COVID-19 Laboratory Testing Certification Program
Lab strengthening and certification program
• COVID-19 PCR labs

ASLM APPROACH

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

ASLM APPROACH

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
WHO Strategic Preparedness and Response Plan for COVID-19

Identification of cases through laboratory testing

SARS-CoV-2 PCR
SARS-CoV-2 Ag RDT
SARS-CoV-2 POCT
African Society for Laboratory Medicine

COVID-19 Laboratory Testing Certification Program

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 (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**

<table>
<thead>
<tr>
<th>Audit Score Sheet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section</strong></td>
</tr>
<tr>
<td>Section 1: Lab Policies and Procedures</td>
</tr>
<tr>
<td>Section 2: Lab testing capacity</td>
</tr>
<tr>
<td>Section 3: Qual Control &amp; Assurance</td>
</tr>
<tr>
<td>Section 4: Test result and data management</td>
</tr>
<tr>
<td>Section 5: Biosafety and Biosecurity</td>
</tr>
<tr>
<td><strong>TOTAL SCORE</strong></td>
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</table>

**Recognition and Certification**

<table>
<thead>
<tr>
<th>No Stars</th>
<th>1 Star</th>
<th>2 Stars</th>
<th>3 Stars</th>
<th>4 Stars</th>
<th>5 Stars</th>
</tr>
</thead>
<tbody>
<tr>
<td>(0 – 58)</td>
<td>(59-68)</td>
<td>(69-80)</td>
<td>(81-92)</td>
<td>(93-103)</td>
<td>(104-116)</td>
</tr>
<tr>
<td>&lt; 50%</td>
<td>50 – 59%</td>
<td>60 – 69%</td>
<td>70 – 79%</td>
<td>80 – 89%</td>
<td>≥90%</td>
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</table>
SECTION 1: LABORATORY POLICIES 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.

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

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

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