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GENERAL POLICIES AND GUIDELINES FOR HANDLING AND PROCESSING SARS-COV-2 (COVID-	Page:
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REVISION HISTORY			
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Reviewed by:	GERARDO S. MANZO, MD Incident Commander	Approved by:	JOEL M. ABANILLA, MD Executive Director
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I. STATEMENT OF THE POLICY

This policy shall serve as a guide to every laboratory and hospital personnel involved in providing diagnostic services as mandated by the Department of Health (DOH) with regard to the **Rapid PCR Testing for SARS-CoV-2 (COVID-19).**

II. POLICY GUIDELINES

1. Specimen Collection and Handling

- 1.1 Prior to specimen collection, appropriate personal protective equipment must be worn including cover all gown, fit tested N95 mask, shoe cover, bouffant cap, gloves, face shield and disposable isolation gown.
- 1.2 After specimen collection, break the nasopaharyngeal and oropharyngeal swab (NPS/OPS) at the indicated break line and place immediately into the viral transport media. Nasopharyngeal and oropharyngeal swab are the only sample acceptable for Xpert Xpress SARS-CoV-2 testing.
- 1.3 Properly label the viral transport medium with the following information such as the Patient's complete name, Age, Sex, Date of Birth, Date and Time of collection, Specimen Type and ward or collection area.
- 1.4 Place the viral transport medium with the patient's sample in a zip lock plastic bag with an adsorbent material inside (e.g. gauze pad, tissue/paper towel) labeled with the patient's name, age, sex, date of birth, date and time of collection. VTM with collected NPS/OPS can be stored for 8 hours at room temperature or 72 hours at 2 to 8 degrees Celsius. (See packaging and transport).

2. Packaging and Transport of Specimens

- 2.1 After specimen collection, the swab sample is placed in a transport box/container (provided by the laboratory) and packed applying the triple packaging system.
 - 2.1.1 Place the swab containing the viral sample into the viral transport medium (primary container).
 - 2.1.2 Wrap the primary container with enough adsorbent to absorb fluids in case of breakage or leak. These adsorbent material will also act as a cushion for the primary container.

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- 2.1.3 Place the primary container into a secondary packaging. Several cushioned primary container may be placed in one secondary packaging.
- 2.1.4 Place the secondary packaging in an outer packaging/transport box (e.g. Coleman, Ice box). This will act as protection from physical damages.
- 2.1.5 Place necessary documents (e.g. request forms, completely filled-out CIF) in a separate zip lock plastic bag if being transported inside the transport box.
- 2.2 Transport the viral specimen to the Molecular Diagnostics Laboratory. Ensure that the required temperature is maintained by using ice packs placed inside the transport box.
- 2.3 Follow the dedicated pathway for transporting specimens for COVID-19 testing from the different units of the hospital going to the Molecular Diagnostics Laboratory located at the basement level of the Medical Arts Building. All personnel assigned to transport specimens shall utilize the side entrance of the building near the engineering department.
- 2.4 Observe and adhere to biosafety guidelines at all times when transporting specimens for COVID-19 testing.

3. Receiving of Specimens

- 3.1 There is a dedicated receiving area in the Molecular Diagnostics Laboratory for SARS-CoV-2 (COVID-19) testing which may only be accessed by authorized personnel transporting specimens from the different units of the hospital.
- 3.2 The laboratory personnel assigned to receive the specimen for SARS-CoV-2 (COVID-19) testing will check the completeness of data in the Case Investigation Form (CIF), and match it with the printed request/charge slip. Only specimens from patients whose name is included in the list approved by the Incident Command Post (ICP) shall be accepted for processing.
- 3.3 The specimens are received daily and the accession number in the specimen receiving logbook is generated.
- 3.5 The medical technologist is informed of specimens received before and during the shift, and pass all received specimens through the passbox.
- 3.6 The medical technologist checks and verifies the integrity of the specimen inside the biosafety cabinet following the biosafety guidelines. He/she will reject and document any leaking specimen containers, and when secondary container (plastic bag) is breached.

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- 3.6 The following are the Criteria for Specimen Rejection:
 - 3.6.1 Grossly bloody specimen.
 - 3.6.2 Use of cotton and wooden swab
 - 3.6.3 Specimen with leak or spillage
 - 3.6.4 Improperly stored specimen
 - 3.6.5 Improperly transported specimen
 - 3.6.6 Mismatch of the patient's information
 - 3.6.7 Improperly or unlabeled specimen
- 3.7 Rejected specimen are decontaminated and disposed of according to the Standard Procedures by the medical technologist-on-duty and inform the sending unit/ward.
- 3.8 The medical technologist informs the sending unit/ward for need of repeat collection, and report the incident to the supervisor and laboratory safety officer for proper documentation and handling.
- 3.9 The Molecular Diagnostics Laboratory will be receive specimens for SARS-CoV-2 (COVID-19) testing from 8:00 AM to 6:00 PM, Monday to Friday. The laboratory will be scheduled for the weekly General Cleaning and Disinfection procedures on Saturday.
- 3.10 Specimens sent after 6:00 PM will be received at the Main Laboratory where it will be stored and transported to the Molecular Laboratory the next day.

4. Processing of Specimens

- 4.1 Processing of specimens for SARS-COV-2 (COVID-19) testing by GeneXpert shall follow the following guidelines:
 - 4.1.1 Specimens for SARS-COV-2 (COVID-19) testing will be processed in chronology of receipt. The accession number created in the receiving area will be the basis for the batch running of specimens.
 - 4.1.2 Specimens with incomplete required data, and/or that which fall in the Rejection Criteria stated in Section 3.6 shall NOT be processed.
 - 4.1.3 The running/processing of specimens will be done by batch as follows:
 - 4.1.3.1 Specimens received from 8:00 AM to 11:00 AM shall be processed in the morning, the results of which will be released in the same day after it has been verified and approved by the pathologist-in-charge.

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- 4.1.3.2 Specimens received from **11:01 AM to 4:00 PM** will be processed in the afternoon, the results of which will be released the next day on or before 11:00 AM after verification and approval by the pathologist-in-charge.
- 4.1.3.3 Specimens received beyond 4:00 PM will be processed the next day.
- 4.1.4 Operating days for SARS-COV-2 (COVID-19) testing are as follows:
 - 4.1.4.1 Monday to Friday, from 7:00 AM to 7:00 PM; Saturday, from 7:00 AM to 2:00 PM. The laboratory operation shall be shortened during Saturdays for the weekly general cleaning and decontamination procedures.

5. Encoding and Releasing of Results

- 5.1 There is a dedicated clean room for processing of reports and other related paper works outside the specimen processing area.
- 5.2 The medical technologist who performed the test will review and countercheck all results prior to release. All results will only be released after it has been validated and approved by the pathologist-in-charge.

1st Batch: cut-off at 11:00 AM, 2nd Batch: cut-off at 4:00 PM,

- 5.3 All results may be viewed in the respective wards after it has been authorized by the medical technologist via Medtrak (HIS).
- 5.4 A printed copy of the results will be sent to the respective wards which will be attached to the patient's chart.
- 5.5 Based on the DOH memo issued last July 8, 2020 on the use of the COVID Document Repository System (CDRS), the CDRS will be used as the new data reporting process for a simpler and harmonized reporting. This will help the laboratories to timely and accurately report their data, which is essential to guide policies and interventions.
- 5.6 A copy of linelist of results shall also be sent to the Hospital Infection Control Committee (ICC).