# ANNUAL REPORT

BIOLABS RED

2022/2023

# 1 ABOUT US

Biolabs Red Services Ltd (U) and its training institution: Ethan Quality Management Institute, are multinational companies specialized in management system consultancy that was first established in Uganda and now with collaborations in East Africa's Kenya, Rwanda and South Sudan and SADC's Malawi. Biolabs Red Services firm 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). Biolabs Red Services is registered to do business with international gov'ts and has partnership with QualExpect Consulting Services(SA), and PECB Canada to deliver on its vision. The company has grown beyond Management system consultancy and now has arms for; Global Health Security, Distributorship, Environmental Impact Assessment and Mitigation planning, Health infrastructure design and construction.

# 2 VISION

To be the leading provider of superior gradation technical assistance services in management and health systems.

# 3 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 sustainable manner.

# 4 CORE VALUES

- Accountability
- Impact & Sustainability
- Integrity
- Quality Services
- Cost Efficiency
- Timely Delivery

# 5 STRATEGIC OBJECTIVES

- To provide technical assistance in improving laboratory capacity to support disease surveillance, diagnosis, treatment, and monitoring.
- To 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.
- To 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.
- To 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.

- To 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
- To use robust sub-granting approaches to complement technical assistance in strengthening evidence-based health care service delivery & decision-making in non-health and health settings at the facility, point of care, and community levels.
- To establish and implement monitored transition strategy(s) as a key element of building capacity for the national institutions of host countries to manage disease responses upon completion of health aid agreements.

# 6 HIGHLIGHTS BY PERFORMANCE PERIOD

- 8 years of experience
- Labs accredited: ISO 15189(24), ISO 17025(3), ISO 17043(1).
- 54 Labs sustained accreditation to ISO 15189
- 40 mentorships accomplished
- 26 Labs sustained
- 360 trainees for QMS & Biosafety Trainings
- 4 National CPDs supported
- 2 International Partnerships 2 National assignments
- 1 Global fund Prequalification
- 1 US/CDC sub award for health laboratory systems strengthening in Uganda (SPHLS) through Joint Clinical Research Centre.

# 7 FORWARD

***Dear Esteemed Reader,***

I heartily invite you to enjoy the BLS' 2022/2023 Annual Technical Report. You will be pleased to note that in line with its vision, BLS has made a significant contribution in building a culture required for proper functioning of quality & risk management systems which is key in achieving and sustaining accreditation. Our technical assistance prowess has collaboratively led to international accreditation of 5 laboratories which included: Kawempe National Referral, Kiruddu National Referral, Soroti Regional Referral, Mbarara Regional Referral and Mukono General Hospitals. The tailored support accorded included; audits, onsite & offsite mentorships, physical and ECHO trainings, and project management.

*Kitwe Derrick,*
*CEO & Managing Partner*

Our training and quality assurance departments have worked cordially with the National implementation mechanisms such as JCRC/SPHLS, UCREP, and regional implementing partner or mechanisms such as RHITES-EC, RHITES-N, RHSP, RHITES-N Lango, Baylor Uganda, EGPAF, IDI, MJAP, TASO-Soroti, MUWRP, RHSP, UPMB, UCMB, and private players to contribute to the country's robust health system. We are committed to continue creating value to final users of health services through technical assistance on our expanded scope as per the capacity statement and therefore continue to seek collaborations with like-minded organizations as we make the world a safer place for now and the future.

# 8 TABLE OF CONTENTS

# 9 CORE COMPETENCE AREAS

- Laboratory systems strengthening
- Global Health Security
- Biosafety and Biosecurity
- Gap analysis through conducting Auditing/Assessments using WHO SLIPTA and accreditation body tools.
- Conduct Trainings; *Management review, Corrective Action and Preventive Action, Statistical Process Control, auditing principles based on ISO 19011, LQMS based on ISO: 15189, 17025, 9001, 17043, 22870, Biosafety and Biosecurity based on ISO35001and ISO 15190.*
- Conduct Mentorships to achieve planned deliverables
- Prepare labs for Accreditation to*: ISO 17025, ISO 17043, ISO 15189*
- Support accreditation bodies to establish, implement, maintain a management system based on ISO 17011
- Prepare labs and other organizations for Certification to; *ISO 9001, ISO 15190*
- Support establishment and accreditation to ISO 17043 of EQA schemes
- Develop QMS implementation mechanisms for all laboratory levels (SLMTA & non SLMTA, LQMS sites)
- Laboratory plan and design
- Equipment management systems

# 10 STAFFING

In order to strengthen the operations department two staff were added in the finance and administration department while one staff was added to support the training department.

| | | |
|---|---|---|
| Phiona Nakimira<br>BLT, MBChB<br>Training coordinator | Pius Temera Wamani Jr<br>BBA, MBA, CPA<br>Senior Accountant | Rebecca Nakitende<br>BBA, CIPS<br>Procurement and Admin officer |

# 11 STAKEHOLDER ENGAGEMENTS

To execute its mandate, Biolabs Red Services worked closely with MOH, NHLDS, Joint clinical Research Centre, Local implementing partners, accreditation bodies such as KENAS & SANAS, and international consultants.

# 12 TECHNICAL ASSISTANCE

### 12.1 Audits

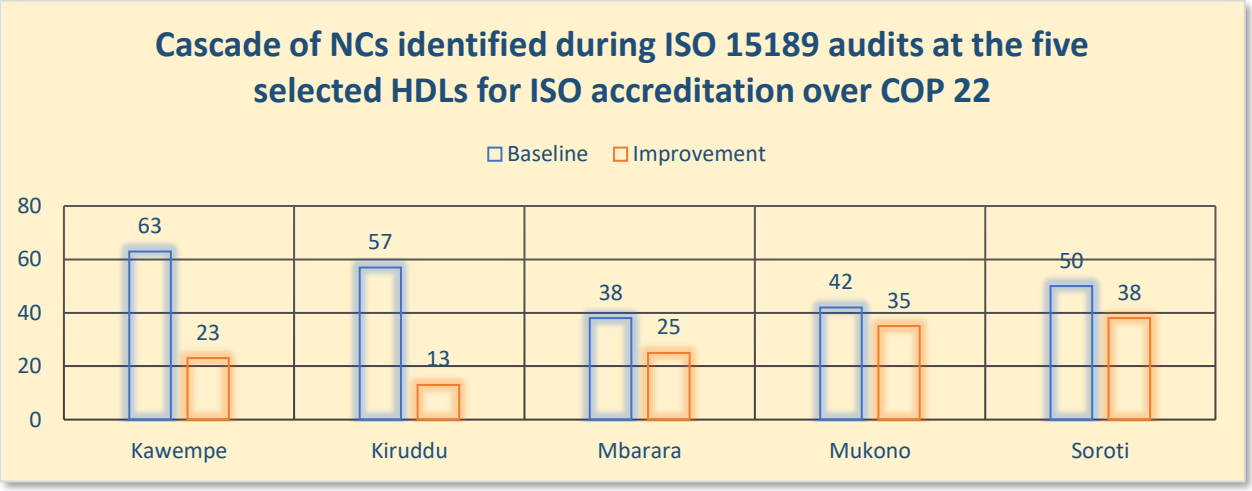
In COP 21, SPHLS supported NHLDS in obtaining ISO accreditation for 15 Health Diagnostic Laboratories (HDLs). Building on these accomplishments, NHLDS, in collaboration with SPHLS/JCRC, identified five

HDLs in the pipeline for ISO accreditation at Kawempe and Kiruddu National Referral Hospitals, Soroti and Mbarara Regional Referral Hospitals, and Mukono General Hostal during the COP 22 period. Baseline audits were performed in the second quarter of COP 22, followed by mentorship cycles 1, 2, 3, and 4 at the five HDLs. In Q3 COP 22, improvement audits were conducted to identify outstanding areas of improvement that would inform subsequent training and mentorship needs.

The specific goals of these assessments were to identify the gaps and opportunities for improvement in the established site-specific QMS; to ensure continuous quality improvement in patient care in accordance with ISO 15189 requirements, and to provide feedback to the site-specific QMS. To supervise, evaluate, and evaluate trainee internal auditors in the targeted HDLs.

**Results:** Findings from this activity noted a decline in the total number of Non-conformities (NCs) identified at the five facilities between Baseline and Improvement audits, indicating gradual improvement in the quality management systems (QMS) following the cascade of mentorship cycles 5, 6 and 7. This indicates the importance of mentorships in laboratory quality management systems strengthening.

***Figure 1: Graph cascading total NCs identified during the various audits from the five selected HDLs for ISO accreditation over the COP 22 period of SPHLS/JCRC support.***




## 12.2 MENTORSHIP

Accreditation to ISO 15189 in Uganda is implemented through a model that requires the target facility to undergo a set of activities ranging from audits, trainings, and mentorships. The audits include; baseline, improvement and mock audits and they are meant to establish gaps for improvement which are addressed in form of trainings and onsite mentorship cycles. In COP 22, the SPHLS/JCRC/Biolabs consortium, in collaboration with Regional IPs, supported QMS implementation in the five (05) HDLs selected by MOH/NHLDS i.e. Kawempe and Kiruddu NRHs, Soroti and Mbarara RRHs, and Mukono GH that were fast-tracked for ISO accreditation. Each of the 5 laboratories had to undergo 4 training which included; ISO 15189, management of potential/nonconformities and management review, internal audit and statistical process control. The four trainings were collectively followed up by 8 mentorship cycles with each mentorship lasting 2 weeks. These LQMS mentorship cycles at the five selected HDLs began in Q1 COP 22 (Cycles 1,2,3, and 4), with each mentorship cycle addressing a different aspect of the QSEs. Three additional LQMS mentorship cycles (5, 6, and 7) were carried out during this reporting period (Q3 COP 22), with the final (8th) cycle taking place in Q4 following initial SANAs assessments to assist these HDLs in addressing the NCs identified.

Each mentorship cycle had unique deliverables based on our internal capacity development model and seeks to build on the knowledge acquired from the trainings to build competence in form of additional knowledge, skills, and attitude to execute all activities required to comply to the standard for which the laboratories seek to be accredited to. A focus in these mentorship cycles is always put on audit outcomes to ensure such gaps are closed. The result of application of this comprehensive model of support to medical laboratories seeking accreditation was all the 5 laboratories being recommended for international accreditation.

## 12.3 TRAINING

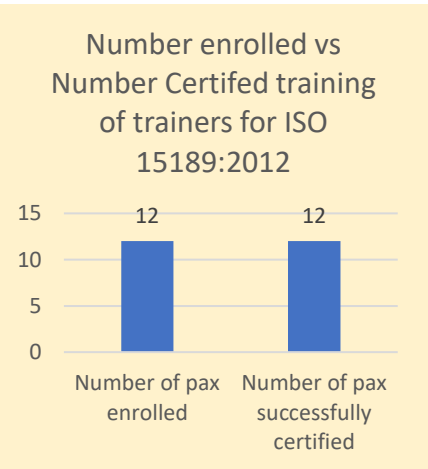
### 12.3.1 Traceability of trainings

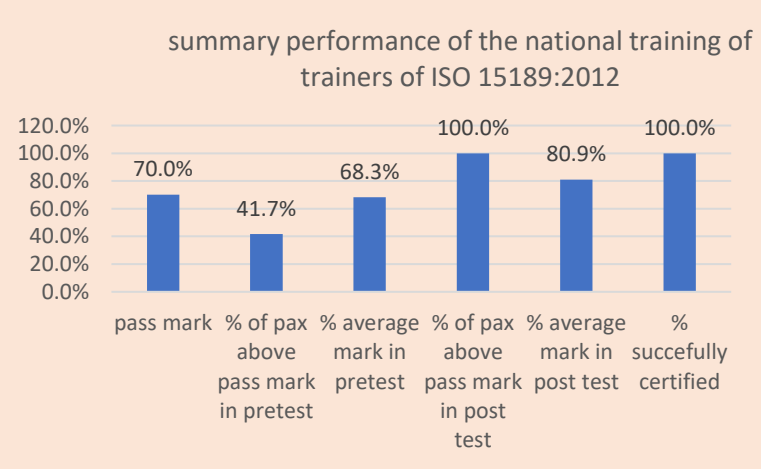
The courses were delivered by 2-4 facilitators who had previously completed training of trainers (TOT) and equivalent training in ISO 15189:2012 and 2022, ISO 22367:2020 as well as performance evaluations (Statistical process control, management review, personnel training and competence, and corrective action & risk treatment) with prior exposure to ISO 15189:2012 implementation. For TOTs, trainers from our partner agency: QualExpect consultants joined in with TCT 212 traceability.

### 12.3.2 ISO 15189:2012 for 5 accreditation labs

In Country Operational Planning year (COP) 22, the Quality Assurance Unit at NHLDS identified laboratories at five facilities (Kawempe National Referral, Kiruddu National Referral, Soroti Regional Referral, Mbarara Regional Referral and Mukono General Hospitals) for fast-tracking to ISO 15189:2012 accreditation.

The ISO 15189:2012 Implementers course is a preliminary training for establishment of quality systems in Medical laboratories. The five days' course was aimed at equipping participants with knowledge on functionalization of Quality Management System in Medical Laboratories based on ISO 15189:2012 with emphasis of developing a quality policy and quality objectives. The training was aimed at; appreciation of the key requirements and the intent of each of the main sections of the ISO 15189:2012 standard; Providing detailed understanding of how medical Laboratories demonstrate their competence, impartiality and consistency; Appreciation of the benefits of a functional Quality Management System (QMS) in Medical Laboratory; facilitate development of capacity to provide patient care using appropriate laboratory procedures while considering ethics, confidentiality and safety.

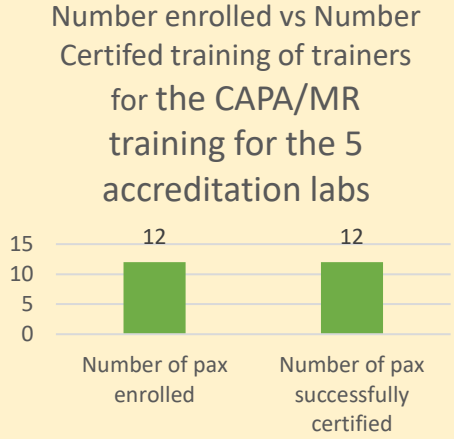


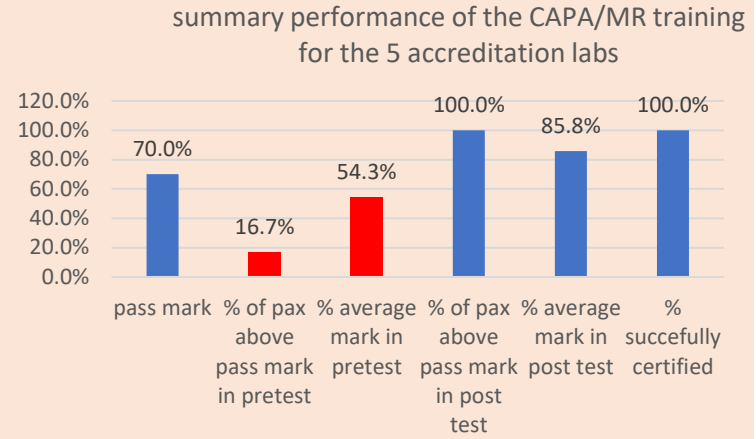



### 12.3.3 CAPA and MR for 5 accreditation labs

The pre-SANAS audits and Cycle 1 LQMS mentorships conducted by SPHLS/JCRC in Q1 of COP 22, identified knowledge gaps among LQMS implementers at these five laboratories in three critical areas: Corrective Actions Preventive Actions (CAPA), Management Reviews (MR). It is therefore upon this background that this five days' training on CAPA was conducted for a select twelve (12) LQMS implementers from the five target laboratories.

The objectives of this training included; Providing course participants with skills in identifying nonconformities (NCs), Conducting Root Cause Analyses for the NCs identified, Designing corrective (CAs) and preventive actions (PAs) from the RCA conducted, Provide skills in conducting risk analysis, Strengthening site-specific structures for management reviews (MRs).

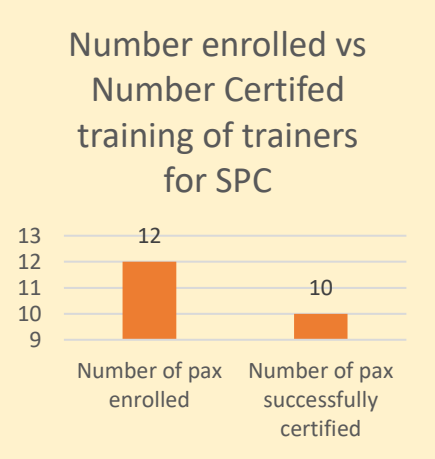


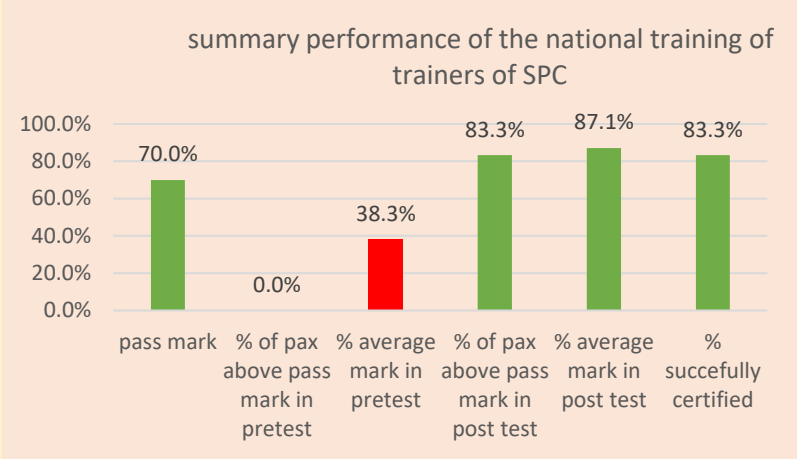




## 13 SPC FOR 5 ACCREDITATION LABS

Statistical process control is one of the tools to evaluate performance and contributes towards continual improvement in the lab's quality management system. The five days course provided a framework for performance and interpretation of process control requirements, and ensure continuous improvement in service delivery by ensuring ongoing appropriateness, sufficiency, effectiveness, and support for patient care in accordance with ISO 15189:2012.

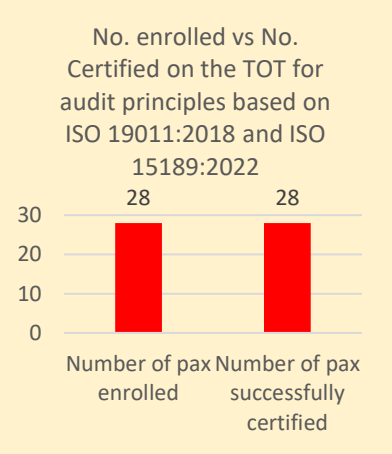
The course was attended by twelve(12) participants drawn from health facilities supported by, IDI, MUWRP, EGPAF, MJAP from the districts of Mbarara, Kampala, Soroti. In terms of gender there were six (6) males and six (6) female as shown below. All participants were laboratory staff involved in implementation of Quality management systems in their respective health facilities. The five days SPC training was aimed at achieving the following; Provide practical knowledge and skills in statistical process control and monitoring for medical laboratory practice; Provide practical knowledge and skills for performance monitoring of Internal and External Quality Assessment data; Provide practical knowledge and skills on method/equipment verification &validation and measurement uncertainty; Provide practical knowledge and skills on general calibration principles andmetrological traceability.

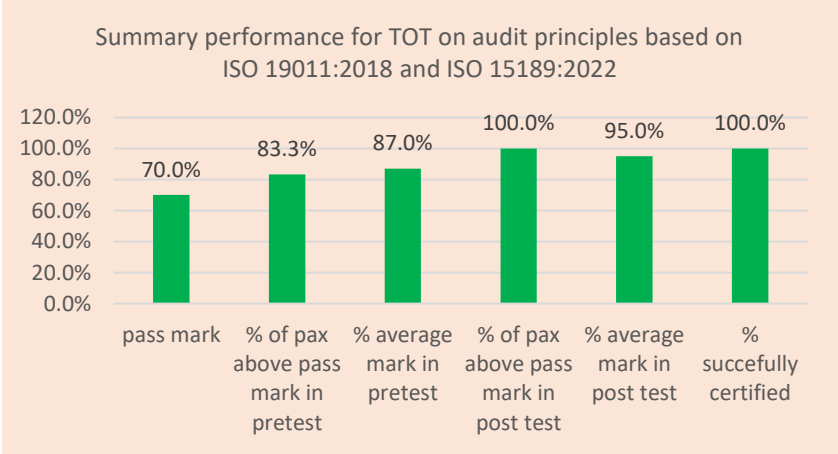



### 13.2.5 Conduct a refresher training on ISO 19011:2018 for the 2nd cohort of national auditors.

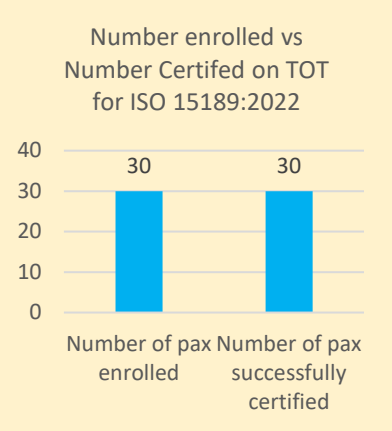
Following the update of ISO 15189:2012 to the 2022 version, the criteria upon which national audits for CABS (laboratories) implementing ISO 15189 subsequently changed. This required a pool of 28 national auditors selected by NHLDS to undergo this TOT so that they would be leveraged to train other auditors that would in turn conduct both internal and external audits for the ISO 15189 CABS. The training was aimed at providing knowledge and skills in the auditing of ISO 15189:2022 based Quality Management systems according to ISO 19011:2018 guidelines.

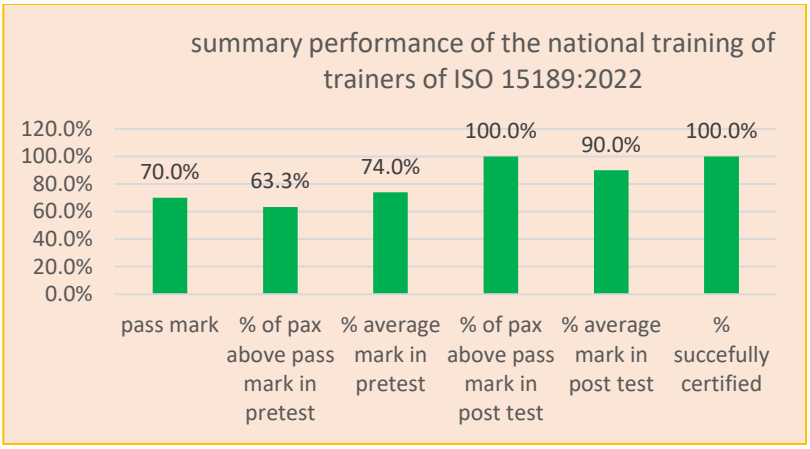



### 13.1.1 Conduct ISO 15189 training for selected national auditors and mentors

For the selected pool of 30 national trainers and 28 auditors, it was deemed necessary to update them on the revised ISO 15189:2022 following its (ISO 15189) publication in Dec 2022. Such capacity would be utilized by the ministry to; sustainably cascade trainings to all accredited laboratories that would be transitioning to the new standard, support processes leading to accreditation of new laboratories and updates to the SLMTA/LQMS CQI models. The training was aimed at providing knowledge and skills in the implementation of a Quality Management System which meets the requirements of ISO 15189:2022 and implementation Risk Management in a medical laboratory according to ISO 22367:2020



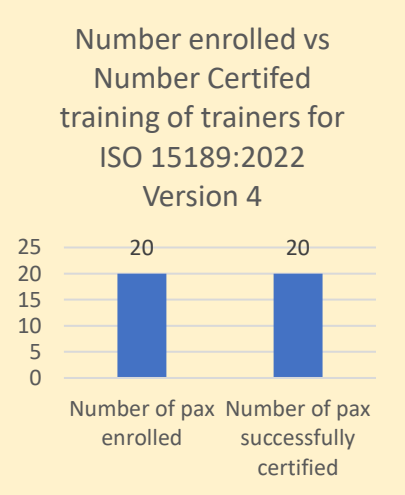



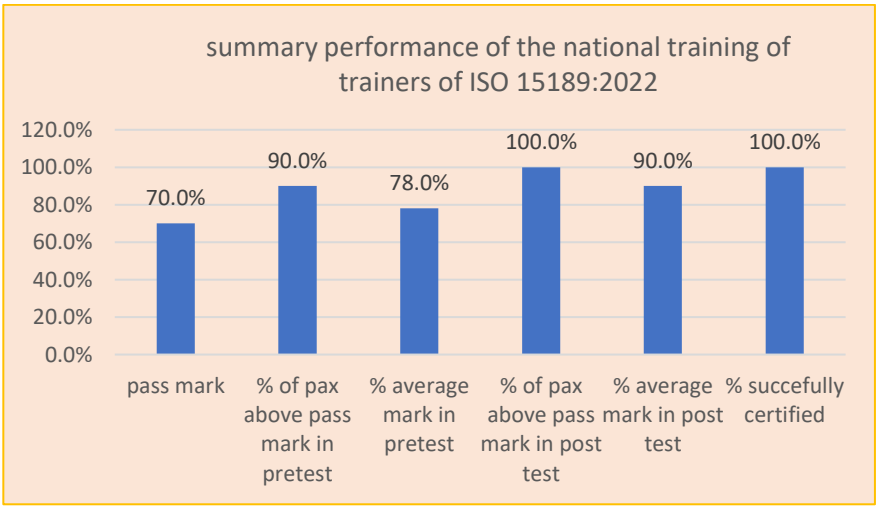

### 13.1.2 Infectious Diseases Institute: Conduct ISO 15189:2022 training for selected auditors and mentors

With the release of ISO 22367:2020 and ISO 15189:2022, new quality management system requirements were introduced which necessitated retraining of IDI - Laboratory Technical Support staff and medical laboratory staff from IDI – supported facilities. This training was aimed at equipping selected participants with knowledge and skills in the implementation of new quality requirements such as risk management and information management.

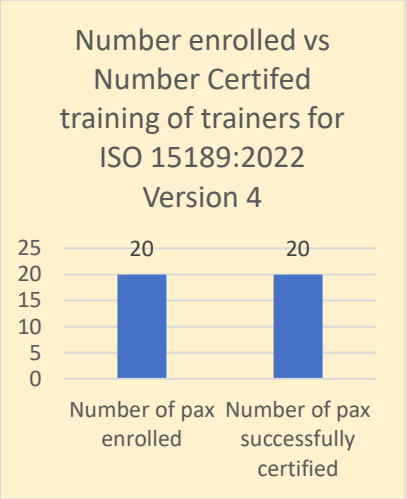
It was against this background that a 2-weeks Trainer of Trainers (TOT) Course was conducted on ISO15189:2022 quality management systems implementation, risk management based on ISO 22367:2020 and Internal Audit. The training was conducted from September 4-15th, 2023.

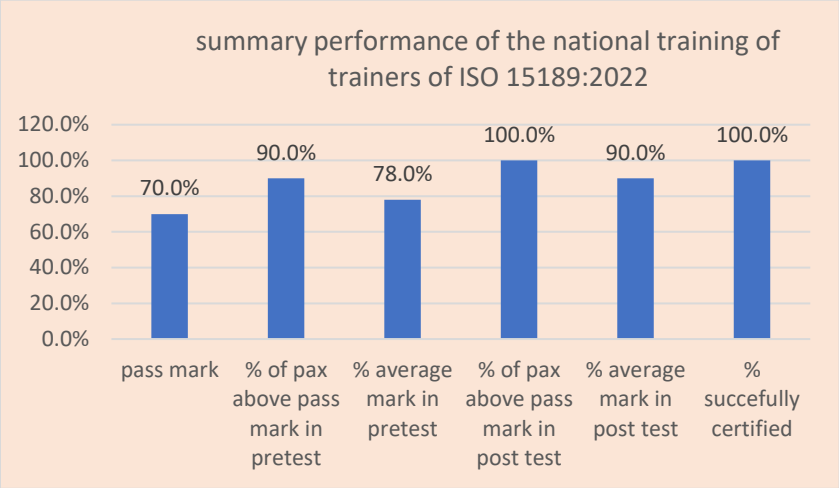
ISO 15189:2023 Class



Audit class

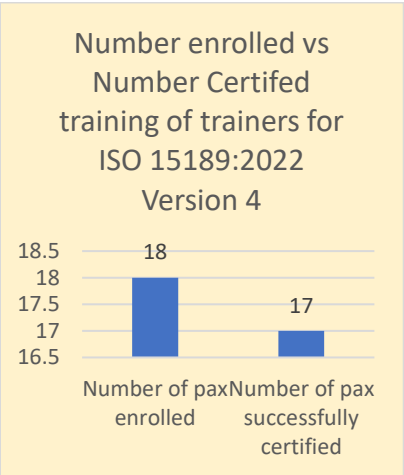


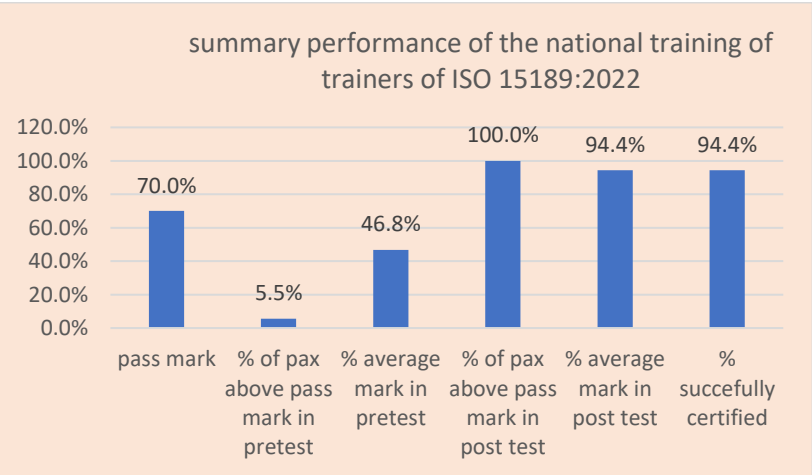




### 12.2.8 Conducted ISO 15189:2022 and risk management training for Lubaga Hospital Laboratory

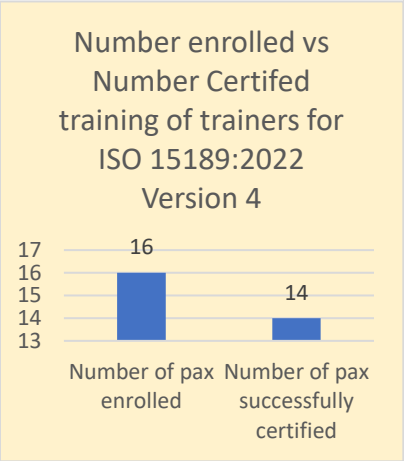
Lubaga Hospital Laboratory is accredited to ISO 15189:2022 an following the publication of the new version of the standard, the laboratory sought to begin on the transition of its management system by training all its staff on the new standard. The training was spread over 2 weeks to allow staff to work in shifts while others studied and hence the two cohorts. The training was aimed at providing knowledge and skills in the implementation of a Quality Management System which meets the requirements of ISO 15189:2022 and implementation Risk Management in a medical laboratory according to ISO 22367:2020

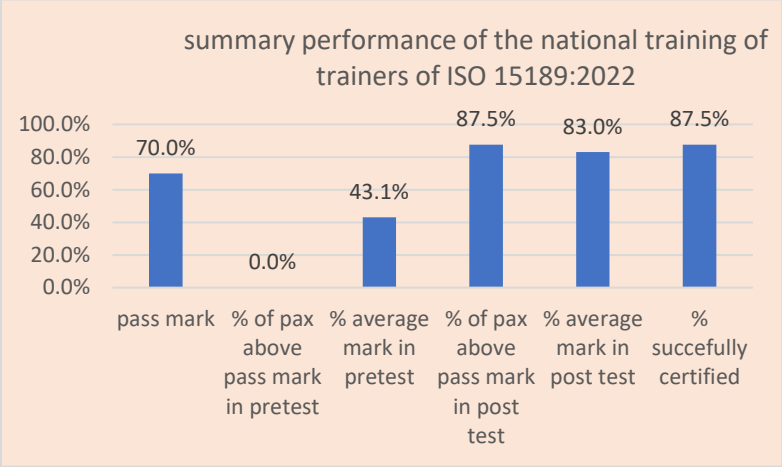
### LHL Cohort 1 performance



## LHL Cohort 2 performance

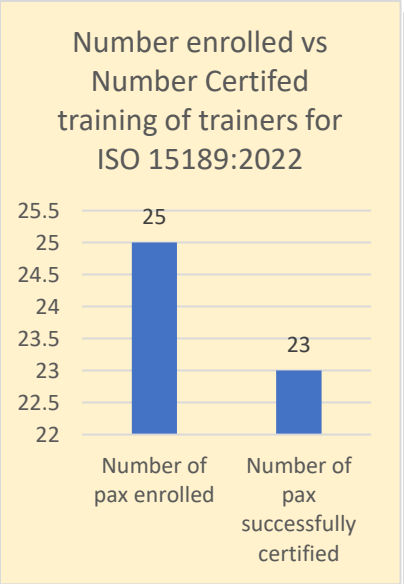


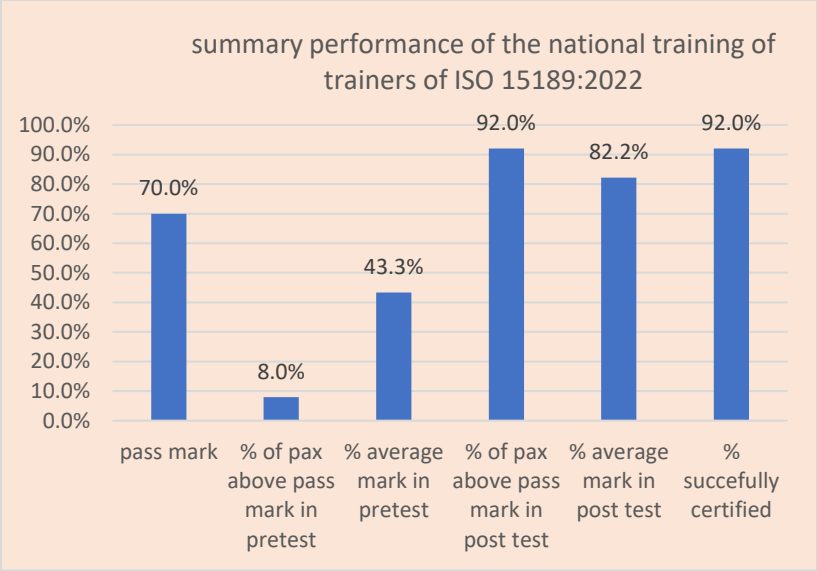




### 12.2.9 Conducted ISO 15189:2022 and risk management training for Nakasero Hospital Laboratory

Nakasero Hospital Laboratory is in the process of preparing for accreditation accredited to ISO 15189:2022. The laboratory staff were initially all trained on ISO 15189:2012 but following the publication of the new version of the standard(ISO 15189:2022), the laboratory change the management system and align to the new standard and hence the need for this training. The training was spread over 2 weeks to allow staff to work in shifts while others studied and hence the two cohorts. The training was aimed at providing knowledge and skills in the implementation of a Quality Management System which meets the requirements of ISO 15189:2022 and implementation Risk Management in a medical laboratory according to ISO 22367:2020

## NHL performance



## Partnerships

| Partner name | Nature of partnership |
|---|---|
| NHLDS | Regulator of technical assistance programs |
| Joint Clinical Research Centre | Prime for SPHLS project |
| Infectious Diseases Institute | Prospective Laboratory technical assistance program |
| QualExpect Consulting Services | Technical Expertise in areas of Training of trainers, implementors courses and audits. |
| Geiten | supplies |
| PECB | PECB is a certification body in 150 countries that provides education, certification, and certificate programs for individuals on a wide range of disciplines. |

## New Partnership

**Biolabs Red Services entered into agreement with PECB-**a certification body that provides education, certification, and certificate programs for individuals on a wide range of disciplines.

Through our presence in more than 150 countries, we help professionals demonstrate their competence in various areas of expertise by providing valuable evaluation, certification, and certificate programs against internationally recognized standards.

The value of PECB certifications is validated by the accreditation from the International Accreditation Service (IAS-PCB-111), the United Kingdom Accreditation Service (UKAS-No. 21923), and the Korean Accreditation Board (KAB-PC-08) under ISO/IEC 17024 – General requirements for bodies operating certification of persons. The value of PECB certificate programs is validated by the accreditation from the ANSI National Accreditation Board (ANAB-Accreditation ID 1003) under ANSI/ASTM E2659-18, Standard Practice for Certificate Programs.

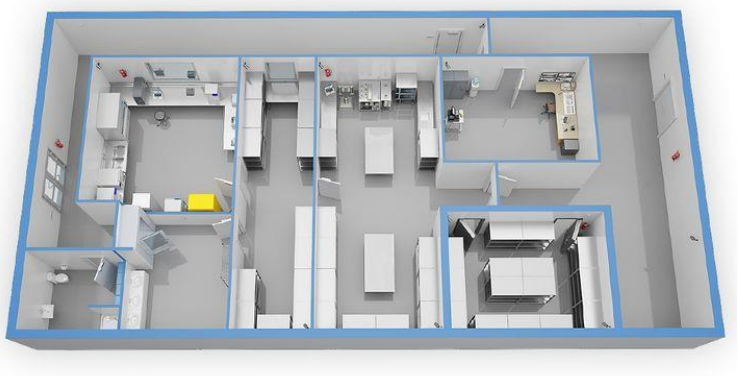
PECB is an associate member of The Independent Association of Accredited Registrars (IAAR), a full member of the International Personnel Certification Association (IPC), a signatory member of IPC MLA, and a member of Club EBIOS, CPD Certification Service, CLUSIF, Credential Engine, and ITCC. In addition, PECB is an approved Licensed Partner Publisher (LPP) from the Cybersecurity Maturity Model Certification Accreditation Body (CMMC-AB) for the Cybersecurity Maturity Model Certification standard (CMMC), is approved by Club EBIOS to offer the EBIOS Risk Manager Skills certification, and is approved by CNIL (Commission Nationale de l'Informatique et des Libertés) to offer DPO certification.

## New scope of work

- Global Health Security


- Continuous Quality Improvement
- Good Clinical Laboratory Practice and Good Clinical Practice training, inspection and certification


- Biomedical and Public Health Research
- Interlaboratory comparison design, implementation and monitoring
- Laboratory plan and design and construction

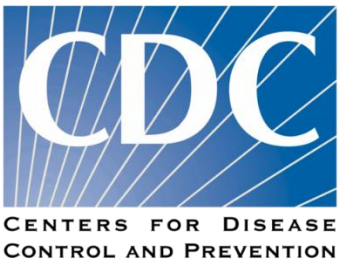


- Equipment management systems and medical distributorship
- PECB certification of trainings

## Clients


THE REPUBLIC OF UGANDA
UVRI
UGANDA VIRUS RESEARCH INSTITUTE


FOR GOD AND MY COUNTRY
THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH


CDC
CENTERS FOR DISEASE
CONTROL AND PREVENTION


Rakai Health
Sciences Program
Improved Health Through Research


Uganda
Catholic
Medical
Bureau


JCRC


MAKERERE UNIVERSITY
IDI
INFECTIOUS
DISEASES
INSTITUTE


UGANDA PRISONS SERVICE


BAYLOR
COLLEGE OF
MEDICINE
Children's
Foundation
UGANDA


USAID
FROM THE AMERICAN PEOPLE


Tigris & Etho Associates


LUBAGA HOSPITAL
SERVICE WITH LOVE


OUR LADY OF CONSOLATA
KISUBI HOSPITAL
Service with love


QualExpect
CONSULTING SERVICES


UGANDA
UPDF

## Statement of financial position

# Bio-Labs Red Services

Annual report and financial statements for the year ended September 30, 2023

**Statement of Profit or Loss and Other Comprehensive Income**

| | Note(s) | 2023 USh '000 | 2022 USh '000 |
|---|---|---|---|
| Revenue | 3 | 815,430 | 566,502 |
| Direct Costs | 4 | (289,422) | (136,734) |
| **Gross profit** | | 526,008 | 429,768 |
| Other operating expenses | 5 | (525,382) | (429,240) |
| **Operating profit** | | **626** | **528** |
| Finance cost and finance income - net | 6 | (626) | (528) |
| **Profit before taxation** | | - | - |
| Taxation | 7 | - | - |
| **Profit for the year** | | - | - |
| Other comprehensive income | | - | - |
| **Total comprehensive profit for the year** | | - | - |

The notes on pages 11 to 24 form an integral part of the financial statements.

## Statement of Financial Position

| | Note(s) | 2023 USh '000 | 2022 USh '000 |
|---|---|---|---|
| **Assets** | | | |
| **Non-Current Assets** | | | |
| Property, plant and equipment | 10 | 4,400 | 11,329 |
| Deferred tax | 11 | - | - |
| Other Assets | 12 | - | - |
| | | **4,400** | **11,329** |
| **Current Assets** | | | |
| Inventories | 13 | - | - |
| Trade and other receivables | 14 | 18,030 | 10,756 |
| Cash in hand and at bank | 15 | - | 2 |
| | | **18,030** | **10,758** |
| **Total Assets** | | **22,430** | **22,088** |
| **Equity and Liabilities** | | | |
| **Equity** | | | |
| Share capital | 16 | 10,000 | 10,000 |
| Retained earnings | | - | - |
| | | **10,000** | **10,000** |
| **Liabilities** | | | |
| **Current Liabilities** | | | |
| Trade and other payables | 17 | 12,429 | 12,088 |
| Current tax payable | 18 | - | - |
| | | **12,429** | **12,088** |
| **Total Liabilities** | | **12,429** | **12,088** |
| **Total Equity and Liabilities** | | **22,429** | **22,088** |

The financial statements on pages 7 to 24, were approved by the board of directors on 20 Jan 2024 and were signed on its behalf by:

Director _____

The notes on pages 11 to 24 form an integral part of the financial statements.

BIOLABS RED SERVICES
OPERATIONS DEPARTMENT
18 MAR 2024
"Healthier Generations"
P.O. BOX 27901, K'LA (U)