

IMPORTANCE OF ACCREDITATION IN COVID- 19 TESTING

The ongoing “Coronavirus disease 2019” or “COVID-19” caused by the SARS-CoV-2 virus (Severe Acute Respiratory Syndrome-Corona Virus 2) pandemic is primarily a health crisis, but it also has far reaching economic consequences. As a global crisis it is posing challenges to humanity that have never been experienced before.

Reliable results of medical laboratories conducting tests to detect the SARS-CoV-2 virus are essential in the management of the pandemic. It is now very evident that quality and accuracy of laboratory results provide essential contribution to the diagnosis, managed care and therapeutic monitoring of the highly infectious diseases such as COVID-19. Molecular assays conducted on nasopharyngeal swabs or other upper respiratory tract specimens are the most commonly used for reliable diagnosis of COVID-19. Most molecular assays have achieved 100% specificity, since the primers are designed specifically for the target gene sequences of SARS-CoV-2. However, sensitivity can be affected by specimen quality, sampling time to symptom onset, testing errors, or other technical deficiencies. Both false- positive and false-negative results have negative implications for disease containment efforts. With the limited resources, workforce and expertise to test, it is worth noting that embracing quality management by the way of accreditation is key. Therefore, it is critical to implement sustainable quality assurance through accreditation in all COVID-19 testing laboratories.

Accreditation to COVID-19 testing in accordance with ISO 15189 provides the following benefits:

- It is means of demonstrating competence to perform testing of COVID-19; and
- It is a guarantee for accurate and reliable test results.

Reliable test results strengthen community confidence in test results. In a health crisis, the need to rely on fast and accurate testing results is higher than usual as authorities use test data to make decisions on lockdown, surveillance and monitoring impact of initiatives aimed at preventing spread of the disease.

Accreditation supports the correct functioning of Medical Laboratories involved in COVID-19 testing. Internationally recognized accreditation bodies such as SADCAS are responsible for providing a formal attestation of the integrity of conformity assessment bodies and their competence to perform specific tests. In the context of the global health crisis, accreditation of medical laboratories conducting COVID-19 testing is particularly important as it ensures recognition of foreign test results. Accreditation provides a “credential” that designates the medical laboratory and its test results as qualified and competent to provide the testing services in the scope in which it is accredited.

In an effort to identify Medical Laboratories undertaking COVID -19 testing in the region, SADCAS conducted a survey. COVID-19 survey questionnaires were sent to 51 Medical Laboratories accredited by SADCAS. According to the survey, 16 out of the 51 accredited Laboratories perform COVID-19 testing. However, these 16 Laboratories are not accredited for COVID-19 testing. Noting the importance of accreditation in ensuring accurate COVID-19 test results and noting that accreditation is test specific, Medical Laboratories already accredited by SADCAS are encouraged to apply for COVID-19 testing scope extension.

Laboratory seeking COVID-19 testing accreditation will undergo rigorous assessments to achieve international accreditation. SADCAS has trained and qualified Assessors in the scope of COVID-19 testing (Molecular Biology) and is ready is to offer COVID-19 testing accreditation services.

Assessments conducted by SADCAS Assessors in the scope of COVID-19 testing focus on the following key areas to ensure quality of results:

Personnel: Laboratory scientists/technologists performing COVID-19 tests need to demonstrate training, experience and competence in handling, transportation and testing of COVID-19 samples.

Equipment and Metrological Traceability: COVID-19 Testing equipment should be maintained in safe working condition and in working order. Laboratory personnel should be trained on PCR techniques used in COVID-19 Testing. Equipment calibration status and metrological traceability should be recorded. Metrology is essential in the context of COVID-19 as accurate biological measurements play a vital role in a health crisis. In this particular field, certified reference materials (CRMs) and reference measurement methods provide stated references upon which medical laboratories can anchor their measurement results. This helps to reduce the potential of having false positives or false negatives test results. In addition, the traceability of measurement results to internationally accepted stated references, together with their stated measurement uncertainties, provide the basis for their comparability and global acceptance.

Method Validation/Verification: The method in use should be the one provided and validated by the manufacturer. Method verification/ validation protocols and reports should be provided as evidence that the COVID-19 method is capable to achieve the intended use. The performance characteristics such as sensitivity and specificity should be acceptable.

Quality Control and Proficiency Testing: Quality Control is a process of systematic internal monitoring of the performance of bench work in COVID-19 testing laboratories, including instrument checks and verifying new lots of test kits. Quality Control validates the competency of testing laboratories by assessing sample quality and monitoring test procedures, test kits, and instruments against established criteria. It also includes the review of PCR results and documentation of the validity of testing methods

Proficiency Testing (PT): Participating in PT allows COVID-19 testing laboratories to assess their performance by comparing their results with results from other laboratories within the network (testing and reference laboratories). Proficiency testing, a prerequisite for accreditation, evaluates testing competency, the performance of the laboratories, reliability of the testing methods, and accuracy of the results reports.

The SADCAS Medical Laboratory Accreditation Scheme (MLAS) was established in June 2010. The MLAS is multi – disciplinary accreditation scheme operated in accordance with ISO/IEC 17011: Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies. The fields of accreditation under the SADCAS MLAS as outlined in SADCAS TG 03: Areas of Accreditation include: Clinical Chemistry; Biochemistry; Cytology; Hematology; Histopathology; Immunology; Microbiology; Pathology; Virology; Serology; Molecular Biology; Endocrinology; Blood Transfusion/Blood Bank; Immunophenotyping; and Andrology. The SADCAS Medical Laboratories Accreditation Scheme is internationally recognized having achieved signatory status in the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) in 2017. SADCAS has accredited 51 medical laboratories in six (6) SADC Member States namely: Botswana (9); Eswatini (3); Namibia (7); Tanzania (17); Zambia (4); and Zimbabwe (10); and 2 non-SADC countries Ghana (1) and Cote d’Ivoire (1). At the same time 14 applications are at the various stages of processing.

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