Research Article

From establishment to ISO15189:2012 Accreditation: the case of Hararghe Health Research Laboratory, Harar, Ethiopia

Zelalem Teklemariam[1,2*], Dadi Marami[1,2], Dagne Bodena[2], Mulu Berihun[2], Mersan Deresa[2], Fami Ahmed[2] ,Daniel Demessie[2], Esrael Solomon[2], Mussie Brhane[2] Mohammed Nasir[2], Nega Assefa[3,4], Lola Madrid[4], Joe O. Oundo[2,4]

[1]*School of Medical Laboratory Sciences, College of Health and Medical Science, Haramaya University, Harar, Ethiopia*
[2] *Hararghe Health Research Laboratory, College of Health and Medical Science, Haramaya University, Harar, Ethiopia*
[3]*School of Public Health, College of Health and Medical Science, Haramaya University, Harar, Ethiopia*
[4]*London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E7HT, UK*

Article Info

Corresponding Author:
Zelalem Teklemariam
School of Medical Laboratory Sciences
College of Health and Medical Science, Haramaya University, Harar, Ethiopia
E-mail : zelalemtmariam@yahoo.com

Keywords
Laboratory, Accreditation, Microbiology, Harar, Ethiopia

Abstract

Background: Accreditation of laboratories offering diagnostic services improves the operation of clinical as well as research performance.

Objective: This case report describes the journey of Hararghe Health Research Laboratory from it's inception to the International Organization for Standardization 15189:2012 accreditation by the Ethiopian Accreditation Service.

Methods: An external consultant conducted a baseline audit in November 2019 following the World Health Organization African Region's Stepwise Laboratory Quality Improvement Process Towards Accreditation guideline. The follow-up internal audit was conducted in January 2021. Then, an on-site laboratory assessment was conducted by experts from Ethiopian Accreditation Service towards the end of 2022.

Findings: The Hararghe Health Research laboratory received multiple remarks during audit by external consultant and drew up a corrective action plan. Some of the actions were revision of quality policy manual, managerial and technical documents, participation in the United Kingdom National External Quality Assessment Scheme and implementation of the International Organization for Standardization 15189:2012 accreditation checklist. The internal audit revealed a total of 26 gaps in the microbiology and 16 in the molecular biology sections and these were filled by the end of April 2022.The laboratory was cited for nine minor non-conformities during an assessment by experts from the Ethiopian Accreditation Service. The laboratory developed a corrective action plan, cleared non-conformities by end of February 2023 and received the accreditation certificate on 3rd May 2023. The laboratory's accreditation achievement in less than five years is a significant milestone and serves as a model for other institutions to achieve it in a similar time frame.

Background

The quality of healthcare is directly influenced by the quality of laboratory services [1, 2]. Laboratory test results often provide information for clinical decision-makers which influence 60-70% of medical diagnoses and patient management [1-4]. To guarantee that medical testing and diagnostic laboratory tests are of the highest quality, it is crucial to have them accredited by recognized accreditation authorities [2, 5]. Accreditation requires the establishment of a quality management system (QMS) [6].

Laboratory accreditation is a voluntary scheme. It is a formal recognition by a third-party expert of a laboratory's credibility and competency in testing services. It also encourages the laboratories to enhance/motivate the management system, technical capability, and competitiveness of laboratory personnel. Continuous improvement and dedicated staff are essential for maintaining quality assurance in an accredited medical laboratory [2].

The International Organization for Standardization (ISO) 15189:2012 since updated to ISO15189:2022, is an international comprehensive standard, which covers management and technical requirements, for the accreditation of medical laboratories [7]. It is used by medical laboratories to develope their QMS and assess their competence. It can also be used to confirm or recognize the competence of medical laboratories by laboratory customers, regulatory authorities, and accreditation bodies [8-11]. Medical laboratories meeting the requirements of the accrediting body will apply for the accreditation assessment. After that, the accreditation body will review the documents and then perform an on-site audit of the applicant's laboratory [2, 5]. Each country may have its own national accreditation body (NAB) which is responsible for granting accreditation. The NAB operates according to ISO 17011, the international standard for accreditation bodies [12]. The Ethiopian Accreditation Service (EAS) Formerly Ethiopian National Accreditation Office (ENAO) provides accreditation services to laboratories, certification bodies, and inspection bodies, that operate both within the Federal Democratic Republic of Ethiopia and outside its borders in countries where either no national accreditation body exists or a national body cannot accredit in a specific field [13] The EAS achieved signatory status in the African Accreditation Cooperation (AFRAC) Mutual Recognition Arrangement (MRA) in May 2017 in testing to International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) 17025 Testing, and Medical Testing to ISO 15189:2012. In addition, the EAS is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (ILAC MRA) [14, 15]. This report summarizes the journey of Hararghe Health Research Laboratory (HHRL) from its establishment to achieving ISO15189:2012 accreditation in Microbioilogy testing.

Description of Setting

There was an initial funding from the Bill and Melinda Gates Foundation through Emory University to the London School of Hygiene and Tropical Medicine (LHSTM) and Haramaya University (HU) to establish a greenfield site for the Child Health and Mortality Prevention Surveillance (CHAMPS), Ethiopia [16]. The LSHTM and HU established the Hararghe Health Research Partnership (HHRP) as a collaborative program for the advancement of health sciences research through strengthening research and surveillance capacity, ensuring best research practices, and informing health policy in maternal and child health in Ethiopia. The program is domiciled at the College of Health and Medical Sciences of Haramaya University, Harar Ethiopia. A student's demonstration and teaching laboratory was allocated to the program and the renovation, refurbishment, and equipping of the laboratory named Hararghe Health Research Laboratory (HHRL) was carried out from May 2017 to December 2018. In February 2019, the laboratory started accepting and processing samples of Minimally Invasive Tissue Sampling (MITS) for isolation and identification of bacterial pathogens, and molecular detection of targeted bacterial, viral, parasites, and fungal pathogens using Real-Time PCR TaqMan Array Cards. Other research protocols such as Maternal Infections Study (MIS), Acute Febrile Illness (AFI), Mortality due to Bacterial Infections Resistant to Antibiotics (MBIRA), Epidemiolocal surveillance of anti-SARS-COV-2 antibody, Invasive Bacterial Diseases (IBD), pneumococcal and meningococcal carriage survey also came onboard.

The HHRL is well-equipped with high-tech laboratory equipment such as EZ1 adavanced XL and EZ2 connect (QIAGEN/ Japan) , QuantStudioTM 7 Flex real-time polymerase chain reaction system (Applied Biosystems/Singapore) used to run TaqMan Array Cards (Applied Biosystems/USA), including 96 and 384 well plates, GeneXpert (Cephied/USA), BACT/ALERT® 3D Microbial Detection Systems (BioMérieux/USA), MicroScan WalkAway bacterial identification and antibiotic susceptibility testing system (Beckman Coulter/USA), aerobic (Genlab,UK) and CO_2 (BINDER,Germany) incubators, biosafety level 2 cabinets (CAS,UK), tissue processors (Leica, Germany), tissue slide scanner (Leica,USA), refrigerators (Lec MEDICAL, UK), ultra-low temperature freezers (Haier,China), ELISA (Biotek 50 TS microplate washer and BioTek 800TS Microplate reader) and other ancillary equipment. The operation as well as the biosafety and biosecurity of the laboratory are monitored and controlled through a closed-circuit television (CCTV) surveillance system, indoor climate control, smoke detection system, and access control systems. The laboratory is also connected to the main national electric utility through an automatic 40-kilovolt (KV) generator and uninterrupted power supply backup providing three layers of redundancy.

The laboratory recruited and has been able to retain medical microbiologists, and medical laboratory technologists. As a public service, it supports public health by identifying and reporting pathogens of public health significance. It was one of

the first laboratories selected by the Federal Ministry of Health and Ethiopian Public Health Institutes to test and provide training to testing laboratories in eastern Ethiopia during the COVID-19 pandemic. The laboratory analyzed 34,647 nasopharyngeal samples collected from eastern and western Hararghe, Dire Dawa Administration, and Somali regional states in Eastern Ethiopia. Additionally, the laboratory performs blood and cerebrospinal fluid cultures, identification and antimicrobial susceptibility testing of bacterial pathogens isolated from severely ill children admitted to the neonatal and pediatric intensive care units at Hiwot Fana Comprehensive Specialized Hospital.

Accreditation Preparation Processes

Baseline assessment by external consultants

The first step was the international competitive hiring of a Laboratory Director as the team leader who then led the hiring of the technical staff and then securing management and staff support for the accreditation process. The HHRP management was very clear about the need for a laboratory accredited to internationally accepted standards.. After this unambiguous set objective from management, the laboratory leadership then started putting in place the pillars that were necessary for the journey to accreditation. The second step was to perform a gap analysis and then subsequent ongoing monitoring through internal and external evaluation using the ISO 15189:2012 accreditation checklist [17]. The initial assessment was conducted in November 2019, by external assessors from Kenya and Nigeria, experienced in auditing medical laboratories ISO 15189:2012 and World Health Organization African Region's Stepwise Laboratory Quality Improvement Process Towards Accreditation considering management and technical processes requirements. The WHO-AFRO/SLIPTA program is used in resource-limited countries as a tool for implementing QMS [18, 19]. The team assessed by observing and reviewing documentation for sample reception and registration, general store, staff room, laboratory equipment, cleaning rooms, molecular, microbiology, and data entry sections..

The external assessment team identified areas for improvement which included: the need for laboratory staff to train on the ISO 15189:2012 standard, laboratory quality management systems and on different documents/blank forms development, internal auditing, root cause analysis, and corrective and preventive action (CAPA). The baseline score was 94/265 (35.5%) (0 stars) (Figure 3). Following the external evaluation, the laboratry strived to meet ISO 15189:2012 accreditation criteria. The WHO-AFRO SLIPTA and ISO 15189:2012 checklists are nearly similar . The ISO 15189:2012 checklist evaluated each question as either conforming or nonconforming, whereas the WHO-AFRO SLIPTA checklist evaluated each question as conformance, partial conformance, and nonconformance and made a step-by-step accreditation process from star 1 to star 5 [20, 21]. The Laboratory converted all the content and structure of SOPs to ISO 15189:2012 standards and used them for the accreditation process.

Following the hiring of a highly skilled and knowledgeable Quality Assurance /Quality Control (QA/QC) officer, the HHRL started creating management, technical, and procedural documents. The HHRL also registered for External Quality Assessment (EQA) with the United Kingdom National External Quality Assessment Scheme (UK NEQAS) for the test types conducted in the laboratory. The staff were also trained on good clinical laboratory practice (GCLP) by certified external trainers.

Process improvement

The following documents and blank forms were prepared between January 2021 and November 2022 and put into use after the HHRL director reviewed and approved them.

1. Quality policy manual

Using the document details the structure of the HHRL and its quality system policies, processes, and operating standard procedures for all the HHRL staff to carry out their job and related activities to achieve the mission of the organization/ laboratory. The QMS is described in the Quality Policy Manual. It also contains basic and simple procedures and referrals to supportive documents. The laboratory revised the quality policy manual developed in 2019 to guide the implementation of the QMS as per ISO 15189:2012 requirements.

2. Managerial and technical requirements documents and blank form preparation

The laboratory developed 16 standard operating procedures and 3 manuals (quality policy, Safety and laboratory client checklists) in 2019. Revision of the previously developed documents and preparation of additional ISO 15189:2012 laboratory management (4.1- 4.15) and technical processes (5.1 - 5.10) QMS [7] document and blank forms were done between January 2021 and November 2022. A total of 139 SOPs, 3 manuals, and 154 documents and blank forms were developed by the end of February 2023.

Service maintenance and calibration of equipment

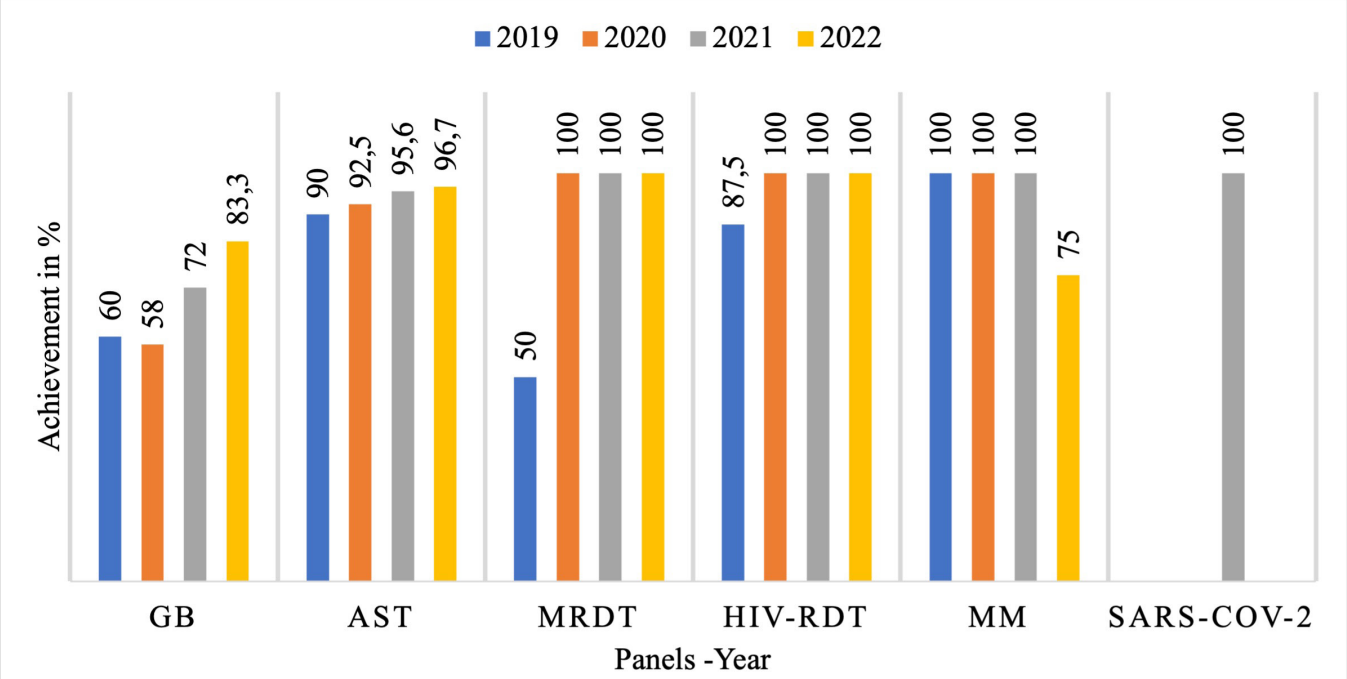
Metrological traceability is the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty [22]. The International Laboratory Accreditation Cooperation (ILAC) and its associate member, the Ethiopian Accreditation Service (EAS) have a mandatory requirement on metrological traceability, i.e., medical laboratories are required to have an established calibration program for critical equipment that directly or indirectly affects examination results [23, 24]. The HHRL outsourced the calibration of major equipment by experts from traceable organizations in Ethiopia like the National Metrology Institute of Ethiopia (NMIE), and other regional companies for each of the various equipment like biosafety cabinets, pipettes, ultra-low temperature freezers, refrigerators, incubators, weighing balances, thermometers and water-baths. More than 50 pieces of equipment were serviced

and calibrated in the period 2021-2022.

Proficiency testing

Accredited test methods must be validated. Personnel, instruments, reagents, and other factors affecting the test results must be checked. The laboratory must prove the correctness of the test results. Proficiency testing programs' test results must be ready for evaluation by assessors [2]. In early 2019, the HHRL enrolled and has been participating in 6 United Kingdom National External Quality Assessment Scheme (UK NEQAS) proficiency testing panels including general bacteriology, antimicrobial susceptibility testing, malaria rapid test using First response malaria parasite lactate dehydrogenase (pLDH) (PF/HRP2)(OBELIS S.A./Belgium) , HIV rapid test using HIV ½ STATPAC (CHEMBIO Diagnostic System inc /USA), molecular detection of Mycobacterium tuberculosis (Xpert® MTB/RIF Ultra Cepheid/Sweden) and molecular detection of SARS-CoV-2 using TaqMan Array Cards(Applied Biosystems/ USA) . The HHRL quality policy manual defines the attainment of at least 80% or an equivalent score in EQA in each panel as verification of personnel competence and appropriateness of methods used. The laboratory made a commitment in its QMS quality plans for the achievement of these objectives to meet the customer and ISO 15189:2012 requirements. The change processes are implemented in a manner that will not compromise these requirements [25]. The progress in EQA participation of HHRL is shown in Figure 1 below.

Figure 1: The UK NEQAS performance of HHRL for the period 2019 to 2022.



GB: General Bacteriology ; AST: Antimicrobial Susceptibility Test; MRDT: Malaria Rapid Test; HIV-RDT: HIV rapid test; MM: Mycobacterium molecular; SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus 2

Note: The laboratory did not participate in SARS COV 2 testing after 2021

Training and implementation of the ISO 15189:2012 documents and records

Laboratory staff competence and understanding of the rationale behind accreditation are crucial for effective compliance with ISO 15189:2012 [10, 26]. Accordingly, the HHRL designed a QMS based on its quality policy manual and ISO 15189:2012 standard. The implementation of QMS would result in a well-organized structure, smooth work relations, and efficient services. The training of staff between October 2021 and February 2022 ensured the full and successful implementation of the system. The staff received training both in-person and online. The first face-to-face training covered all Standard Operating Procedures (SOPs), management and technical requirements, and manuals. It was provided by experienced senior staff in the laboratory who have training certificates. The other face-to-face training, which covered guidelines for auditing management systems, ISO 19011:2018 and Ethics, and ISO 15189:2012, was provided by a consulting company from Kenya. All staff received both free and purchased online training on Good Clinical Laboratory Practice (GCLP), Saf -T pack for Shipping Infectious Substances and Related Materials, Bloodborne Pathogens, Firefighting, Ergonomics, and Ethics.

Internal audit and action plan

The initial gap analysis and then the continuous monitoring through internal assessment provided invaluable tools for root cause analysis, corrective and preventative actions, and the eventual successful accreditation to ISO 15189:2012 [27]. The internal audit was conducted in January 2021 using the 15189:2012 checklist. A total of 26 gaps in microbiology and 16 in molecular biology sections were identified. The non-conformity reduced from 64.5% during baseline assessment by an external consultant to 9.8% (Figure 2). An action plan was developed after the internal audit and a final correction completion date of April 2021 was put in place. The progress, challenges, and suggested solutions in the accreditation process were discussed in the weekly laboratory staff meetings and implemented.

The sustainability of the implementation of QMS was routinely monitored via selected quality indicators ensuring the continuous regulation of the entire laboratory process from the pre-analytical, analytical, and post-analytical phases.The Laboratory management draws up annual quality objectives in line with its policy statement. The quality objectives are reviewed and revised during the annual management review meeting to ensure their suitability. The Turnaround times (TAT) to generate at least 85% test results within the set TAT, External Quality Assessments to attain at least 80% or equivalent score, and customer satisfaction levels, to maintain above 80% based on regular feedback, are the current quality objectives for the laboratory in 2023/2024 calendar year.

The HHRL recognizes that any feedback from service users is vitally important to achieving continual quality improvement of the diagnostic services. To monitor user experiences and satisfaction levels the HHRL undertakes regular user satisfaction surveys annually. This is done through the distribution of questionnaires to customers which contains courtesy staff, TAT, errors corrected promptly, professionalism of staff, reporting of critical results, service conformance with requirements, and past complaints if applicable . The customer concerns are evaluated and provided to the management for remedial actions. The customer satisfaction was 84% and 86% in 2021 and 2022, respectively. General positive feedback was provided by customers regarding the services provided by the HHRL. The customers gave negative feedback about delays in results reporting and communication. This was solved through awareness creation and distribution of the laboratory client handbook to customers, particularly health-care personnel. The customers were encouraged to refer to the handbook for information on the nature and time required for processing and reporting microbiology and molecular biology samples..

Submission of Application Document, Assessment and Accreditation

Phase 1: Scope of accreditation and documents review

It is a requirement for the candidate laboratory to determine the 'Scope of Accreditation' and the areas and names of tests, which will be specifically examined by expert assessors [2]. Our laboratory requested to be accredited for bacteriological culture tests and molecular detection of pathogens using TaqMan Array cards. These were based on the clinical and research testing requirements of the HHRP.

In April of 2022, the HHRL made a formal accreditation application to the EAS and submitted the following documents: the quality policy manual, managerial and technical requirement procedures, checklists, forms, proficiency test (PT) participation plan and recent results, a summary of internal audit, non-conformity clearance audit report, laboratory legal entity and risk assessment and mitigation reports. The EAS reviewed the documents and provided feedback, which helped us prepare for the physical in-person audit.

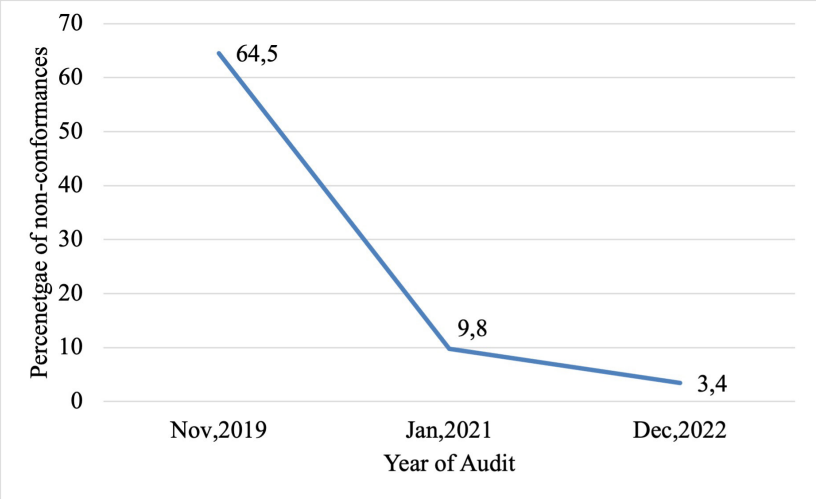
Phase 2: Accrediting body assessment physical visit

The ISO 15189:2012 accreditation involves an independent third-party assessment of the medical laboratory that includes an examination of personnel qualifications and competence, equipment, reagents, and supplies, quality assurance, pre-analytical, analytical, and post-analytical factors. Qualified assessors perform an in-depth evaluation of all factors that influence the production of test data [28].

An on-site assessment of the HHRL was conducted by EAS from November 30th to December 3rd , 2022. Three assessors, comprising a technical expert, a managerial expert, and an observer were assigned by EAS. The assessment process started with an opening meeting with laboratory staff to provide information about the objective and activities of the assessment process. After visiting the laboratory, the assessors began the assessment process. They verified the implementation of all technical and managerial documents in the submitted application to ensure their availability and utilization by the laboratory staff. The assessors reviewed the workflow process, including sample reception, processing, result dispatch, and waste disposal, using laboratory request forms that were previously reported. Additionally, the assessors also verified the competence of the laboratory director, and QA/QC officer on management and the laboratory staff/technical signatories through observance performing tests according to approved SOPs and reviewing personnel files for evidence of required staff training.

The assessors found nine minor non-conformances, and the laboratory was given four months to clear these non-conformances. The reduction of non-conformity between the initial assessment in 2019 and the final audit in 2022 showed significant improvement (Figure 2).

Figure 2: The percentage of non-conformances by year of audit.



Phase 3: Non-conformities clearance , action plan development and accreditation.

The non-conformites were reviewed by the laboratory director and an action plan was developed. The HHR laboratory team worked tirelessly to clear all the cited non-conformities by March 2023 and submitted a report with accompanying documents to EAS. The laboratory was accredited for medical microbiology on May 3rd, 2023. The EAS did not have the capacity to review and accredit the molecular testing section of our laboratory. The sustainability of the accreditation of the laboratory is maintained through active participation of staff in detecting and presenting non-conformities, in the weekly staff and monthly quality improvement (QI) meetings followed by prompt rectification. Figures 3 and 4 show the summary process followed by HHRL towards being accredited by EAS and the accreditation certificate.

Figure 3: Summary process followed by Hararghe Health Research Laboratory for accreditation from October 2021 and February 2023.

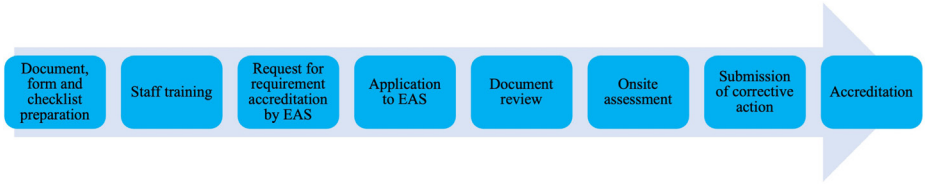


Figure 4: Accreditation certificate awarded to Hararghe Health Research Laboratory by Ethiopian Accreditation Service.

ETHIOPIAN ACCREDITATION SERVICE

ACCREDITATION CERTIFICATE

Hararghe Health Research Laboratory

Harar, Ethiopia

Facility Accreditation No: **M0075**

Is accredited by the Ethiopian Accreditation Service (EAS) to perform tests in accordance with the attached *Scope of Accreditation* in the field of

Medical Testing

The facility is accredited in accordance with the requirements of ISO/IEC 15189:2012, General requirements for the competence of Medical laboratories. The accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use the Combined ILAC-EAS accreditation mark/symbol to issue test reports and/or certificates.

Effective Date: **29 December 2023**

Certificate Expires: **2 November 2027**

Mr. Bonsa Bayissa
Director General
Ethiopian Accreditation Service

Benefits accruing to the HHRL due to this accreditation

The HHR laboratory is reportedly one of only five microbiology-accredited laboratories in Ethiopia, and this accreditation process has helped the HHRL in the standardization and traceability of its test processes which continues to contribute to improvement in the quality of laboratory services and patient care. The accreditation showed a significant improvement in the motivation and job satisfaction of laboratory staff, as evidenced by their bench work and weekly and monthly quality improvement meetings/discussions. The laboratory's accreditation has led to increased visibility at both national and international levels, establishing it as a reputable research center of excellence. This recognition has enabled the laboratory to attract research grants and protocols, allowing them to address community health issues in eastern Ethiopia. The data collected from these efforts will provide valuable insights to both the national and international public health communities, aiding in informed decision-making.

Challenges, limitations and solutions

The adoption and utilization of different documents, records, or quality standards was costly and labor-intensive [29]. The HHRL had challenges with the calibration and maintenance of laboratory equipment because of the limited availability of qualified biomedical engineers, spare parts, and traceability of organizations in Ethiopia. This challenge was overcome by utilizing the services of companies external to Ethiopia. The other challenge was low staff commitment and cooperation on the implementation of the ISO 15189:2012 standard, but this was solved through continuous training, continuous awareness creation, motivation, mentoring, and supervision. Another challenge was the difficulty of HHRL staff in accessing Continuous Professional Development programs. This was resolved by conducting training by using experienced and certified senior staff, procurement of online training and invited trainers from outside Ethiopia. The other limitation was the non assessment of the molecular testing section due to the absence of technical ability by the EAS at the time of the assessment.

Discussion

The accreditation of clinical laboratories enhances laboratory processes by reducing errors in the pre-analytical, analytical, and post-analytical phases, aiding in accurate and prompt diagnostics, supporting faster and more effective treatments, and encouraging ongoing improvement efforts [5, 30].

The ISO 15189:2012 serves as a universal benchmark for accrediting medical laboratories.[7]. Adherence to this standard showcases laboratories' capability to consistently deliver top-tier service, resulting in enhanced patient safety and better clinical outcomes[8-11].

The initial gap analysis and continuous monitoring, both through internal and external assessment, provided us with invaluable tools for successful accreditation [17]. This approach significantly reduced the accreditation process timeline. The World Health Organization (WHO) introduced the Strengthening Laboratory Management Towards Accreditation (SLMTA) and Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) programs to facilitate working towards accreditation in African medical laboratories. Under this scheme, the laboratories gradually go through an assessment process, starting from 0 stars and working their way up to 5 stars, before applying for the ISO 15189:2012 accreditation [31, 32]. Due to the availability of resources and strong management commitment, we were able to shorten the time required to complete these stages.

Effective implementation of accreditation standards and day-to-day compliance with ISO 15189:2012 requirements are significant challenges. It demands effort, active involvement, and commitment from all levels of laboratory staff and management. Maintaining full conformity to the specified objectives within time and cost constraints is crucial [10, 26, 33, 34]. To ensure the smooth implementation of the processes, the HHR partnership and laboratory management have demonstrated their commitment by monitoring and implementing the ISO 15189:2012 standard through the provision of necessary human and equipment resources and vital support.

Even though the laboratory experienced significant improvements in the quality of performance throughout the entire process, it faced challenges in obtaining in-country services for calibration and maintenance of equipment, as well as staff continuous professional development. These challenges are not unique to this laboratory, as others in Ethiopia and other countries have also faced similar issues during the accreditation process [29, 35, 36]. Consequently, these challenges resulted in extended equipment downtime, service interruptions, and delays in service delivery, leading to an increase in complaints from clinicians and customers [29]. However, thanks to the HHR partnership and laboratory management's remarkable efforts, the laboratory was able to sustain its services and achieve ISO 15189:2012 accreditation.

Conclusion

The Hararghe Health Research Laboratory successfully completed the ISO 15189:2012 accreditation process in just 36 calendar months, which is a relatively short time frame compared to similar or larger institutions. This achievement was made possible due to the strong support of management and the dedication of the staff. The accreditation serves as evidence that it is indeed possible to establish and accredit a greenfield laboratory within a relatively short time. This publication provides valuable insights for medical and research laboratories, as well as federal, local health, and other related stakeholders who are working towards accreditation.

Lessons learned, recommendation and working to align with ISO15189:2022 requirements

Lessons learned

Most laboratories rely on mentors from their baseline assessment

until they receive an accreditation certificate. However, HHRL did not have a mentor because it used senior staff members who have extensive experience in ISO 151189:2012 and the College of American Pathologists accreditation schemes. The laboratory management demonstrated readiness and commitment by identifying gaps through internal and external audits and resolving them through a development action plan. Another valuable lesson we learned was the importance of utilizing available human resources, both domestically and internationally, to enhance the capacity of our staff, calibration, and maintenance of equipment. Lastly, we evidenced the fact that the accreditation process necessitates willingness, financial support, and material resources from the management of the facility.

Recommendation

Laboratories should view both internal and external audits as valuable opportunities to address non-conformities, strengthen their systems, and ensure optimal efficiency and effectiveness in their operations. Therefore, they should actively participate in the auditing process and use it to identify areas for improvement. Additionally, this practice highlights the importance of involving facility management in the laboratory accreditation process, emphasizing the need for dedicated financial resources, supplies, and effective leadership. Laboratories should also evaluate their internal capacity and actively seek external opportunities for their accreditation process.

Working to align with ISO15189:2022 requirements

The laboratory management has received the revised and updated iso15189:2022 documents and we are in the process of performing gap analysis and aligment with the new requirements which we have set a timeline to be completed by May of 2025.

Author contributions

ZT conceptualization and design, write up the manuscript. DM, DB, MB: data extraction, write-up, review, and editing manuscripts. MD, FA, DD, ES, MB and MN: reviewing the manuscript. JO: conceptualization, critical revision, and editing of the manuscript. LM and NA: critical revision and editing of the manuscript. All authors read and approved the submitted version manuscript.

Conflict of Interest

The authors didn't have any conflict of interest.

Acknowledgment

The Authors would like to acknowledge HHR laboratory management, staff, and external assessors. We would also extend our gratitude to HHR partnership management for support in the facilitation of the accreditation process.

References

1. Carinci F, Van Gool K, Mainz J, Veillard J, Pichora EC, Januel JM, et al. Towards actionable international comparisons of health system performance: expert revision of the OECD framework and quality indicators. Int J Qual Health Care. 2015;27(2):137-146. DOI: 10.1093/intqhc/mzv004.
2. Guzel O, Guner EI. ISO 15189 accreditation: Requirements for quality and competence of medical laboratories, experience of a laboratory I. Clin Biochem. 2009;42(4-5):274-278. DOI: 10.1016/j.clinbiochem.2008.09.011.
3. Green AD, Kavanagh-Wright L, Lee GR. Investigation of the long-term yield of auditing for conformity with the ISO 15189:2012 quality standard in a hospital pathology laboratory. Pract Lab Med. 2020;20:e00159. DOI: 10.1016/j.plabm.2020.e00159.
4. Agarwal R. Quality-Improvement Measures as Effective Ways of Preventing Laboratory Errors. Lab Medicine. 2014;45(2):e80-e8. DOI: 10.1309/lmd0yifptowzonad.
5. Zima T. Accreditation of Medical Laboratories - System, Process, Benefits for Labs. J Med Biochem. 2017;36(3):231-237. DOI: 10.1515/jomb-2017-0025.
6. Yanikkaya-Demirel G. ISO 15189 accreditation: Requirements for quality and competence of medical laboratories, experience of a laboratory II. Clin Biochem. 2009;42(4-5):279-283. DOI: 10.1016/j.clinbiochem.2008.09.099.
7. International Organization for Standardization (ISO). ISO 15189 : Medical laboratories—particular requirements for quality and competence. 2012 [Available from: https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-3:v2:en.
8. Plebani M, Sciacovelli L. ISO 15189 accreditation: navigation between quality management and patient safety. J Med Biochem. 2017;36(3):225. DOI: 10.1515/jomb-2017-0038.
9. Plebani M, Sciacovelli L, Chiozza ML, Panteghini M. Once upon a time: a tale of ISO 15189 accreditation. CCLM. 2015;53(8):1127-1129. DOI: 10.1515/cclm-2015-0355.
10. Sciacovelli L, Aita A, Padoan A, Antonelli G, Plebani M. ISO 15189 accreditation and competence: a new opportunity for laboratory medicine. JLPM. 2017;2(9). DOI: 10.21037/jlpm.2017.09.05.
11. Thelen MH, Huisman W. Harmonization of accreditation to ISO15189. CCLM. 2018;56(10):1637-1643. DOI: 10.1515/cclm-2017-0820.
12. International Organization for Standardization (ISO) ISO/IEC 17011 :Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies. 2017. Available from: https://www.iso.org/obp/ui/en/#iso:std:iso-iec:17011:ed-2:v1:en
13. Ethiopian Accredion Serivice About us 2022 [Available from: https://eas-eth.org/about-us/
14. ILAC. ILAC MRA SIGNATORY SEARCH 2024 [Available from: https://ilac.org/signatory-search/
15. EAS. ENAO achieved signatory status in the African accreditation cooperation (AFRAC) 2017 [Available from: https://eas-eth.org/2017/10/enao-achieved-signatory-status-in-the-african-accreditation-cooperation-afrac/
16. Assefa N, Hassen JY, Admassu D, Brhane M, Deressa

M, Marami D, et al. COVID-19 Testing Experience in a Resource-Limited Setting: The Use of Existing Facilities in Public Health Emergency Management. Front Public Health. 2021;9 . DOI: 10.3389/fpubh.2021.675553.
17. Zamir K, Qassas O, Johani A, Aboud A. 23 The successful journey of the first A2LA ISO 15189: 2012 medical laboratory in the kingdom of saudi arabia. BMJ Open Quality. 2019;8. DOI: 10.1136/bmjoq-2019-PSF.23.
18. Maruta T, Motebang D, Mathabo L, Rotz PJ, Wanyoike J, Peter T. Impact of mentorship on WHO-AFRO strengthening laboratory quality improvement process towards accreditation (SLIPTA). Afr J Lab Med. 2012;1(1):8. DOI: 10.4102/ajlm.v1i1.6.
19. Nguyen TT, McKinney B, Pierson A, Luong KN, Hoang QT, Bond KB, et al. SLIPTA e-Tool improves laboratory audit process in Vietnam and Cambodia. Afr J Lab Med. 2016;5(2):1-5.
20. SLIPTA. Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2:2015 2015 [Available from: https://www.slmta.org/uploads/SLIPTA-checklist-v2-English.pdf
21. EAS. ISO/IEC 15189:2012 Checklist for Medical Laboratories 2022 . [Available from: https://eas-eth.org/wp-content/uploads/2022/08/F07-06B-15189-Medical-Lab-Horizontal-Check-List-1.pdf
22. JCGM. International vocabulary of metrology – Basic and general
concepts and associated terms (VIM) . 2008 version with minor corrections 2012 [3rd edition:[Available from: https://www.bipm.org/documents/20126/2071204/JCGM_200_2012.pdf/f0e1ad45-d337-bbeb-53a6-15fe649d0ff1
23. ILAC. ILAC Policy on traceability of measurement results 2002 [Available from: https://www.nist.gov/system/files/documents/nvlap/ILAC_P10_2002_ILAC_Policy_on_Traceability_of_Measurement_Result.pdf
24. EAS. PM10 /01: policy on the Traceability of Measurement Results Ethiopian Accreditation Services ,Addid Ababa2022 [updated 11/01/2023. Available from: https://eas-eth.org/wp-content/uploads/2022/08/PM10-01-Policy-on-Traceability.pdf
25. HHRL. Ethiopia, quality policy manual. HHRL/ALS/QMP4.2-01, version2 ,2021. 2021.
26. Lapić I, Rogić D, Ivić M, Tomičević M, Kardum Paro MM, Đerek L, et al. Laboratory professionals' attitudes towards ISO 15189: 2012 accreditation: an anonymous survey of three Croatian accredited medical laboratories. Biochem Med (Zagreb). 2021;31(2):331-341. DOI: 10.11613/BM.2021.020712.
27. Abebe N. Successful ISO 15189 Accreditation in the Bethzatha Advanced Medical Laboratory in Ethiopia. Ejifcc. 2016;27(4):351.
28. ACCB. Accreditation For Medical Laboratories. 2021 [Available from: http://www.accreditationboard.org/medicallaboratory.php (
29. Getahun MS, Yemanebrhane N, Desalegn DM, Kitila KT, Dinku TT, Wondimagegnehu DD, et al. Medical laboratory accreditation in a resource-limited district health centre laboratory, Addis Ababa, Ethiopia. Afr J Lab Med. 2019;8(1):1-5. DOI: 10.4102/ajlm.v8i1.793.
30. Peter TF, Rotz PD, Blair DH, Khine A-A, Freeman RR, Murtagh MM. Impact of Laboratory Accreditation on Patient Care and the Health System. Am J Clin Pathol. 2010;134(4):550-555. DOI: 10.1309/ajcph1skq1hnwghf.
31. Gershy-Damet G-M, Rotz P, Cross D, Belabbes EH, Cham F, Ndihokubwayo J-B, et al. The World Health Organization African region laboratory accreditation process: improving the quality of laboratory systems in the African region. Am J Clin Pathol. 2010;134(3):393-400. DOI: 10.1309/AJCPTUUC2V1WJQBM.
32. Yao K, Luman ET. Evidence from 617 laboratories in 47 countries for SLMTA-driven improvement in quality management systems. African journal of laboratory medicine. 2016;5(2):1-11. DOI: https://hdl.handle.net/10520/EJC161599.
33. Aslan D. Which skills are needed and how they should be gained by laboratory medicine professionals for successful ISO 15189 accreditation. Ejifcc. 2018;29(4):264.
34. Long-Mira E, Washetine K, Hofman P. Sense and nonsense in the process of accreditation of a pathology laboratory. Virchows Arch. 2016;468:43-49. DOI: 10.1007/s00428-015-1837-1.
35. Zeh CE, Inzaule SC, Magero VO, Thomas TK, Laserson KF, Hart CE, et al. Field experience in implementing ISO 15189 in Kisumu, Kenya. Am J Clin Pathol. 2010;134(3):410-8. DOI: 10.1309/AJCPZIRKDUS5LK2D.
36. Girma M, Desale A, Hassen F, Sisay A, Tsegaye A. Survey-defined and interview-elicited challenges that faced Ethiopian Government Hospital Laboratories as they applied ISO 15189 accreditation standards in resource-constrained settings in 2017. Am J Clin Pathol. 2018;150(4):303-309. DOI: 10.1093/ajcp/aqy049.