PURPOSE:

1. To ensure that all generated results from the PCR Run is 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 eliciting 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 it matches one another.
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. If so, 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.

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 from the 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.

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 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.

REFERENCES:

1. http://www.cdfd.org.in/images/COVID19/COVID-SOP.pdf
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7268832/
3. https://www.fda.gov/media/137651/download
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
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

APPROVAL:

	Name/Title	Signature	Date
Prepared by:	**LOUIE MAE A. TICAR, RMT** Molecular Biology Laboratory Analyst		07/11/2022
	ORLANDO S. DELA PEÑA, RMT Molecular Biology Laboratory Analys		07/11/2022
Verified:	**DAVID G. PEDROZA, MD** Associate Pathologist		07/11/2022
	MONICA B. VILLANUEVA, RN, RMT, PhD Laboratory Director		7-11-2022
	MELANIE ROSE B. ZERRUDO, MD, FPSP Chair, Department of Pathology		7-11-2022
Reviewed by:	**DENNIS C. ESCALONA, MN, FPCHA, FPSQua** Quality Assurance Supervisor		7-11-2022
Recommending Approval:	**ROSARIO D. ABARING, MN, MBA-HA, PhD, FPCHA** Ancillary Services Division Officer		
	HENRY F. ALAVAREN, MD, FPSMID, FPSQua Total Quality Division Officer		
Approved:	**GENESIS GOLDI D. GOLINGAN** President and CEO		

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.	: XXXXXXX	Run Time	: 5:03 pm
Birth Date	: 06/21/1993	Patient ID	: XXXXXXX	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 corona virus 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. XXXXXXX

_____, RMT
Molecular Biology Laboratory – Analyst
License No. XXXXXXX

_____, RMT
Molecular Biology Laboratory – Analyst
License No. XXXXXXX

_____, RMT
Molecular Biology Laboratory – Analyst
License No. XXXXXXX

Encoded by:

_____
Molecular Biology Laboratory - Encoder

Verified by:

Michelle Alexis G. So, RMT
Molecular Biology Laboratory – Section Head
License No. XXXXXXX

Validated by:

David G. Pedroza, MD
Head of Molecular Biology Laboratory
License No. XXXXXX

DR. PABLO O. TORRE MEMORIAL HOSPITAL

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6100

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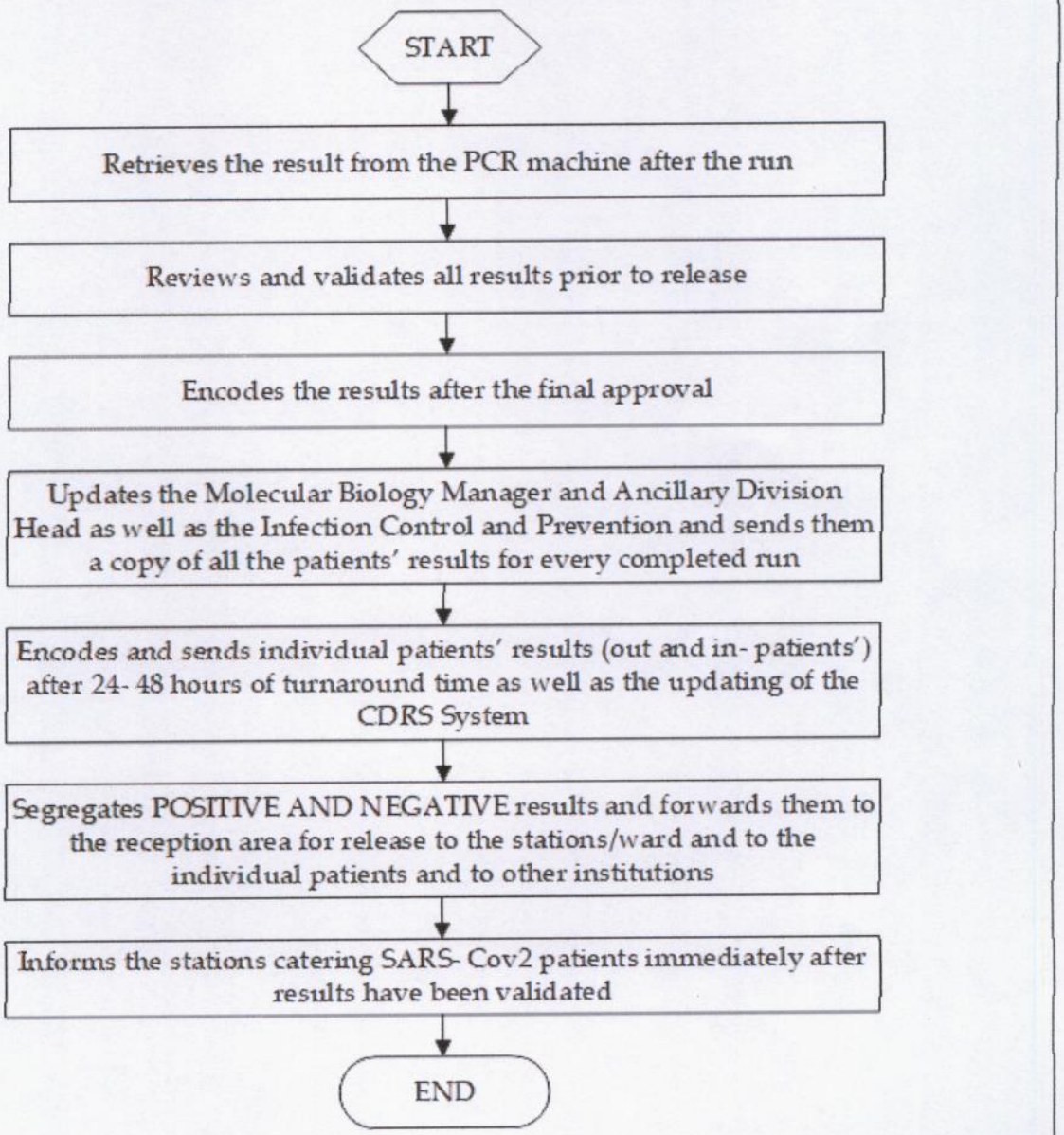
Page Number:	1 of 2
Department/Section:	Molecular Laboratory
Document Title:	**REPORTING OF SARS- COV2 RESULTS**

FLOWCHART



APPROVAL:

	Name/Title	Signature	Date
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Recommending Approval:	**ROSARIO D. ABARING, MN, MBA-HA, PhD, FPCHA** Ancillary Services Division Officer		
	HENRY F. ALAVAREN, MD, FPSMID, FPSQua Total Quality Division Officer		
Approved:	**GENESIS GOLDI D. GOLINGAN** President and CEO		

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	
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