Research Institute for Tropical Medicine - Department of Health
9002 Research Drive, Filinvest Corporate City, Alabang, Muntinlupa City, 1781 Philippines
Tel Nos.: (632) 8809-7599 / 8807-2631/32/37 • Website: www.ritm.gov.ph

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

Updated January 2021

RATIONALE

Pursuant to Republic Act (R.A.) No. 3720 as amended by Republic Act (R.A.) 9711, test kits and in-vitro diagnostic reagents must be registered with the Food and Drug Administration (FDA) of the Department of Health before release into the Philippine market.

In accordance with Department Order No. 393E s.2000, (Designation of National Reference Laboratories and Transfer of Corresponding Equipment, Instruments, Supplies, Specimens, Records from the Bureau of Research and Laboratories), the Research Institute for Tropical Medicine has been mandated to perform evaluation of test kits to ensure their quality and good performance in the local setting.

SCOPE/COVERAGE

These guidelines shall apply to all manufacturers, traders, suppliers, and distributors (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 (such as virus transport media, nasopharyngeal and oropharyngeal swabs).

GUIDELINES

1. Submission of requirements

All requests for evaluation of In-Vitro Diagnostic Medical Devices (reagents, PCR kits, extraction kits, PCR systems) 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:

1. Accomplished Document Requirements Checklist (Annex A)
   NOTE: Applicable only to the companies requesting for validation of RT PCR kits, Nucleic Extraction Kits, Virus/Universal Transport Media, and Nasopharyngeal and Oropharyngeal Swabs.
2. Formal request for evaluation of the product addressed to the Director:

   CELIA C. CARLOS, MD, CESO III
   Director IV
   Research Institute for Tropical Medicine

3. Product brochure
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.

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

NOTE: Soft copies of all documents shall also be e-mailed to lrd.ritm@gmail.com with email subject: PRODUCT EVALUATION FOR (Insert type of product i.e. VTM/UTM, RT PCR kit, NPS/OPS, Nucleic Extraction Kits).

3. Processes

3.1. ANTIGEN AND ANTIBODY TEST KITS

1. Interested companies should apply to the Food and Drug Administration. Once requirements are approved, FDA shall endorse the documents to RITM. **RITM shall not accept applications for Antigen and Antibody test kit evaluations that have not been endorsed by FDA.**
2. Upon receipt of the requirements from FDA, 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.
4. Upon passing the initial assessment, the RITM Evaluation Team shall ask the company thru 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.
6. Requesting company shall deliver product/s for evaluation with attached copy of Official Receipt to the RITM Evaluation Team.
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. FDA shall be in-charge of releasing the evaluation report.

3.2. RT PCR KITS, VIRUS TRANSPORT MEDIUM/UNIVERSAL TRANSPORT MEDIUM (VTM/UTM), NASOPHARYNGEAL AND OROPHARYNGEAL SWAB (NPS/OPS).

1. Upon receipt of the requirements, the Director's Office shall endorse the received requirements to the Laboratory Research Division Office (LRD Office) for initial assessment and tracking.
2. Upon passing the initial assessment, the LRD Office shall ask the company thru email (copy furnished LRD Office and Accounting Department) for payment of validation fee which shall be settled by the company to the RITM Cashier.
3. Official Receipt shall be issued by RITM upon receiving payment.
4. LRD Office shall inform the company through its submitted contact for the schedule of delivery of product/s for evaluation and payment of fees.
5. Requesting company shall deliver product/s for evaluation with attached copy of Official Receipt to the LRD Office.
6. Product/s shall be evaluated in accordance with RITM protocols.
7. Evaluation result shall be submitted to the Laboratory Research Division Office for review and endorsement by the Division Chief to the Director.

8. The Director shall approve the final evaluation report and forward the evaluation to the FDA and the company shall be provided with a receiving copy of the evaluation report submitted to FDA.
9. RITM Kit Evaluation Team/LRD Office shall be in-charge of releasing the receiving copy of FDA submitted evaluation report.

4. Schedule of Fees

Payment for the product evaluation shall be required to defray costs of evaluation. Product evaluation shall follow the below schedule of fees:

Product/Item	Evaluation Fee
SARS-CoV-2/COVID-19 PCR Kit	PHP 50,000.00
Nucleic Acid Extraction Kit	PHP 40,000.00
SARS-CoV-2/COVID-19 Antibody/Antigen Kit	PHP 40,000.00
Virus Transport Media	PHP 5,000.00
Oropharyngeal/Nasopharyngeal Swab	PHP 5,000.00

NOTE: Product evaluation fees are subject to change upon notice. Any product/item not included in the above schedule shall be evaluated by the RITM Evaluation Team prior to proceeding with submission of requirements.

5. Prescribed Quantity of Product/s for Evaluation

The company shall submit the following prescribed quantity of product/s for evaluation:

Product/Item	Quantity*
SARS-CoV-2/COVID-19 PCR Kit	Minimum of 300 tests
Nucleic Acid Extraction Kit	Minimum of 150 isolations
SARS-CoV-2/COVID-19 Antibody/Antigen Kit	Minimum of 100 tests
Virus Transport Media	10 units
Oropharyngeal/Nasopharyngeal Swabs	10 pieces

NOTE: Additional product/s may be requested by the RITM Evaluation Team as needed to complete its evaluation. Quantity of products may also change depending on the number of suppliers carrying the same product, in which case, RITM shall notify the appropriate parties.

6. Submission of Product/s for Evaluation

1. Expiration of product/s for evaluation should be **at least six (6) months from the date of delivery.**
2. For PCR kits, two (2) different production lot numbers should be submitted to determine lot variability of the kit.
3. Proper transport of product/s for evaluation according to the manufacturer's recommendation must be strictly observed by the applicant so as not to compromise the results of the evaluation.

7. 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.

8. Multiple Requests for Evaluation of the same Specific Product

1. In case of request for evaluation by a different supplier/distributor with the same evaluated product, RITM through the Laboratory Research Division, shall inform subsequent requestors.
2. All requesting suppliers/distributors are to pay for the same evaluation fee as provided for in this guideline. Cost-sharing between suppliers and distributors is for the number of kits to be provided to RITM for evaluation.
3. RITM shall only accept evaluation of the same product provided that the samples have different lot numbers.

9. Repository Office for Kit Evaluation Reports

1. RITM Evaluation Team at Virology Department shall act as repository office for product evaluation reports.
2. The Director's Office shall provide RITM Kit Evaluation Team a scanned receiving copy of the evaluation report.

10. Inquiries and Follow Up

Direct all inquiries to the following email address to ritmkitevaluation@gmail.com and lrd.ritm@gmail.com or mobile number **0919 927 9193**. **No follow up shall be entertained during the course of the evaluation process. Companies must wait for the dates of payment and deliveries.** Turn-around time will only start from the date of **COMPLETE** delivery of sample products.

11. Requests for Re-evaluation

Companies may request for re-evaluation through a formal communication to the RITM Director. Re-evaluation of product/s shall be subject to approval of the RITM Director and following these guidelines.

12. 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.

Effectivity

This order shall take effect by January 25, 2021

CELIA C. CARLOS, MD, CESO III
Director IV
Research Institute for Tropical Medicine

Research Institute for Tropical Medicine - Department of Health
9002 Research Drive, Filinvest Corporate City, Alabang, Muntinlupa City, 1781 Philippines
Tel Nos.: (632) 8809-7599 / 8807-2631/32/37 • Website: www.ritm.gov.ph

DOCUMENT REQUIREMENT CHECKLIST
PRODUCT EVALUATION (IVDMDs AND OTHER RELEVANT COVID-19 LABORATORY SUPPLIES

Date of Submission	

I. To be filled out by Requestor:

Applicant Contact Information			
Full Name			
Company Name (Complete name registered with the SEC)			
Designation		Landline Number	
E-mail address		Mobile Number	

Product Information	
Product	❑ Polymerase Chain Reaction Kit (PCR) ❑ Nucleic Acid Extraction Kit ❑ Virus Transport Media ❑ Oropharyngeal Swab ❑ Nasopharyngeal Swab ❑ Antigen Test Kit (Ag) ❑ Antibody Test Kit (IgM/IgG) ❑ Other (please specify):
Brand/ Lot Number/Expiry Date	
Machine Requirement	
Catalog Number	
Manufacturer	
Manufacturer Address	
Manufacturer Website	

Reason for Evaluation	

CONFORME:
We understand that by applying for evaluation of the aforementioned product, we are expressly giving our consent to publish the results at the RITM Website. Any inquiries or clarifications on the results will be formally made through a letter addressed to the RITM Director.

Name and Signature of Authorized Representative	
Company Name	
Date	

II. To be filled-out by Product Validation staff:

Documentary Requirements			
No.	**Item**	**Assessment**	**Remarks**
1	Formal request for evaluation of the product addressed to the Director	❑ **Yes** ❑ **No**	
2	Product brochure	❑ **Yes** ❑ **No**	
3	Technical information *NOTE: For PCR kits, include performance data, sensitivity and specificity; cross reactivity against human coronaviruses, and limit of detection data; previous evaluations by other laboratories; publications, if any*	❑ **Yes** ❑ **No**	
4	Regulatory status: Global Product Certification (CE IVD, RUO) by National Regulatory Agencies of the country of origin	❑ **Yes** ❑ **No**	
5	Manufacturer's Instructions for Use (IFU)	❑ **Yes** ❑ **No**	
6	Proof of Quality Management System: ISO/IEC	❑ **Yes** ❑ **No**	
7	Other/s (please specify):		

Documents evaluated by: Signature over printed name	
Date:	