 <p>B.S. Aquino Drive, Bacolod City, Negros Occidental, 6100</p> <p>DR. PABLO O. TORRE MEMORIAL HOSPITAL</p>	Document Code:	DPOTMH-E-60-P08
	Effective Date:	08-30-2022
	Document Type:	Policy
	Page Number:	1 of 4
	Department/Section:	Molecular Laboratory
	Document Title:	<b>RECEIVING OF SPECIMEN, SWABBING AND PROCESSING SCHEDULES, RELEASING OF OFFICIAL RT-PCR RESULTS</b>

### **PURPOSE:**

The purpose of the policy is to provide guidelines to all stakeholders on the receiving of specimen, swabbing and processing schedules and the releasing of RT-PCR results.

### **LEVEL:**

Molecular Laboratory Receptionists/Encoder, Medical Technologists/Analyst, Molecular Pathologists, Attending Physicians, Station Head and Staff Nurses, Special Area Managers/Heads and Staff Nurses, Medical Department Chairpersons.


### **DEFINITION OF TERMS:**

1. ***Receiving of Specimen.*** This is operationally defined as the actual reception of specimen from the moment it is turned-over or endorsed to the Molecular Laboratory Receptionist for processing.
2. ***Swabbing and Processing Schedule.*** These refer to the process of taking swab samples and processing them aligned to the established schedules so to guide all stakeholders on the proper timing of requisition, actual swabbing and releasing of results.
3. ***Releasing of Results.*** This refers to the process of releasing the official RT-PCR results duly signed by the Medical Technologists and the Molecular Pathologists under the official RMCi Logo with QR Codes.

### **POLICY:**

1. It is the policy of the Molecular Biology Laboratory that all stakeholders shall abide by the swabbing and processing schedules so to facilitate ease of transactions.




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2. All swabbing shall be done in an appropriate area at a designated date and time.
3. All swabbing procedures and processing of specimens shall abide by the standards set forth by WHO, DOH as reduced into a policy by the RMCi Molecular Biology Laboratory.
4. Aligned to the Policy and procedures on Receiving Specimens for SARS-COV-2 Testing, the receiving cut-off time as herein stated shall be observed:
  - 4.1 Monday – Sunday: 08:00 o'clock AM Cut – Off Time for 1<sup>st</sup> batch & 02:00 o'clock PM Cut – Off Time for the 2<sup>nd</sup> batch
  - 4.2 All samples received beyond 02:00 o'clock PM shall be queued for the next day processing.
5. The following swabbing schedules shall be strictly observed:

PATIENT CATEGORY	SWABBING SCHEDULES	EXPECTED RESULT TAT
Patients for Surgery (In & Outpatients)	Shall be swabbed right away after assessment is completed	Within 24 hours
In – Patients (General)	Shall be swabbed right away after assessment is completed	Within 24 hours
Out – Patients (General)	Preferred swabbing schedule	24 – 48 hours
STAT Cases ***Specimen shall be considered a priority and shall be included in the soonest available schedule for processing.	Shall be swabbed right away	Within 24 hours



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6. Personnel Protective Equipment shall be duly observed by all staff assigned in the swabbing area and the RMCI Molecular Biology Laboratory, including the proper donning and doffing of these PPE's.
7. The Protocol on proper swabbing, packaging and transporting swab specimens shall be strictly observed.
8. Safety protocols shall be adhered in disposing of these swab specimens.
9. Data Privacy Act shall be strictly observed in maintaining the confidentiality of records and in the releasing of results.
10. All RT-PCR results shall be with QR Code, in official RMCI Result Template, duly and completely signed by the Medical Technologist/Analyst and the Molecular Pathologist.


**DOCUMENTATION:**

New Policy


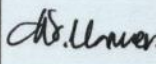
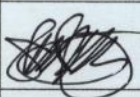
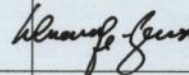

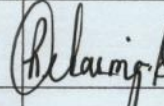
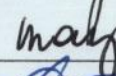

**DISSEMINATION:**


1. Policies and Procedures Manual
2. Unit Orientation
3. Unit Meeting



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**APPROVAL:**

	Name/Title	Signature	Date
Prepared by:	<b>JESSA CHRIS B. REMOLLENO, RMT</b> Molecular Biology Laboratory Analyst		9/02/2022
Verified by:	<b>MONICA B. VILLANUEVA, RN, RMT, PhD</b> Laboratory Director		9-2-2022
	<b>DAVID G. PEDROZA, MD</b> Associate Pathologist		9/2/2022
	<b>MELANIE ROSE B. ZERRUDO, MD, FPSP</b> Chair, Department of Pathology		9-2-2022
Reviewed by:	<b>DENNIS C. ESCALONA, MN, FPCHA, FPSQua</b> Quality Assurance Supervisor		9-2-2022
Recommending Approval by:	<b>ROSARIO D. ABARING, RN, MN, PhD, FPCHA</b> Ancillary Services Division Officer		09.02.2022
	<b>MA. ANTONIA S. GENSOLI, MD, FPPS, FPCHA</b> Vice President – Chief Medical Officer		9-13-22
Approved by:	<b>GENESIS GOLDI D. GOLINGAN</b> President and CEO		9/22/22

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### **PURPOSE:**

1. To ensure that all generated results from the PCR Run are valid and accurate following the *SOP on Results Validation*.
2. To ensure a more precise collation, validation, and reporting of SARS- Cov2 results and to eliminate the risk of releasing false-negative and false-positive results.

### **SCOPE:**

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


### **PERSON RESPONSIBLE:**

Molecular Biology Laboratory Analyst, Molecular Biology Laboratory Analyst, Molecular Biology Laboratory Pathologist, Molecular Biology Laboratory Encoder


### **GENERAL GUIDELINES:**

1. All test controls should be examined prior to interpretation, validation and release of patient results.
2. Always double check the samples with its label and lab request. Make sure they match.
3. Follow strict order of lab accession number according to the number of samples and date when the samples were received. Avoid errors such as mismatched and/or misspelled data. When it happens, inform the contact person of the sending institution for clarification.
4. If the controls are not valid, the patient results cannot be interpreted.
5. If no amplification is detected, the final result will be SARS-CoV-2 (causative agent of COVID-19) viral RNA NOT detected.
6. If an amplification  $ct < 39.99$ , the final result will be SARS-CoV-2 (causative agent of COVID-19) viral RNA detected unless otherwise specifically indicated by the manufacturer.



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7. If an amplification  $ct > 40$ , the final result will be Amplification beyond cut-off value.
8. The Ct cut- off value of this kit is set as 40 and the end user is required to review fluorescent curves before final interpretation.
9. All the positive curves should be typical S- shape amplification curves or without plateau for weakly positive samples.
10. All the results (both negative and positive) shall be recorded in a dedicated laboratory record book (not in the general laboratory register where other test data is recorded) or electronic laboratory information system ensuring that it aligns with the sample collection information or case investigation form on the respective test request forms.
11. Each individual result (both negative and positive) shall be signed off by the Molecular Biology Pathologist with the date and time of release as a sign of verification.
12. Only approved Molecular Biology staff shall release the results following the approved chain of custody from requester to final results owner.
13. The reporting of positive results shall be handled as an emergency by the lab, immediately notifying the Molecular Biology Section Head.
14. All completed results (whether individually produced or in batches) shall immediately be entered into the Hospital Information System to enable timely utilization. (For example, if a machine runs a batch of 93 samples, this batch of 93 results shall verified and immediately uploaded into the electronic results dispatch system as other specimen are being loaded into the machine.)
15. Electronic requesting and reporting should be the accepted standard. All laboratories referring and receiving requests should seek to automate this process.
16. Laboratories should seek to ensure transmission of results via Text is possible.
17. In Results Reporting, the following shall be followed:
  - 17.1. The samples received have a turnaround time of at least forty-eight (48) hours before releasing the results. However, this may vary according to the number of specimens received, reagent availability, validity of the PCR run and a need for a repeat extraction.

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## **PROCEDURE:**


*(The interpretation of results shall be based on manufacturer's instruction as outlined in the kit insert)*

1. Molecular Biology Analyst retrieves the result from the PCR machine after the run.
2. All results shall be reviewed and validated by the Molecular Biology- Section Head and Molecular Biology Pathologist (approved signatories) prior to release.
3. Encoding of results shall be done by the Molecular Biology Encoder after the final approval.
4. The Molecular Biology Manager and Ancillary Division Head as well as the Infection Control and Prevention Unit shall be updated and will receive a copy of all the patients' results for every completed run.
5. Encoding and sending of individual patients' results (out and in-patients') shall be handled by the Molecular Biology Encoder after 24- 48 hours of turnaround time as well as the updating of the CDRS System.
6. The Clerk/Receptionist shall segregate POSITIVE AND NEGATIVE results and forwarded <sup>here</sup> to the reception area for release to the stations/ward and to the individual patients and to other institutions.
7. Stations catering SARS- Cov2 patients shall be informed immediately after results have been validated.

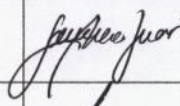

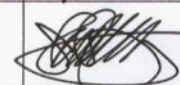
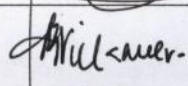
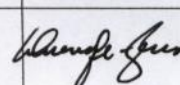

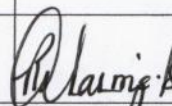
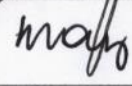
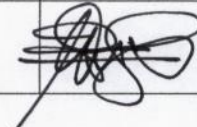
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4. <https://www.rcpath.org/uploads/assets/90111431-8aca-4614-b06633d07e2a3dd9/Guidance-and-SOP-COVID-19-Testing-NHS-Laboratories.pdf>
5. [https://doh.gov.ph/sites/default/files/health-update/dm2020-0294\\_0.pdf](https://doh.gov.ph/sites/default/files/health-update/dm2020-0294_0.pdf)
6. <https://www.doh.gov.ph/sites/default/files/health-update/dm2020-0258.pdf>
7. <http://www.doh.gov.ph/press-release/DOH-ENHANCES-COVID-19-REPORTING-TO-SIMPLIFY-COMPLEX-DATA-FOR-THE-PUBLIC>



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**APPROVAL:**

	Name/Title	Signature	Date
Prepared by:	<b>LOUIE MAE A. TICAR, RMT</b> Molecular Biology Laboratory Analyst		08-31-22
	<b>ORLANDO S. DELA PEÑA, RMT</b> Molecular Biology Laboratory Analyst		09-01-2022
Verified:	<b>DAVID G. PEDROZA, MD</b> Associate Pathologist		
	<b>MONICA B. VILLANUEVA, RN, RMT, PhD</b> Laboratory Director		
	<b>MELANIE ROSE B. ZERRUDO, MD, FPSP</b> Chair, Department of Pathology		10-10-22
Reviewed by:	<b>DENNIS C. ESCALONA, MN, FPCHA, FPSQua</b> Quality Assurance Supervisor		10-10-2022
Recommending Approval:	<b>ROSARIO D. ABARING, MN, MBA-HA, PhD, FPCHA</b> Ancillary Services Division Officer		10-10-2022
	<b>MA. ANTONIA S. GENSOLI, MD, FPPS, FPCHA</b> Vice President – Chief Medical Officer		10-12-22
Approved:	<b>GENESIS GOLDI D. GOLINGAN</b> President and CEO		10/25/22





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## ANNEX:



## RIVERSIDE MEDICAL CENTER, INC.

Owner and operator of the Dr. Pablo O. Torre Memorial Hospital  
A proud member of the Metro Pacific Hospital Holdings, Inc.

### MOLECULAR BIOLOGY LABORATORY REPORT



Patient Name : DELA CRUZ, JUAN MABINI	Document No. : XXXXXXXX	Run Time : 5:03 pm
Birth Date : 06/21/1993	Patient ID : XXXXXXXX	Run Date : 12/12/2020
Age/Gender : 27/M	Specimen No. : XXXXXXXX	Request Date : 12/11/2020 8:11 PM
Room : OPD		Release Date : 12/12/2020 3:20 PM
Req.Doc : HC, SURGERY		

### SARS-COV-2 RT-PCR Test Result

#### Test Result

#### POSITIVE FOR SARS-COV-2 RNA

Interpretation of Results	Target Amplification	Internal Control
POSITIVE FOR SARS-COV-2 RNA	Presence of Typical S-shape amplification at FAM(ORF1ab region) and/or ROX(N gene), Ct ≤40	Typical S-Shape Amplification at CY5 (RNase-P)
NEGATIVE FOR SARS-COV-2 RNA	Absence of typical S-Shaped amplification curve (No Ct) or Ct >40 at FAM and ROX Channel	Amplification curve detected at CY5 (RNase-P) ≤ 40
INVALID	There is no typical S-shape amplification curve detected at FAM (ORF1b) region, ROX(N gene) and CY5(Rnase-P) (No Ct), or Ct > 40. It is indicated that the specimen's concentration is too low, or there are interfering substances that inhibit the reaction. Repeatedly invalid result requires repeat sample collection.	

#### Intended Use Of This Test

Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is used for qualitative detection of ORF1ab and N genes of novel coronavirus (2019-nCoV) in nasopharyngeal swab, oropharyngeal swab, and alveolar lavage fluid from suspected pneumonia cases with coronavirus infection, patients with suspected clusters of novel coronavirus infection, and other patients requiring diagnosis of novel coronavirus infection. Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is only used for the auxiliary diagnosis of related cases and the emergency reserve for in vitro diagnosis during the pneumonia outbreak of novel Coronavirus (2019-nCoV) and should comply with "Technical Guidelines for Laboratory Testing of Novel Coronavirus in China CDC."

The test results of diagnostic kit can be used for clinical reference. The symptoms and physical signs, disease history, and other laboratory examinations and therapeutic reactions of the patients should be comprehensively considered during their clinical diagnosis. Due to the characteristics of swab and other sample collection process and viral infection process itself, false negative results may be caused by insufficient sample volume, which should be combined with other clinical diagnosis and treatment information for comprehensive judgment, retest when necessary.

Note: Please consult with your physician regarding the interpretation of this examination result. This examination result does not serve as a medical clearance. You can use the QR Code to validate the result. If QR Code is tampered, this result is considered invalid.

#### Performed by:

\_\_\_\_\_, RMT  
Molecular Biology Laboratory – Analyst  
License No. XXXXXXXX

\_\_\_\_\_, RMT  
Molecular Biology Laboratory – Analyst  
License No. XXXXXXXX

#### Encoded by:

\_\_\_\_\_  
Molecular Biology Laboratory - Encoder

#### Verified by:

\_\_\_\_\_, RMT  
Michelle Alexis G. So, RMT  
Molecular Biology Laboratory – Section Head  
License No. XXXXXXXX

#### Validated by:

\_\_\_\_\_, MD  
David G. Pedroza, MD  
Head of Molecular Biology Laboratory  
License No. XXXXXXXX






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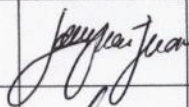

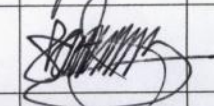
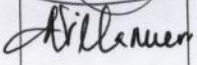
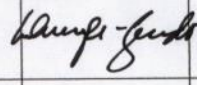

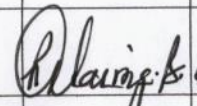
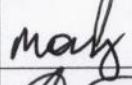
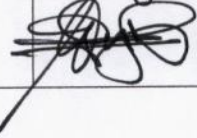
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KEY TASKS	PERSON RESPONSIBLE
1. Retrieves the result from the PCR machine after the run	Molecular Biology Analyst
2. Reviews and validates all results prior to release	Molecular Biology- Section Head and Molecular Biology Pathologist
3. Encodes the results after the final approval	Molecular Biology Encoder
4. Updates the Molecular Biology Manager and Ancillary Division Head as well as the Infection Control and Prevention and sends them a copy of all the patients' results for every completed run	
5. Encodes and sends individual patients' results (out and in- patients') after 24- 48 hours of turnaround time as well as the updating of the CDRS System	
6. Segregates POSITIVE AND NEGATIVE results and forwards them to the reception area for release to the stations/ward and to the individual patients and to other institutions	
7. Informs the stations catering SARS- Cov2 patients immediately after results have been validated	



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**APPROVAL:**

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Prepared by:	<b>LOUIE MAE A. TICAR, RMT</b> Molecular Biology Laboratory Analyst		08-31-22
	<b>ORLANDO S. DELA PEÑA, RMT</b> Molecular Biology Laboratory Analyst		09-01-22
Verified:	<b>DAVID G. PEDROZA, MD</b> Associate Pathologist		
	<b>MONICA B. VILLANUEVA, RN, RMT, PhD</b> Laboratory Director		
	<b>MELANIE ROSE B. ZERRUDO, MD, FPSP</b> Chair, Department of Pathology		10-10-22
Reviewed by:	<b>DENNIS C. ESCALONA, MN, FPCHA, FPSQua</b> Quality Assurance Supervisor		10-10-2022
Recommending Approval:	<b>ROSARIO D. ABARING, MN, MBA-HA, PhD, FPCHA</b> Ancillary Services Division Officer		10.10.2022
	<b>MA. ANTONIA S. GENSOLI, MD, FPPS, FPCHA</b> Vice President – Chief Medical Officer		10.12.22
Approved:	<b>GENESIS GOLDI D. GOLINGAN</b> President and CEO		10/15/22



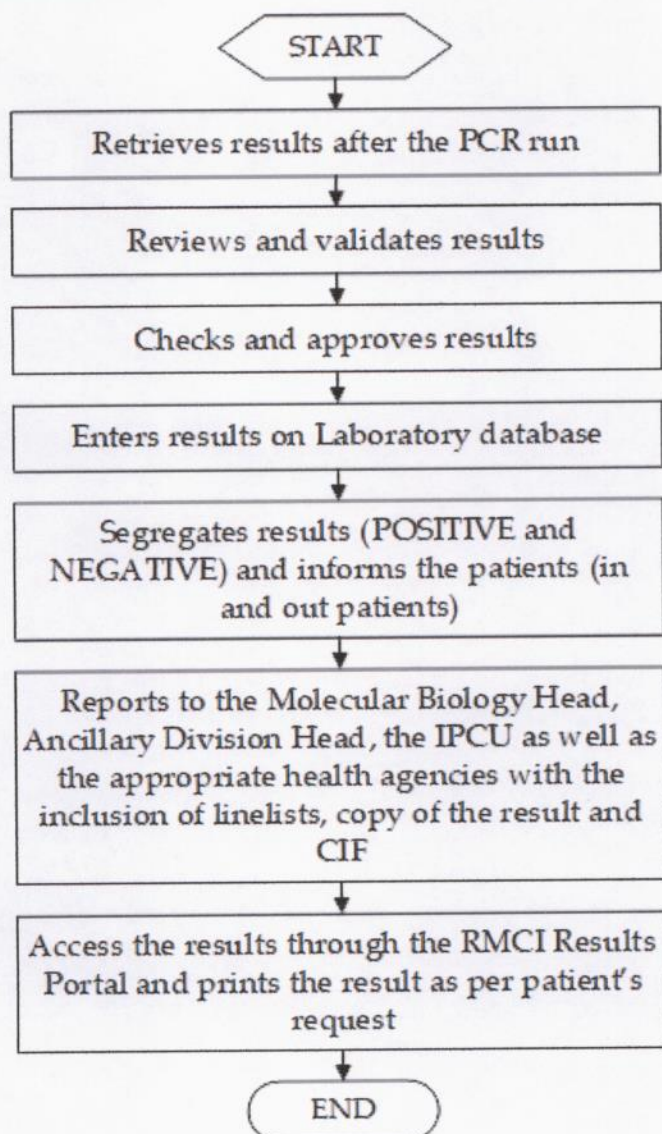



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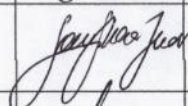

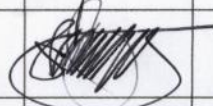
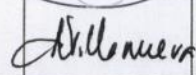
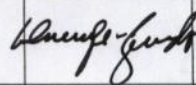

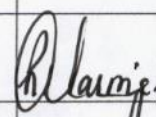
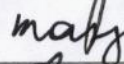
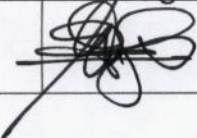
Document Code:	DPOTMH-E-60-P08-FC01
Effective Date:	08-30-2022
Document Type:	Flowchart
Page Number:	1 of 2
Department/Section:	Molecular Laboratory
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## FLOWCHART



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