## PURPOSE:

This is a guidance document to help managers and staff in conduct of a comprehensive quality assurance program for COVID-19 testing in Molecular Biology Laboratory. The document provides procedural framework and use of standardized registration formats as a quality tool, quality control (QC), enrollment of laboratories in external quality assessment (EQA) schemes and use of EQA performance data for continuous quality improvement for COVID-19 testing.

## LEVEL:

Pathologists, Molecular Diagnostic Laboratory Section Head, All Molecular Diagnostic Laboratory Staffs

## DEFINITION OF TERMS:

1. ***Quality assurance.*** (QA) is the part of the quality management system that focuses on providing confidence for the fulfillment of quality requirements.

2. ***Quality Control.*** QC is a material or mechanism that monitors the analytical performance of the test when used with or as part of a test system.

3. ***Extraction Positive Control.*** RNA extraction control to demonstrate successful recovery of RNA and the integrity of the extraction reagent. The expression levels of this protein do not vary drastically due to cellular treatment, which is another reason the protein makes a suitable control.

4. ***No template control (NTC).*** Checks contamination during specimen extraction and/or plate set up. If any NTC reactions are defined positive, sample contamination may have occurred and the test must be repeated with strict

adherence to the testing procedures. It also indicates whether PCR NTC is either a nuclease-free water or unused viral transport medium.

5. ***Positive template control(s)*: Indicates the limit of detection and robustness of the assay.**

## POLICY:

1 Molecular assays conducted on nasopharyngeal swabs or other upper respiratory tract specimens are the most commonly used and reliable tests for the diagnosis of COVID-19.

1.1 A variety of RNA gene targets are used by different molecular assays, commonly targeting one or more of the envelope (env), nucleocapsid (N), spike (S), RNA-dependent RNA polymerase (RdRp), and the first open reading frame (ORF1) genes.

1.2 Most molecular assays have achieved 100% specificity, since the primers are designed specifically for the target gene sequences of SARS-CoV-2. However, sensitivity can be affected by specimen quality, sampling time to symptom onset, testing errors, or other technical deficiencies.

2 False-negative SARS-CoV-2 polymerase chain reaction (PCR) test results have been documented in a few positive cases after having two consecutive negative PCR tests within a 24-hour period.

2.1 This could be due to technical errors from sampling to testing. Both false-positive and false-negative results have negative implications for disease containment efforts.

2.2 Therefore, it is critical to implement quality assurance measures in all COVID-19 testing laboratory networks.

3 **Test Characteristic of RMCi SARS-CoV2 RNA RT-PCR testing.** The testing methodology use in each performance of the test uses:

3.1 **Extraction positive control**: RNA extraction control to demonstrate successful recovery of RNA and the integrity of the extraction reagent.

3.1.1 The test platform uses internal control from mammalian cell recovered during extraction.

3.1.2 Common internal extraction control is either RNAse-P or Beta-actin. RNase P target is also amplified as a quality control for the extraction method and to corroborate the absence of PCR-inhibitors in the sample. Control. Beta-Actin (42 kDa) is commonly chosen as a loading control due to its general expression across all eukaryotic cell types.

3.1.3 The expression levels of this protein do not vary drastically due to cellular treatment, which is another reason the protein makes a suitable control.

4 **No template control (NTC)** checks contamination during specimen extraction and/or plate set up.

4.1 If any NTC reactions are defined positive, sample contamination may have occurred and the test must be repeated with strict adherence to the testing procedures.

5 **Positive template control(s)** Indicates the limit of detection and robustness of the assay.

5.1 Positive template controls are incorporated in each run. These controls are incorporated in the testing kit and is added in accordance to manufacturer's instruction.

5.2 This control is handled inside the Reagent preparation with caution to prevent possible cross-contamination.

6 EQA is a process that allows COVID-19 testing laboratories to assess their performance by comparing their results with results from other laboratories within the network (testing and reference laboratories) via panel testing and retesting.

6.1 EQA also includes the onsite evaluation to review the quality of the laboratory performance during the process of renewal of the license to operate.

6.2 EQA usually evaluates testing competency, the performance of the laboratories, reliability of the testing methods, and accuracy of the results reports, including follow-up for unacceptable EQA results with corrective action.

6.3 Thus it is imperative the management will support to the participation to Proficiency testing annually prior to renewal of license to operate. For participation to RITM External Quality Assurance Scheme through Proficiency testing.

7 On site evaluation are done by DOH bureau of licensing as part of maintenance of license to operate. Internal quality assessment done by the section head and verified by the pathologist should be done every three months to ensure compliance to standards.

7.1 Section head shall schedule every six months to observe correct sample collection procedure by all staff assigned in the sample collection as describe in the SOP.

7.2 Create a schedule for periodic review of documents to have all listed documents reviewed annually.

7.3 Section head/Manager shall make a schedule to periodically review performance of staff in terms of Biosafety adherence.

7.3.1 Periodic review of health record

7.3.2 Periodic review of requirements for vaccination

7.3.3 Periodic review of fit-test.

7.3.4 Periodic review of donning and doffing procedure.

7.3.5 Periodic review of adherence to correct decontamination and disinfection procedures.

7.4 Documented and maintenance of records by running through the Assessment Tool checklist in a periodic manner and provide appropriate documentation.

7.5 Staff competency assessment by reviewing QC failures, direct observation of staff extraction, template adding, and reagent preparation.

7.6 Assessment should include laboratory aide autoclaving procedure, encoder steps in result encoding and CDRS upload of reports.

7.7 Staff competency assessment should be scheduled in a manner that the staff doing the assessment is free from work during the period of assessment to ensure adequate staff assessment.

7.8 Every new staff that will rotate in the molecular biology laboratory must first shadow experience staff and staff should be able to observe consistent adherence to SOP before staff will perform the procedure by herself/himself.

8 **QUALITY IMPROVEMENT (QI) is** a process by which the components of SARS-CoV-2 testing services are analyzed to identify areas requiring improvement, to plan and undertake improvements, and to evaluate the effectiveness of improvements.

8.1 QI is also recognized as process improvement and involves continuous monitoring, identifying defects, and remedial action, such as refresher training, to prevent recurrence of problems.

8.2 Data collection, data analysis, and creative problem solving are the key components of this process. It may require data from audits, participation in EQA schemes, and onsite evaluation to improve testing processes.

8.3 The ultimate target of QI is to take corrective action against the identified problem, remove its root cause, and reduce or eliminate its recurrence.

8.4 Implementing preventive action reduces the likelihood of recurrence.

**DOCUMENTATION:**

New policy

**DISSEMINATION:**

1. Terms of Reference
2. Hospital Communicator

**APPROVAL:**

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