MAKERERE UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF IMMUNOLOGY AND MOLECULAR BIOLOGY

Genomics, Molecular and Immunology Laboratories

CLIENT HANDBOOK

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Location

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Retirement section

	Name	Date
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Acknowledgment of reading and understanding the client handbook

No.	Name	Signature	Date
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Abbreviations and Acronyms

- **GMI Labs-**Genomics, Molecular and Immunology Laboratories
- **Lab**-Laboratory
- **BAL-** Bronchoalveolar Lavage
- **CMV**- Cytomegalovirus
- **COVID-19** Corona Virus Disease 2019
- **CT-** Cycle Threshold
- **CTAB-** Cetyl Trimethyl Ammonium Bromide
- **EBV**-Epstein Barr Virus
- **ERIC-** Enterobacterial Repetitive Intergenic Consensus
- **ESBL-** Extended Spectrum Beta lactamase
- **HLA-** Human leukocyte antigen
- **HPV**- Human Papilloma Virus
- **HSV**- Herpes Simplex Virus
- **IRB-**Institutional Review Board
- **LIMS-**Laboratory Information Management System
- **MDR**-Multidrug Resistant
- **MIRU-VNTR-** Mycobacterium interspersed Repetitive Units Variable Number of Tandem Repeats
- **MLST-** Multi Locus Sequence Typing
- **MRSA-**Methicillin Resistant *Staphylococcus aureus*
- **MTB-***Mycobacterium tuberculosis*
- **NGS-** Next Generation Sequencing
- **PPE-** Personal Protective Equipment
- **QC**-Quality Control
- **RAPD-** Random Amplified Polymorphic DNA
- **REP-** Repetitive Element Palindromic sequences
- **SARS-CoV-2** Severe Acute Respiratory Syndrome Corona Virus 2
- **SOP**- Standard Operating Procedure
- **STD-**Sexually Transmitted Disease

- **STI-**Sexually Transmitted infection
- **TAT-** Turnaround time
- **VRSA-**Vancomycin Resistant *Staphylococcus aureus*
- **XDR-** Extensively drug-resistant

Glossary of terms

Turnaround time: This refers to the maximum time from the date the sample was received in the Genomics, Molecular and Immunology Laboratories to the date or time when results are ready for dispatch

Final result report: This is a record of all test results for examination requested by the client

MDRTB: Tuberculosis that is resistant to at least the following first line ant-TB drugs; Isoniazid and Rifampicin

Preamble

The Genomics, Molecular and Immunology Laboratories (GMI Labs) have designed a Client Handbook to inform both its local and international clients of the services they offer and to guide them on the general sample handling procedures from collection to samples delivery.

To improve its efficiency and effectiveness, GMI Labs provide advice to her clients on each service requested in order to minimize misuse of resources and to fully satisfy clients' needs.

Consult the Manager or the Quality Assurance and control officer if you have any difficulties understanding any section of the manual.

Genomics, Molecular and Immunology Laboratories are headed by a Laboratory Director, and the operations of the laboratories are overseen by the Laboratory Managers, Quality Assurance and Quality Control Officers who ensure adherence to the Quality Management System.

The Director of the Genomics, Molecular and Immunology Laboratories is ultimately responsible and committed in ensuring good quality services for all clients.

Prof. Moses Joloba

Laboratory Director

1.0 Introduction

The Genomics, Molecular and Immunology Laboratories (GMI Labs) believe that the best way to promote effective utilization of the laboratory services begins with ensuring that scientifically sound information is accessible to the clients. Therefore, the laboratory has devised platforms for communicating laboratory information with the customer.

The client handbook is shared with all clients who are responsible for primary sample collection. The GMI-Client handbook (GMI-M003) advises clients on the examination and scope of service, including the required sample type, clinical indication, limitation of examination procedures, and frequency of performing the examination.

Professional judgment is used by the analytical team in the interpretation of examination before releasing test results from the laboratory. As a basis for this judgment, analytical staff must provide the following information where necessary;

- **a)** The precision and accuracy of methods used in the laboratory or measurement uncertainty
- **b)** The significance of test results concerning the laboratory's reference values
- **c)** The clinical significance of the requested assay and fitness for purpose or suitability to solve the clinical problem in question

2.0 Mission

The Genomics, Molecular and Immunology Laboratories strives to contribute to health improvement in Uganda and Africa through the pursuit of excellence in quality Diagnostic services, Research and Training or Teaching for infectious and non-infectious diseases of humans including Zoonoses under Biosafety level 2

3.0 Vision

To be a powerful Diagnostic and training Hub in Africa, and to become the leading center of excellence in Genomics, Molecular and Immunology research for infectious, non-infectious, and zoonotic diseases of humans in Africa

4.0 How do we strive towards our mission?

GMI Labs have set forth the following guidelines, which we are working towards meeting;

1. **Quality:** We focus on all our clients and the general public. We therefore, strive for excellence in Personnel Management, Training and Competence Assessment and Continual improvement program and Quality Indicators.
2. **Caring:** We are committed to serving with empathy, passion and compassion as well as performing satisfying work with respect, trust and support for each other
3. **Human Life:** We offer the highest priority to the preservation of human life, by adhering to the turnaround time and requirements of Institution Ethics Review boards.
4. **Integrity:** We hold ourselves to high standard of moral and ethical conduct respecting our customers' confidentiality.
5. **Professionalism:** We strive for excellence in leadership and client handling.
6. **Loyalty:** We are faithful to our mission and Vision
7. **Teamwork:** We offer a conducive environment for collaboration as well as inter and intra-laboratory teamwork to enhance the quality of our services

5.0 Quality Policy

Implementation of the Quality Policy is by the Laboratory Director who has the authority, competence, and responsibility for the services provided by the GMI Labs which is to;

1. Comply with ISO 15189:2012 standards at all times;
2. Maintain excellence in laboratory services using the standard method;
3. Ensure compliance with the statutory and regulatory requirements;
4. Ensure adequate resources and staff competence, enabling effective professional services;
5. Complete the laboratory tests and report the results in an effective and timely manner;
6. Maintain the confidentiality of client results and or information
7. Ensure continued client satisfaction through a continuous improvement system
8. Prevent the occurrence of potential nonconformities

The Quality policy forms the basis of the laboratory's quality objectives. This policy is reviewed annually during management reviews to ensure it remains relevant and for continual suitability to the laboratory. The policy is communicated to all personnel directly involved in laboratory activities.

All personnel are required to read, understand and acknowledge reading the contents of the quality policy, quality manual, and all procedures relevant to their work assignments and the management of the laboratory.

6.0 Services provided

The Genomics, Molecular and Immunology Laboratories provide numerous services as summarised in table 1.

Table 1: Laboratory services or tests offered, Sample type, and expected turnaround (TAT).

Services or tests offered	**Sample type**	**Expected turnaround time**
1. COVID-19 or SARS-CoV-2		
a) Diagnostic PCR (Express)	Nasal swabs Oropharyngeal swabs	4 hours
b) Diagnostic PCR (Routine)		24 hours
c) Whole Genome sequencing	Nasal swabs Oropharyngeal swabs Other body fluids Tissues	30 working days
2. Tuberculosis (TB)		
a) Hain Genotype *MTBDR$_{Plus}$*	Decontaminated Sputum Heat inactivated *Mycobacterium tuberculosis* isolates/cultures	48 hours
b) Hain Genotype *MTBDR$_{sl}$*		48 hours
c) Single Nucleotide Polymorphism genotyping d) (*Real-time PCR assays*)		48 hours
e) Long Sequence Polymorphisms genotyping f) (*Conventional PCR assays*)		72 hours

g) MIRU-VNTR based genotyping	*Mycobacterium tuberculosis* isolates/cultures	14 working days
h) Restriction Fragment Length polymorphism-based genotyping and Spoligotyping	*Mycobacterium tuberculosis* isolates/cultures	14 working days
2. Non-tubercular *Mycobacterium*		
a) Hain Genotype CM	Decontaminated Sputum Isolates/cultures	48 hours
3. Respiratory tract infection		
a) Detection of bacterial pathogen	Sputum BAL	48 Hours
4. *Human Papilloma Viruses*-HPV		
a) Detection and quantification of genotypes 18 and 16	High Vaginal swabs Saliva	48 Hours
b) Common low-risk genotypes		48 Hours
5. Viral load		
a) CMV/EBV/HBV, b) HSV, c) HHV8, d) HIV	Blood Other body fluids	48 Hours
6. STIs		
a) *Detection of Gonorrhoea*, *Chlamydia*, *Mycoplasma*, and *T. Vaginalis*)	Vaginal swabs, Urethral swabs, Penile swabs	48 Hours
7. Bacterial Drug resistance testing		
a) Gram-negative bacteria	Bacterial Isolates	48 Hours
b) Gram-positive bacteria		48 Hours
8. Malaria		

a) Detection and drug resistance testing b) Speciation of *Plasmodium* pathogens	Blood DBS	48 Hours
9. HLA typing	Blood Other body fluids	48 hours
10. *Staphylococcus aureus* Resistance		
a) Spa typing	*Staphylococcus aureus* isolates	72 hours
11. Multi Locus Sequence Typing (MLST)	Bacterial isolates	72 hours
12. Plasmid Profiling	Bacterial Isolates	72 hours
13. Sequencing		
a) Sanger	DNA Amplicon	30 working days
b) Next Generation Sequencing-NGS		
i. Targeted or Amplicon	Swabs, Stool, Sputum, Tissues, Body fluids, DNA, Amplicons	30 working days
ii. 18S ITS Metagenomics	Sputum, Stool, Vaginal swabs, other biological and Environmental samples	60 working days
iii. 16S Metagenomics		60 working days
iv. WGS for small genomes	Bacterial isolates	60 working days
14. Restriction Enzyme digestion	Biological samples	72 hours
15. Electrophoresis		
a) Agarose gel electrophoresis		48 hours

b) Capillary electrophoresis	Extracted nucleic acids, Amplicons	24 hours
16. Protein purification and analysis	All biological samples	4 weeks
17. Human Identification	Body swabs, Blood, other body fluids Tissue	72 hours
18. Prenatal testing a) Prenatal trisomy screening	Maternal blood	14 Working days
19. DNA Extraction	Bacterial isolates Biological specimens such as body fluids, Swabs, Tissues, Stool, Environmental specimens such as Soil and water Plant materials	4 working days
20. RNA Extraction	Bacterial isolates Biological specimens such as body fluids, swabs, tissues, stool, Environmental specimens such as soil and water	4 working days

	Plant materials	
21. DNA or RNA Quantification		
a) Nano Drop Spectrophotometry	Extracted DNA Extracted RNA	24 hours
b) Qubit Fluorimetry	Extracted DNA Extracted RNA Amplicons	24 hours
22. Primer design	Gene(s) of interest	12 hours
23. Primer probe design		12 hours
24. ELISAs for ; CRP, HIV, HSV-2, Toxoplasmosis, Rubella, CMV, HBsAg, AntiHB, HBV CoreAg, HPV, IgE, Interleukins, IFN-gamma, TNF-α, T.Spot	Serum Plasma	7 working days
25. QuantiFERON TB Gold plus	Plasma, Serum	21 working days
26. RPR	Serum	1hour
27. TPHA	Serum	1hour
28. HCG	Serum, Urine	1hour
29. HBsAg	Serum	1hour
30. HIV rapid test	Serum	1hour
31. SARS-CoV-2 IgG	Nasal swab	1hour
32. SARS-CoV-2 IgM	Serum	1hour
33. Urine LAM	Urine	1hour
34. PBMC isolation	Whole blood	24hours
35. Serum processing	Plain tube blood	1hour
36. Plasma processing	Whole blood	1hour
37. Multiplexing with Luminex	Serum, Plasma, CSF	3 working days
38. Cell Culture	Cells/ tissues	90 working days
39. Flowcytometry	Cells	72hours
40. Legend plex	Serum	72hours

7.0 Laboratory Description

The GMI Labs constitute two Units; The Genomics and Molecular Unit and the Immunology Unit. The Genomics and Molecular Unit is located on the third floor (Level 3), Pathology-Microbiology Building, while the Immunology Unit is on first floor or level 1 School of Medicine building at Makerere University College of Health Sciences.

From the early 2000, the GMI Laboratories originally existed as one facility, the Molecular Biology Laboratory also previously known as Molecular Diagnostic Laboratory, from which evolved another Laboratory called the Immunology Laboratory. Recently, the Genomics and Molecular Biology Unit emerged from the Molecular Biology Laboratory, as the Immunology Unit was formulated from the native Immunology Laboratory. Both facilities operate under one complex, the Genomics, Molecular and Immunology Laboratories (GMI Labs), which name was adopted in January 2022 for ease of operationalization.

Since May 2019, the Genomics and Molecular Unit has adopted and implemented the Laboratory Quality Management System, ISO 15189:2012 whereas Immunology Unit adopted the same system in February 2022.

The aggregation of the laboratories was done in order to improve and standardise the quality of the Diagnostic, Training and Research services offered to the different clients of these laboratories using the most advanced Genomics, Molecular and Immunology techniques and while complying to the ISO 15189:2012 requirements for medical laboratories.

7.1 Name of the laboratory

Genomics, Molecular and Immunology Laboratories (GMI Labs)

7.2 Legal entity

The Makerere University Biomedical Research Centre (MakBRC) is the body that manages the GMI Labs. The MakBRC is registered with the Allied Health Professionals' Council under the Allied Health Professional **Act CAP 268,** with Registration Number **AHPC20/1758/P**. GMI labs is part of laboratories within the confines of the Makerere University, College of Health Sciences, School Biomedical Sciences, which are directly under the administration of MakBRC, under Makerere University.

7.3 Laboratory Layout and Design

The Genomics and Molecular Unit; and Immunology Unit have different layout and designs as described below.

7.4 The Genomics and Molecular Unit

The Genomics and Molecular Unit has five sperate sections or laboratories under one roof and in each has a defined set of processes or activities are carried out. Each laboratory has its own set of equipment which are relevant to the lab processes performed as described below;

7.4.1 Sample Reception and Accessioning Area

This is where all clients deliver their samples. Here, the samples are received, sorted and/or checked. A sample delivery log where the number of samples delivered, the person who delivers the samples, the time the samples are delivered, and the initials of the staff who receives them are recorded.

There's a sample accessioning book or register and computers to facilitate entry of sample information in electronic system where each sample details are captured including assigned laboratory code or number. There's also a sample accessioning book or register where these details are captured as well.

The sample reception and accessioning area has a sample window through which samples are passed to the lab personnel. It also has a work table or bench tops and Biosafety cabinet where samples are sorted and assigned numbers accordingly.

7.4.2 RNA Extraction Laboratory

RNA extraction is done in this section. This lab is equipped with equipment that performs RNA extraction as well as sample processing for RNA isolation. The equipment in this laboratory include, Biosafety Cabinet Class II, Centrifuges, Thermomixer, Waterbath, Confocal Microscope, Eppendorf epMotion 5075.

7.4.3 Sequencing Laboratory

This area is where most of the sequencing work and sample preparations for sequencing are done. It houses sequencing machines like the MGI seq and Nano String, freezers, among other equipment.

7.4.4 Pre-Amplification Laboratory

Reagent preparation and storage are done in this section. This room has equipment that is used for the preparation or storage of reagents. No samples and/or nucleic acids are allowed in this room. It has a Laminar Flow Hood, Centrifuges, vacuum pumps, Pipettes, Fridges and Freezers, among other.

7.4.5 DNA Extraction laboratory

DNA extraction is done in this lab. This lab is equipped with equipment that is used for DNA extraction, quantification as well as sample processing. The equipment in this laboratory include, Laminar flow hood, Homogenizer, NanoDrop OneC Spectrophotometer, Thermomixer, Centrifuges, Fridges and Freezers.

7.4.6 Post Extraction Laboratory

All post nucleic acid extraction (DNA and RNA) processes such as PCR, Reverse Hybridization, Library preparation and sequencing are carried out in these Labs (one located after RNA Extraction lab and the other after DNA Extraction lab).

This lab is equipped with six functional Real Time PCR with the latest technologies, Two Conventional PCR, a Sanger Sequencer/SeqStudio, Illumina MiSeq, Laminar Flow Hood.

7.5 The Immunology Unit

The Immunology Unit has 4 different sections housed in the same space.

7.5.1 Sample Reception and Accessioning Area

This is where all clients deliver their samples. Here, the samples are received, sorted and/or checked. A sample delivery log where the number of samples delivered, the person who delivers the samples, the time the samples are delivered, and the initials of the staff who receives them are recorded.

There's a sample accessioning book or register and a computer to facilitate entry of sample information in electronic system where each sample details are captured including assigned laboratory code or number.

There's also a sample accessioning book or register where these details are captured as well. The sample reception and accessioning area has a sample window through which samples are passed to the lab personnel. It also has a work table or bench tops where samples are sorted and assigned numbers accordingly.

7.5.2 Sample processing area

This is the area all samples in the immunology laboratory are processed. It is comprised of working benches and 2 Biosafety Cabinet Class II and other equipment which include freezers, Fridges, Nitrogen tanks, ELISA reader, ELISA washer, CO_2 Incubators, and Microscopes.

7.5.3 The Flow Cytometry Room

This room has a Flow Cytometer and cell sorter. It is where all flow cytometry assays are performed.

7.5.3 Database accessioning area

This is an area found on the bench near -80^0C freezers. The place has a computer with freezer works, label making machine and label scanner. This is where all samples are accessioned in freezer works after processing before final storage.

7.6 Sample storage

The GMI Labs have ample sample storage facilities that comprise of $+4^0$C, $-20\ ^0$C -80^0C and -196^0C (liquid nitrogen). These Fridges and freezers are used for temporary storage of samples prior to processing and analysis or during processing. Samples are then stored permanently in the -80^0C and or -196^0C. Samples are also stored in the BioBank at -80^0C and or -196^0C

7.7 Supporting Facilities

GMI Labs are not standalone, facilities, they operate alongside the Biorepository and Bioinformatics facilities, all of which are located on the same floor as the Genomics unit.

The GMI labs have an office, a conference room, store, kitchen, and lavatories. Almost all administrative work is in the managers' offices located where the different laboratories are housed; the data room and the director's office are situated on the second floor of the building that houses the Genomics and Molecular Unit.

GMI Labs has enough storage facilities for its supplies and consumables away from the lab with a well-controlled environment and with restricted access.
The Immunology Unit store is located behind the pathology building meanwhile the Genomics and Molecular Unit store is located on level two of the same building.

8.0 Location of the Laboratories

The Genomics, Molecular and Immunology Laboratories are located at the Department of Immunology and Molecular Biology, School of Biomedical Sciences, Makerere University College of Health Sciences (MakCHS).
Genomics and Molecular Unit is located on the third floor (level 3), Pathology-Microbiology building. While the Immunology Unit is located on the first floor (level 1), School of Medicine building.

8.1 Access to the Laboratories

Access to the Genomics and Molecular Unit is through the Main Entrance located immediately after the elevator on level 3 of the Pathology-Microbiology building MakCHS. The main entrance has restricted access control to the non-long-term staff and clients.

As well, the clients and other stakeholders can access the Genomics and Molecular Unit through the elevator or by use of stairs located to the right when facing the Makerere University Walter Reed Project Laboratories.

Access to the Immunology Unit is through the Main entrance of the School of Medicine building. The Immunology Unit Main entrance is directly opposite the Biomedical Sciences Research Ethics Review Board (IRB) offices for School of Biomedical Sciences.
Children and animals are all not allowed into the laboratories. Trainees, students and clients may be allowed into the lab sections with approval from Management/Administration

8.2 Address

Email: info@gmi.mak.ac.ug

Website: https://gmi.mak.ac.ug

Telephone: +256414674494

Postal Address: P.O Box 7076, Upper Mulago Hill Road, Mulago, Kampala- Uganda

8.3 Hours of operation

The Genomics, Molecular and Immunology Laboratories are Open 8am to 5pm from Monday to Friday and from 10am to 4pm on Saturdays, Sundays and Public Holidays.

Extra hours for sample reception and results dispatch to clients can be organized on special arrangements with the client or the facility.

Note: GMI Labs operate in accordance with the rules and regulations of Makerere University's Department of Immunology and Molecular Biology, MakCHS.

9.0 Advisory Services

The Genomics, Molecular and Immunology Laboratories are committed to providing professional advisory services about all research and diagnostic tests to all its clients.

Clients are free to contact the Managers, Technical Supervisors, Quality Assurance and Control Officers, Laboratory Director, Head of department or any lab staff for information regarding the services we offer, the turnaround time of the tests, sample types required for the tests and any other professional advice.

However, depending on the staff contacted, the client(s) may be provided the information or referred depending on the nature of information needed.

The contact details of Director, the head of the department, the Managers, Quality Assurance and control Officer, the Technical supervisors can be found at the laboratories' website or provided from the lab as necessary.

10.0 Patient Preparation Guidelines

The Quality of samples collected is affected by patient preparation, therefore ensure proper prep beforehand.

1. Always wear necessary PPE like gloves and lab or clinical coat before interacting with study participant or patient.

2. Make sure to introduce and identify yourself to the patient and explain in easily understandable terms what the testing is about and the purpose of the test.
3. Always ask for all patient information as required by our request form and match it to the request form. Do not proceed to collect sample unless you have all proper patient information.
4. Explain the benefits and possible risks associated with the testing and the sampling procedure to the patient and any discomforts they may feel and ask if there are any questions or concerns the participant or patient might have.
5. Be considerate of the patients age and culture while handling them.
6. Inquire about any possible allergies to the PPE material especially latex likely to be used in contact to the patient's body and use alternative materials in case of any reported allergies
7. Make sure to prepare all materials needed before you start sample collection.
8. When collecting samples for research involving human subjects, make sure to obtain informed written consent from the participant (as per the study protocols) before proceeding to collect the sample.

Note: For QFT sample draw if collecting directly, follow the tube order:

a) Nil
b) TB-1
c) TB-2
d) Mitogen

- We recommend use of high altitude QFT blood collection tubes. Incase low altitude tubes are to be used, use a syringe and immediately transfer 1ml to each of the tubes in order.
- Blood should be filled with in the range of the indictor mark (black mark) on the tube. If outside the range of the indicator mark, a new blood sample should be obtained.
- Tubes should be between 17^0C- 25^0C at the time of blood filling.
- If not collecting directly into the QFT tubes, use a tube with Lithium Heparin anticoagulant.

11.0 Sample Collection And Transportation Requirements

1. Specimen submitted to GMI Labs are requested using the request forms which at a minimum meet the ISO 15189:2012 requirement.

2. The GMI Labs have request forms (Appendix 2) which are given to clients as a form of service Agreement to use to order for test or a service(s) in any of the GMI Lab units.
3. However, being a research facility as well, the GMI labs may accept Research specific forms provided they meet the ISO requirements for requesting for examination.
4. However, exception is made for COVID-19 requests, where samples are delivered without request forms, as clients enter all the information which should have formed part of the request form into the CRS LIMS. In this case samples are accepted if the information in the system conforms to that on the sample(s) delivered to the lab.
5. The GMI Lab request form has the following sections;
   - **a)** Participant ID,
   - **b)** Age & Gender,
   - **c)** Address & contact,
   - **d)** Next of Kin Contact & address (important as an emergency contact for example during critical results and also for notification in the case of failure to reach out to patient/participant)
   - **e)** Requestor' details,
   - **f)** Clinical notes,
   - **g)** Sample collector's details,
   - **h)** Sample type, date of collection and sample ID,
   - **i)** time and date the specimen is delivered in the laboratory,
   - **j)** Initials of the person delivering the specimen and initials of the person receiving the specimen.
   - **k)** An array of tests that can be requested.
6. Handling of patient samples after collection
   - **a)** After blood draw into a tube, invert slowly for 10 times.
   - **b)** For QFT, samples should be maintained and transported at room temperature (22^0C +/- 5)

11.1 Guidelines for patient-collected samples

1. Patients/participants should carefully read and follow the instructions provided by the laboratory for collecting and handling the samples. This includes information about

how to collect the sample, the type of container to use, and any storage or transport requirements.

2. Patients/participants should wash their hands thoroughly and clean the collection site with soap and water before collecting the sample. This helps to reduce the risk of contamination and ensures that the sample is as clean as possible.
3. Patients/participants should use a sterile collection container. The container should be opened just before collecting the sample to prevent contamination.
4. Patients/participants should collect the correct amount of sample as specified by the laboratory. Collecting too little sample affects the accuracy of the test results.
5. Patients/participants should label the sample container with the sample ID or participant/patient ID, date of sample collection and present it together with a fully filled lab request form. This helps to ensure that the sample is properly identified and tracked throughout processing and analysis.
6. Patients/participants should store and transport the sample as instructed in ***appendix 1*** of this handbook. This may include keeping the sample on cold chain and delivering it to the laboratory in a timely manner.

11.2 Sample monitoring during transportation

1. The sample collector or courier should ensure to monitor both sample temperatures and transportation time lapses using small digital thermometers and timers.
2. The sample transportation conditions and duration/time for sample in transit for both Molecular and Immunological assays are shown in Table 2.

   Note: These conditions should be adhered to always.

Table 2: Sample type, collection medium, Volume, container and transportation condition

Sample type	**Collection Medium, volume and container**	**Transportation condition**
Blood for DNA analysis	EDTA Tube **(at least 1 ml)** PAXgene Blood DNA tube Blood **(at least 9 mls)** FTA card (Dry blood spots)	The Triple packaging system is used. Primary receptacle (collection tube)secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with ice packs)
Nasal /oral pharyngeal swabs	Viral transport buffer The swab should be suspended in ≥**3ml** buffer;	The Triple packaging system is used. Primary receptacle (collection tube)secondary receptacle (a Ziploc bag)

	bigger volume might be needed as may by requested by lab personnel depending on test to be performed)	and a tertiary receptacle (cooler box with ice packs)
Blood for RNA analysis	EDTA Tube (at least 1 ml) PAXgene blood RNA tube (at least 9 mls)	The Triple packaging system is used. Primary receptacle (collection tube)secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with ice packs)
Sputum	Nuclease-free sterile 50 ml propylene screwed tube or sputum cup containing 20ml activated guanidine Thiocyanate. Wrap the tube with aluminum foil	The Triple packaging system is used. Primary receptacle (collection tube) Secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with ice).
Decontaminated sputum (Following processing in BSL-3 Lab)	Nuclease free 1.5ml screw cupped centrifuge tube. Resuspend pellet or sediment in 100µl Lysis Buffer (A-LYS)	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box)
Saliva	Nuclease free sterile 50 ml propylene screwed tube Nuclease free sterile sputum with activated GTC, RNA later, or Trizol, Genotek DNA Saliva collection tube	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with ice)
Stool	Nuclease free sterile screw cupped stool containers Nuclease free sterile screw cupped stool containers with RNA stabilizer	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with ice)
DNA	Nuclease free DNA LoBind Screw capped skirted tube **(at least 50 µl of nuclease free DNA**)	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with ice packs)
RNA	Nuclease free DNA LoBind Screw capped skirted tube **(at least 50 µl of nuclease free DNA**)	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with dry ice)

Other Body fluids	Nuclease free sterile screw cupped containers (1.5-2ml) cryo-vails 15ml or 50ml falcon tubes Nuclease-free sterile screw cupped stool containers For stool indeed for RNA analysis, an RNA stabilizer should be added	The Triple packaging system is used. Primary receptacle (collection tube) Secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with dry ice).
Tissue Biopsies	Nuclease free sterile screw cupped containers for DNA analysis Nuclease free sterile screw cupped containers with RNA stabilizer for samples intended for RNA analysis	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with dry ice)
Blood for serum harvesting	Sterile vacutainers with red top screw caps. Sterile serum separating tubes with yellow screw caps and containing silica and a polymer gel. (at least 4ml of blood)	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box at ambient temperature)
Whole blood for Plasma harvesting and whole blood assays	Sterile vacutainer tubes with purple screw caps and containing EDTA anticoagulant Sterile vacutainer tubes with green screw caps and containing heparin (at least 4ml of blood)	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box at ambient temperature)
Whole blood for PBMC isolation	Sterile vacutainer tubes with green screw caps, containing sodium heparin anticoagulant. Sterile CPT tubes with tiger blue screw caps containing sodium heparin anticoagulant Sterile vacutainer tubes with yellow screw caps containing ACD anticoagulant.	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box at ambient temperature)
Cell lines and cryopreserved cells	Sterile Nalgene cryovials containing freezing medium	The Triple packaging system is used. Primary receptacle (collection tube) secondary receptacle (a Ziploc bag) and a tertiary receptacle (cooler box with dry ice at -80oc)

11.3 Sample collection and transportation for DNA or RNA, or Protein assays

The procedure for collection and transportation should ensure that the integrity of nucleic acids (DNA and RNA) and proteins is maintained in the primary specimen.

1. All samples should be collected by a trained and competent personnel.
2. When collecting these specimens, devices coated with a substance capable of inhibiting enzyme-based reactions should not be used for example anticoagulants such as heparin and preservatives like formalin should not be used unless stated.
3. The specimen should be collected in a medium that preserves nucleic acids and protein otherwise should be transported to the lab for primary processing under a cold chain before downstream processes.

Note: These precautions should be adhered to as they potentially interfere with all the downstream processes and interpretation of results.

11.4 Sample collection and transportation for immunological assays

1. All samples should be collected in sterile sample containers. Specimens for serum harvesting should be collected in red top screw vacutainers or serum separator tubes (SST) tubes.
2. Specimens for plasma harvesting should be collected in vacutainers containing either sodium heparin or EDTA or acid citrate dextrose.
3. Urine, semen and breast milk should be collected in suitable sterile containers.
4. Samples for PBMC isolation should be collected in sterile vacutainers containing sodium heparin, acid citrate dextrose anti-coagulants or in CPT tubes to preserve the integrity of the mononuclear cells.
5. Transportation of all samples for PBMC isolation to the lab should be done within 3 hours after collection in order not to compromise the viability of the cells.

11.5 Sample Transit time

1. The sample transit time is dependent on the test requested, however, freshly collected samples for DNA and RNA analysis should be transported to the laboratory within 12 hours of sample collection.
2. Samples for other Immunology based assays should be transported and delivered to the lab within 4 hours of collection.

11.6 Sample labelling

1. The Specimen container must be identified with at least a participant ID, Specimen type, and the Collection Date.
2. The labeling must be readable and done with indelible ink markers or printed labels.
3. The above information on the sample containers must be 100% identical to that written on the laboratory request form.

12.0 Factors that may Significantly Affect Performance of the Examination and Result Interpretation

1. Samples taken from venous access devices (Can cause sample hemolysis, sample can be contaminated with IV fluids and the risk of introducing bacteria into circulation. Avoid taking blood samples from such devices)
2. Posture (posture is critical for accurate results. Normal ranges are usually drawn using ambulatory patients)
3. Prolonged tourniquet application (Veins must be accessed within one minute of tourniquet application. If above not achieved, tourniquet must be released and put on different arm or re-applied to the same arm only after 2 minutes. minimize effects of hemoconcentration on the sample.)
4. Order of blood draw (be keen on recommended order of blood draw)
5. Hemolysis (Avoid slow draws coming from poorly positioned needles. Do not pull hard on plunger of syringe. Gently invert tube 5-10 times to mix)
6. Blood clotting (usually caused by inadequate mixing of sample, always mix samples thoroughly by inverting 5-10 times immediately after collection.)
7. Specimen transportation: Once the specimen is collected, transport it to the GMI laboratories in a timely and appropriate manner to avoid changes in the specimen's properties.
8. For example, some specimens may need to be transported on ice to prevent degradation, while others may need to be transported at room temperature to maintain stability. **Refer to subsection 11.2**
9. Specimen processing: The processing of the specimen before analysis is also important to ensure accurate results.

10. Where the sample is pre-processed before delivery to the GMI laboratories, the client or referring facility should ensure this is done as per the standard operating procedures.
11. Any storage of the specimen done by client or referring facility before analysis must done at temperatures appropriate for the sample.
12. Proper documentation is essential for tracking the specimen from collection to analysis. The client, patient or participant should ensure to label the specimen and complete the GMI lab request form with the correct information for submission to the lab.
13. Analytical factors: Analytical factors refer to factors that occur during the actual laboratory analysis. The GMI labs practice a high degree of proficiency and professionalism keeping such factors at the minimum.
14. Certain contaminating substances interfere with laboratory test results, either by affecting the performance of the test itself or by altering the biochemical properties of the sample.
15. Collect sample in sterile containers and keep away any contaminant during sample collection.
16. Technical limitations: Some laboratory tests performed at the GMI labs have more sensitivity and/or specificity than others.
17. This may lead to discordance in results of similar samples by different tests.
18. The GMI labs technical team always ensures to explain such situations to the clients, when they arise.

13.0 Sample Rejection Criteria

Samples are rejected if they have any of the following features;

1. The specimen or sample container is broken, damaged, or leaking. Do not try to rescue such a sample as it may expose you to infection risks
2. The specimen container is not labeled or there is not enough information on the container to match with the laboratory request form
3. The information on the laboratory request form does not match that on the sample tube
4. The specimen Request form(s) is not filled to completion (only sections required to be completed by the requester and the sample runner should be empty)
5. The request form(s) is filled incorrectly

6. The specimen was not accompanied by a request form and no sample details in the lab LIMS.
7. Request form sent without a sample
8. Sample collected in an inappropriate container
9. The sample volume is too little and the container appears empty
10. A wrong sample is delivered for the test
11. Sample delivered under inappropriate conditions especially temperature, as specified in **subsection 11.2** of this handbook.
12. Samples delivered after period of time that exceeds stipulated timelines for given test

    Note; If such a situation occurs client(s) is informed in time and another sample collected or the request reconciled accordingly

    Note: If there is any inconsistency between sample ID label and request form or when the sample(s) was/were delivered without the request form(s) but can be traced, the Technologist in charge of sample reception at the time notifies the requester for Reconciliation

1. If the sample is rejected, the Technologist indicates **REJECTED** on the respective sample requisition form, appends signature and date
2. The technologist then records the event on the sample rejection and reconciliation log.
3. The original copy of the completed requisition form(s) with **REJECTED** is kept on the respective file in GMI Labs, while a copy is sent back to the requester, along with the sample rejection log details.

   Note: The requester is always notified about the rejected sample(s).

13.1 Handling accepted samples

1. Once samples have been accepted, the sample(s) are recorded in the laboratory sample delivery and reception log or in the reception book, by the person who has delivered the samples and reception must be acknowledged a lab personnel.
2. All the information deemed necessary by the ISO 18189:2013 at a minimum is captured by the staff in GMI into the lab information management system.

14.0Result Reporting and the result report contents

Upon sample reception and performance of the required tests, the result(s) is reviewed, approved and reported following our Result Reporting and Critical Value Reporting SOP**.**

The Result report generated and issued by GMI Labs to clients contain at least the following information or sections;

- **a)** Clear identification of the examination(s) performed and or method used
- **b)** Identification of the laboratory that issued the report
- **c)** identification of all examinations that have been performed by a referral laboratory if any
- **d)** client identification (name or unique number)
- **e)** Client or patient location where applicable
- **f)** Name or unique identifier, and address of the requester
- **g)** Sample information (sample type, quality, Date/time the sample was collected and received in the laboratory)
- **h)** Referral sample ID
- **i)** Clear and concise results of tests analyses
- **j)** Date and time of the result generation
- **k)** Page number in the format of page 1 of 2…
- **l)** Version and date the version was effective
- **m)** Examination Procedure used where applicable
- **n)** Information on Kit used where applicable
- **o)** Biological reference ranges where applicable
- **p)** Comment; This section is completed in cases where results could have been compromised by sample quality. It may also have cautionary or additional explanation of the result and or the assay, a need for a repeat sample, summary of results interpretation, examinations undertaken as part of a research and for which no specific claims on measurement performance are available, among other comments.
- **q)** The identity of the person who performed the examination(s)
- **r)** Identity of the reviewer and approver/authorizer
- **s)** Any other information as maybe deemed necessary by a study or any standard requirements

14.1Result release or dissemination

1. Since samples are received from other facilities or clinics (referred facilities), the approved results are realised by staff in the result dispatch section or in that respective section directly to the requester.

   Note; The requester may be a contact in the referring facility or collection site or the study site or Principal investigator or study coordinator.

4. In cases where a client or a patient delivers their samples directly to the lab, the results may be given directly to that client following prior agreement.
5. Where quality of the sample has compromised a result, result report is released with such comments which necessitate a repeat sample for a rerun.
6. Only original copies of result are issued to clients (requester), electronically or manually (hard copy).
7. Copies are made and kept on a respective file or study file in the lab and it is used for references. Also, soft copies of the result are kept for some tests such as SARS-CoV-2 RT- PCR and also sequencing results, among others
8. In case results reported are not collected by the requestor, where they are required to collect, the original copy(s) is kept in a file pertaining to that study. And the client is reminded by staff in that section to collect them.
9. Preliminary or interim results where necessary may be released (depending on the format) verbally over the home or via email or their personal hard drive or via a link.
10. Once a full and complete analysis is finished as per the requested examination, a complete report is then issued following it.

    Note: SARS-CoV-2 RT-PCR results are not printed but are shared or sent to clients via emails and or WhatsApp groups and usually release as a complete report.

    Note: In cases where there is a breakdown in the RDS (for COVID-19 PCR), local and Manual GMI Labs results may be printed and given to the respective client or requester following authorization from the MoH.

14.2 Reporting critical results or critical decision values

1. Staff performing the examination is responsible for bringing critical values to the IMMEDIATE attention of the supervisor.

2. Critical results are reported immediately by sending a notification or informing the client via email or through a phone call, prior to release of an approved result report.
3. The staff reporting the Critical result(s) informs that a critical value is being reported, Client name or Id and the result. Record of such communication is documented and filed in the respective result file.
4. Where results were disseminated via telephone or verbally, staff who performed the test and or who gave the verbal report then prepares a hard copy of the report and issues an approved copy to the client who was informed.

15.0 Clinical Advice on Ordering of Tests/Assays and on Interpretation of Test Results

1. The magnitude of QFT measured interferon gamma levels cannot be correlated to the stage or degree of infection. level of immune responsiveness or likelihood for progression to active disease.
2. Results from the QFT plus testing must be used in conjunction with each individual's epidemiological history, current medical status and other diagnostic evaluations.
3. Samples types delivered for nucleic acid extraction or related processes must be ideal for the organisms of interest, that is, the sample type must truly contain a life stage of the organism for example blood for malaria rather than mucus, mucus for mycobacteria rather than urine, urine for chlamydia rather than mucus.
4. Measurable and Absolute results contain ranges that are usually proportional or inversely proportional to severity of test parameter, for example real time PCR assays have results in terms of Cycle Thresholds (CTs), these values are inversely proportional to amount of nucleic acid in the sample and subsequently copies of organism being detected.
5. Text result types are usually descriptive of the result. File and internet links usually contain result types that require more processing to output more meaningful information for the client. This processing can also be done by the GMI labs upon request by the client, such results include sequencing results with fastqs or bcl files as results.

6. GMI labs communicate different result formats depending on the nature of tests requested. The lab managers, technical supervisors or designees are usually available to elaborate more on the results when needed.

16.0 Sample Retention and Disposal

1. Depending on the agreement that the GMI Labs had made with the clients whose samples were analysed from any of the GMI labs, otherwise they may be disposed of following 3 days after results release.
2. For studies where all samples are stored, these are processed and stored according our laboratory protocols. For these samples, storage timelines are agreed upon with the client in a memorandum of understanding (MOU), in case the MOU does not specify storage timelines, these are discarded five years after study completion and closure.
3. Samples to be disposed of are treated as hazardous materials, are autoclaved where applicable, and discarded with hazardous waste according to our Infectious and Non-infectious Waste management protocols.

17.0 Clients' Complaints and Client Satisfaction Surveys

1. In compliance with ISO 15189.2012 accreditation requirements which requires laboratories to seek information relating to user perception as to whether the laboratory has met the needs and requirements of users, GMI labs have set out to conduct customer satisfaction surveys annually.
2. Client satisfaction survey forms are distributed electronically or in hard copies to laboratory clients who are required to complete the forms. Completed hard copies of survey forms are to be returned to the Laboratory Quality Officer. Electronic surveys are controlled and managed by the IT team which also include the Quality Officer.
3. Client Satisfaction survey feedbacks are analyzed and presented in reports discussed with the Director and the entire lab team to see how better to improve and to sustain the best practices that satisfy our client needs and requirements.
4. Feedback is usually provided to the clients depending on the complaints or suggestions raised. All dislikes are treated as a Non-conformity (NCs) and are handled following the GMI protocols for Identification and Management of NCs
5. Communications, Client Complaints Management and Feedback are handled following

GMI lab documented procedures. Records are captured on the Complaint Resolution forms.

18.0 Informed Consent, Study Protocol, and IRB Approval

1. It is the responsibility of the Principal Investigators (PIs) or the Researchers of given research project or study to ensure that Informed Consent is obtained from patients/ participants before collecting samples from study participants for research purposes.
2. For any research samples to be accepted or received in the GMI Labs, the researcher or PI must provide the GMI Labs with at least an approved study protocol and IRB approval.

   Note: Also, the Uganda National council of science and technology approval and proof of consent may be required.
3. If samples are collected from patients for use in their care and management then there will be no need to obtain consent from them.

19.0 Confidentiality

1. The GMI Labs has a policy in place to ensure that no information provided by the Clinicians and or a Researcher is released to unauthorized persons.
2. Records of participant's information are kept under lock and key. Access to such files can only be authorized by the laboratory Manager.
3. A memorandum of understanding is made between the laboratory and its clients where all the obligations and duties of the laboratory in maintaining confidentiality are clearly stated.
4. All the clients intending to perform research in the laboratory are expected to present their study protocols and letters of approval from a recognized Institutional Review board.
5. GMI Labs require that all Investigators or Researchers who intend to do research in the laboratory, GMI facility organizes and conducts a study protocol training for lab staff especially those who will be required to conduct the work.
6. In addition, the researcher is required to make a PowerPoint presentation and present the study to the lab team before the processes to the lab staff before the study's laboratory work commences.

20.0 References

1. **GMI#M003-C**lient Handbook Version 3.0
2. ISO 15189:2012

21.0 Attachments

- Request form
- Result Report
- Communication and Complaint's Resolution form
- Client Satisfaction Survey form
- Sample Rejection and Reconciliation form

Annex 1: Revision History Table

Revision No	Effective Date	Description of Changes Made from Preceding Revision	Approved by/ Date
01	30-Apr-2021	The entire Handbook was revised, Subsection 5.0 the Lab descriptions were revised to include, Post-Extraction Lab, DNA Extraction Lab, and the Reception, former Sequencing Section 6.0 to 9.0 were revised, the Quality policy was revised (section 12.0), Section 13.0, 14.0, 15.0, 16.0 to 22.0 were revised accordingly. Attachments were including, that is Complaint resolution form, Communication log, Client satisfaction survey forms for Students, Researchers, and The Clinician/Hospital/Clinic team	Kia Praiscillia 30-Apr-2021
02	21-Mar-2022	MBL was replaced with GMI Labs and the description of tests performed were removed	Kigozi Edgar 18-Mar-2022
03	09-Jan-2023	The entire Handbook was revised Missing sections required by the ISO standards were added	Dr. Rose Nabatanzi

Annex 2: Documentation of Suggested Changes to this Client Handbook

Clause	Suggestion	By	Date

Request form

Makerere University College of Health Sciences
School of Biomedical Sciences
Department of Immunology and Molecular Biology
Genomics, Molecular and Immunology Laboratories (GMI Labs)
Specimen Request Form

Participant ID: _____ *Age:* _____ *Gender:* _____ *Address:* _____
Contact(s): _____ *Next of kin contact:* _____ *Address* _____

Test requested by: _____ *Contact:* _____ *Date* _____

Clinical notes:

Samples collected by: _____ *Contact:* _____ *Date/Time:*

Sample Type (Tick where applicable)		
☐ Blood Red/Purple/green/light green/yellow/gray/gold/blue ☐ Urine ☐ Induced Sputum ☐ Decontaminated sputum ☐ PAXgene RNA ☐ PAXgene DNA ☐ Saliva ☐ Swabs *(Specify)*	☐ Stool ☐ Tissue ☐ DNA ☐ Isolates ☐ Environmental specimens ☐ Breast Milk ☐ *Others (specify)*	*Sample ID:* _____ *Study Name/Code:*

Sample Delivered by: Date D D M M M Y Y Y Y Time H H M M

Sample Received by: Date D D M M M Y Y Y Y Time H H M M

Tests Requested (Tick where applicable)

Genomics and Molecular Assays;		Immunology assays		Processing and Storage
PCR assays for;	**Sequencing**	**ELISA Tests**	**Serology**	
☐ SARs-CoV-2 ☐ *MTBDRplus* ☐ *MTBDRsl* ☐ Detection and viral load for *CMV☐, EBV☐, HBV☐, HSV☐ HHV6☐* ☐ qPCR HPV genotypes 16 &18 ☐ Malaria-Detection of *P. falciparum* ☐ Antibiotic Resistance *MRSA ☐ VRSA ☐ VER ☐ ESBLs☐* ☐ SNP genotyping ☐ MIRU VNTR ☐ Spoligotyping ☐ MLST* ☐ Plasmid profiling	☐ Whole genome seq ☐Exom sequencing ☐ 16S Metagenomics ☐ Targeted seq ☐ 18S/ ITS Metagenomics	☐ CRP ☐HIV ☐ HSV-2 ☐ Toxoplasmosis ☐ Rubella ☐ CMV ☐ HBsAg ☐ Anti-HB ☐ HBV Core Ag ☐ HPV ☐ Interleukins ☐ IFN-γ ☐TNF-α ☐ QuantiFERON TB ☐ Gold plus in tube ☐ IgE	☐ Covid-19 ☐ HIV rapid Test ☐ RPR ☐ TPHA ☐ Serum HCG ☐ Urine LAM **Other assays** ☐ Cytotoxicity assays ☐ Flowcytometry	☐ DNA Extraction ☐ RNA Extraction ☐ PBMC ☐ Plasma ☐ Serum ☐ Multiplexing using Luminex ☐ Aliquoting primary Sample and storage ☐Nucleic Acid QC

Other tests; please specify the Organism(s), or Gene or Marker of interest or the assays

Reviewed by/Date:

Version 5.0 Effective 29-Mar-2022
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Page 1 of 1

Result Report form

MAKERERE UNIVERSITY

COLLEGE OF HEALTH SCIENCES

School of Biomedical Sciences

Department of Immunology and Molecular Biology

Genomics, Molecular and Immunology Laboratories

Result Report

Lab No:
Participant ID:
Sample ID:
Name:
Age: **Gender:**
Address:
Study Name:

Requester
Name:
Telephone:
Email:
Date Requested:
Organization:

Test Requested: **Sample Type:**

Collection Date: **Date Received:** **Result Date:**

Results:

Comments:

Kit Used: **Verified Kit Lot:** **Kit Expiry Date:**

Performed By: **Reviewed By:** **Approved by:**

1 of 1

Printed By: Print Date: Printed # time(s)

Communication and Complaint's Resolution form

Genomics, Molecular and Immunology Laboratories		
Title	**Communication and Complaints Resolution form**	
FM#GMI-P005-F01	**Effective Date: 28-Mar-2022**	**Version 4.0**
Prepared by: Kia Praiscillia		**Approved by: KEG**

PART 1*(To be completed by Receiver)*

Complaint No:

Date of reporting:			**Receivers Name**		
Complainant's name and contact			Organization/Health Facility		
Subject :			Mode of communication		
Category:			**Responsible person to resolve:**		
***Categories:** **Please tick**	**Pre-Analytical** Reception Data entry Sample approval Others;	**Analytical** Sample sorting Analysis Result validation Results transcription	**Post-Analytical** Printing Q/C Other	**Human Resource**	**Others**
Brief description of Complaint					
Receivers response to customer					

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Page 1 of 2

Genomics, Molecular and Immunology Laboratories		
Title	**Communication and Complaints Resolution form**	
FM#GMI-P005-F01	**Effective Date: 28-Mar-2022**	**Version 4.0**
Prepared by: Kia Praiscillia		**Approved by: KEG**

PART 2*(To be completed by responsible person)*

Rootcause
Corrective Action taken
Date/Initials
Feedback given to the customer
Date/Initials
Date action completed/Initials:

PART 3*(To be completed by the lab manager or designee)*

Turn Around Time (TAT)
Verification of Completion and effectiveness of corrective action:
Date/Initials

Comments: _____

Reviewed by: _____ Date: _____

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Client satisfaction Survey form

Genomics, Molecular and Immunology Laboratories		
Title	**Client Satisfaction Survey form**	
FM#GMI-P005-F02	**Effective Date: 28-Mar-2022**	**Version 3.0**
Prepared by: Kia Praiscillia		**Approved by: KEG**

The objective of the *Genomics, Molecular and Immunology Laboratories (GMI Labs)* is to provide high quality diagnostic and analytical services to support patient management, research, clinical trials, and training. To ensure the quality of our services as well as to aid our Quality Assurance and Improvement Program, we send a periodic survey to all our clients. We need your feedback to ensure that we are providing you with the best services possible. Please take a few minutes to complete the questionnaire and provide your contact details in order to ensure efficient communication and service delivery.

Name:_____ Facility/Organisation: _____

Position/Title _____Date survey completed:_____

Services GMI Labs is offerring to you or your organisation: _____

Please tick the appropriate box to indicate your degree of Satisfaction. Where: 5=Excellent/Yes 4= Very Good, 3= Maybe/Good,2= Fair,1= No/Poor

No.	Topic	1	2	3	4	5	Comments / Suggestions
1.	**Customer care:** In your opinion, how courteous are our staff members when dealing with clients?						
2.	**Professionalism:**						
	How do you rate the knowledge of our laboratory staff in the services they are offering to you when interacting with them?						
	For Students-Based on the techniques the Technologist taught you, how would you rate his/her expertise?						
	Did he/she have knowledge or experience of the techniques offered at GMI Labs?						
3.	**Scope of services:**						

Genomics, Molecular and Immunology Laboratories		
Title	**Client Satisfaction Survey form**	
FM#GMI-P005-F02	**Effective Date: 28-Mar-2022**	**Version 3.0**
Prepared by: Kia Praiscillia		**Approved by: KEG**

	We offer a wide range of services. How would you rate their scope?						
	Are our services up to your expectations?						
4.	**Turn Around Time(TAT):**						
	How do you rate the timeliness of our test results?						
	Would you consider them satisfactory for patient management or its intended purpose?						
	Do we meet our specified TAT for the service(s) you request?						
5.	**Quality of service(s):**						
	How would you rate the impact of our results on patient management and/or research?						
	How useful are they for answering your research question(s)?						
	For students: How do you rate the contribution of our practical training program in bridging the gap between theory and practical skills?						
6.	**Clarity & Comprehensiveness of the test result report**						
	How do you rate our test reports?						
	Do the results, interpretations, and comments provide a clear and concise explanation of the results?						
7.	**Comprehensiveness of the request form**						
	How would you rate the GMI Laboratories' request form in terms of ease of use and content?						
	Does it provide you with sufficient information for the submission of samples to our lab?						
8.	**GMI Labs facilities:**						

Genomics, Molecular and Immunology Laboratories		
Title	**Client Satisfaction Survey form**	
FM#GMI-P005-F02	**Effective Date: 28-Mar-2022**	**Version 3.0**
Prepared by: Kia Praiscillia		**Approved by: KEG**

	How do you rate the conduciveness of the GMI Laboratories' facilities for students training and other services provided?						
9.	**Practical Teaching sessions** *(Students):*						
	Is the GMI Laboratories well equipped for hands-on training/practicals?						
	Are the practical teaching session adequate for skills to be acquired?						
10.	What do you **dislike** about our services?						
11.	What services of the GMI Labs have you used between 2021 and 2022?						
12.	What do you propose we should do to satisfy your requirements even more?						
13.	Would you recommend another client to our facility?						
14.	Any other comments or suggestions?						

For more information, please contact the Laboratory Management of the GMI Labs. Thank you

Sample Rejection and Reconciliation form

Genomics, Molecular and Immunology Laboratories		
Title	Sample Rejection and Reconciliation form	
FM#GMI-T001-F02	Effective Date: 23-Feb-2022	Version 2.0
Prepared by: Kia Praiscillia		Approved by: KEG

Part 1	Sample Rejection								
Date	Client/Sample Source	Participant ID/Name	Lab ID	Sample type	Test requested	Collection time	Delivered by/Time	Received by/Time	Reason for rejection

Genomics, Molecular and Immunology Laboratories		
Title	Sample Rejection and Reconciliation form	
FM#GMI-T001-F02	Effective Date: 23-Feb-2022	Version 2.0
Prepared by: Kia Praiscillia		Approved by: KEG

Part 2	Sample request Reconciliation								
Date	Client/Source	Participant ID/Name	Lab ID	Sample type	Test requested	Collection time	Delivered by/Time	Received by/Time	Reason for the reconciliation

Reviewed by: _____ **Date & signature:** _____

Comments: _____

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