



ANNUAL REPORT

2019/2020

Biolabs Red
Services

Quality Management Systems

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EXECUTIVE SUMMARY

Biolabs Red Service Ltd (U) is a multinational company registered as a Laboratory, Health and Eco Consultancy firm in Uganda with collaborations in East Africa (Kenya, Rwanda and South Sudan). The consultancy was recognized (ADM:171/388/01) by the Ministry of Health Uganda to not only offer Quality Assurance consulting but also technical support services for medical laboratories in the health laboratory sub-sector and, is directly supervised by the Uganda National Health Laboratory Services/Central Public Health Laboratories (UNHLS/CPHL).

The company envisions to be the leading provider of superior gradation consultancy services in quality management systems by delivering technical assistance that is centered around a scope of conducting; audits, trainings, mentorship and preparing laboratories for quality management systems accreditation and/or certification based on a preferred standard.

In line with the vision, the firm managed to conduct a number of activities previously and in first year of accreditation which included: 83 mentorship cycles, 2 labs supported to achieve international accreditation, 6 labs supported to achieve ASLM LQMS certification, and 7 system trainings. Efforts to pursue ISO 9001 certification are ongoing where, 83% of the company's required documentation has been accomplished in order to have an internal system that guides and controls Biolabs Red Services in regard to provision of consistent and quality technical assistance services. Human resource & capacity building and Strategic partnerships have also been given ample attention, where key recruitments and partnership with certification bodies traceable to ILAC have been achieved respectively.

Our next tenure will be hinged upon strategic actions to generate multidisciplinary proposals centered on building laboratory capacity to satisfy the dynamic demands from national and international Governments in collaboration with Health Development Partners. We do recognize the need to have a Memorandum of Understanding between the Implementing partners and Biolabs Red Services so as to structure technical support activities so as to aid timely and sustainable implementation of Quality Management System activities.

Biolabs Red Services appreciates the East Africa Public Health Laboratory Network (EAPHLN) Project, IDI, RHITES-E and Muni University for facilitating the aforementioned technical activities. In a special way, we also appreciate Ministry of Health Uganda and UNHLS/CPHL for the guidance and support provided towards the implementation of the same.

REVIEWS AND APPROVALS

UNHLS/CPHL Review

Name			
Role			
Signature		Date	
Review comments			

UNHLS/CPHL Approval

Name			
Role			
Signature		Date	



TABLE OF CONTENTS

Executive Summary	2
Reviews And Approvals	3
Acronyms	5
Introduction	6
Vision.....	6
Mission	6
Technical Services Scope	7
Training	8
What's Next	12
Challenges& Recommendations	13
Acknowledgments	14
Pictorial.....	15

ACRONYMS

ASLM	African Society for Laboratory Medicine
BLS	Biolabs Red Services
CAPA	Corrective action and preventive action
CPHL	Central Public Health Laboratories
EAPHLN	East Africa Public Health Laboratory Network Project
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
MR	Management Review
NTRL	National Tuberculosis Reference Laboratory
QMS	Quality Management Systems
RHITES-E	USAID Regional Health Integration to Enhance Services in Eastern
SANAS	South African National Accreditation System
SLMTA	Strengthening Laboratory Management Toward Accreditation
SPC	Statistical process control
UNHLS	Uganda National Health Laboratory Services

INTRODUCTION

Biolabs Red Service Ltd (U) is a multinational company registered as a Laboratory, Health and Eco Consultancy firm in Uganda with collaborations in East Africa (Kenya, Rwanda and South Sudan). The consultancy was recognized (ADM:171/388/01) by the Ministry of Health Uganda to offer Quality Assurance consulting and technical support services for medical laboratories in the health laboratory sub-sector and is directly supervised by the Uganda National Health Laboratory Services/Central Public Health Laboratories (UNHLS/CPHL).

The company's head offices are located at BMK House Suite 12, Wampewo Avenue, Kololo. We can also be contacted through email: isekidde@biolabsred.com, mobile: +256(0)706 468 465/706 087 552 or Tel: +256(0)393 240 121.



VISION

To be the leading provider of superior gradation consultancy services in quality management systems covering; laboratory, health and eco fields within the Eastern and Central Africa with paramount integrity, efficiency and liability to our clients



MISSION

To offer quality management system consultancy services in resource limited settings with utmost professionalism so as to enable clients to attain their commercial intentions through cost optimization while satisfying their customers in a suitable manner



- √ Quality Services
- √ Cost Efficiency
- √ Timely Delivery

- √ Accountability
- √ Impact & Sustainability
- √ Integrity



TECHNICAL SERVICES SCOPE

We conduct audits, offer trainings and prepare all types of laboratories for quality management systems accreditation or certification based on a preferred standard, regulatory and accreditation body.

The Quality Management Systems trainings are based on specific standards and these include;

- System courses based on ISO 15189, ISO 17011, ISO 35001, ISO17043 and ISO 17025
- Certification courses aligned to ISO 9001, 19011 and 15190
- Implementation based trainings including CAPA, MR, and SPC.
- We also offer technical support through mentorships

The full scope of services includes the following;

- ✓ Audit
- ✓ Trainings
- ✓ Mentorship
- ✓ Presentation for accreditation/certification
- ✓ QMS for lab licensure
- ✓ External quality assessment
- ✓ Point of care quality systems
- ✓ Health Impact Assessment
- ✓ Occupational health and safety
- ✓ Lab design and lay-out
- ✓ Health Information System

For more information about our scope of service click: [here](#)

TECHNICAL ASSISTANCE & OTHER ACHIEVEMENTS

Narrative Summary Of The Achievement

Biolabs Red Services managed to conduct ISO 15189:2012 implementers' training and biosafety and biosecurity training for Muni university from 22nd June to 3rd July 2020 at Muni University hall, in Arua district. This training was conducted with an objective of instilling a culture of quality, prepare the laboratory to support the covid-19 public health response through providing quality testing services, and work towards becoming a center of excellence.



Training Strategic Objective 1

- To conduct Quality Management Systems laboratory training based on ISO 15189: 2012

Through a collaborative approach, RHITES-E and Biolabs Red Services organized and conducted a 5 days ISO 15189:2012 implementers' course (BLS/ISO-C/001-2020) at Timisha Hotel in Soroti district for selected Rhites-E supported laboratories, these included; Kibuku H/C IV, Buginyanya H/C III, Kapchorwa Hospital, Agule H/C III, Butiru H/C III, SIPI H/C III, Tororo General Hospital, Mbale Regional Referral Hospital, Buwasa H/C IV, Bufumbo H/C IV, Busolwe Hospital, Kabwangasi H/C III, Budadiri H/C IV, Kaabong Hospital, Kaproron H/C IV, Budaka H/C IV, Namatala H/C III, Moroto Regional Referral Hospital, Kasasira H/C III, , Busiu H/C IV, Bududa Hospital, IKI-IKI H/C III, and Kotido H/C IV.

This training was aimed at providing participants with a detailed understanding of how medical laboratories demonstrate their competence, impartiality, consistency and, ensure that the participants appreciates the benefits of a implementing functional and sustainable Quality Management System (QMS).

A total of 32 Laboratory personnel were trained, to whom a Pre-Test and Post-Test was administered to ascertain the level of knowledge transfer to participants. The Pre-Test percentage average score was 42.1%, compared with that of the Post-Test which was 78% (**Figure 1**), this gave a clear indication that participants gained sufficient understanding and implementation knowledge of the ISO 15189:2012.

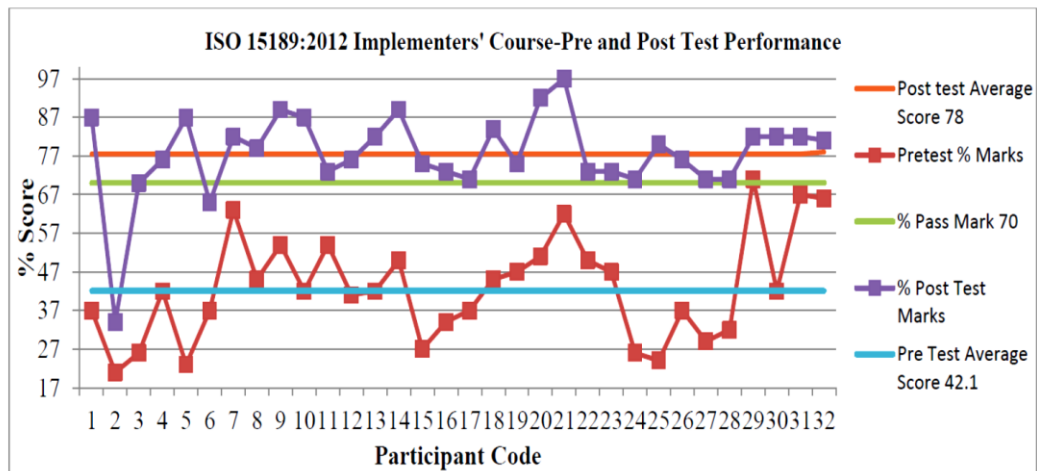


Figure 1: Participants' Pre & Post test scores

Narrative Summary Of The Achievement

Moroto Regional Referral Hospital Laboratory was one of the laboratories under East Africa Public Health Laboratory Network (EAPHLN) Project and, Rhites-E that was scheduled for SANAS Assessment by the end April/2020. Following technical support activities that were organized for the laboratory by Rhites-E and EAPHLN, Biolabs Red Services in collaboration with the Implementing Partners prepared the laboratory for SANAS assessment from which the lab was accredited to ISO 15189.

Our technical team was individually engaged by both IDI and Baylor-Uganda (latter especially in the transition period) to offer technical support and had them laboratory recommended for international accreditation by SANAS. The technical support activity was based on the ISO 15189:2012 requirements, African Society for Laboratory Medicine (ASLM) exit audit findings, and the laboratory's documented procedures. This covered the entire quality management system for the laboratory with emphasis on the accreditation scope tests i.e. HIV, CBC, and Tuberculosis (ZN Microscopy and GeneXpert).

Similar support is being offered to Mbale Regional Referral Hospital laboratory which is set to apply for SANAS accreditation to ISO 15189.



Support labs to attain international accreditation

Strategic Objective 2

- To support Medical Laboratories to attain ISO 15189:2012 international accreditation

Narrative Summary Of The Achievement



Mentorships

Strategic Objective 3

- To offer Technical support to SLMTA Laboratories and prepare them for ASLM certification

Koboko General Hospital Laboratory and Adjumani District Hospital Laboratory under IDI were scheduled for African Society for Laboratory Medicine (ASLM) exit audit in August/2019. IDI organized mentorships for these Laboratories and Biolabs Red services technical team members were engaged individually to work with the technical support teams to prepare the laboratories for the exit audit. Both laboratories registered a tremendous performance of **4 Stars** from 2 **Stars**. The collaboration was commendable.

Technical team members from Biolabs Red Services also supported Anaka General Hospital laboratory under RHITES-Acholi towards preparations for the ASLM SMLTA exit audit where the lab obtained a **STAR 4** SLIPTA rating. The technical capacity of staff was improved and the spirit to sustain QMS was lifted.

Biolabs Red Services in collaboration East Africa Public Health Laboratory Network (EAPHLN) Project also supported Arua Regional Referral Hospital Laboratory in preparation for the annual peer assessment where the Laboratory scored **4 Stars** from **0 Stars**. This was possible with the support and guidance from UNHLS/CPHL, and implementing partners who facilitated the Biolabs Red Services mentors to do the work.



Review of course materials

Strategic Objective 4

- To revise and update all training materials and tool kits in line with updated versions of respective standards and annual course review calendar

Narrative Summary Of The Achievement

All training materials and tool kits for courses were reviewed and/or aligned to respective standards to ensure their continuing suitability for intended use. These included; ISO 19011:2018, ISO 15189 QMS course, Identification and management of nonconformance, management review and statistical process control. The materials were successfully uploaded on google drive and web backed up. This allows for offsite accessibility for the technical teams.

Name	Date modified	Type
CS 1 LQMS VR. 3	12/10/2020 12:00 PM	File folder
CS 2 ISO 15189 VR. 4	12/10/2020 11:59 AM	File folder
CS 3 CAPA for ISO 15189 & 17025 VR. 4	12/10/2020 11:59 AM	File folder
CS 4 Internal audit 19011 VR. 3	12/10/2020 11:59 AM	File folder
CS 5 SPC VR 3.0	12/4/2020 10:13 AM	File folder
CS 6 BRM ISO 35001 & 15190 VR 2.0	12/10/2020 11:58 AM	File folder
CS 7 SLMTA VR 3.0	12/10/2020 12:00 PM	File folder
CS 8 SPI-RT Trainers guide VR 2.0	11/27/2020 12:54 PM	File folder
CS 9 Certifications bodies 17011 VR 1.0	12/10/2020 12:00 PM	File folder
CS 10 QMS for 17043 VR 1.1	12/10/2020 12:00 PM	File folder
CS 11 QMS for POC VR 1.0	12/10/2020 12:00 PM	File folder
CS 12 QMS for testing labs VR 2.0	12/10/2020 12:00 PM	File folder
CS 13 ISO 9001 VR 1.0	12/10/2020 12:00 PM	File folder
CS 14 Risk management VR 1.0	12/10/2020 12:00 PM	File folder

Narrative Summary Of The Achievement

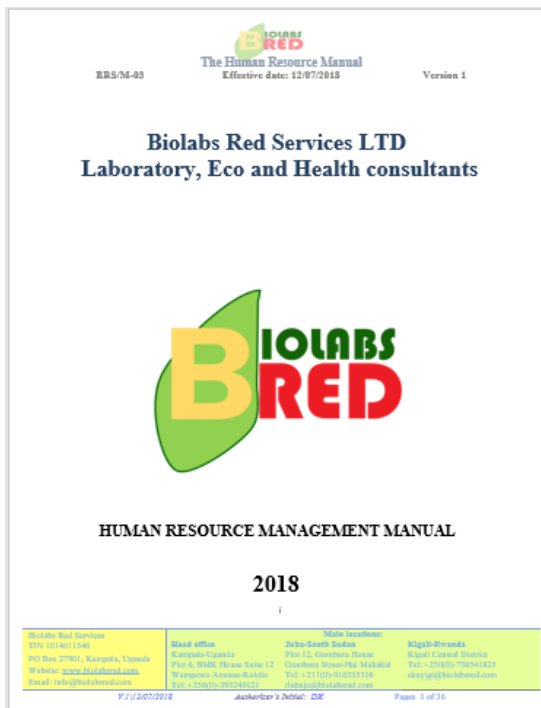


Documentation of QMS for Biolabs Red Services

In order to have an internal system which guides and controls Biolabs Red Services in regard to provision of consistent and quality technical assistance services, 83% of the company's required management system documents has been accomplished. Among accomplished documents include; the policy manual, SOP for authorization, financial management and human resource manuals. The board resolved to have ISO 9001 certification by June 2021.

Strategic Objective 5

- To ensure that customers get consistent, good-quality products and services through establishment, documentation and implementation of a quality management system based ISO 9001 for Biolabs Red Services.



Human Resource & capacity building

Narrative Summary Of The Achievement

Through our talent acquisition policy, we have brought on board 2 new staff whose technical capacity to provide technical assistance in line with ISO 15189 is being built. At the end of their training, competence assessment shall be done to ensure their fitness for technical support.

Strategic partnership

Narrative Summary Of The Achievement

Biolabs Red Service Ltd is in partnership with ACSQ (www.acsq.it) a certification body in Italy recognized by ACCREDIA-ILAC member body (www.accredia.it) to certify Conformity Assessment Bodies for compliance to ISO 14001: Requirements for an effective environmental management system (EMS), ISO 45001:

Occupational Health and Safety, ISO 9001: Requirements for a quality management system. Biolabs Red Services has successfully entered into an agreement with South African based QualExpect consulting services to build capacity of its staff on ISO 17025:2017.



Strategy

WHAT'S NEXT

Our strategic actions in the next tenure will be to generate proposals to ensure; improved laboratory capacity to support disease surveillance, diagnosis, treatment, monitoring; work with national and international Governments in collaboration with Health Development Partners, to provide technical assistance to National Health Laboratory Services so as to build institutional capacity and strengthen sustainability; enhance sustainable laboratory information systems and infrastructure capacity to improve data availability, quality, and use by supporting the provision of technical assistance and strategic planning to line ministries and, other partnering institutions for comprehensive and integrated responses to needs in health and non-health industries; provide technical assistance in establishing and sustainably functionalizing the bio-risk management systems; establish high-quality laboratory infrastructure capable of consistently churning out accurate test results in resource-limited settings in line with relevant international and national standards of host countries; leverage existing efforts and implement innovative initiatives to ensure the delivery of quality health laboratory and testing laboratory services by providing technical assistance in quality management systems implementation and to strengthen the capacity of essential staff through training and mentorship to provide those services in human, testing, calibration and animal health settings.



CHALLENGES & RECOMMENDATIONS

Challenges

- At the time of implementation of these activities, Biolabs Red Services Ltd did not have a documented Memorandum of Understanding with the respective Implementing partners and occasionally hampered timely execution of these activities because specific roles of the two parties were not defined.
- At the time of preparation for assessments, some laboratories had limited evidence for the implementation of their established Quality Management Systems. This was due to the lack of a clear site-specific road map that would guide timely execution of planned QMS activities.
- Laboratories had registered stock outs of reagents, controls and consumables which greatly affected their performance given the fact that some scope tests had to be dropped. This was mainly due to inconsistency in IQC performance which further resulted into a prolonged break of testing services

Recommendations

- There is a need to have a Memorandum of Understanding between the Implementing partners and Biolabs Red Services so as to structure technical support activities. This will aid timely and sustainable implementation of Quality Management System activities.
- After exit audits, accreditation Laboratories should be supported to develop clear accreditation road maps as this will enhance the timely and structured implementation QMS related activities at facility level.

ACKNOWLEDGMENTS



Biolabs Red Services appreciates the East Africa Public Health Laboratory Network (EAPHLN) Project, IDI, and RHITES-E and Muni University for facilitating these activities. In a special way, we also appreciate Ministry of Health Uganda and UNHLS/CPHL for the guidance and support provided towards the implementation of these activities.



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PICTORIAL



One of the participants explaining a concept to others after grasping it well from the trainer-Timisha hotel.



Group discussions on course activity-Timisha hotel



Group discussions on course activity-Timisha Hotel



Group discussions on course activity-Timisha hotel



A trainer supporting a group discussion



A trainer guiding a discussion on a subject matter



Group discussion in a Biosafety training at MUNI university



Lab manager giving remarks at Muni University