure 1. 3-5 mL EDTA tubes seald with Parafilm or wrapped with absorbent tissue and packed inside a small zip lock bag.

  - Labeled samples will be sealed with either Parafilm or wrapped in absorbent tissue before being placed in a small zip-lock bag. Other pertinent information such as the patient's name, patient ID, date of birth, specimen type, and date collected should be indicated on the shipping packet.
- **For FFPE samples (blocks/slides):**
  - For slides, they should be inserted into plastic slide holders, then placed inside a foam, and finally placed in the transport box.
  - If sending FFPE tissue blocks or cassettes, the block tray should be inserted into a plastic block tray holder, followed by placing a foam, and finally, inserting it into the transport box. This will help to protect the samples during transportation and prevent any damage to the specimens that could affect the results of the molecular testing.

SAMPLE SUBMISSION GUIDELINES

+ Detailed Workflow

C. GUIDELINES FOR PACKING AND SHIPPING OF SAMPLES

- Ensure that the specimen is labeled with patient name and number. A minimum of two patient identifiers is REQUIRED for each specimen.
- FFPE block should be shipped within 24 hours at room temperature.

- **PGC-CMOL accepts packages Monday through Friday from 8 AM to 5 PM.** We recommend that you send your package so that it leaves your facility Monday through Thursday. Please do not request Saturday delivery.
- If you have any questions regarding kits instruction, please contact us at: **clinicalgenomicslaboratory@up.edu.ph** or call at xxx-xxx-xxx

D. TRANSPORT OF SAMPLES

- All samples must be coordinated via phone with the PGC-CMOL staff during office hours (8:00 AM to 5:00 PM) at 8-981-8500 local 4707 prior to transport regardless of their origin.
- Samples are accepted until 5 PM, Monday through Friday. However, if samples are received after 11 AM on Fridays, they will be processed during the subsequent sequencing run.
- The partner healthcare collecting institution shall be responsible for transporting the samples to the PGC. These samples must be placed in ice boxes or container depending on the type of specimen and accompanied by the sample submission forms, informed consent, patient information sheet and other relevant data.
- Blood and FFPE are included in infectious substances Category B. As such, they should be transported as "diagnostic specimens" (UN3373), following the guidelines and precautions discussed previously. Refer to WHO guidance on regulations for the transport of infectious substances 2019-2020 (WHO/WHE/CPI/2019.20) for further instructions.
- Coolants, such as ice packs, should be utilized when transporting clinical specimens like whole blood to maintain their integrity during transit. On the other hand, if you are shipping FFPE blocks/slide, it is imperative to use a durable primary container and ensure that controlled temperature conditions are maintained to prevent any damage or melting of the paraffin.
- All properly packed clinical specimens for transport should be marked and labeled appropriately to provide information about the package contents, nature of the hazards and packaging standards that have been applied. All marks and labels must be clearly visible. The following details must be clearly visible in the shipping packet: patient's name, ID number, specimen type, and date collected.
- The following labels must be provided on the outer package of all infectious substances:

Shipper's (sender's or consigner's) name and address	(Name of Facility collecting institution)
Receiver's (consignee's) name and address	UP Philippine Genome Center

SAMPLE SUBMISSION GUIDELINES

+ Detailed Workflow

D. TRANSPORT OF SAMPLES

- Send the specimen to this address:

Attn: PGC - Clinical Multi-omics Laboratory
Philippine Genome Center
A Ma. Regidor Street, National Science Complex, U.P. Campus
Quezon City, Metro Manila, 1101
Contact Person: PGC Personnel

- In addition to the labels above, the mark below must be indicated in the box for the transport of samples (Category B material):

SHIPPER
JUAN DELA CRUZ
TIMELY LOGISTICS
ADDRESS

RECEIVER
MARIA SANTOS
PGC-CGL
ADDRESS

"To" and "From" marks, showing the name and address of the shipper and receiver; these are required for all packages

BIOLOGICAL SUBSTANCE CATEGORY B

The UN number and proper shipping name marks (for Category B packages subclassified as UN 3373)

- Receipt of any sample by the PGC-CGL staff from a partner institution will be reported to the Laboratory Manager, Dr. Edsel Ayes (09399082296) or to the Medical Specialist II, Dr. Bernadette Reyna (09989563472).

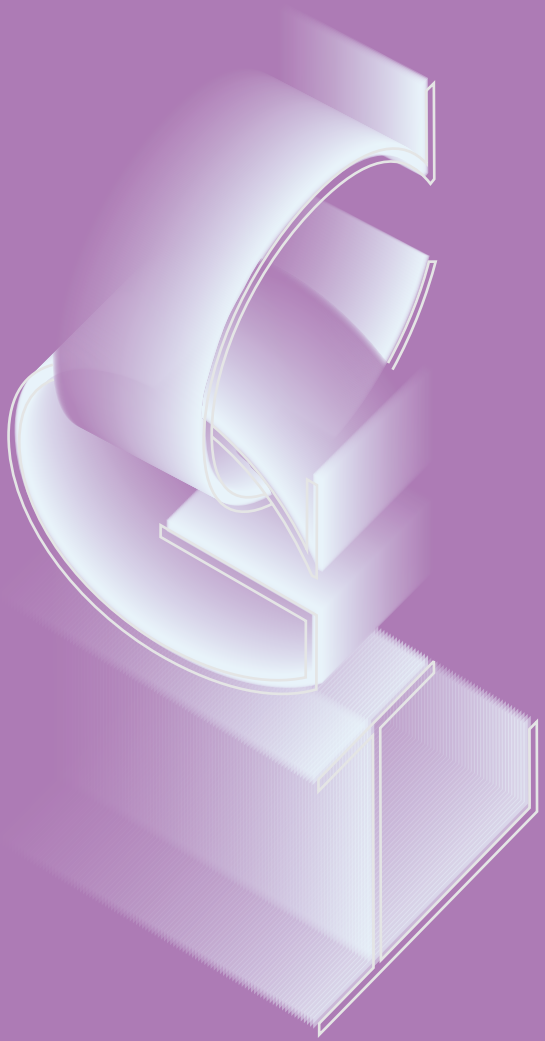
E. DOCUMENTARY REQUIREMENTS

- **Request for NGS testing form (PGC-CMOL-FORM-0001):** This form is completed by the client and includes the type of molecular test requested, the patient's basic information, and any relevant clinical information. See appendix xxx.
- **Patient consent form (PGC-CMOL-FORM-0002):** A written consent form signed by the patient, or their legal guardian is required to perform any medical tests. The consent form should include the purpose of the test, risks and benefits, and options for future testing. See appendix xxx.
- **Patient information sheet and specimen collection sheet (PGC-CMOL-FORM-0003):** This form captures the patient's medical history, including their diagnosis, treatment history, and current symptoms. Additionally, the form also documents the type of sample collected, date and time of collection and the person who collected the sample. See appendix xxx.
- **Laboratory results form:** This form is used to document the results of the molecular test and includes the test results, interpretation of the results, and any relevant recommendations for follow-up tests or treatments. See appendix xxx.

UNIVERSITY OF THE PHILIPPINES
PHILIPPINE GENOME CENTER

Clinical Genomics Laboratory

SAMPLE SUBMISSION GUIDELINES



Contact Us

ADDRESS	**Philippine Genome Center Building** A. Ma. Regidor Street University of the Philippines Diliman Quezon City 1101, Philippines
LANDLINE	+63 • 2 • 8981 • 8500 local 4713 +63 • 2 • 8981 • 8625 +63 • 919 • 095 0958
EMAIL	clinicalgenomicslaboratory@up.edu.ph pgc@up.edu.ph
WEBSITE	https://pgc.up.edu.ph

PGC
PHILIPPINE GENOME CENTER