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THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PROTOCOL FOR LABORATORY PERFORMANCE EVALUATION OF SARS-CoV-2 ANTIGEN ASSAYS

FIRST EDITION

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TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma - Tanzania, Tel: +255 (26) 2961989/2061990/ +255(22) 2450512/2450751/2452108, Email: info@tmda.go.tz, Website: www.tmda.go.tz, Toll free: 08001100834

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ACKNOWLEDGEMENTS

The COVID-19 pandemic has highlighted the paramount importance of public health surveys including assessments of seroprevalence for estimating the cumulative incidence of SARS-CoV-2 infection at population level. Evaluations limited to data for confirmed cases or deaths greatly underestimate disease propagation, due to the large proportion of mildly affected or asymptomatic individuals and the lack of Reserve Transcriptase Polymerase Chain Reaction (RT-PCR) screening tests at the start of the pandemic.

With this, I want to extend my sincere gratitude to the Tanzania Medicines and Medical Devices Authority (TMDA) staff and other experts who gave their valuable time and experience in the development of these guidelines. The acknowledgements are particularly extended to Ms. Rehema Mariki, Dr. Goodluck Gotora, Mr. Christian Kapinga, Ms. Edina Zebedayo, Mr. Edinanth Gareba, Mr. Octavian Aron Ngoda, Mr. James Tanguye, Ms. Emmanuela Mkalawa and Ms. Adelina G. Gadiye from Muhimbili National Hospital (MNH). Furthermore, it is with honor I appreciate the outstanding technical contribution offered by Prof. Willy Urassa, a World Health Organization (WHO) consultant, from the early stages of development of this protocol.

I would also like to thank the International Medical Devices Regulators Forum (IMDRF), the World Health Organization (WHO) as well as Medical Device Coordination Group (MDCG) established by European Union (EU) for making their guidelines available for referencing.

The proper use and implementation of this protocol will ensure that the SARS-CoV-2 Antigen Assays which have been designated to be of public health importance will perform clinically as claimed by manufacturers.



Dr. Kissa W. Mwamwitwa
Director for Medical Devices and Diagnostics Control

FOREWORD

Performance evaluation is one of the critical steps in ensuring safety and performance of in-vitro diagnostics. Diagnostics that perform well provides assurance in obtaining positive or negative results in clinical practice. It is through this assertion that the TMDA has drafted this protocol which outlines the requirements for the applicant to design and execute performance evaluation studies in Tanzania. Data on performance evaluation is needed by TMDA as part of marketing authorization of in-vitro diagnostics in Tanzania. This is one of the legal requirements stipulated in the Tanzania Medicines and Medical Devices Act, Cap 219.

Applicants and manufacturer are henceforth compelled to read the details as provided for in this protocol to streamline and expedite the approval process of diagnostics targeting Tanzania market. Together with the existing legal framework including TMDA Act and Regulations in force, applicants will also be required to refer the ISO 20916 Standard when conducting performance evaluation studies. Studies done comprehensively and pursuant to this protocol will allow for generation of adequate data and subsequent authorization of in-vitro diagnostics for marketing in Tanzania.

It is envisaged that the protocol will be helpful to our stakeholders and harmonize the performance evaluation process and therefore any suggestions for improvement of the same are likewise welcomed.



Dr. Adam M. Fimbo
Director General

ABBREVIATIONS

IFU	-	Instructions for use
ISO	-	International Organization for Standardization
NPHL	-	National Public Health Laboratory
PCR	-	Polymerase Chain Reaction
PI	-	Principal Investigator
QC	-	Quality Control
RT-PCR	-	Reverse Transcriptase - Polymerase Chain Reaction
TMDA	-	Tanzania Medicines and Medical Devices Authority

DEFINITION OF TERMS

Authority
Means the Tanzania Medicines and Medical Devices Authority or the acronym "TMDA" established under section 4(1) of the Act.

Applicant
Means any person or institution or company that applies formally for performance evaluation of IVD in Tanzania.

Clinical Performance
Means ability of an IVD to yield results that are correlated with a particular clinical condition/ physiological state in accordance to target population and intended use.

Conformity Assessment
Means the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Authority, to determine that an IVD is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices.

Diagnostic Sensitivity
Means the ability of a device to identify the presence of a target marker associated with a particular disease or condition.

Diagnostic Specificity
Means the ability of a device to recognize the absence of a target marker associated with a particular disease or condition.

Ethics Committee (EC)
Means an independent body composed of members with expertise in both scientific and non-scientific arenas which functions to ensure the protection of human rights and the well-being of research subjects based on six basic principles of autonomy, justice, beneficence, no maleficence, confidentiality and honesty.

Error rate
Means a measure of the degree of prediction error of a model made with respect to the true model.

In Vitro Diagnostics Devices
Means a device whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body and animals principally to provide information for diagnostic, monitoring or compatibility purposes. IVD include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used for example for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological status.

Manufacturer
Means any person or a firm that is engaged in the manufacture of IVDs.

Negative likelihood ratio (LR-)
Means a probability that a person with the disease tested negative divided by the probability that a person without the disease tested negative.

Negative predictive value
Means the ratio of subjects truly diagnosed as negative to all those who had negative test results (including patients who were incorrectly diagnosed as healthy).

Performance evaluation
Means the assessment and analysis of data to establish or verify the performance (analytical performance and where applicable, clinical performance) of an IVD.

Positive predictive value
Means the ratio of patients truly diagnosed as positive to all those who had positive test results (including healthy subjects who were incorrectly diagnosed as patient).

Positive likelihood ratio (LR+)
Means probability that a positive test would be expected in a patient divided by the probability that a positive test would be expected in a patient without a disease.

1 Introduction

This protocol describes the procedures for performance evaluation of SARS-CoV-2 assay antigen detection assays submitted for TMDA for market authorization. This protocol is not intended to replace validation and verification studies that need to be conducted by the manufacturer in order to fulfil TMDA product dossier requirements.

The performance evaluation determines the accuracy of SARS-CoV-2 antigen detection assays in comparison with established performance criteria. These characteristics include sensitivity, specificity, negative and positive predictive values. In addition, several operational characteristics are assessed including the suitability for use in laboratories and/or testing settings with limited infrastructure. Assays for the detection of SARS-CoV-2 antigen are covered in this protocol.

The SARS-CoV-2 specimen reference panel shall comprise a minimum of 500 SARS-CoV-2 antigen positive and SARS-CoV-2 antigen negative nasopharyngeal swab and oral pharyngeal specimens from Tanzania. To ensure consistency in preparation of evaluation reports, these protocols should be read together with the current TMDA Guidelines for Conducting Performance Evaluation of In-vitro Diagnostic Devices submitted for marketing authorization which among other things provides for format of clinical performance study report based on the class of the IVD medical device.

2 Study objectives

2.1 Overall objective

The overall objective is to evaluate and compare the accuracy of currently available SARS-CoV-2 assays antigen assays for detection of SARS-CoV-2 antigen against established performance criteria.

2.2 Specific objectives

The specific objectives of the performance evaluation are:

- To determine the sensitivity and specificity of currently available SARS-CoV-2 rapid diagnostic tests for the detection of antigen to SARS-CoV-2 as compared to a reference algorithm (PCR);
- To assess lot-to-lot variation;
- To assess inter-reader variability (for subjectively read assays); and
- To describe and assess the operational characteristics and ease of use of SARS-CoV-2 rapid diagnostic test.

3 Study implementation.

3.1 Performance evaluation laboratory

The laboratory shall hold one of the following certifications for quality management within the laboratory: ISO 17025 *General requirements for the competence of testing and calibration laboratories*, ISO 15189 *Medical laboratories: Requirements for quality and competence* or equivalent.

The Head of the Laboratory will act as the Principal Investigator (PI) for the work performed by the laboratory.

3.2 Training, performance evaluation and supervision

The following issues are key to minimizing error and maximizing the value of this performance evaluation:

- The PI will be responsible for training the laboratory professionals on the details of the evaluation protocol and on the performance of each assay undergoing evaluation.
- Only those personnel who have received specific training for a particular assay evaluation will be employed.
- Accurate record keeping is crucial to the success of the evaluation and the PI will be responsible for ensuring that all data required for the evaluation are recorded on the agreed data collection sheets and are accurate and up to date.
- It is important to plan work in advance and follow standard operating procedures as prepared and controlled by the laboratory.
- To reduce the risk of adding an incorrect specimen to a test device/well, before starting the test run, the operator will prepare worksheets and label all tubes, dilution vessels, test devices or plates with the specimen’s unique number.

- Because objective, machine-generated, permanent results for simple/rapid diagnostic tests are not feasible, it is essential that the PI emphasizes to the operator performing the tests the need for accurate recording of results and recordkeeping.
- To minimize the risk of error, it is recommended that the results are read and recorded independently by three trained staff members.
- To allow immediate correction of erroneous recording of results (rather than differences in visual interpretation), the PI or designee should assess the results as soon as possible to allow her/him to return to the original test device to investigate apparently discordant readings.
- For the performance evaluations performed at the laboratory, at least one representative result from both a SARS-CoV-2 antigen positive and negative specimens will also be recorded by taking electronic images. Unexpected test results will also be digitally recorded as well an image of the instructions for use.

3.3 Safety

All specimens are to be treated as potentially infectious and universal precautions must be used. The testing facilities undertake to follow the manufacturer's IFU and to handle, use, store and dispose of all specimens and consumables in accordance with procedures defined by appropriate national biohazard safety guideline or regulation. Any deviations from manufacturer's IFU will be cleared with the manufacturer and duly noted in results.

3.4 Storage of assays

All reagents must be stored as indicated in the instructions for use. Some assays may not need refrigeration. If refrigerated storage space is inadequate to store the entire test kit, they may be divided so that labile reagents can be refrigerated separately from the non-labile supplies. Calibrated thermometers are placed at each location where reagents and specimens are stored, i.e. ambient, refrigerator and freezer. Temperatures are recorded daily on the laboratory temperature logs. The lot numbers of the test kits received/used, and their expiry dates are recorded on the individual run worksheets.

Two separate production lots (with different lot numbers and different expiry dates) will be requested for evaluation, according to the following definition of a lot: *"The amount of material that is uniform in its properties and has been produced in one process or series of processes. The material can be either starting material, intermediate material or finished product.*" Each lot shall comprise different production (or manufacturing, purification, etc.) runs of critical reagents. Furthermore, lots must be sourced from a representative production run and not produced especially for the purpose of this evaluation. TMDA will verify this information before the product assessment has been finalized.

4 Specimens

4.1 Clinical performance specimen panel

A panel of 500 well-characterized nasopharyngeal and oral pharyngeal swab clinical specimen, including 100 nasopharyngeal swab or oral pharyngeal specimens antigen positive specimens and 400 nasopharyngeal swab and oral pharyngeal specimens antigen negative specimens, will be used for this evaluation.

4.2 Specimen collection and storage

As much as possible, specimens used in this evaluation will be representative of the intended use population, i.e. from clients screened for SARS-CoV-2 infection from different regions in Tanzania.
The panel may consist of the following specimens:

- Left-over specimens from National Public Health Laboratory (NPHL).
- Left-over specimens from Research Institution

After removing all the specimen identifiers, specimens are assigned a unique identification number at the laboratory. Once the specimens have been processed and labelled, they are aliquoted and frozen immediately at -70°C. During the period of testing the specimens are stored at 2 - 8 °C and this time period does not exceed 72 hours after collection. After the completion of testing, they are again stored at -70 ^{o}C. Not undergoing more than one freeze-thaw cycle.

4.3 Characterization of the SARS-CoV-2 specimen reference panel

The SARS-CoV-2 clinical specimen panel shall be characterized using a state-of-the-art RT-PCR assay. These results are used to determine SARS-CoV-2 status of each specimen for the purpose of the performance evaluation.

Initially, each specimen is tested on a state-of-the-art RT-PCR assay.

Specimens that are negative on the state-of-the-art RT-PCR assay are assigned as SARS-CoV-2 negative.

Specimens that are positive on the state-of-the-art RT-PCR assay are assigned as SARS-CoV-2 positive.

5 Laboratory testing

With regarding to PCR a ‘test run’ for archived frozen sample is recommended for samples with only one thawing cycle.

Kit controls, if available and external quality controls will be conducted as stated in the quality manual of the specific laboratory.

5.1 Review of the instructions for use

Each product under evaluation is used strictly in accordance with the instructions for use (IFU) issued by the manufacturer. The laboratory will send a hard or electronic copy of the IFU to TMDA upon delivery of the test kits and prior to the commencement of the laboratory evaluation. The IFU must be reviewed against the IFU submitted to TMDA as part of the dossier assessment for market authorization procedure. If the IFU has been updated since dossier submission, a letter from the manufacturer detailing changes made must be sent to TMDA prior to the laboratory evaluation commencing.

5.2 Clinical performance panel

The specimen reference panel is run in order that approximately one half of the specimen panel will be run with the one lot and the other half of the panel with the other lot. The specimens of the Hepatitis specimen reference panel should initially be tested in singular and in a blinded manner.

Specimens with invalid result should be retested in singular on the same lot.

Specimens which are found to be indeterminate by the criteria stated in the instructions for use (e.g. grey zone for EIAs) should be retested in duplicate on the same lot number of assay and singular on the other lot. In the case that the testing result cannot be resolved after all testing, the specimen is to be called indeterminate.

Specimens with results discrepant from the reference results are retested in duplicate using the same lot number by the same operator. The results that occur two out of three times are recorded as the test results. If the result is again discrepant, the specimen is retested on a second lot number, if available. If the result on the second lot is concordant with the reference result, no further testing is required.

In all cases of repeat testing, all results (initial and repeat testing) should be recorded.

5.3 Criteria to continue testing.

After testing the first 50 specimens (for rapid tests) an interim analysis is done, and results are communicated to TMDA. If less than 90% of the results are concordant with the reference results, then the evaluation is stopped, and troubleshooting should be done by TMDA and the manufacturer.

5.4 Lot-to-lot variation panel

Lot-to-lot variation is assessed by testing the same ten dilution series on two separate production lots of the assay under evaluation in the same testing session.

5.5 Interpretation of results

The interpretation of results for each assay under evaluation is made strictly according to the manufacturers' instructions within the IFU. Invalid test results are recorded on the data collection sheets including where the control line does not appear or in any other way the test result is invalid as defined by the IFU. For test results that are indeterminate according to the IFU, the results are recorded on data collection sheets.

Testing was performed according to the test kit instructions for use (IFU) by one operator. The results will be read by that operator and one additional reader. The second reader will be blinded to the results reported by the first reader. The intensity of the test and control lines will be graded according to the reading scale in Table 2. When consensus for the sample reading is not met, a third independent reader will record their results and the eventual consensus (2 of 3 readings being the same) will be used as the final results. A grading of 0 will be considered a negative result. Any test result that was invalid according to the IFU was recorded. For RDTs invalid results were when the control line did not appear or invalid due to obviously defective test device or associated kit components. For PCR, invalid test runs will occur when the kit controls failed the manufacturer's validation criteria.

All test results are recorded on standardized test result worksheets and then entered in a Microsoft Excel spreadsheet for further data analysis.

Where applicable for PCR, test results will be recorded electronically directly from the plate reader and then entered in a Microsoft Excel spreadsheet for further data analysis. Printed records will also be generated from the PCR reader, and these will be used to cross-check a sample of the imported data.

For subjectively read assays such as rapid diagnostic tests or line immunoassay, the intensity of band/line/spot is additionally entered into the data collection sheet

5.6 Recording test results

All test results are recorded on standardized test result worksheets and then entered in a Microsoft Excel spreadsheet for further data analysis.

For subjectively read assays such as rapid diagnostic tests the intensity of band/line/spot is additionally entered into the data collection sheet. The intensity rating system reads as described in Table 1.

Table 1. Result legend for subjectively read assays.

Scoring index	Intensity reading scale
0	Non-reactive
1	Very Weak
2	Weak
3	Medium to Strong Reactivity
7	Invalid

6 Quality control and interpretation of test results

6.1 Test kit controls.

Manufacturer/Applicant supplied positive and negative test kit controls will be run as indicated in the IFU for all test formats included in each test run for EIAs and at the commencement of each testing session for rapid diagnostic tests and other formats. Where positive and negative test kit controls are not supplied by the manufacturer/applicant, as will be the case for many rapid diagnostic tests, the external quality control specimen will act at the control specimen.

6.2 Internal control lines for rapid diagnostic tests

Generally, rapid diagnostic tests contain a control band, line or spot to determine migration of the reagents, or the sample has occurred. Most control bands/lines/spots will become visible with the addition of reagent (i.e. buffer). However, some rapid diagnostic tests will contain a control band/line that becomes visible with addition of specimen (i.e. presence of IgG). It is imperative that the exact nature of the control band/line is ascertained and included in the report. An experiment is performed to verify this point, if not explicitly mentioned in the IFU.

6.3 External quality control specimen

The laboratory will supply an external quality control (QC) specimen which is tested in singular at the beginning of each test session for rapid diagnostic tests. The QC specimen

represents a weakly reactive SARS-CoV-2 positive sample. The QC specimen is prepared by the laboratory or acquired commercially, depending on the assay under evaluation.

6.4 Competency panels

User competency must be established for each assay by each operator before the evaluation commences. This may be established at the time of assay demonstration by the manufacturer or for training purposes.

6.5 Limits of acceptability

All results on test kits controls and QC specimens are entered on the data collection sheets. Should the test kit controls or the QC specimen not give results within the expected ranges, evaluation testing on that assay is suspended until the cause has been identified and a satisfactory solution identified. Such problems must be communicated immediately to TMDA and recorded on the data sheets. The PI is responsible for carefully checking all data entry forms for legibility, accuracy and completeness.

7 Analysis of data

7.1 Invalid devices

The number of invalid test runs (if PCR) is recorded as the number of invalid runs as a percentage of the total number of runs performed for clinical specimens only (excluding the lot variation panels).

The number of invalid devices (if rapid diagnostic test or other format) is recorded as the number of invalid test devices as a percentage of the total number of devices used for the evaluation testing with clinical specimens (excluding, lot to lot variation panels).

Invalid results may mean test results as defined by the instructions for use such as where the control line/band/spot does not appear or invalid due to obviously defective test device or defective transfer pipette.

7.2 Inter-reader variability

The inter-reader variability is calculated when test results must be read without any objective reading instruments i.e. rapid diagnostic tests. Three persons independently interpret each test result. The inter-reader variability is expressed as the percentage of specimens for which initial test results are differently interpreted (i.e. reactive or non-reactive or indeterminate, if applicable) by the independent readers for the clinical specimens (excluding commercially acquired panels, TMDA reference preparations, culture supernatant panels, lot to lot variation panels).

8 Clinical performance characteristics

The following strategies are used to calculate the clinical performance characteristics by comparing the results of the assay under evaluation and reference testing results on the clinical specimen panel.

Table 2. 2 x 2 table for calculation of performance characteristics

	Reference testing results

		SARS-CoV-2 - positive	SARS-CoV-2 - negative	Total
Results of assay under evaluation	Reactive	a (true positives)	b (false positives)	a + b
	Non-reactive	c (false negatives)	d (true negatives)	c + d
	Total	a + c	b + d	a+b+c+d

8.1 Sensitivity

Sensitivity is the ability of the assay under evaluation to detect correctly specimens that contain the analyte (reference results positive). Thus, sensitivity is the number of true positive specimens identified by the assay under evaluation as positive (a), divided by the number of specimens identified by the reference assays as positive (a+c), expressed as a percentage.

$$\textbf{Sensitivity} = \frac{a}{a+c} \; x100\%$$

8.2 Specificity

Specificity is the ability of the assay under evaluation to detect correctly specimens that do not contain the analyte (reference results negative). Thus, specificity is the number of true negative specimens identified by the assay under evaluation as negative (d), divided by the number of specimens identified by the reference assays as negative (b+d), expressed as a percentage.

$$\textbf{Specificity} = \frac{d}{b+d} \; x100\%$$

8.3 Confidence intervals

The exact 95% confidence intervals for binomial proportions are calculated for both sensitivity and specificity.

8.4 Initial and final sensitivity and specificity

The initial sensitivity and specificity are calculated based on the initial results obtained for the assay under evaluation (except for invalid results, for which the result of repeated testing is used). If the initial result is indeterminate, then the specimen is excluded from this analysis. The proportion of initial indeterminate results is reported.

The final sensitivity and specificity values are calculated taking into consideration the repeat testing performed on the same lot and further testing second lot of the assay under evaluation, if applicable (i.e. for specimens with initial indeterminate or discrepant results).

9 Analytical performance characteristics

9.1 Results from lot-to-lot variation panel

The results of the lot-to-lot panel for the two production lots are compared and a variation of +/- 1 dilution series is considered acceptable. The number of series with acceptable and non-acceptable variation is reported.

9.2 Laboratory professional's appraisal

The technical aspects of the assay under evaluation are assessed by the Laboratory professional(s) who performed the testing. These assessments, along with other selected assay characteristics, contribute to an overall appraisal of each assay's suitability for use in small laboratories. To enable comparison between assays, a scoring system is used to rate specified operational characteristics (Annex 1).

9.3 Report preparation and dissemination.

The preliminary data analysis and drafting of the report will be carried out by the evaluating laboratory according to pre-defined report templates.

The draft report will be shared simultaneously with TMDA and the manufacturer.

9.4 Acceptance criteria

The following criteria will be used to assess the assay under evaluation. Other parameters included in this evaluation are provided for information but are not used as pass/fail criteria for this assessment.

Table 3. Minimum acceptable performance for SARS-CoV-2 assays in the TMDA prequalification performance evaluation

Parameter	Rapid diagnostic tests
Initial sensitivity estimate	≥ 99%
Final specificity estimate	≥ 98%
Inter-reader variability	≤5%
Invalid rate	<5%

10 Materials and supplies

The manufacturers of products will provide the products and any equipment necessary for the evaluation free of charge.

Table 4. Number of tests required to perform this evaluation.

	Lot A	Lot B
Clinical panel	700	700
Lot-to-lot variation	100	100
Total	800	800
Total + 20% for controls and repeats (for antigen detecting assays)		

11 Roles and responsibilities

11.1 Responsibilities of the Evaluating Laboratory

i. Ensure availability of SARS-CoV-2 specimen reference panel, lot-to-lot variation, panel;
ii. Conducting the performance evaluation in accordance with internationally recognized best practice;
iii. Preparation of QC specimens and proficiency panels;
iv. Preparation of draft report on laboratory evaluation;
v. Advising TMDA on operational characteristics of assays evaluated.

All source data, data analysis records and all correspondence are retained and archived for a period of at least ten years.

11.2 Responsibilities of TMDA

i. Technical advice to the PI;
ii. Technical and administrative management of the laboratory evaluation;
iii. Verification of the draft report, seeking of comments from manufacturer in case of List one laboratories;
iv. Preparation and dissemination of the final report;
v. Formal contacts with authorized contacts of the manufacturers.

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WHO. Guidance for procurement of in vitro diagnostics and related laboratory items and equipment.https://iris.who.int/bitstream/handle/10665/255577/9789241512558-eng.pdf?sequence=1

EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
ISO 17025 (General requirements for the competence of testing and calibration laboratories)
ISO15189 (Medical laboratories — Particular requirements for quality and competence)

Annex 1: Operational characteristics and ease of use

This assay requires/does not require laboratory equipment and can/cannot be performed in laboratories with limited facilities or in non-laboratory settings. *If applicable, add specifics on why it cannot be used in laboratories with limited facilities: e.g.* the instrument requires a stable source of electricity and significant physical space. Furthermore, training and implementation of good laboratory practice is essential to obtaining accurate results. *If*

technical support was needed during evaluation: Adequate technical support from manufacturer or representative is critical.

The assay was found easy to use / not easy to use by the operators performing the evaluation. *If applicable, add specific information provided in comments in the ease of use table.*

For RDTs (and ELISA)

Key operational characteristics	
Number of steps*	X steps in total X steps with precision pipetting *(only for serum/plasma)*
Time to result	X minutes
Endpoint stability (interval)	X minutes (the test can be read between xx and xx minutes after addition of specimen/diluent)
Internal QC	Yes/no, *insert brief description. [The test has an internal control line. The presence of the control line indicates that migration of liquid has occurred; however, it does not guarantee that the correct specimen type or volume was added or that the test procedure was followed correctly.]*

** Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).*

For instrument-based assays

Key operational characteristics	
Number of steps for one specimen*	X steps in total X steps with precision pipetting
Number of steps for instrument management**	X steps per run/day
Time to result for one test/run	X minutes
Operator hands-on time for one test/run	X minutes
Level of automation	
Quality controls	QC are/are not provided by the manufacturer and should be purchased separately. *Add information on type of QC (eg. high positive, low positive, negative)*
Operating temperature	xx- xx °C, any comments on temperature stability of conducting the test.
Result display and connectivity	Results are displayed on the instrument / connected computer. They may be printed using a standard/specific printer. The results can be exported to the laboratory information system and other health information systems.
Power sources	Main power / Battery / Solar power The use of a UPS is recommended, as stable electricity is required

Biosafety *(outside of infectious specimen handling)*	Operators reported no biosafety concerns for the user. *Add information if applicable*
Waste	The volume of liquid was is approx. xx per test/run. The volume of solid waste is approx. xx per test/ run. Waste disposal requires / does not require specific measures in addition to usual laboratory biohazard waste disposal procedures. *Add information if applicable.*
Calibration	Calibrators are/are not provided by the manufacturer and should be purchased separately. *Add frequency of calibration recommended.*
Maintenance	Daily / Weekly / Monthly / Yearly / No maintenance is required.
Other specific requirements	*If applicable (eg. space requirements, weight to surface area ratio, installation by manufacturer)*

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