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INSTRUCTIONS FOR LABORATORIES ACTIVATED FOR COVID-19 RESPONSE

2021 RITM EQA Panel for SARS-CoV-2 Detection by Real-time PCR (Cartridge-based RT-PCR)

Ver Junel 2021

A. PANEL DESCRIPTION

The proficiency testing panel consists of 10 challenge (contrived) samples (10 vials in total). Target-positive challenge sample/s are spiked with non-infectious RNA from laboratory-confirmed samples of SARS-CoV-2 (at predetermined concentrations) suspended in RNA stabilizer, while target-negative challenge samples only contain RNA stabilizer.

The following are the expected results:

Challenge sample classification	PCR result	PCR result reporting
Target-positive samples	Should exhibit amplification for assay/s targeting SARS-CoV-2	SARS-CoV-2 viral RNA detected
Target-negative samples	Should not exhibit amplification for assay/s targeting SARS-CoV-2	SARS-CoV-2 viral RNA NOT detected

Note:

- Run validity must be established: positive control should be positive, negative control should be negative, IC positive control should be positive
- Assume internal control for the panel samples (target-positives and target-negatives) is positive

The panel has been pre-validated after preparation and prior to dispatch.

B. LIMITATIONS

This PT panel is designed and validated for the following molecular detection format:

- Spin-column-based (solid-phase) nucleic acid extraction and Real-Time PCR assays for SARS-CoV-2 detection
- Cartridge-based molecular assays for the detection of SARS-CoV-2

For molecular detection formats other than the one stipulated above, please coordinate with the RITM Molecular Biology Laboratory (ritm.molbioqa@gmail.com, mobiolab.ritm@gmail.com; (02) 8

807 2632 local 410) prior to PT panel processing, to report: (1) the molecular detection format to be used, (2) brand and (3) catalog number of nucleic acid extraction kit/method.

Important Information: For cartridge-based molecular assay that requires nucleic acid extraction, this PT panel is NOT compatible with: (1) MANUAL extraction method using the SANSURE BIOTECH SAMPLE RELEASE REAGENT, and (2) extraction methods involving Proteinase K reagent.

C. SAFETY WARNINGS AND PRECAUTIONS

1. Pressure may develop during transport and freeze/thaw; briefly spin down all vials prior to opening.
2. This PT panel is non-infectious in nature, but samples in this PT panel should be treated as though containing infectious material and should be handled and disposed of according to BSL 2 practices and precautions.

D. STORAGE

1. All panel components must be stored at or below -20°C until processing.
2. During processing, samples should be treated as clinical material and stored accordingly.
3. Any modification of handling or storage conditions is NOT recommended.

E. WHAT TO DO WHEN YOU RECEIVE YOUR SAMPLES

1. When you receive your panel, please carefully read all the documents enclosed paying special attention to this set of instructions.
2. The panel contents should be stored at or below -20°C until required for processing.
3. Confirmation of receipt of panel should be made immediately and sent by completing the 2021 RITM EQA for SARS-CoV-2 Detection by Real-Time PCR - Receiving form and sending the accomplished copy to the following e-mail address: ritm.molbioqa@gmail.com copy furnished molbiolab.ritm@gmail.com.

F. PROCESSING OF PT PANEL SAMPLES

1. The PT panel samples should be treated as regular clinical samples for molecular diagnostic testing.
2. Equilibrate PT panel samples and extraction reagents to room temperature (around 25^0C) before performance of nucleic acid extraction procedures.
3. **Important:** Please pay special attention to the safety warnings and precautions section of this document before processing the samples included in the panel.
4. Turnaround time: Each laboratory is given three days to process the PT panel samples and submit the test results. The start of processing time shall be counted as the date on which the scanned

copy of the accomplished receiving form was sent by email to the RITM Molecular Biology Laboratory (refer to section E.3.). The end date shall be the date on which the accomplished reporting form was submitted to RITM Molecular Biology Laboratory (I.2).

G. TROUBLESHOOTING

For problems encountered in PCR run, you may refer to the RITM's **Troubleshooting Guide for Real-time PCR Runs for SARS-CoV-2 Detection**. This will guide you on identifying the possible causes of errors and to appropriately address them. This document can be accessed and downloaded from RITM website through:

RITM TROUBLESHOOTING GUIDE
http://bit.ly/TroubleshootingGuideRITM

RITM COVID-19 INCIDENT REPORT FORM
http://bit.ly/IRformRITM

H. RESULTS ENCODING

1. Based on the results of your Real-Time PCR runs, accomplish the Reporting Form electronically.
2. Encode the Ct value/s obtained on the space provided, per target.
3. Select the Final Qualitative result per sample from the dropdown menu.

I. SUBMISSION OF RESULTS

1. Upon completion of the EQA Panel testing, the 2021 RITM EQA Panel for SARS-CoV-2 Detection by Real-Time PCR - Reporting form (attached herewith) should be completed.
2. To report results for this EQA, the following should be submitted to ritm.molbioqa@gmail.com, copy furnished molbiolab.ritm@gmail.com:
   - Electronically accomplished Reporting form (this will be sent by email by RITM-MBL upon receipt of the accomplished receiving forms).
   - pdf copy of the PCR run files exhibiting the amplification curves and Ct values of properly labeled reaction wells.
3. Results should be submitted on or before the deadline.

4. CONTACT INFORMATION. For inquiries, please contact the RITM Molecular Biology Laboratory-Quality Assurance Section through the following:
   · Telephone: +632 8809 – 7599 / 8807 2631/32/37 loc 410
   · Email: ritm.molbioqa@gmail.com, cc molbiolab.ritm@gmail.com.