

ASLM

AFRICAN SOCIETY FOR LABORATORY MEDICINE

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

COVID-19 Laboratory Testing Certification Program

ASLM APPROACH

Lab strengthening and certification program

- COVID-19 PCR labs

Activities

Create DEMAND/Awareness for the Platform

Create a standardised certification program

Listed on the platform

M & E Database of labs

Target

COVID – 19 TWG

Individual Labs

Trusted travel platform

Labs and TWG

COVID-19 Certification program for labs conducting COVID-19 testing

Assessment checklist

- Background
- Scope of the assessment

Role of MoH

- In-country coordination
- Receiving applications
- Send to ASLM

Laboratory

- Implementing the requirements
- Apply MoH
- Gaps – work with MoH / ASLM

ASLM

- Handle applications
- Evaluation / certification / training

**Identification of
cases through
laboratory
testing**

WHO Strategic Preparedness and Response Plan for COVID-19

**SARS-CoV-2
PCR**

**SARS-CoV-2
Ag RDT**

**SARS-CoV-2
POCT**

Identification of cases through laboratory testing

WHO Strategic Preparedness and Response Plan for COVID-19

SARS-CoV-2
PCR

SARS-CoV-2
Ag RDT

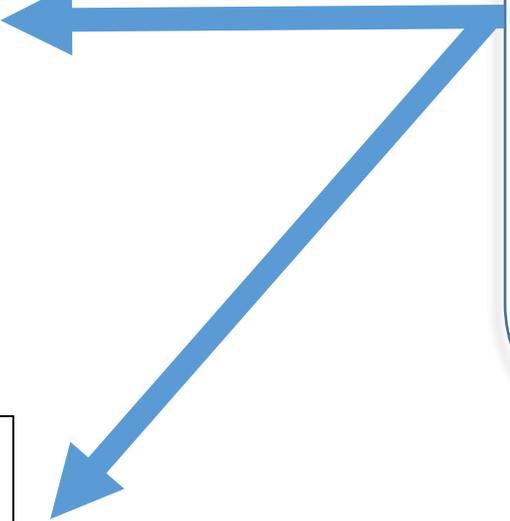
SARS-CoV-2
POCT



Africa CDC Trusted Travel Platform requires that there be a database of authorized laboratories certified to conduct COVID-19 testing

African Society for Laboratory Medicine

COVID-19 Laboratory Testing Certification Program



African Society for Laboratory Medicine

COVID-19 Laboratory Testing Certification Program

STRUCTURE

Requirements for Quality,
Biosafety and Biosecurity -
WHO

Evaluate compliance using
standard assessment tool

Authorizes Testing for
SARS-CovV-2

PROCESS

Coordination by MoH -
Identification of priority
Labs, receive applications
and submit to ASLM
Institutionalization

**Enrolment of Laboratories
into the Program by ASLM**
Completed Application Forms

**Deployment of Assessment
Teams by ASLM**
In-country Certified
Auditors

RECOGNITION

**Review of Assessment
Reports by ASLM**
Audit Findings

**Award Recognition on an
incremental scale
0-5 Stars**

**Certify to conduct SARS-
CoV-2 testing if achieved
> 95% (5 Stars)**

African Society for Laboratory Medicine

COVID-19 Laboratory Testing Certification Program (CoLTecP)



COVID-19 LABORATORY TESTING
CERTIFICATION ASSESSMENT CHECKLIST

Requirements

- ISO 15189:2012
- ISO 15190:2020
- WHO Biosafety Manual 4th Ed
- WHO Interim Guidance on SARS-COV-2 testing

Scope

Audit Score Sheet	
<i>Section</i>	<i>Total Points</i>
Section 1: Laboratory Policies and Procedures	20
Section 2: Laboratory testing capacity	28
Section 3 : Quality Control & Assurance	22
Section 4: Test result and data management	16
Section 5: Biosafety and Biosecurity	30
TOTAL SCORE	116

Recognition and Certification

No Stars (0 – 58) < 50%	1 Star (59-68) 50 – 59%	2 Stars (69-80) 60 – 69%	3 Stars (81-92) 70 – 79%	4 Stars (93-103) 80 – 89%	5 Stars (104-116) ≥90%
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**Checklist
Section**

**Level of
compliance**

SECTION 1: LABORATORY POLICES AND PROCEDURES

This section looks at the laboratory documentation and records for COVID-19 testing. The following procedures must be (i) up to date (ii) approved by authorized staff (iii) accessible to relevant staff

	Checklist item	Yes	Partial	No	Comments	Score
1.0	Are the following policies and procedures in place:					2
1.1	COVID-19 testing procedures written and readily available to staff, as required					2
1.2	COVID-19 specific sample collection and transportation documented and available to relevant personnel in the laboratory?					2
1.3	COVID-19 specific sample collection and transportation documented and available to relevant personnel in the collection sites?					2

**Question
Score**

**Yes = 2 Points
Partial = 1 Point
No = 0 Points**

**Checklist
Question**

**Comment
No and Partial - Explain**

Next Steps

- Mobilise countries to adopt the **Trusted Travel Platform and Certification Program**
- Training and Certification of Auditors
 - Request nominations from countries through MoH
 - Conduct training to build local pool of auditors for each country
- Receive applications and enrol laboratories

Next Steps

- Deploy audit teams - receive and review audits reports
 - Recognize and certify Labs
 - Recognize by issuance of corresponding star (0-4)
 - Certify Labs meeting 5 Star requirements
- Provide TA and Mentorship to Laboratories
 - In collaboration with MoH assist labs close identified gaps
 - Monitor effectiveness of corrective actions