PAMDRAP GENERAL MEMBERSHIP MEETING

EVALUATION OF IN VITRO DIAGNOSTIC MEDICAL DEVICES AND OTHER RELATED LABORATORY DIAGNOSTIC SUPPLIES FOR COVID-19

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Department of Health
RESEARCH INSTITUTE FOR TROPICAL MEDICINE

The COVID-19 pandemic ushered in new laboratory diagnostic tests (PCR detection kits, antibody tests, antigen tests)

- In general, evaluations are done:
  - **To confirm that the product will perform satisfactorily according to its intended use**
  - **To minimise the risk of harm:**
    - Safety
    - Accurate clinical diagnoses and effective disease management

NOT our objective

- ✗ Delay authorization of products
- ✗ Limit access of the public to IVDMDs
- ✗ Cause financial distress to manufacturers, suppliers, distributors

Objective of RITM Evaluation

- **Evaluate test kit performance under local conditions, using specimens representative of the local population**
  - **NOTE:** Evaluations focus on test kit performance
  - Not on quality of manufacture
- **Provides independent evidence of test kit performance**
  - Confirm that the test kit will perform satisfactorily according to its intended use

Considerations

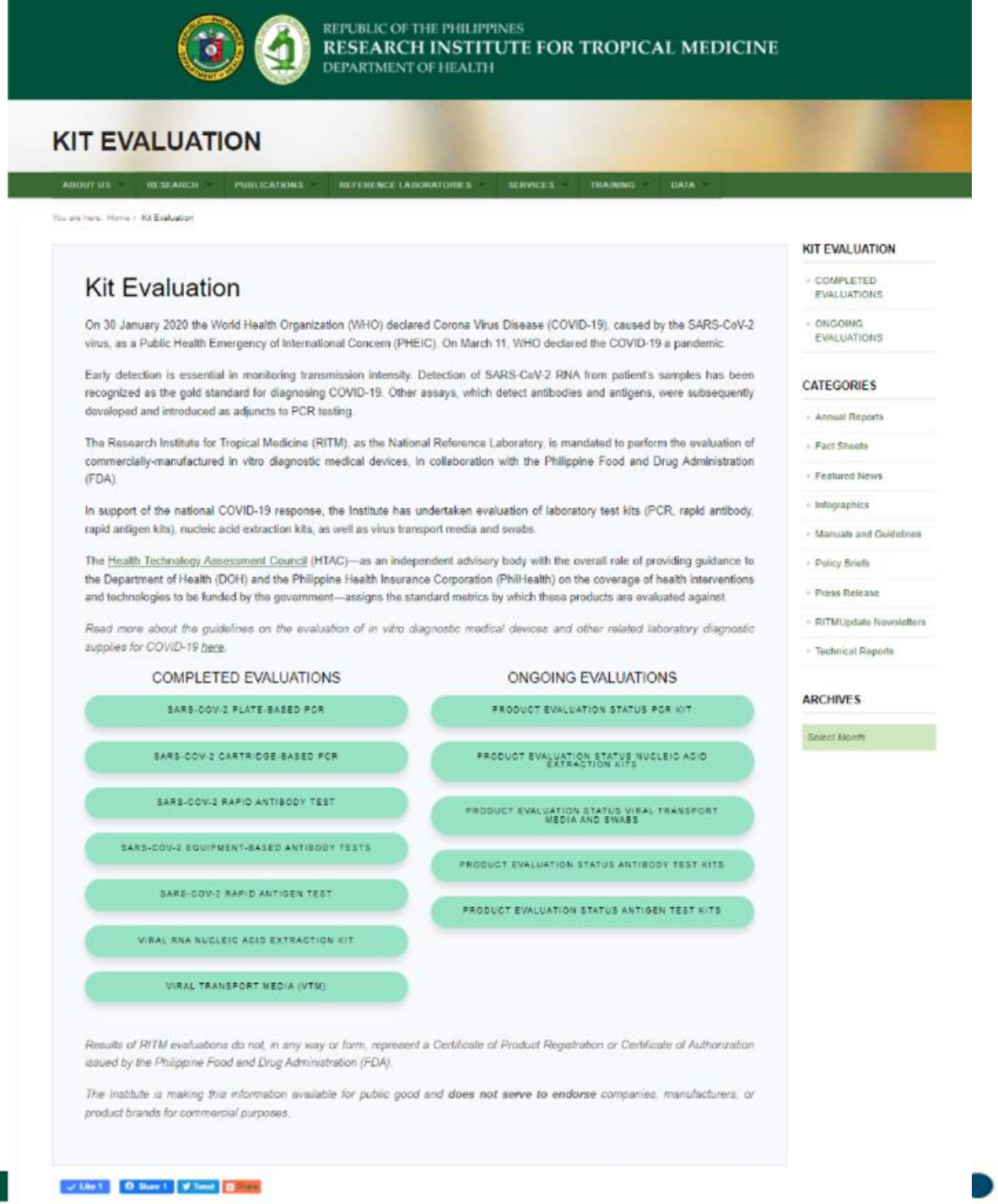
- Required specimens to conduct the evaluation of product's diagnostic performance:
  - **For evaluation of PCR kits:** Stored known PCR-positive and negative NPS/OPS swabs
  - **For evaluation of Rapid Antibody kits:** Acute and convalescent serum from confirmed cases of COVID-19 (ideally, serially collected from patients)
  - **For evaluation of Rapid Antigen kits:** Point-of-care settings with parallel swab testing for PCR
- Coordination with collection sites to acquire appropriate specimens
- Availability of laboratories and technical staff for conduct of evaluation

Following ARTA meeting last March 2, 2021

RITM improved transparency of information on kit evaluation

in our website: https://ritm.gov.ph/covid-19-kit-evaluation/

- Information on completed and ongoing evaluations were reflected to guide suppliers
- Standard protocols for evaluation were made available including the updated guidelines for requests for product evaluation

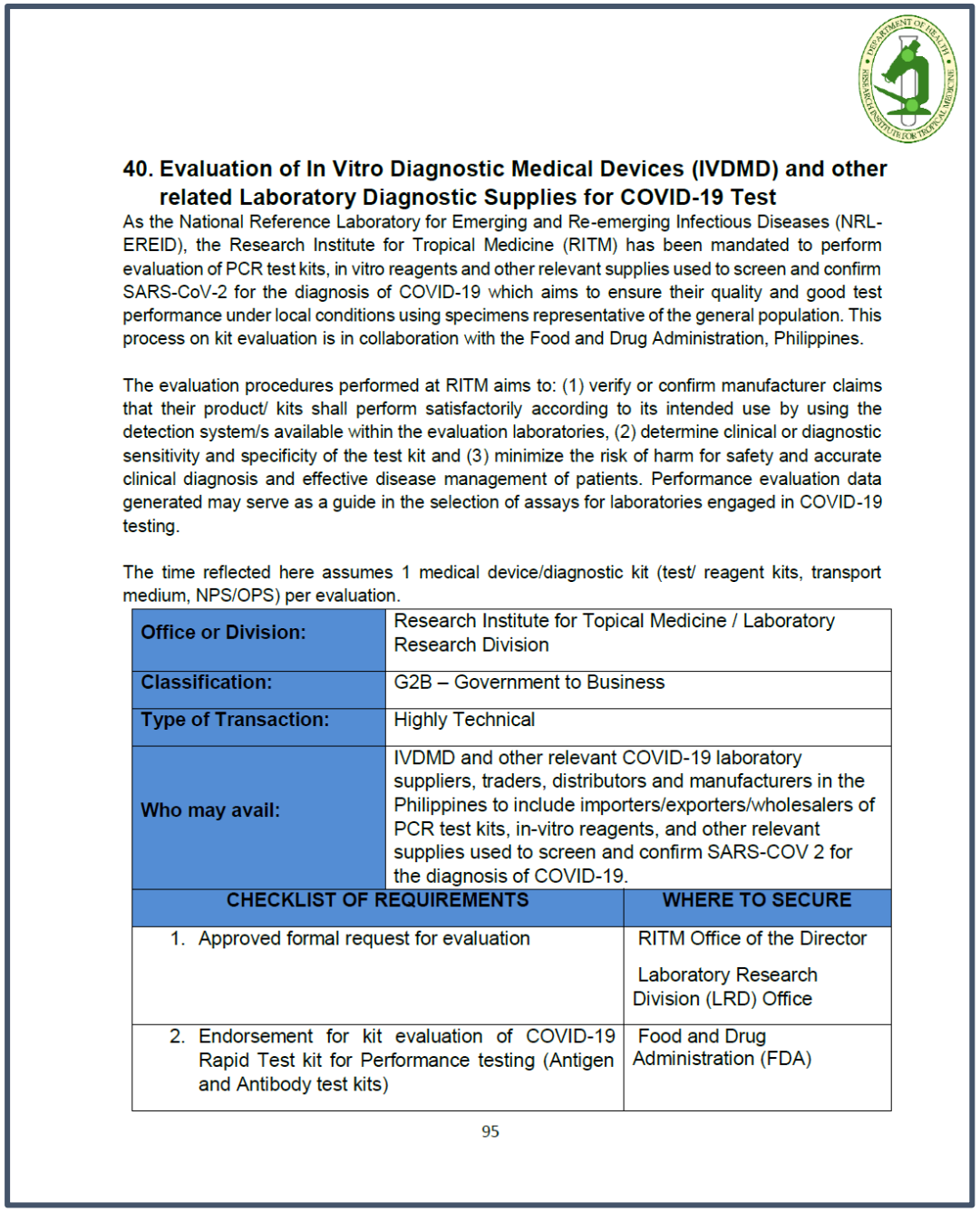


Following ARTA meeting last March 2, 2021

RITM updated Citizen's Charter to reflect the process of requests for evaluation of in vitro diagnostic medical devices (p. 95, RITM Citizen's Charter)

https://drive.google.com/file/d/1qaSsc2Jee56x6lcyCHDbyiScoPDH2iEg/view

- Total Computed Turn Around Time upon complete requirements ≃ **20 days**



40. Evaluation of In Vitro Diagnostic Medical Devices (IVDMD) and other related Laboratory Diagnostic Supplies for COVID-19 Test

As the National Reference Laboratory for Emerging and Re-emerging Infectious Diseases (NRL-EREID), the Research Institute for Tropical Medicine (RITM) has been mandated to perform evaluation of PCR test kits, in vitro reagents and other relevant supplies used to screen and confirm SARS-CoV-2 for the diagnosis of COVID-19 which aims to ensure their quality and good test performance under local conditions using specimens representative of the general population. This process on kit evaluation is in collaboration with the Food and Drug Administration, Philippines.

The evaluation procedures performed at RITM aims to: (1) verify or confirm manufacturer claims that their product/ kits shall perform satisfactorily according to its intended use by using the detection system/s available within the evaluation laboratories, (2) determine clinical or diagnostic sensitivity and specificity of the test kit and (3) minimize the risk of harm for safety and accurate clinical diagnosis and effective disease management of patients. Performance evaluation data generated may serve as a guide in the selection of assays for laboratories engaged in COVID-19 testing.

The time reflected here assumes 1 medical device/diagnostic kit (test/ reagent kits, transport medium, NPS/OPS) per evaluation.

Office or Division:	Research Institute for Topical Medicine / Laboratory Research Division
Classification:	G2B – Government to Business
Type of Transaction:	Highly Technical
Who may avail:	IVDMD and other relevant COVID-19 laboratory suppliers, traders, distributors and manufacturers in the Philippines to include importers/exporters/wholesalers of PCR test kits, in-vitro reagents, and other relevant supplies used to screen and confirm SARS-COV 2 for the diagnosis of COVID-19.
CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Approved formal request for evaluation	RITM Office of the Director Laboratory Research Division (LRD) Office
2. Endorsement for kit evaluation of COVID-19 Rapid Test kit for Performance testing (Antigen and Antibody test kits)	Food and Drug Administration (FDA)

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Guidelines on the Evaluation of IVDMDs and other related Laboratory Diagnostic Supplies for COVID-19

Guidelines shall apply to all manufacturers, traders, suppliers, and distributors (importers/exporters/wholesalers) of PCR test kits, antibody and antigen test kits, in vitro reagents, and other relevant supplies used to screen and confirm SARS-CoV-2 for the diagnosis of COVID-19 (such as virus transport media, nasopharyngeal and oropharyngeal swabs).

https://ritm.gov.ph/guidelines-on-the-evaluation-of-in-vitro-diagnostic-medical-devices-and-other-related-laboratory-diagnostic-supplies-for-covid-19/

GUIDELINES

1. Submission of requirements

All requests for evaluation of In-Vitro Diagnostic Medical Devices (PCR kits, antibody and antigen test kits, extraction kits,) and other related laboratory supplies (swabs, viral transport media) for COVID-19 testing, shall be received through the Director's Office.

2. Requirements

All interested applicants are requested to submit TWO (2) PRINTED copies of the following documents to the RITM Director's Office:

2.1. Accomplished Document Requirements Checklist (Annex A)

2.2. Formal request for evaluation of the product addressed to the Director.

2.3. Product brochure

2.4. Technical information

NOTE: All requests for evaluation must contain relevant technical information, such as but not limited to performance data, sensitivity and specificity, cross reactivity against human coronaviruses, and limit of detection data; previous evaluations by other laboratories; publications, if any.

2.5. Regulatory status: Global Product Certification (CE IVD, RUO) by National Regulatory Agencies of the country of origin
2.6. Manufacturer's Instructions for Use (IFU)
2.7. Proof of Quality Management System: ISO/IEC
2.8. Contact information (name of official contact person with e-mail address, landline, mobile number)

PROCESSES

1. Interested companies should apply to the Food and Drug Administration. Once requirements are approved, FDA shall endorse the applicants to RITM (FDA Memo No. 2021-009). **RITM shall not accept applications that have not been endorsed by FDA.**

2. Suppliers shall follow the submission process.
Upon receipt of the requirements, the Director's Office shall endorse these to the Laboratory Research Division Office (LRD Office) for tracking and determination of other possible additional requirements.

3. LRD Office shall endorse requirements to the RITM Kit Evaluation at the Virology Department.

PROCESSES

4. Upon passing the initial assessment, the RITM Evaluation Team shall ask the company through email (copy furnished LRD Office and Accounting Department) for payment of validation fee which shall be settled by the company to the RITM Cashier. Official Receipt shall be issued by RITM upon receiving payment.

5. RITM Evaluation Team shall inform the company through its submitted contact for the schedule of delivery of product/s for evaluation and payment of fees. Requesting company shall deliver product/s for evaluation with attached copy of Official Receipt to the RITM Evaluation Team.

PROCESSES

7. Product/s shall be evaluated in accordance with RITM protocols.

8. Evaluation results shall be submitted to the Laboratory Research Division Office for review and endorsement by the Division Chief to the Director.

9. The Director shall approve the final evaluation report and forward the evaluation to the FDA.

10. RITM will provide the result to the applicant.

Flow of Product Evaluation

Step 1	• Application to FDA and endorsement to RITM	Suppliers, manufacturers are to apply their product to FDA. FDA shall endorse the product to RITM for evaluation.
Step 2	• Submission of Requirements to RITM	Suppliers, manufacturers to submit request, product brochure, technical information on the kit to RITM
Step 3	• Assessment of requirements	Evaluation team shall assess the requirements and advise applicant to pay the evaluation fee
Step 4	• Payment and delivery of products for evaluation	Supplier, manufacturer pays the evaluation fee and await schedule of evaluation
Step 5	• Product evaluation	RITM conducts actual product evaluation in the laboratory
Step 6	• Submission of report to FDA	Reports are submitted to FDA; copy is provided to supplier/manufacturer

TURNAROUND TIME

Product evaluation shall take at least twenty (20) working days depending on the load of the RITM Evaluation Team. The turnaround time shall commence from complete compliance to ALL requirements:

1. **Complete submission of documentary requirements;**
2. **Payment of evaluation fees; and**
3. **Complete submission of required number of product samples.**

Any delays in Turnaround Time due to uncontrollable and non-preventable factors shall be taken into consideration.

The company shall be informed if there is a need for more working days to complete product evaluation.

RELEASE OF EVALUATION RESULTS

Evaluation results shall be released after the DOH Central Office and Food and Drug Administration have been duly notified of the results.

Does RITM evaluate other lab consumables and equipment?

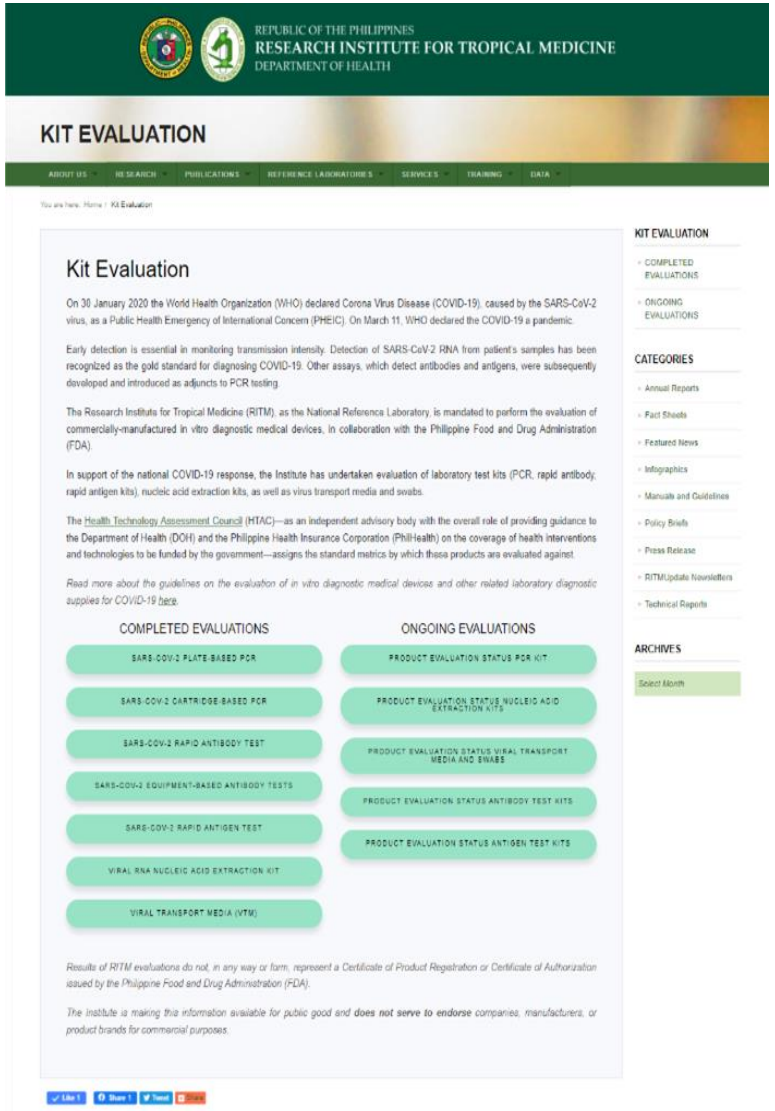
RITM product evaluations do NOT cover laboratory consumables (such as PCR tubes, strips, plates) and equipment (which requires technical expertise on instrumentation).

Evaluation of a diagnostic product which requires a specific equipment

Evaluation of a specific equipment or instrument

What is the frequency of updating the evaluation status at the RITM website?

The website is updated every 15th and 30th of month. For completed evaluation results, the website is to be updated once FDA and DOH is duly noted of the results.



In light of the many products that are in queue for evaluation at RITM and the lack of samples for evaluation, will RITM be accepting performance validation conducted by WHO, FIND, US CDC, US FDA and other counterpart reference laboratories and international agencies?

YES. We do provide recommendations to FDA to consider completed performance evaluations by WHO, FIND, FDA, and other NRAs if available.

What does RITM define as other counterpart reference laboratories and international agencies?

Other counterpart reference laboratories
Government laboratories which have similar mandates with RITM, serving as the public health laboratory in their respective government.

Reputable international agencies
These may be non-government non-profit laboratories which perform independent product evaluations such as FIND, WHO

According to FDA Memorandum 2021-009 issued last 23 March 2021, all issued Special Certifications shall have a validity period of 6 months from the date of issuance of such memorandum.. meaning that Special Certifications will be valid only up to 23 Sept 2021. How can we ensure the continuous supply of COVID test kits?

We understand the “deadline” and we will do our best to evaluate as many as we can and as fast as we can without sacrificing the quality of the evaluation, and in consideration of other ongoing activities.

How are evaluations being queued? Is it a first come first serve basis considering that there are companies renewing their certificates?

Those that were on queue from the start, do they need to queue again since they need renewal and no performance evaluation has been done yet? Example: I have a Special Cert before for antibody test but it has never been evaluated yet. When I submit for renewal, do I need to queue again or do I keep my original queue?

Applications with complete documentary requirements are queued on “first come first served” basis.

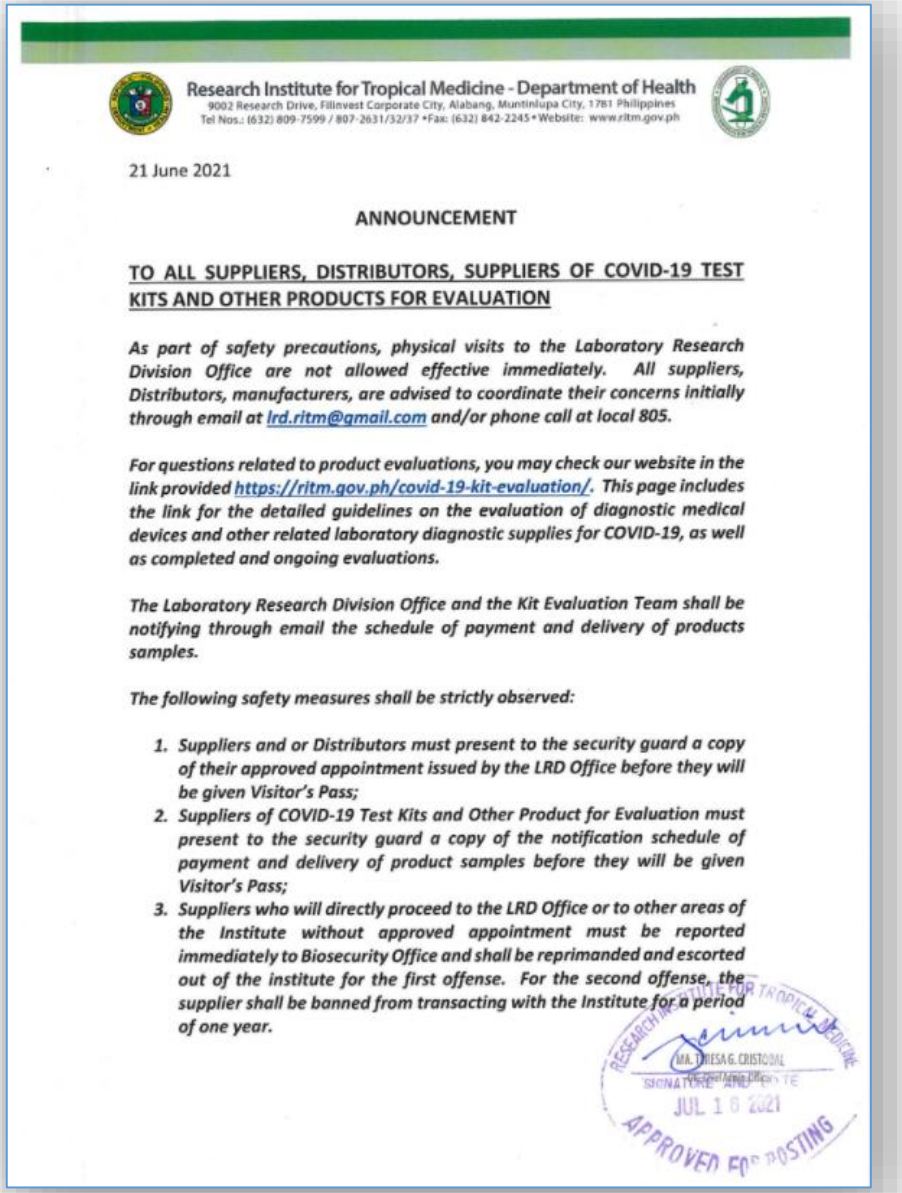
Also, is the queue dependent on other factors such as sample availability, space availability (for those with instruments)?

We follow the “first come first served” policy with a consideration that applications fulfilling **all required technical documents including the appropriate number of machines or instruments needed are queued first.**

Email address and working contact numbers to make follow ups including person in charge for ff ups

For traceability purposes, we prefer that no telephone or in person follow ups be done. All queries shall be emailed to: lrd.ritm@gmail.com and ritmkitevaluation@gmail.com

https://ritm.gov.ph/announcements/to-all-suppliers-distributors-supplies-of-covid-19-test-kits-and-other-products-for-evaluation/



Research Institute for Tropical Medicine - Department of Health
9002 Research Drive, Filinvest Corporate City, Alabang, Muntinlupa City, 1781 Philippines
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21 June 2021

ANNOUNCEMENT

TO ALL SUPPLIERS, DISTRIBUTORS, SUPPLIERS OF COVID-19 TEST KITS AND OTHER PRODUCTS FOR EVALUATION

As part of safety precautions, physical visits to the Laboratory Research Division Office are not allowed effective immediately. All suppliers, Distributors, manufacturers, are advised to coordinate their concerns initially through email at lrd.ritm@gmail.com and/or phone call at local 805.

For questions related to product evaluations, you may check our website in the link provided https://ritm.gov.ph/covid-19-kit-evaluation/. This page includes the link for the detailed guidelines on the evaluation of diagnostic medical devices and other related laboratory diagnostic supplies for COVID-19, as well as completed and ongoing evaluations.

The Laboratory Research Division Office and the Kit Evaluation Team shall be notifying through email the schedule of payment and delivery of products samples.

The following safety measures shall be strictly observed:

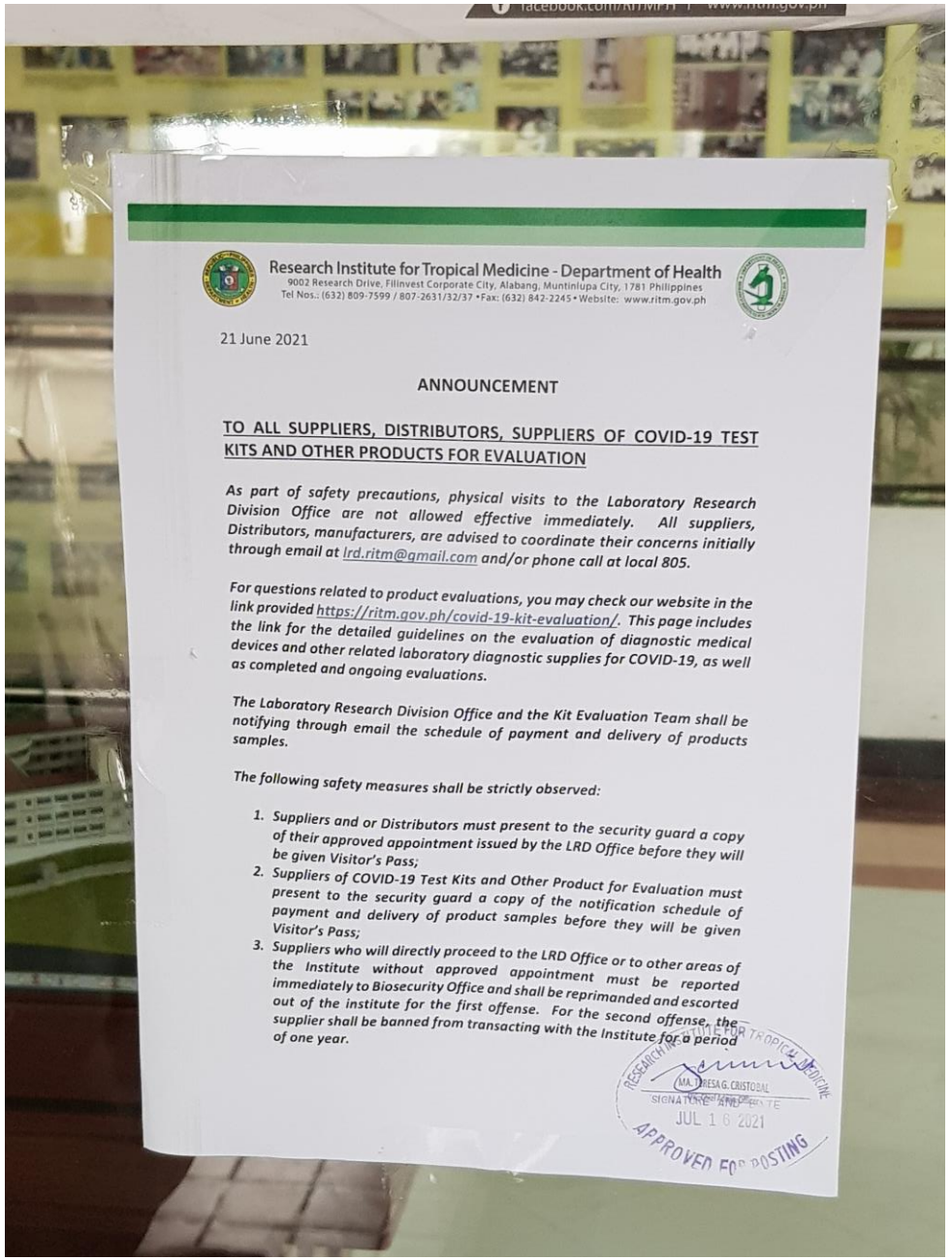
1. *Suppliers and or Distributors must present to the security guard a copy of their approved appointment issued by the LRD Office before they will be given Visitor's Pass;*
2. *Suppliers of COVID-19 Test Kits and Other Product for Evaluation must present to the security guard a copy of the notification schedule of payment and delivery of product samples before they will be given Visitor's Pass;*
3. *Suppliers who will directly proceed to the LRD Office or to other areas of the Institute without approved appointment must be reported immediately to Biosecurity Office and shall be reprimanded and escorted out of the institute for the first offense. For the second offense, the supplier shall be banned from transacting with the Institute for a period of one year.*

MA. TERESA G. CRISTOBAL
JUL 16 2021
APPROVED FOR POSTING

Physical visits are not allowed

For safety reasons, we do not entertain face-to-face visits from manufacturers, suppliers, distributors to follow up on the status of their product evaluation.

- E-mail/phone call for coordination.
- We are exerting efforts to regularly update the website status.



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RESEARCH INSTITUTE FOR TROPICAL MEDICINE
MA. TERESA G. CRISTOBAL
SIGNATURE ABOVE PRINTED NAME
JUL 16 2021
APPROVED FOR POSTING

We are on queue for equipment based antibody test since September 2020 and the product which we submitted for local testing will now be replaced and be discontinued. Can we use the slot of our current product for the validation of the new one?

We will consider your situation. Please coordinate with us through email.

What are the agency's hurdles /causes of delay in the process from receiving of applications to release of performance test results? (1/2)

For antibody and antigen test kits, the usual cause of delay is the availability of samples.

What are the agency's hurdles /causes of delay in the process from receiving of applications to release of performance test results? (2/2)

For PCR kits- the usual cause is the completeness of the technical documents provided and the feedback from respective suppliers for any clarifications from the technical teams.
Additionally, for the last few months, the team for RT PCR evaluations were involved in different activities ie. genomic sequencing, assay optimization, and thus the limited number of kits evaluated per month.

We are applying for a product which needs evaluation but the product has been applied by other distributor and has been evaluated by RITM. Do we still need to give our samples for the evaluation? or only the submission of the documents and payment?

No need to provide sample test kits for evaluation. Applications for evaluation still needs to be submitted together with other required documents. This is to ensure that the product matched the catalogue no. of previously evaluated product

How do we ensure continuous supply. i.e. product did not meet the minimum requirement as per FDA memo on minimum req’ts and company will request to conduct performance validation again, how soon can they do the re-validation?

The “minimum” requirements refer to the WHO Target Product Profiles (performance) for IVDMDs adopted by FDA.
There are only specific instances in which re-evaluation shall be accepted by RITM. We are working with FDA on criteria for re-evaluation.

Repeating the testing will not guarantee passing the evaluation.

- We stand by our evaluation results.
  - Staff are experienced and trained. There are quality checks.
  - Our protocols are standardized and based on FIND, WHO, FDA but are not as extensive or as exhaustive. These are also publicly available in our website.
  - Our sample bank is carefully maintained to minimize degradation. In any case, we retest challenge samples with our reference test/comparator test as part of the process.
- If you have concerns with our evaluations, please coordinate with us.

What are the action plans of RITM on the numerous applications received to be able to meet expectations or service satisfaction of clients?

PRODUCT EVALUATION STATUS

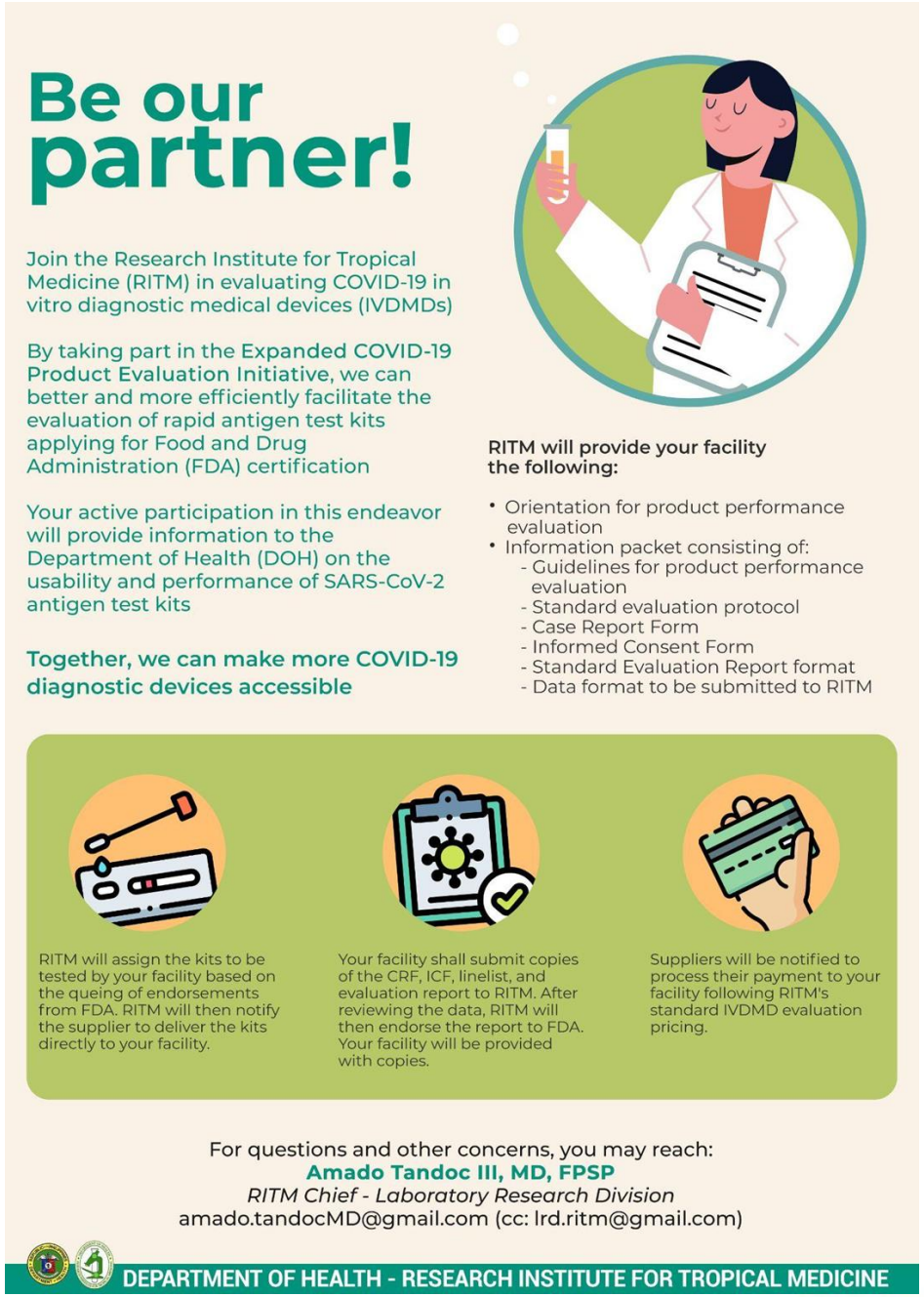
TYPE OF KIT	TOTAL NO. OF KITS RECEIVED TO DATE	TOTAL KITS TESTED TO DATE	TOTAL NUMBERS OF KITS FOR EVALUATION
Plate-based RT PCR kit	**69**	**32**	**37**
Cartridge-based RT PCR kit	**10**	**8**	**2**
Rapid Antigen Kit	**100**	**10**	**90***
Antibody	**79**	**46**	**33**

STRATEGIES TO FACILITATE EVALUATIONS

- Refocusing on reference laboratory activities
- Increased number of support staff to improve coordination activities
- Continued coordination with potential collection sites in high prevalence areas in NCR and CALABARZON
- Hiring of technical staff to create more specimen collection teams and testing teams

Enhanced Kit Evaluation Initiative

- Launching of “Enhanced Kit Evaluation” Initiative which aims to engage additional facilities and testing sites
- Invitation of 10 additional COVID-19 Hospitals/Facilities to participate
- Multiply force to complete evaluations.
- Build capacity to “evaluate” products.



THANK YOU!

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