KENYA ACREDITATION SERVICE

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Kenya Accreditation Service (KENAS) is the Sole National Accreditation Body for Kenya established vide Legal Notice No. 55 of 2009 under the States Cooperation Act.

Its principal functions include to:

- Develop, regulate and review the requirements for accreditation of Conformity assessment bodies.
- Promote accreditation as a means of facilitating regional and international trade
- Raise awareness and importance of accreditation
- Promote competence and equivalence of accredited bodies.

KENAS scopes for accreditation include but not limited to:

- Management systems Certification Bodies - ISO/IEC 17021:2011
- Product certification bodies- ISO/IEC 17065: 2012
- Personnel certification bodies - ISO/IEC 17024:2012
- Proficiency Test providers - ISO 17043:2010
- Inspection bodies - ISO/IEC 17020:2012
- Veterinary laboratory accreditation- ISO 17025:2005 + OIE
- Medical reference laboratories- ISO 15195:2003

KENAS is a member of the International Accreditation Forum (IAF) and an Associate member of the International Laboratory Accreditation Cooperation (ILAC) and. KENAS participates actively in both regional (Eand international fora on conformity assessment, quality and regulatory infrastructure development.
MEDICAL LABORATORY ACCREDITATION IN KENYA

Accreditation is emerging as a preferred framework for building quality medical laboratory systems in resource-limited settings. Despite the low numbers of laboratories accredited to date, (10 medical laboratories in Kenya are accredited by KENAS and SANAS) accreditation has the potential to improve the quality of health care for patients through the reduction of testing errors and hence decreases inappropriate treatment.

Accredited laboratories can become more accountable and less dependent on external support. Efforts made to achieve accreditation may also lead to improvements in the management of laboratory networks by focusing attention on areas of greatest need and accelerating improvement in areas such as supply chain, training, and instrument maintenance. Laboratory accreditation may also have a positive influence on performance in other areas of health care systems by allowing laboratories to demonstrate high standards of service delivery.

Accreditation thus, provides an effective mechanism for health system improvement yielding long-term benefits in the quality, cost-effectiveness, and sustainability of public health programs. Further studies are needed to strengthen the evidence on the benefits of accreditation and to justify the resources needed to implement accreditation programs aimed at improving the performance of laboratory systems.

Medical/clinical laboratories are the key partners in patient safety. Laboratory results influence 70% of medical diagnoses. Quality of laboratory service is the major factor which directly affects the quality of health care. The medical/clinical laboratory as a whole has to provide the best patient care promoting excellence.

Recent years have seen unparalleled investment in expanding and improving health care for major diseases in the developing world. Countries, with support from the US President’s Emergency Fund for AIDS Relief, The World Bank, The Gates Foundation, and other donors, have invested in expanding and strengthening public health services to save lives, reduce morbidity, and improve patients’ quality of life to Fight HIV, Tuberculosis and Malaria. Medical Laboratory testing is an essential component of improved health care for patients in resource-limited settings. Accurate and rapid diagnostic tests are required to diagnose illness, identify causative factors, monitor the effectiveness of treatment, and perform surveillance for key diseases. Reliable and actionable test results are often a prerequisite to the delivery of high-quality patient care.

Historically, laboratories in developing settings have been under resourced and marked by poor performance. This has fostered distrust in laboratory data among clinicians and helped to
reinforce cycles of underinvestment in laboratory systems. Nevertheless, the demand for diagnostics in developing settings has increased substantially in recent years to meet the needs of expanded treatment and prevention programs for HIV and other major diseases, and there has been significant recent investment in improving access to testing. Expanded test menus are now available at even the lowest level of health care facility.

However, it is not enough to invest in the expansion of diagnostic access. Simultaneous improvements in the quality of laboratory testing are needed to ensure clinician and patient confidence in test results.

Accreditation is widely used in developed countries to encourage or enforce improvements in the quality and reliability of laboratories.

Value of Laboratory Testing in Patient Care

Laboratory results are required for confirmation of a large proportion of medical decisions. In developed countries, an estimated 60% to 80% of patient management decisions are confirmed based on laboratory data. Diagnostics and clinical patient management have an interdependent relationship: laboratory data provide justification for clinical decision making, while clinical signs or the clinical management protocol often prompt laboratory testing. For example, during the management of HIV infection, poor performance of tests at any stage of the care and treatment continuum (i.e., diagnosis, disease staging, treatment initiation, the monitoring of drug efficacy and toxic effects) can reduce the effectiveness of treatment and deny appropriate care to patients in need by impeding the path of patients along the continuum.

Without an accurate CD4 cell count, many patients cannot have their disease correctly staged, which could prevent them from accessing lifesaving antiretroviral drugs before the onset of serious illness. Once a patient is receiving therapy, ongoing CD4, clinical chemistry, hematology, and, in some settings, viral load tests provide clinicians with necessary information on the safety and efficacy of the drugs. If these tests are not available or are inaccurate, treatment outcomes for patients are likely to be poorer, with higher mortality and more frequent illness. Reliable laboratory testing is needed, or the scale-up of treatment programs may be retarded and their long-term effectiveness and sustainability reduced.

While cost and infrastructure development are notable challenges to providing laboratory testing services, policy-makers have to weigh the benefits of diagnostics against the opportunity to invest in other areas of the health care system.

Laboratory Accreditation
The variability of test results and the frequency of errors can be reduced by implementing and monitoring a comprehensive laboratory quality management system. Additionally, participation in regular proficiency testing (PT) and interlaboratory comparisons is important. Accreditation provides a third party attestation that the laboratories are adhering to established quality and competence standards deemed necessary for accurate and reliable patient testing and the safety of staff and the environment.

Laboratories that achieve accreditation are recognized for superior test reliability, operational performance, quality management, and competence. A functional national laboratory accreditation initiative within a country requires at least 3 elements: a laboratory policy framework that makes accreditation a requirement for laboratories, designated quality standards against which laboratories can be assessed, and accrediting bodies (local or international) authorized to assess laboratories and certify their performance against the designated quality standards.

Accreditation is most effective when it is rooted in a policy framework for evaluating laboratory quality and patient safety. In some countries, accreditation is a mandatory requirement for testing operations, while in other countries, accreditation is voluntary and driven by market incentives. Governments may stipulate that laboratories that are not accredited submit detailed improvement plans and take timely action to demonstrate compliance, with continued failure to comply resulting in penalties, service limitations, and prohibitions against further testing in order to safeguard the health and safety of the citizens of this country.

To set up a national laboratory policy in-country may require new laws or an update of existing legislation. For example, in the United States, the Clinical Laboratory Improvement Amendments (CLIA) provide an example of legislative action to regulate laboratories and improve the quality of testing services. The amendments stipulate that all laboratories conducting non-research testing on humans observe certain minimum quality standards, participate in PT, and submit to biannual inspections. International standards are the backbone of accreditation. Standards provide the guiding framework within which laboratory performance is evaluated. ISO 15189, a laboratory standard, specifies quality management system and competency requirements for medical testing. The standard has gained widespread recognition as a reference standard for accrediting clinical laboratories. While accreditation is common throughout the developed world, most laboratories in resource-limited settings are not accredited.

**Importance of accreditation to the Government**

There are many duties placed on government departments, local authorities and other agencies to ensure that trust is maintained. Whether it be health, water quality, food, consumer goods or transport safety, for example, the regulators provide the framework for the assurance that goods and services are safe and the environment we live in is clean and secure.
Accreditation by KENAS can limit the need for government to regulate industry and professions since it provides an alternative means of ensuring the reliability of activities that have the potential to impact on public confidence or the national reputation.

**Conclusions**

As governments, donors, and other organizations seek to strengthen access to essential diagnostics in resource-limited settings, simultaneous improvement in the quality of testing should be of high priority. Laboratory accreditation to ISO 15189 is the internationally accepted framework for increasing test quality and reducing the frequency of laboratory errors, hence improving laboratory throughput. Higher quality laboratory testing associated with accreditation is expected to improve patient care by aiding the timeliness and accuracy of medical decision making.

Accreditation programs can help drive improvements in the management of individual laboratories and laboratory networks and may also have positive spillover effects on the performance in other sectors of the health care system. Efforts being made through the stepwise process therefore need to be accelerated with the aim of making accreditation of public laboratories a high priority and coordinated efforts undertaken to integrate accreditation programs into their policy, planning, and health system strengthening initiatives.