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GUIDELINES FOR THE RITM NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME (RITM-NEQAS)

As of February 24, 2022

RATIONALE

As a DOH-designated National Reference Laboratory for infectious diseases (DO 2020-0820), RITM is mandated to provide EQA to laboratories in the country for bacteriology (including mycobacteriology), parasitology, transfusion-transmissible infections, and SARS-CoV-2.

An External Quality Assessment Scheme (EQAS) evaluates the performance of participating laboratories by assessing the integrity of the entire testing process from sample receipt to releasing of test results. This would allow comparison of the laboratory's testing to the performance of a peer group and/or the national reference laboratory. EQAS is one of the components of a laboratory's overall quality assurance program.

Moreover, participation in EQAS as part of an overall laboratory quality assurance program is required under local regulatory policies for securing a license to operate.

SCOPE/COVERAGE

These guidelines shall apply to all clinical laboratories participating in the EQA programs offered by the Institute, and may serve as a reference for DOH regulatory/licensing officers and ISO15189 accreditation.

DESCRIPTION

National Reference Laboratories prepare and ship challenge panels consisting of a combination of positive and negative samples that are designed to mimic patient samples. Results of completed tests are then encoded online via Oneworld Accuracy System (OASYS), a cloud-based application developed by 1WA, and the data are then analyzed under ISO 13528. Performance reports are provided to the participants to assess their results and–-where relevant—compare their performance against their peer group.

Primary Objectives

1. To provide quality assurance to patients and clients, that laboratory results are accurate and reliable;
2. To help laboratories identify errors and trigger corrective and preventive measures;
3. To encourage good laboratory practices

Secondary Objectives

1. To assess the quality of laboratory performance on a national level and provide data to the DOH for regulation and policy making
2. To serve as a platform for providing updated information on infectious disease diagnostics;

DEFINITION OF TERMS

Coordinator

One or more individuals with responsibility of organizing and managing all of the activities involved in the operation of an EQA/PT scheme

External Quality Assessment Scheme (EQAS)

Also referred to as National External Quality Assessment Scheme (NEQAS); A scheme for objectively checking the laboratory's performance using an external agency or facility; evaluation of participant

performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2010)

Interlaboratory Comparison
Organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

Organizer
Agency or institution that provides the NEQAS

Participant
A laboratory enrolled in the NEQAS program relevant to its service capabilities, for which a proficiency test panel is provided; client/customer

Proficiency
Demonstrated competence or skill of medical technologist/laboratory technical staff, in the context, of EQA

Proficiency Test Panel
Specimen, product, artifact, reference material, piece of equipment, measurement standard or data set provided to one or more participants, or submitted by participants, in a proficiency testing round (ISO/ IEC 17043:2010)

Program
Discipline being offered for the EQAS/PT cycle

Program Code
Alphanumeric code assigned to each program

PT Event/Test Event
Single complete sequence of distribution of proficiency test items, and the evaluation and reporting of results to all participants in a proficiency testing scheme (ISO/IEC 17043:2010)

PT Cycle
Proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection (ISO/IEC 17043:2010)

Quality Assurance (QA)
Overall program undertaken by a laboratory that ensures that the final results reported by the laboratory are as correct and accurate as possible

RITM NEQAS
Integrated EQA scheme of the Research Institute for Tropical Medicine ~~which includes several programs~~

RITM NEQAS Secretariat
Administrative office of the RITM NEQAS under the office of the Chief of the Laboratory Research Division

GUIDELINES

1. **Organizer and Coordinator**
   The Research Institute for Tropical Medicine is the organizer of the RITM NEQAS. The Laboratory Research Division of the Research Institute for Tropical Medicine, as the RITM NEQAS Secretariat, serves as the coordinator for the RITM NEQAS.

2. **Contact Information**
   Office address:
   RITM NEQAS Office, 1st Floor-RITM Training Center, Research Drive Filinvest Corporate City, Alabang, Muntinlupa City 1781
   E-mail address: neqas@ritm.gov.ph
   Direct line: (02) 88501949

3. **Programs**
   The following are the Programs under RITM NEQAS:

PROGRAM CODE	DISCIPLINE	PROGRAM
PART414	Parasitology	Microscopy for Parasitology
TBMC412 TBCL415	Mycobacteriology	TB Microscopy TB Culture and Drug Susceptibility Test
BACS413	Bacteriology	Bacterial culture Antimicrobial sensitivity
HVHT4220 MLRA423	Transfusion Transmissible Infections Parasitology	Serology Malaria microscopy (detection)
CVRM4110	Virology	Molecular detection of SARS-CoV-2

4. **Target Participants**
   All clinical laboratories and blood service facilities in the Philippines shall participate in the RITM NEQAS depending on their relevant service capability, in accordance with local regulations.

5. **Frequency**
   The following table summarizes the frequency of events per RITM NEQAS Program and a brief description of the panels provided by each program. All RITM NEQAS panels are prepared by trained technical staff from the National Reference Laboratories using either archived clinical specimens or isolates from its Biobank, or collected from the field, following standardized procedures. Appropriate quality control measures are taken to ensure that panels are properly labeled, well-characterized, stable, verifiable, and stored in the appropriate temperature.

PROGRAM CODE	EVENTS PER YEAR	PANEL DESCRIPTION
PART414	1	The panel consists of three (3) stained blood films, and one (1) formalized stool sample. Positive samples are collected from endemic areas from known positive individuals. All samples are examined using different procedures and examined by trained and experienced microscopists.
TBMC412	1	The panel for TB Microscopy consists of two (2) smears stained using the Ziehl-Neelsen hot method with standardized grading following the IUATLD/WHO guidelines.
TBCL415	1	The panel for TB culture and drug susceptibility testing consists of five (5) analytes suspended in liquid medium. Participating laboratories are required to identify the analytes as to whether *M.tuberculosis complex* or not, and perform drug susceptibility testing for at least the first line anti-TB drugs.
BACS413	1	The panel for Bacteriology consists of 3 analytes (3 vials) with 1 principal organism per analyte. Participating laboratories are required to identify the organisms and perform antimicrobial susceptibility testing using their routine/standard operating procedures or methods. Only the first analyte (labeled A) requires antimicrobial susceptibility testing with the recommended antibiotics according to the latest CLSI guidelines.
HVHT4220	2	The panel consists of twenty (20) samples obtained from blood donors from different regions of the country. Panels may either contain individual or pooled samples. Pooled samples are prepared by mixing similar volumes of at least two samples that have similar antibody and antigen profiles. All samples are subjected to filtration prior to aliquoting. The samples are then aliquoted and their homogeneity confirmed. The samples are then tested in a range of assays to confirm their reactivity.
MLRA423	2	The panel consists of three (3) smears prepared from samples obtained from malaria endemic areas and prepared by the Malaria – National Reference Laboratory.
CVRM4110	1	The panel consists of ten (10) contrived samples. Target-positive challenge samples are spiked with non-infectious RNA from laboratory-confirmed samples of SARS-CoV-2 (at predetermined concentrations) suspended in RNA stabilizer/equivalent , while target-negative challenge samples only contain RNA stabilizer/equivalent spiked with negative cellularity control.

6. Registration

- **RITM NEQAS online registration portal**
  All participants shall register using the RITM NEQAS online portal (https://apps.ritm.gov.ph/neqas/), and shall be issued a specific participant code.

- **Registration requirements**
  Requirements for registration include completely providing required information in the registration portal. A soft copy of the participant's current License to Operate (LTO) is required to be uploaded in the system.

  NOTE: It is the participant laboratory's responsibility to provide complete, current, and accurate information in the registration, especially for designated personnel for coordination/communication, providing working contact numbers and e-mail addresses, and shipping information (see Item 8).

- **Opening of Registration**
  Participation in the RITM NEQAS shall begin on a scheduled date to be announced by the RITM NEQAS Secretariat within the first quarter of the current year.

- **Deadline for Registration**
  Registration shall promptly end at 12:00 midnight of 31 May of the current year.This is the deadline for registration for all EQA programs of all NRLs in the country.

7. Payment

- **Participation Fees**
  The following schedule of fees shall be followed. The fees shall be reviewed annually and updated accordingly.

PROGRAM	AMOUNT (PHP)
Bacteriology, Parasitology, TB	7,500.00
Bacteriology with/without Parasitology or TB	7,500.00
Parasitology and TB/Parasitology or TB	4,200.00
Transfusion Transmissible Infections	13,000.00*
SARS-CoV-2	No fees applied**

* Covers two test events
**Currently subsidized by the Department of Health

- The Organizer reserves the right to defer completion of registration until payment has been made.
- **Acceptable Modes of Payment**
  The following are the acceptable modes of payment
  - **Landbank e-payment portal** - online payment system that is verified by the Cashier; proof of transaction is needed for processing
  - **Cash payment** - applicable for walk in registrants only
  - **Manager's/Cashier's check payable to RITM** - may be sent via courier or processed via walk-in
  - **Modified Disbursement System Checks*** - for select government agencies only

*Checks issued by the Bureau of Treasury, applicable to select government agencies as a payment option.

Once the RITM NEQAS Secretariat has verified registration details, an order of Payment is made to the participant who will process the registration fee through the available payment portal. Proof of payment must then be uploaded in the registration portal.

- **Confirmation of Registration and Issuance of Official RITM Receipt**
  Upon confirmation of payment, the official receipt and enrollment confirmation will be issued to the participants. However, for those who sent their documents via courier, a scanned copy of their receipt and a digital notice of enrollment will be sent to their email address while the official receipt will be sent together with their PT samples.

8. Panel Shipment

- **Courier**
  RITM NEQAS uses the services of a commercial distribution or courier service for the shipment of PT panels to participants. The Institute shall inform all participants on the courier service provider contracted for the year's event.

- **Delivery Address**
  It is the responsibility of the participant to ensure that the correct delivery address is provided in the registration portal.

  Re-shipment
  There are times that the panels received are not optimal for testing (e.g., breakage or spillage during transit; shipping temperature is not maintained). RITM NEQAS Secretariat shall coordinate with the participant laboratory if re-shipment is deemed necessary. The latter shall bear all the costs of re-shipment due to incomplete or incorrect delivery address. Depending on circumstances, an extension to the test event may or may not be granted, at the discretion of the NEQAS organizer.

- **Transport regulations**
  RITM NEQAS Shipment contains material obtained directly from humans and does not include animal material. The material was neither inoculated with, nor exposed to infectious agents of agricultural concern (including zoonotic agents), cultures or recombinant material.

  NOTE: **A shipper's declaration for dangerous goods IS NOT required.** Following International Air Transport Association (IATA) Classification, the panel shipment is classified as Category 6.2: UN3373 - Biological Substance, Category B. **EXCEPT for panels for TB culture and drug susceptibility testing** that may contain *M.tuberculosis* strains which shall be shipped under Category 6.2: UN 2814 - Infectious substance, affecting humans.

9. Handling of RITM NEQAS Proficiency Test Panels

RITM NEQAS samples are potentially infectious and should be handled using universal safety precautions. The Institute recommends handling in at least a Biosafety Level 2 (BSL-2) containment; BSL2+ is recommended for those participating in TB culture and drug susceptibility. Although your laboratory has been asked to test for a specific analyte, these samples may contain other infectious agents.

All RITM NEQAS panels shall be received, processed, tested, and stored/discarded following the laboratory's routine processes.

10. Submission of Results

Each participant is given a deadline for submission of test results. Completed tests performed by the participant are encoded online via Oneworld Accuracy System (OASYS), a cloud-based application developed by 1WA (www.oneworldaccuracy.com).

For detailed instructions on submitting results, please visit our Support Center at https://oneworldaccuracy.zendesk.com/hc/en-us.

Participants who require assistance with data submission should contact Oneworld Accuracy Support as soon as any difficulties are experienced, to allow sufficient time for submission of results before the test event closing date.

11. Analysis and Feedback

Submitted data from the participants through OASYS are analyzed under ISO13528:2015 (Statistical methods for use in proficiency testing by interlaboratory comparison).

A **performance report** shall be provided to each participant at the end of each test event, while the **certificate of proficiency** shall be provided at the end of the cycle. These are sent directly to the registered email address of the participant.

An **RITM NEQAS summary report** shall also be provided to the participants and to the DOH at the completion of each cycle.

12. Late Participation

The Institute shall no longer accommodate participants who have not registered for the RITM NEQAS within the deadline. This is in consideration of the schedule of panel preparation, shipment, and test event duration. Participants may opt to participate in other available equivalent EQA programs.

13. Appeals, Disputes, Complaints

Appeals, disputes, and complaints may be forwarded to the RITM NEQAS Secretariat through: neqas@ritm.gov.ph. The technical team shall define the actions required based on the information collected, investigated, checked and documented. The recommendations shall be communicated to the participant, with documentation of corrective and preventive actions.

14. Panel Disposal

Panels provided by RITM NEQAS may be used only for the purpose of EQAS. No other use is permitted without express agreement from the Institute.

Once the EQAS event has concluded, any remaining NEQAS sample for each program may be stored for a certain prescribed storage period to allow for resolution of aberrant results. The following table summarizes the maximum period that the panels may be stored.

PROGRAM	STORAGE PERIOD
PART414	6 months at 20-24℃ (Blood film), 2 weeks at 20-24℃ (formalinized stool)
TBMC412	2-3 months at ambient temperature
TBCL415	3 months at -20℃ 6 months at -70 to -80 ℃
BACS413	1 week at 2-8℃
HVHT4220	6 months at 2-8℃
MLRA423	6 months at 20-24℃
CVRM4110	6 months at -40 ℃ (for non-Sansure assays) TBE (for Sansure assay)

Beyond this period, panels should be disposed of in accordance with the laboratory's waste management policies and local regulations.

15. Use of NEQAS data

The information and data from RITM NEQAS are the intellectual property of RITM. The data may not be reproduced, in whole or in part, for any purpose without the written permission from the Institute. If permission is granted, acknowledgment of RITM is required.

RITM NEQAS information and data may not be used for advertising or sales promotion.

16. Sharing of data to DOH

Although conditions of confidentiality are observed, participant data from the RITM NEQAS may be provided to the DOH Office of Health Laboratories (OHL) and DOH Health Facility Services Regulatory Bureau (HFSRB) for monitoring, regulatory, and policy making purposes.

17. References

- ISO 17043:2010 Conformity Assessment - General Requirements for Proficiency Testing
- ISO 13528:2015 Statistical methods for use in proficiency testing by interlaboratory comparison

18. Effectivity

These guidelines shall take effect by 1 March 2022.

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