VALIDATION PROTOCOL FOR COVID-19 DIAGNOSTIC ITEMS

Dynamic document subject to change as per national protocol and guidelines

Approved on 12 October 2020

1. BACKGROUND:

Validation is defined as the "confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled." Validation determines the fitness of an assay, which has been properly developed, optimized and standardized, for an intended purpose. Validation is required since a newly introduced assay/ technology is always associated with a certain degree of risk and uncertainty.

In the context of COVID-19 pandemic, various testing kits based on different technologies (such as RT-PCR, antibody detection, antigen detection, LAMP, iAMP etc.) are being developed and marketed, at both international and national levels. These kits may be used for various purposes as per national guidelines for diagnosis, screening, surveillance and research. While such rapid advances in technologies are surely a welcome move, care should be taken at the same time for ensuring safety and quality of such products. Surveillance measures should be in place at various phases, especially before approval of use of such kits, i.e, before putting such kits into routine use

Validation or evaluation of kits can be considered as one of such surveillance measures, which can be used to monitor performance and effectiveness of such kits. A robust and consistent system of kit validation at national level definitely ensures safeguarding of public against unregistered and substandard products. Meanwhile, it can also reduce the discrepancies in laboratory results that is frequently in scene, since a basic level of standardization is guaranteed.

2. VALIDATION

2.1 RT-PCR Kits

2.1.1 US-FDA approved and WHO listed or recommended kits will not require validation.

2.1.2 CE-IVD approved/ Non US-FDA approved/ Indigenous: Kits will require validation

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2.2 RNA Extraction

2.2.1 US-FDA approved and WHO listed or recommended kits will not require validation.

2.2.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: Kits will require validation

2.3 VTM Kits:
2.3.1 US-FDA approved and WHO listed or recommended kits will not require validation.
2.3.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: Kits will require validation

2.4 Antigen kits:
2.4.1 US-FDA approved and WHO listed or recommended kits will not require validation.
2.4.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: Kits will require validation

2.5. Antibody kits:
2.5.1 US-FDA approved and WHO listed or recommended kits will not require validation.
2.5.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: Kits will require validation.

2.6 Others:
2.6.1. If NPHL considers any other non-FDA and non-WHO WHO listed or recommended technologies may be appropriate for Nepal**,** NPHL can request HTAC/ MOHP to facilitate the approval process.
2.6.2. If a non government entity wants to bring a new technology, which is not approved by the FDA or WHO, for research purpose, that entity can do so by submitting proper application to the NHRC stating the purpose of research. If the new technology is planned to be used and marketed in Nepal, the application must get approval by both HTAC and NPHL.

3. AGENCIES ELIGIBLE FOR REQUESTING FOR VALIDATION:

3.1 Supplier/ Manufacturer of kits

3.2 Logistic management division, DOHS

4.PROCEDURE FOR VALIDATION

4.1 Government bodies should come through Logistic management division, DoHS for requesting validation of available kits

4.2 Manufacturer or supplier can directly approach NPHL for kit validation

4.3 Any organization requesting kit validation shall send request (PCR kits/ RNA extraction kits/ VTM) to NPHL via email (neqas@nphl.gov.np) and also submit written request letter.

Complete information regarding kits to be validated must be filled and attached in mail/ letter in given format (annex I)

4.4 The request will be received, scrutinized for details and validation work will be commenced.

If the kit is for second time validation or subsequent validation or in case of any other issue; the manufacturer has to provide justification which will be reviewed at NPHL and decision will be communicated to manufacturer/supplier within a week.

The request for re-validation will only be considered if there is any significant change in the composition or type of reagents in the kit.

4.5. Once the kit is delivered to the NPHL with adequate number of test reactions required, reagents, methodology (complete set at least for 100 tests)etc; validation work will be commenced.

4.6. Any extra special equipment required for the test to conduct has to be supplied by vendor requesting validation

4.7. Training or any other form of technical assistance, whenever required for validation purpose, will have to be provided by the vendor

4.8. If needed, NPHL can request for any kind of support by other institutions (Government/Non-Government) during validation process. This process will be mediated by MoHP/ HTAC.

5.TIME TAKEN FOR VALIDATION:

Minimum two weeks

6. Minimum requirement to accept a kit for validation ;

The kit should have a fulfill requirement of minimum sensitivity and specificilty to be accepted for validation. This will depend upon the accepted specification by DOHS

7. COST:

7.1. For Government bodies: No cost will be charged

7.2 For suppliers/ manufacturers: RS .30,000 (for each component)

ANNEX I:

Format for information for validation of kits and consumables:

A. RT-PCR kit

Name of company/ manufacturer	Name of supplier	Name of kit and Batch no/ lot no	Multiplex or singleplex (state genes targeted)	First time validation(Yes/ No)	If it is not first time validation	
					Details of last validation along with validation report	Difference in kit composition as compared to first validation

B. RNA extraction kit

Name of company/ manufacturer	Name of supplier	Name of kit and Batch no/ lot no	Principle of extraction (eg. column based/ magnetic separation)	First time validation(Yes/ No)	If it is not first time validation	
					Details of last validation along with validation report	Difference in kit composition as compared to first validation

C. VTM

Name of company/ manufacturer	Name of supplier	Name of kit and Batch no/ lot no	Principle of extraction (eg. column based/	If it is not first time validation	
				Details of last	Difference in kit

			magnetic separation)	validation along with validation report	composition as compared to first validation

D. Antibody kit:

Name of company/ manufacturer	Name of supplier	Name of kit and Batch no/ lot no	Principle of antibody detection or quantification(eg .Lateral flow immunoassay/ ELISA/ CLIA)	If it is not first time validation	
				Details of last validation along with validation report	Difference in kit composition as compared to first validation

E. Antigen kit:

Name of company/ manufacturer	Name of supplier	Name of kit and Batch no/ lot no	Principle of antigen detection (eg. Lateral flow immunoassay/ Fluorescence immunoassay)	If it is not first time validation	
				Details of last validation along with validation report	Difference in kit composition as compared to first validation

F. Others:

Name of company/ manufacturer	Name of supplier	Name of kit and Batch no/ lot no	Principle of assay (eg. LAMP/ iAMP etc.)	If it is not first time validation

				Details of last validation along with validation report	Difference in kit composition as compared to first validation

Cost Breakdown:

SN	Title	Cost (NRS)
1.	Extra Kits and consumables	25,000
2.	HR support	3000
3.	Space and equipment support	2000
	Total cost	30,000