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	Document Title:	SAMPLE REJECTION AND ACCEPTANCE

PURPOSE:

1. To ensure the proper receipt and processing of patient samples.
2. To explain the criteria for whether to reject or accept a sample.

SCOPE:

Applies to all Molecular Laboratory Personnel of Dr. Pablo O. Torre Memorial Hospital

PERSON RESPONSIBLE:

Molecular Laboratory Analyst, Receptionist, Medical Technologist, Nurses and Attending Physicians

GENERAL GUIDELINES:

1. Personnel sending and receiving the specimen shall be in an appropriate complete PPE.
2. All specimen for SARS-COV-2 PCR test shall be transported to the Molecular Laboratory in a triple packaging system.
3. Receiving personnel shall inspect the transport box upon arrival checking for any leakages on the outer box and disinfect it with 10 % bleach disinfectant solution or 70% ethanol.
4. RMCI/DPOTMH Medical Technologist shall secure specimen integrity and all the documents needed before sending out for processing.
5. RMCI/DPOTMH Molecular Biology Laboratory Receptionist shall receive the transport box and documents such as Line list and Case Investigation Form.
6. All required fields in the Case Investigation Form issued by the Philippine Integrated Disease Surveillance and Response latest version
7. After complete assessment, the receiving personnel shall note the date and time of receiving the specimen on the logbook tracker of the sending personnel



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8. Receiving personnel now shall handover the assessed specimen through the pass box for the actual inspection to be done inside the Class II Biosafety Cabinet by the molecular laboratory analyst.
9. After unboxing of the transport box which contains the sample, RMCI/DPOTMH Molecular Biology Laboratory Analysts shall inspect sample integrity for possible acceptance or rejection.
10. Any criteria met for specimen rejection calls for cancellation of SARS-COV-2 RT-PCR test and recollection of sample if necessary. Upon rejection personnel must inform immediately the hospital or requesting station about the verdict.
11. Receiving personnel shall fill up the SPECIMEN REJECTION LOGBOOK with the date, time and corresponding reason for rejection indicating the complete name and signature of the sending personnel.
12. The transport box shall be disinfected using 10 % bleach disinfectant solution or 70% ethanol and shall return it to the sending personnel through the pass box and if to be reused, otherwise hand it to the molecular laboratory aid for proper disposal.

PROCEDURE:

Initial tasks upon receipt of patient sample:

1. Document the date and time the sample was received.
2. Assign an accession number to be used as sample identification in the laboratory.
3. Verify that the patient identification on the laboratory test request form matches the identification on the sample.
4. Examine the sample visually to evaluate for acceptability.
5. Review and evaluate the test request for suitability of the type of sample collected for the test.
6. Determine the suitability, with respect to the test(s) ordered, of the transport conditions, including the following:
 - 6.1. Transport medium or preservative for the sample
 - 6.2. Temperature of sample upon receipt

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- 6.3. Length of time between sample collection and receipt
- 6.4. Transport container intact, i.e. no leaks or cracks.
7. A reception room is ONLY for administrative tasks. Samples cannot be opened in the reception room.

Actions for when samples are rejected:

1. If the unacceptable sample can be replaced, notify the requesting healthcare provider.
2. Document the reason for the sample unacceptability and request another sample.
3. Do not discard the sample until the patient's healthcare provider has confirmed that another can be collected.
4. If the patient has already been started on antimicrobial/anti-viral therapy or if a repeat sample cannot be collected, this must be documented.
5. If a repeat sample is not available, document the problem and proceed with the test if possible.
6. In order to ensure safety in all work areas that comes in contact with potential transmissible biologic material. The workflow for each of the task assigned for personnel are outline in figures 1 and 2 with the table of their corresponding activities.

REFERENCES:

1. Guidance on regulations for the transport of infectious substances 2019–2020. Geneva: World Health Organization; 2019(WHO/WHE/CPI/2019.20). License: CC BY-NC-SA 3.0 IGO.
2. Institute of Biomedical Sciences. IBMS Professional Guidance. Patient Sample and Request Form Identification Criteria. (Version 2, 2009)
3. Health and Safety Executive. HID 5-2011. Provision of Key Clinical Information on Laboratory Specimen Request Forms. (Dec 2011).
4. Medical Laboratories Requirements for Quality and Competence (ISO 15189). BSN EN ISO 15189:2012.




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ANNEX:

CRITERIA FOR SAMPLE REJECTION	
Unlabeled or mislabeled samples	
Duplicate samples <ol style="list-style-type: none"> 1. Most duplicate samples received on the same day are unacceptable unless the nasopharyngeal and oropharyngeal samples are indicated correspondingly. 2. Each sample must be correctly identified bearing the patient's name, age and sex and the person who collected the specimen. 3. The specimens must have the corresponding appropriate storage temperature during transport and minimum time for corresponding storage. 	



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4. If it has been verified by the person collecting the sample that two samples received at the same time are identical, for the purpose of testing, these samples may be combined and processed as one.
5. If duplicate samples are received at different time on the same day, notify the patient's physician or nurse, and document. If it is acceptable not to process the sample, report "Duplicate sample: test not performed", and note the reference number of the sample that was processed.

Leaky containers

1. A sample is unacceptable when the outside of the container is grossly contaminated with the sample. In this case, request a new sample. Dispose the sample promptly. Disinfect first with suitable chemical disinfectant.
2. If the container is leaking, analyze the sample only if the sample is not compromised and if the leakage will not contaminate any laboratory equipment during the testing process.





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Contaminated samples

1. Contaminated samples are unacceptable. Types of contamination include when another type of sample is mixed with the desired sample.
2. In the case of a contaminated sample, request a new sample.


Inappropriate sample sources

1. Samples that do not conform to the type of sample needed for the requested test(s) are unacceptable.
2. If an incorrect or inappropriate sample type is received, request a new sample and specify the proper sample for the test requested.




Delayed transport time and sample processing.



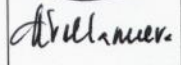
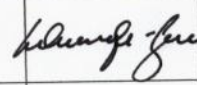

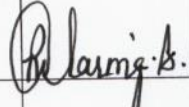
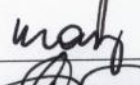
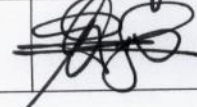
1. Ideally, all samples should be less than an hour old when received.
2. Appropriate transport media and detailed instructions should be available for samples transported to laboratories
3. If the time between sample collection and receipt is too long for a valid test to be performed, with respect to sample requirements for the requested test(s), request a new sample.
4. If a sample was received after prolonged delay but is not rejected by the laboratory, document it and indicate the length of time after collection that the sample was received.

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KEY TASKS	PERSON RESPONSIBLE
1. Reviews and evaluates the test request for suitability of the type of sample collected for the test	Medical Technologist/ Molecular Laboratory personnel
2. Notifies the requesting healthcare provider if the unacceptable sample can be replaced, notify the requesting healthcare provider.	
3. Documents the reason for the sample unacceptability and request another sample	
4. Does not discard the sample until the patient's healthcare provider has confirmed that another can be collected	
5. Documents the problem and proceeds with the test if a repeat sample is not available	

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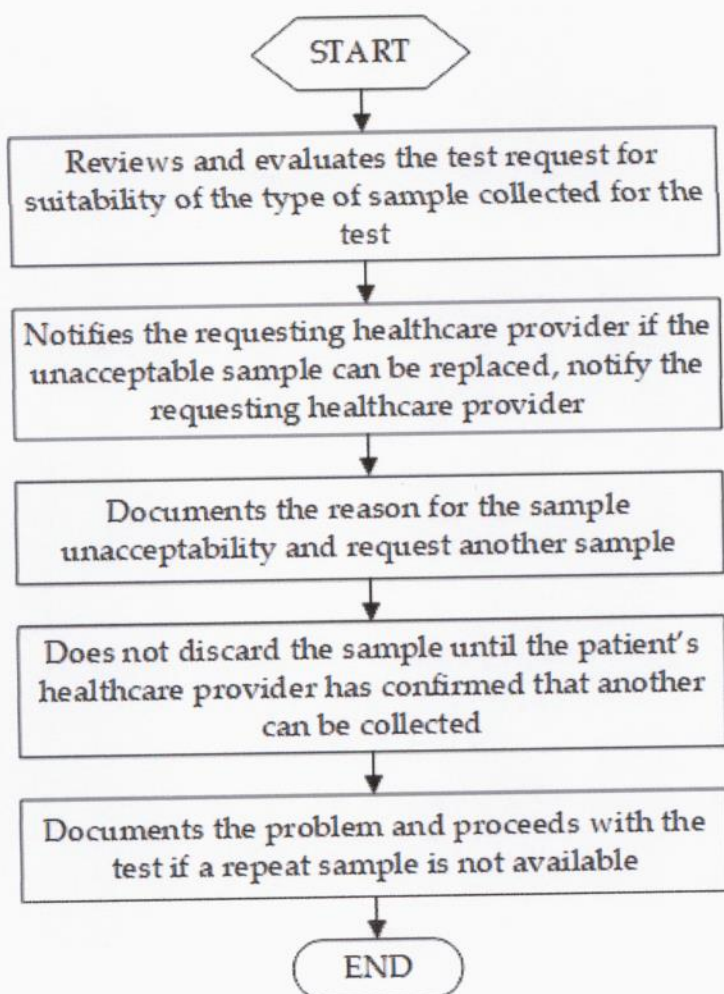


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FLOWCHART





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