THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

National Health Laboratory & Diagnostic Services

Setting up and Running a Sustainable National Equipment Maintenance and Calibration Centre: Ugandan Experience

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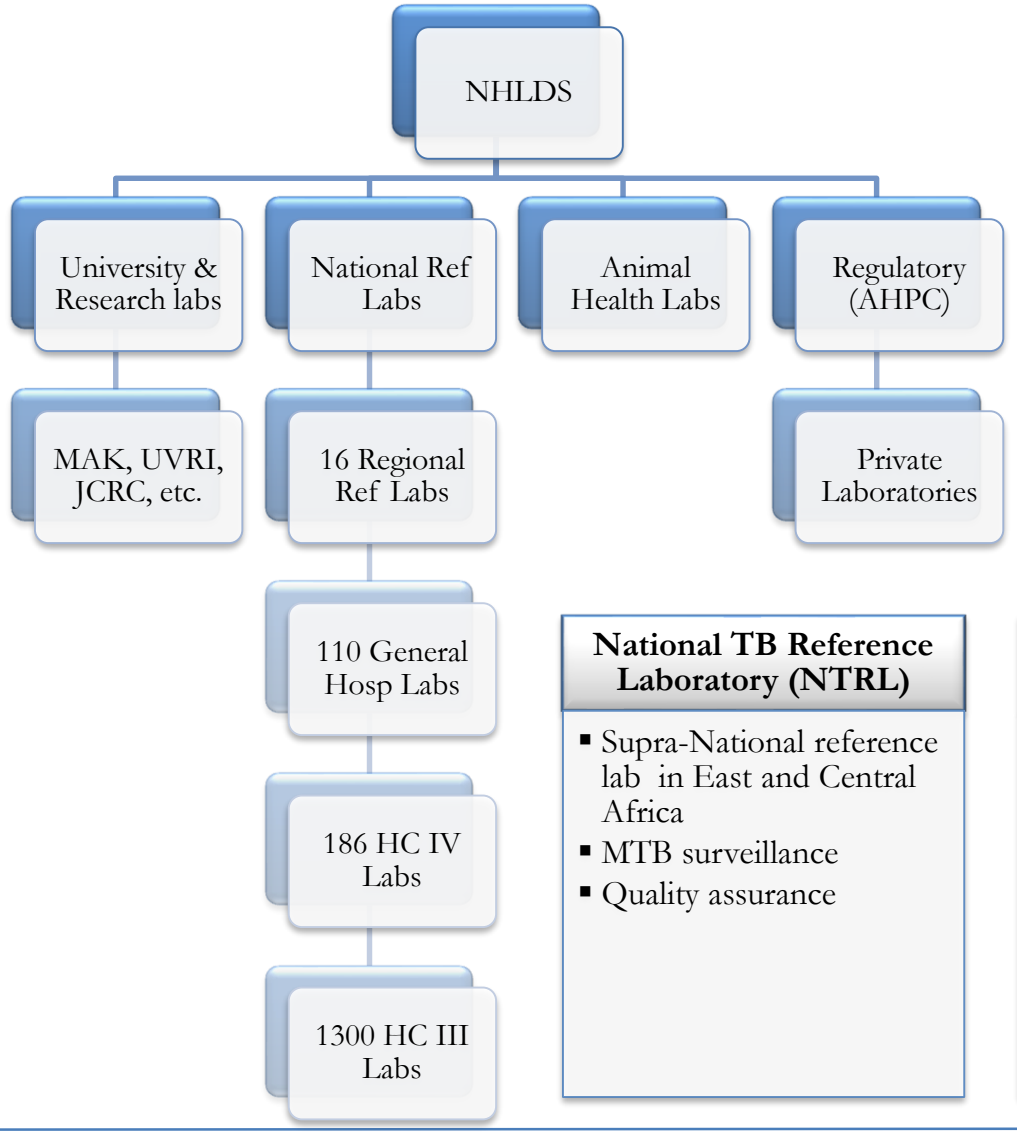
Commissioner, NHLDS

Public & Private Tiered Laboratory & Diagnostics Network



NHLDS ~department under the Directorate of Public Health of the Ministry of Health

Major functions

- Stewardship and Management of the Laboratory systems in Uganda
- Provision of specialized reference testing; the National reference laboratories include; CPHL , NECL and NTRL

National TB Reference Laboratory (NTRL)

- Supra-National reference lab in East and Central Africa
- MTB surveillance
- Quality assurance

Central Public Health Laboratories (CPHL)

- Clinical Molecular Reference lab
- National Microbiology Reference Laboratory
- Genomics reference lab
- Malaria reference lab
- Diagnostic Evaluation lab
- National Biorepository

National Equipment Calibration Centre

- Calibration of Auxiliary Lab Equipment
- Certification of Biosafety Cabinets
- Laboratory Equipment Maintenance
- In-service Training

Quality Assurance Laboratory

- HIV EID EQA
- HIV Viral load EQA
- Serum Crag EQA
- TB EQA
- Microbiology/AST EQA
- Malaria EQA

Background

Embraced the Maputo Declaration-2008

- Automated Lab Equipment harmonization
- Management of maintenance and service contracts
- Developed policies, guidelines and strategies

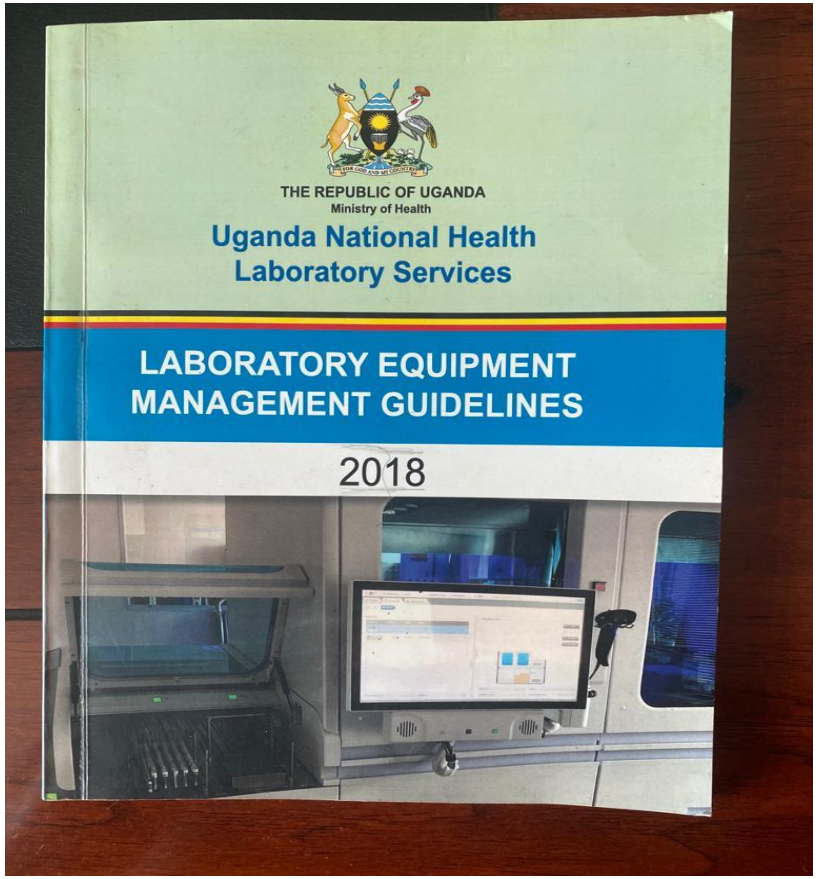
As such, there has been significant transformation in the laboratory which has seen over 70 laboratories attain ISO accreditation.

THE APPROACH TO A ROBUST EQUIPMENT MAITENANCE PROGRAM

- Recruitment of Biomedical Engineers
- Carried out needs assessment.
- Equipped them with the necessary tools.
- Developed training curriculum and materials based on the identified training needs
- Offered targeted training
- Developed equipment maintenance guidelines
- Established the National Equipment Calibration Centre

EQUIPMENT MAINTENANCE GUIDELINES

1. Procurement
2. Installation and commissioning
3. Operation and maintenance
4. Decommissioning
5. Disposal



The National Equipment Calibration Centre

- It was established in 2017 to address the ever increasing costs for equipment, Maintenance, Calibration, Biosafety cabinet certification and Training and to reduce the over reliance of out sourced services

The Center consists of four units;

1. The National Equipment Calibration Lab (Equipment calibration)
2. The National Biosafety Cabinet Certification section (BSC certification)
3. The Lab Equipment workshop (Equipment maintenance and repair)
4. The training and mentorship section (Training and Capacity building)

The Process

- Baseline assessment.
- Infrastructure improvement.
- Equipment procurement.
- Mandatory training.
- SOP development
- Pre-accreditation assessment

The Calibration-Lab

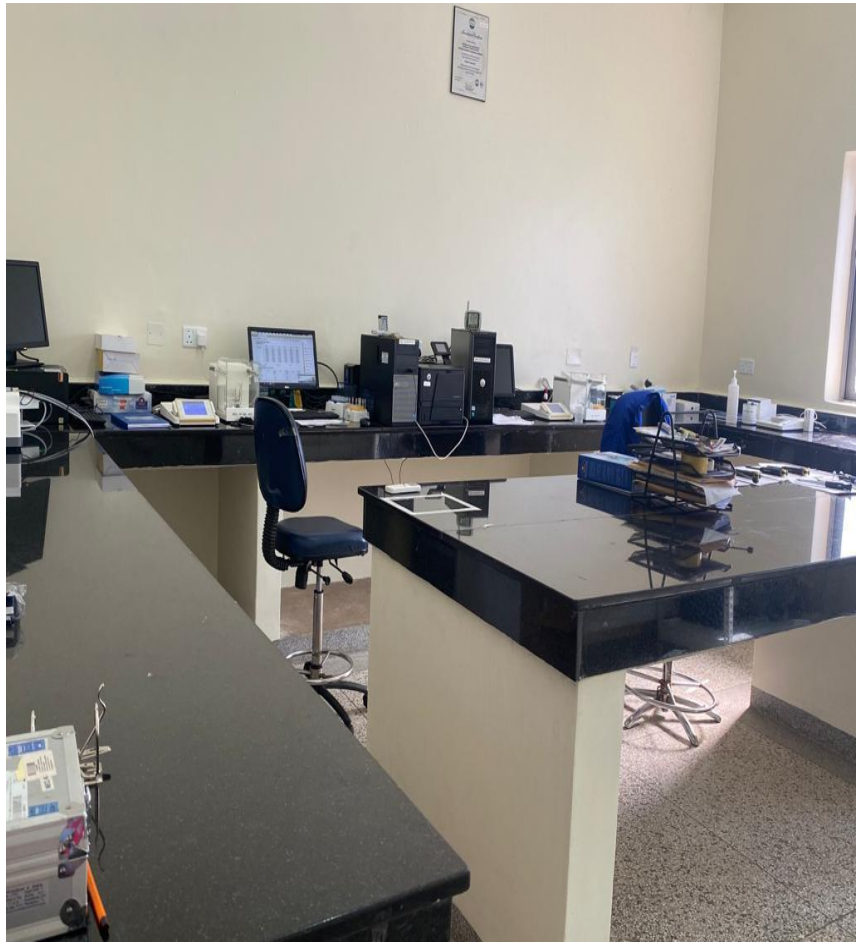
It attained ISO 17025:2017 accreditation in 2020 with the underlined scope

- Volume- Pipettes and glass ware
- Speed- Rotational speed like centrifuges, shakers
- Mass- Analytical balances and mass pieces
- Temperature- Thermometers and conditioned chambers
- Time- Timers, stop watches and clocks
- Humidity- Thermo hydrometers, hygrometers

Later added on

- PH- PH meters
- Pressure- Gauges

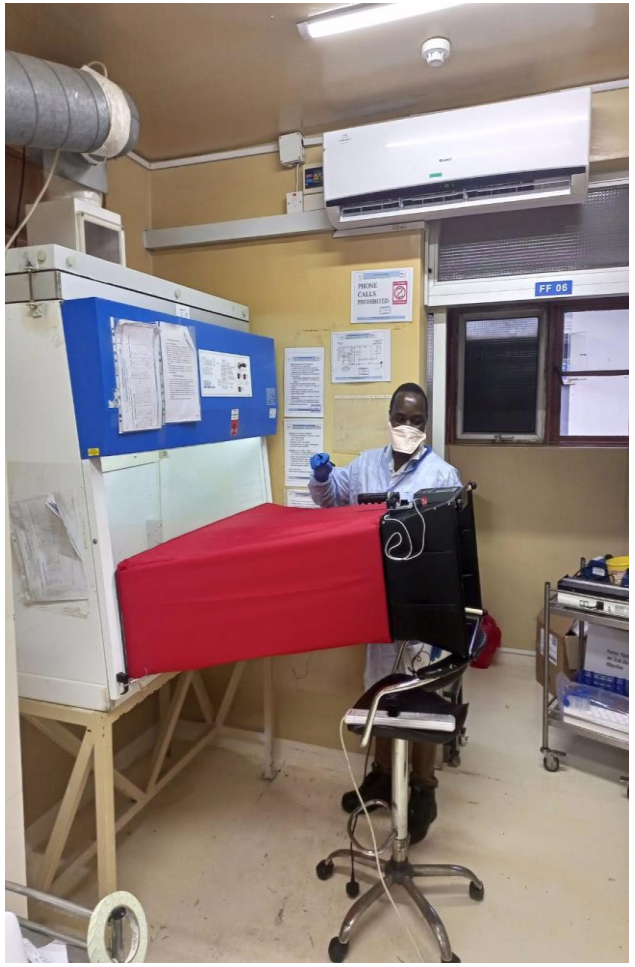
CALIBRATION LAB



2. BIOSAFETY CABINET CERTIFICATION UNIT

- 8 trained Biomedical Engineers with 4 NSF accredited engineers
- Responsible for certification of biosafety cabinets and containment room
- Training of lab personnel on proper use and first line maintenance

BIOSAFETY CABINET UNIT



3. LAB EQUIPMENT MAINTENANCE WORKSHOP

- Service and repair of Laboratory equipment
- Together with 16 regional workshops, the service is done across the country.

4. TRAINING AND MENTORSHIP UNIT

- Training curriculum developed and approved by NCDC
- Train and mentor in service engineers on equipment maintenance
- Train equipment users on proper use and first line maintenance of equipment

CD/2019/026

NCDC
NATIONAL CURRICULUM DEVELOPMENT CENTRE

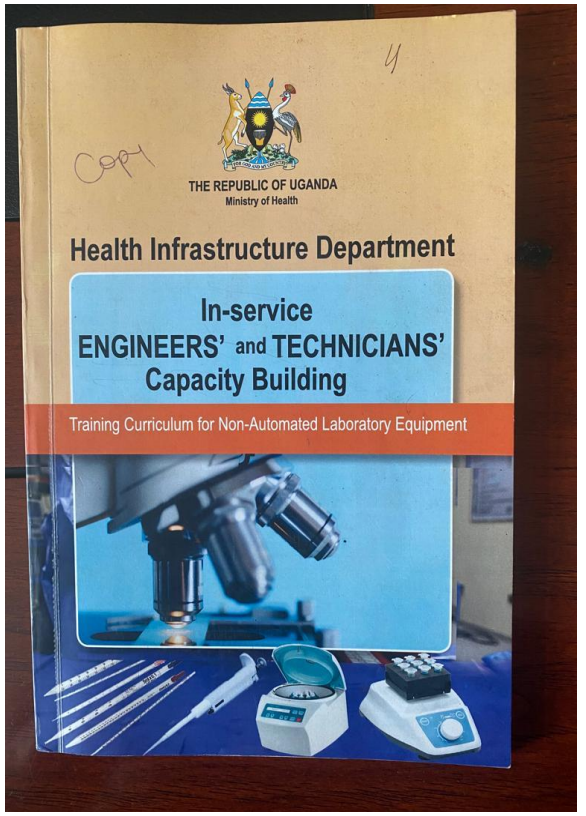
Certificate of Approval

This is to certify that this material:
Curriculum for In-service Engineers and Technicians' Capacity Building in Laboratory Equipment

By: Ministry of Health – Health Infrastructure Division

has been evaluated by National Curriculum Development Centre and deemed appropriate for use at Tertiary Level.

Signed
DIRECTOR
NCDC



TRAINING AND MENTORSHIP UNIT

CALIBRATION CENTER CAPACITY

- **Personnel**
- 12 Trained Engineers in equipment maintenance and repair of automated and non automated laboratory equipment
- 12 Trained Engineers in Calibration of non automated laboratory equipment
- 9 Trained TOT with 2 certified by KTTC

CALIBRATION CENTER CAPACITY

- **Equipment**
- 5 sets of Biosafety cabinet certification tools
- 5 sets of Refrigeration kits
- Customized tool kits for laboratory equipment maintenance
- Training aids and equipment
- Training facility in terms of space

OUR CLIENTS

- All Ministry of Health facilities
  - National Referral Hospitals
  - Regional Referral Hospitals
  - General Hospitals
  - Health Center IVs
  - Health Center IIIs
- Research Institutes/Laboratories
  - Medical
  - Veterinary
  - National water Laboratories
- Private Not for Profit and Private for profit H

Metrological Traceability and Interpretation of Calibration results

Equipment calibration and metrological traceability

- Clause 6.5.1 of ISO 15189:2022 states that: “The laboratory shall specify calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results”

6.5.2 The laboratory shall have procedures for the calibration of equipment that directly or indirectly affects examination results. The procedures shall specify:

- a) conditions of use and manufacturer's instructions for calibration;
- b) recording of the metrological traceability;
- c) verification of the required measurement accuracy and the functioning of the measuring system at specified intervals;
- d) recording the calibration status and date of re-calibration;
- e) ensuring that, where correction factors are used, these are updated and recorded when recalibration occurs;
- f) handling of situations when calibration was out of control, to minimize risk to service operation and to patients.

How facilities request

- A request form detailing
- The client address, contact person,
- Details of equipment for calibration as well as the preferred measurement points
- The Date of request
- For equipment calibrated at the calibration Lab, the request form is sent along with the equipment
- For those that are calibrated at the client's facility, the request is verified while at site.

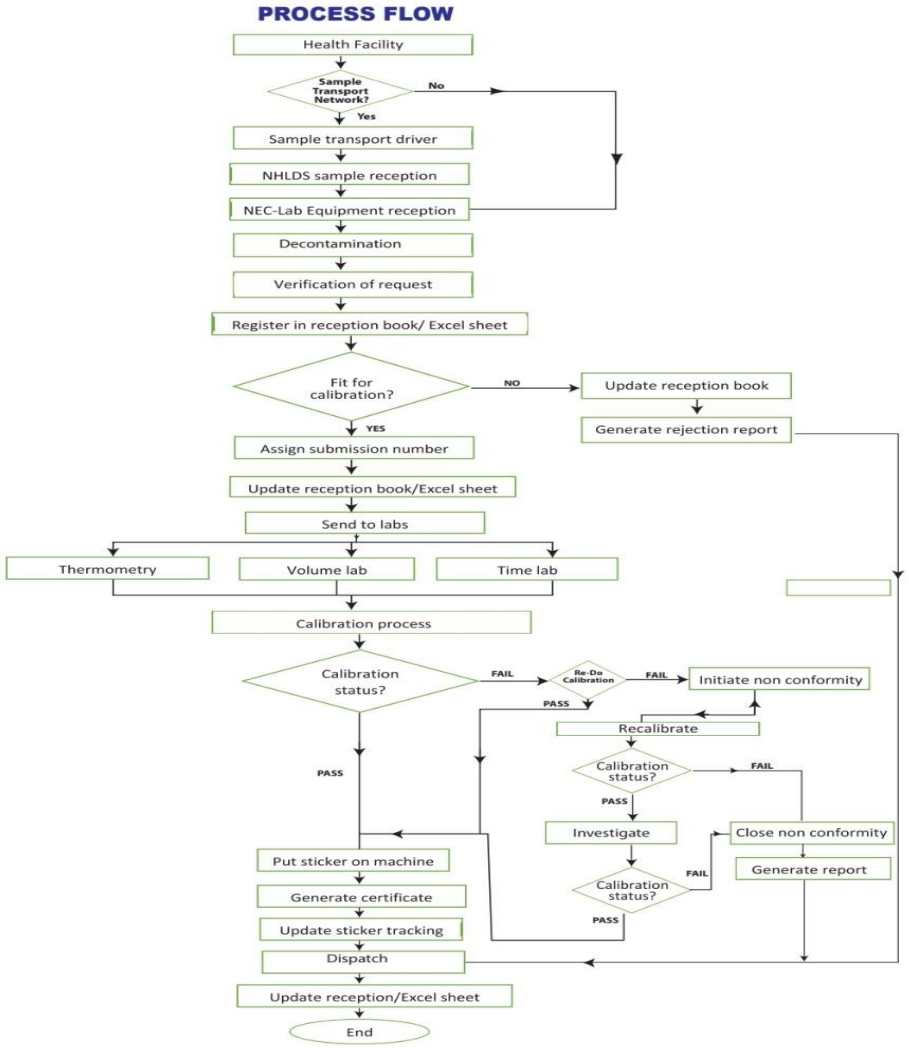
How equipment is received(Uganda)

- Request is made to the Technical Manager
- A request formed is filled
- For equipment being sent, the sample transport network is used to deliver the items while for those at the facility, the date for the visit is agreed upon
- After calibration, a sticker and certificate/report is generated as per clause 7.8 of ISO 17025:2017

NATIONAL HEALTH LABORATORY AND DIAGNOSTICS SERVICES (NHLDS)
Plot 106-1062-, Butabika Road, Kampala
Email: cphlug@gmail.com , Tel: Toll free: 0800221100

NEC-Lab
"A CENTER OF TRUST"

NHLDS ENGINEERING DEPARTMENT
NATIONAL LABORATORY EQUIPMENT CALIBRATION AND TRAINING CERTIFICATION AND TRAINING CENTER (NLECC)
Email: nleccug@gmail.com, Tel: +256 703 771 631



INTERPRETATION OF CALIBRATION RESULTS

- **Calibration certificates/ reports**
- **Biosafety cabinet reports**

Calibration certificate

Identification

- Calibration Laboratory
- Client
- Equipment

Metrological traceability

- Equipment
- Personnel
- Calibration procedure
- Result including units and uncertainty

Result interpretation

- The true value- the expected value
- The Unit under test value- value read by the equipment under calibration
- The correction- Value added to the reading to obtain a true value
- The uncertainty- the range of doubt for performance of equipment.

Note: These are used during the verification of equipment after calibration

Calibration Certificate

NEC-Lab
"A CENTER OF TRUST"

KENAS ilac-MRA

National Health Laboratory and Diagnostics Services (NHLDS)-P.0.BOX 7272, Kampala
National Equipment Calibration Laboratory (NEC-Lab)Plot 106-1062, Butabika Road
Email: nleccug@gmail.com Toll Free Line: 0800221100, Tel: 0703771631

CALIBRATION CERTIFICATE

CUSTOMER NAME	: Bududa General Hospital
DISTRICT	: Bududa
CONTACT PERSON	: 0789089471-Lab Manager
SECTION	: Main Lab
EQUIPMENT NAME	: Fridge
MANUFACTURER	: Arctiko
MODEL/TYPE	: BBR300
SERIAL NUMBER	: 1117077
ID NUMBER	: BHL/EQ/126
DATE OF RECEIPT	: 29-May-2024
SUBMISSION NUMBER	: FR202405-053
PLACE OF CALIBRATION	: Bududa General Hospital-Main Lab
DATE OF CALIBRATION	: 29-May-2024
CERTIFICATE NUMBER	: NEC-Lab/CC/FR/202405-049
STICKER NUMBER	: 004485

1.0 STANDARDS/ EQUIPMENT USED

1.1	Equiopment Name	: Multichannel TC Thermometer
1.2	Serial Number	: H399570
1.3	ID Number	: NECL-TE-THR-015
1.4	Certificate Number	: KEBS/MET/4/3/135/102
1.5	Traceability	: The measurements are traceable to the SI Unit through KEBS
1.6	Environmental Monitoring	: NECL-TE-HGM-002

2.0 CALIBRATION PROCEDURES

2.1	Procedure	: NECL-TM-005 Procedure Calibration of chambers
2.2	Method Used	: Comparison
2.3	Reference Document	: NECL-EXT-018 HKAS Information Notes No.3 Guidance on calibration and performance verification of tempereture chambers (Calibration of conditioned Chambers),NECL-EXT-027 Guidelines on the calibration of Temperature and/or Humidity controlled enclosures

Calibrated by:	Johnson Kuruga	Date: 29-May-2024
Reviewed by:	Omar Muballe	Date: 29-May-2024
Approved and Issued by:		Date:

Director Equipment/Authorised officer

Ver 3.1

3.0 CALIBRATION RESULTS

3.1 Summary of the calibration results is as below

Set Temperature(°C) 4 °C

	UUT READING	4.0	4.0	4.0	4.0	4.0	AVG
TOP	LEFT	4.4	4.5	4.3	4.6	4.5	4.5
	MIDDLE	4.3	4.0	4.1	3.9	3.8	4.0
	RIGHT	4.0	4.3	4.5	4.5	4.5	4.4
MIDDLE	LEFT	4.8	4.8	4.5	4.3	4.5	4.6
	MIDDLE	4.6	4.4	4.5	4.5	4.5	4.5
	RIGHT	4.7	4.8	4.6	4.6	4.7	4.7
BOTTOM	LEFT	3.9	3.8	4.0	4.1	4.2	4.0
	MIDDLE	4.1	4.5	4.7	4.6	4.7	4.5
	RIGHT	4.4	4.5	4.6	4.5	4.3	4.5
						AVG IN WHOLE CHAMBER	4.4
						AVERAGE ERROR	0.4

3.2 In order to get the actual temperature value, add the correction value to the indicated reading
Correction Factor (°C) 0.4

3.3 The uncertainty in measurement is ± (°C) 0.5

3.4 The reported uncertainty is reported as an expanded uncertainty which was multiplied by a coverage factor of k=2, which gives a confidence level of approximately 95%.

4.0 ENVIRONMENTAL CONDITIONS

4.1 During the calibration, the environmental conditions were monitored and recorded.

4.2 Temperature(°C) At Start 26 At End 26

4.3 Relative Humidity(%) At Start 62 At End 62

5.0 REMARKS

5.1 Status Passed

5.2 Close doors well when operational

6.0 VALIDITY

6.1 This certificate is valid till May-2025

END

Calibration certificate without a signature and official stamp is not valid. This certificate has been issued without any alterations and may not be reproduced without a written approval from NHLDS. All results contained within this certificate relate only to the item(s) calibrated as received. A number of factors may cause the calibrated items to drift out of calibration before the end of validity period. If undelivered, please return to above address.

Page 2 of 2

Making use of the Values on the Certificate

- Correction Value to be stuck on the machine for easy identification
- Uncertainty Value used to calculate the acceptable working range of the equipment on return into service.

Next session:

- How to perform verification
- Interpretation of Biosafety Cabinet certification certificate

THANK YOU

THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

KOFIH

THE GLOBAL FUND

UGANDANS AND AMERICANS
IN PARTNERSHIP TO FIGHT HIV/AIDS
PEPFAR

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

JCRC
Joint Clinical Research Centre

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

ACKNWOLEDGEMENT

THANK YOU