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"Pathology Laboratory Quality Management System for Effective Detection and Diagnosis of Communicable and Non-communicable Diseases

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Presentation Outline

1. Background
2. Effective Diagnosis: accurate, reliable, timely and relevant results
3. Introduction: QMS; QA & QC
4. Five Quality System Essentials to Ensure Effective Detection & Diagnosis
   - Competence Assessment
   - Method validation/verification
   - Internal and External Quality Control
   - External Quality Assessment (EQA)
   - Equipment Selection, Maintenance and Calibration
5. QMS Implementation in Tanzania
6. QMS Challenges
7. Recommendations
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Background

- Have you ever wondered why should a patient have different results from different laboratories on the same condition (communicable and non-communicable diseases)
  - Communicable Disease e.g. HIV, COVID-19: Detectable/not detectable.
  - Non Communicable Disease e.g.DM, HT: Hypo/hyperglycemia; hypo/hypertension
- Physiological variation in human being and animals: Hgt, Wgt, Hgb, BP, RBS
- Immunological variation: Reactive/Non-reactive, Detectable non detectable
- Normal distribution (Normal range/Critical value)
- Standards (Local, National and International)

QMS for effective detection of abnormal ranges (Diseases)

Normal Distribution Vs. Standard Normal Distribution

- A normal distribution is determined by two parameters the mean and the variance.
- A normal distribution with mean of 0 and a standard deviation of 1 is called a standard normal distribution
  - Variance
  - Range
  - Mean
  - Mode
  - Standard Deviation

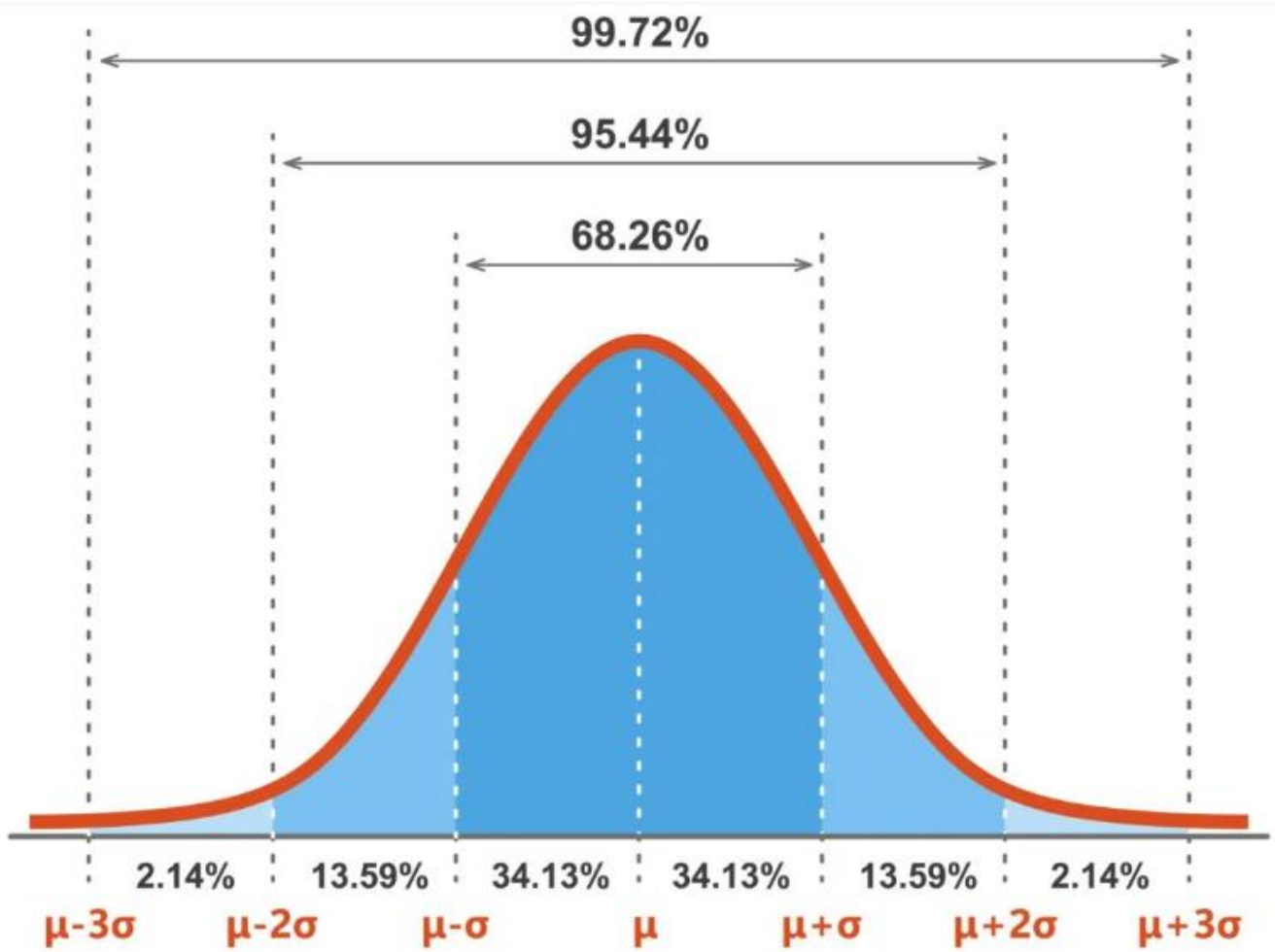


Fig 1: Standard Normal Distribution
Source: https://www.simplypsychology.org/z-score.html

Effective Detection and Diagnosis:

QMS for

- Accurate results
- Precise Results
- Reliable results
- Timely results
- Relevant results

QMS for effective Detection & Diagnosis

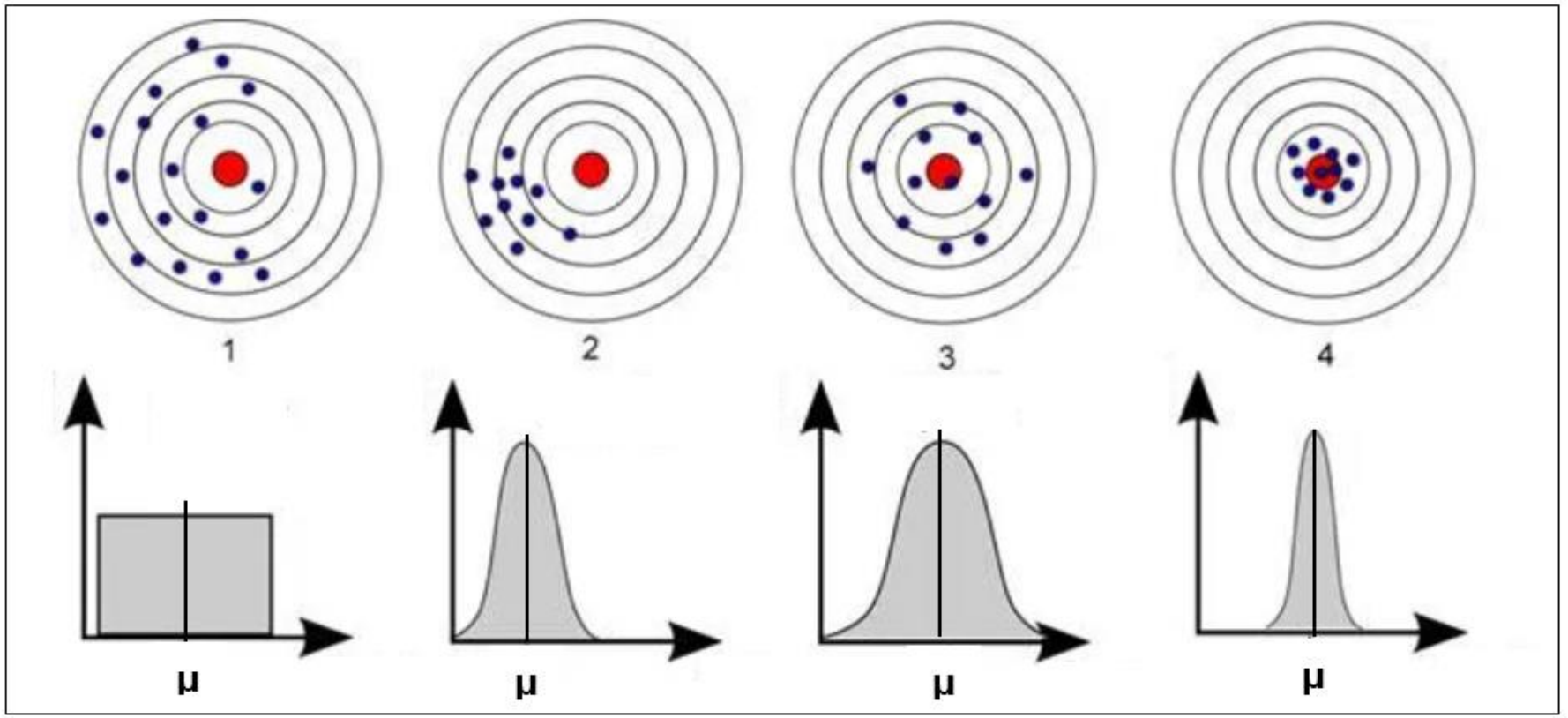


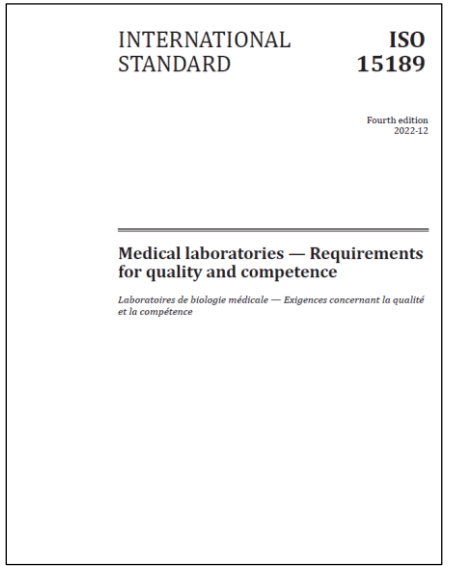
Figure 2: Accurate Vs. Precise Laboratory Results
Source: Modified from www.medium.com

Quality Management System (QMS)…1/2

Standards for QMS Implementation

- **ISO 9001:2015:** Quality Management Systems-Requirements
- ISO 9001:2015 specifies the requirements for a QMS that organizations can use to develop their own programs
- **ISO 17025: 2017**: General requirements for the competence of testing and calibration laboratories
- **ISO 15189:2022**: Medical Laboratories-Requirements for Quality and Compliance.

QMS ~ ISO 9001


INTERNATIONAL STANDARD **ISO 15189**

Fourth edition
2022-12

Medical laboratories — Requirements for quality and competence

Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence

Quality Management System (QMS)…2/2

- A quality management system (QMS) is defined as a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

- A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis

The Quality Management System Model for Laboratory Services (CLSI GP26-A4)

Fig 3: Laboratory Quality Management System for Lab Services (CLSI, 2012)

Quality Management System (QMS), Quality Assurance (QA), and Quality Control (QC) Relationships

Figure 4: QMS, QA & QC Relationship

Quality Assurance (QA)

- Quality assurance: Is part of Quality Management System (QMS) focused on **providing confidence** that quality requirements will be fulfilled.

- All the planned and systematic activities implemented within the quality management system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality."

- The confidence provided by quality assurance is two fold:
  - Internally to management (Laboratory Management; Top Management)
  - Externally to customers, government agencies, regulators, certifiers, and third parties.

Quality Assurance

Quality Assurance (QA) begins and ends with the patient

Quality Assurance Cycle

1. **Pre examination**
2. **Examination**
3. **Post Examination**

Figure 5: Quality Assurance Cycle
Source: www.slideserve.com

Quality Management System (QMS), Quality Assurance (QA), and Quality Control (QC) Relationships

Figure 4: QMS, QA & QC Relationship

Quality Control…1/2

- Quality control (QC) can be defined as "part of *quality management* focused on fulfilling *quality requirements*."
- Quality control is more of the inspection aspect of quality management.
- "The operational techniques and activities used to fulfill requirements for quality."

Quality Control…2/2

- Quality control procedures are performed in a clinical laboratory to help the laboratory ensure that patients results are **reliable** and **correct**:
- Reliability refers to both accuracy and precision
  - **Accuracy**: How close the test is on an average, to patients' true results
  - **Precision**: How close to each other are the tests performed at different times (consistence)
- NOTE: Quality control applies not only to specimen testing, but also to collection, storage and transportation

Quality Management System (QMS)

- Implementation of QMS helps to ensure effective detection & diagnosis of diseases.

- Five laboratory quality management system processes to ensure effective detection & diagnosis of diseases
  1. Competence Assessment
  2. Method validation/verification
  3. Internal and External Quality Control
  4. External Quality Assessment (EQA)
  5. Equipment Selection, Maintenance and Calibration

Quality System Processes and Procedures to Ensure Effective Detection & Diagnosis of Diseases

Figure 6: Essential Quality System Processes & Procedures for Effective Detection and Diagnosis

Competence Assessment

- Competency assessment: any system for measuring and documenting personnel competency.
- The goal of competency assessment is to identify problems with employee performance and to correct these issues before they affect patient care

Competence Assessment

- Training (Competence based curriculum)
  - Knowledge
  - Skills
  - Attitude
- Competence Assessment
  - Observation (especially, results with higher impact on patient)
  - Retest or recheck results
  - Review and analyse (e.g. PT results, QC Records, Worksheet)
  - Quiz (Assess knowledge or problem solving skills)

Example at MoH: CPD / Pre-registration exams

Equipment Selection, Maintenance & Calibration

- Equipment Selection
  - Manual, Semi-automated, Automated
  - Open Vs Closed system
  - Low, Moderate, High volume

- Planed Preventive Maintenance
  - Equipment placement
  - Reagent rent
  - Reagent bundle

- Equipment calibration

- Example at MoH: Equipment Specification / Equipment service contract

Method validation/verification

Equipment/Reagent

- **Validation:** the device meets the needs and requirements of its intended users and the intended use environment
- **Verification:** ensuring that the device meets its specified design requirements

Validation/Verification

- **Quantitative:** Accuracy, precision, Linearity
- **Qualitative:** Sensitivity, Specificity, Predictive value

- **Example at MoH: Equipment Evaluation / Equipment commissioning**

Quantitative

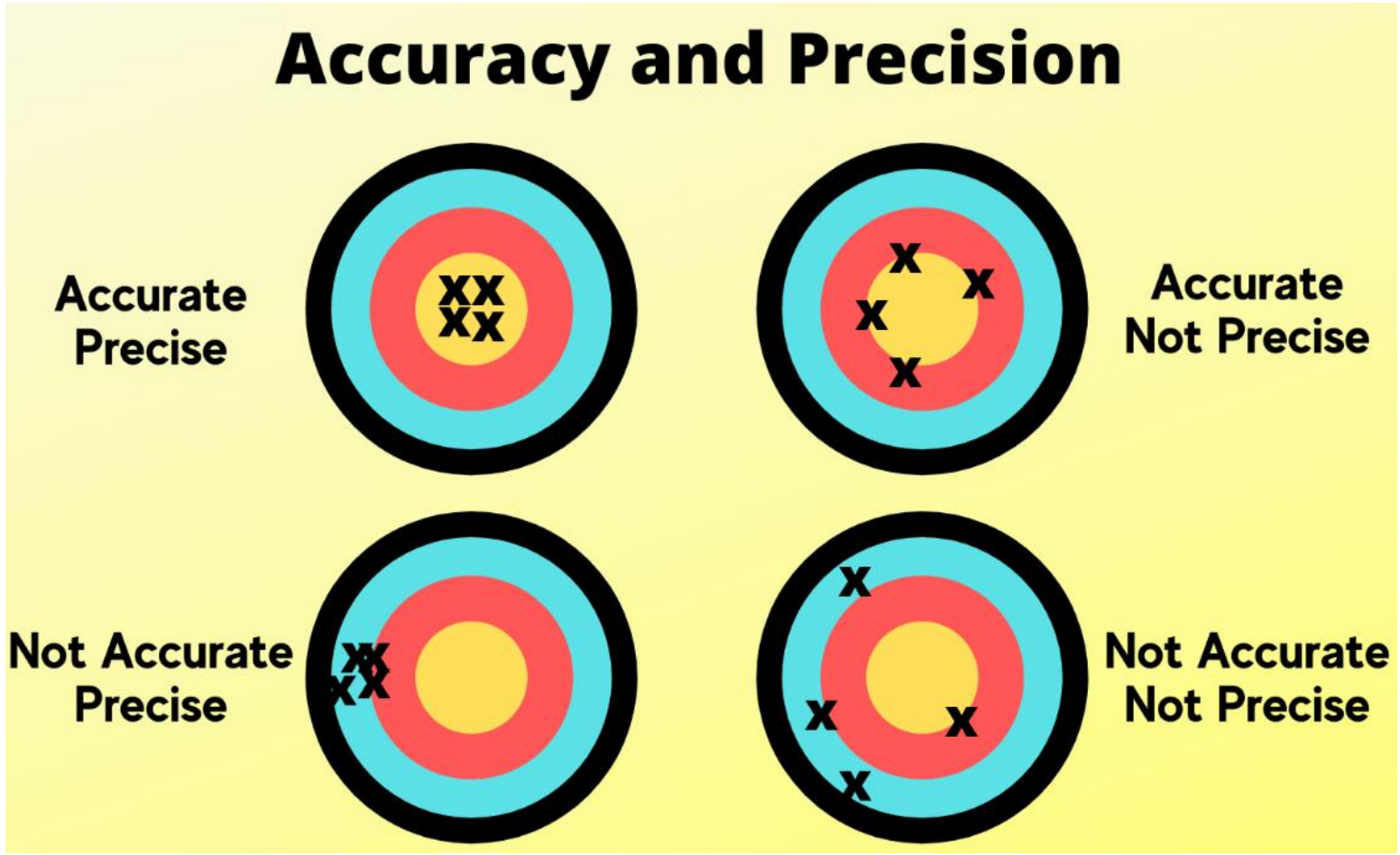


Fig 7: Accuracy and Precision in Quantitative Method validation
Source: www.science.org (Sep. 2023)

Qualitative

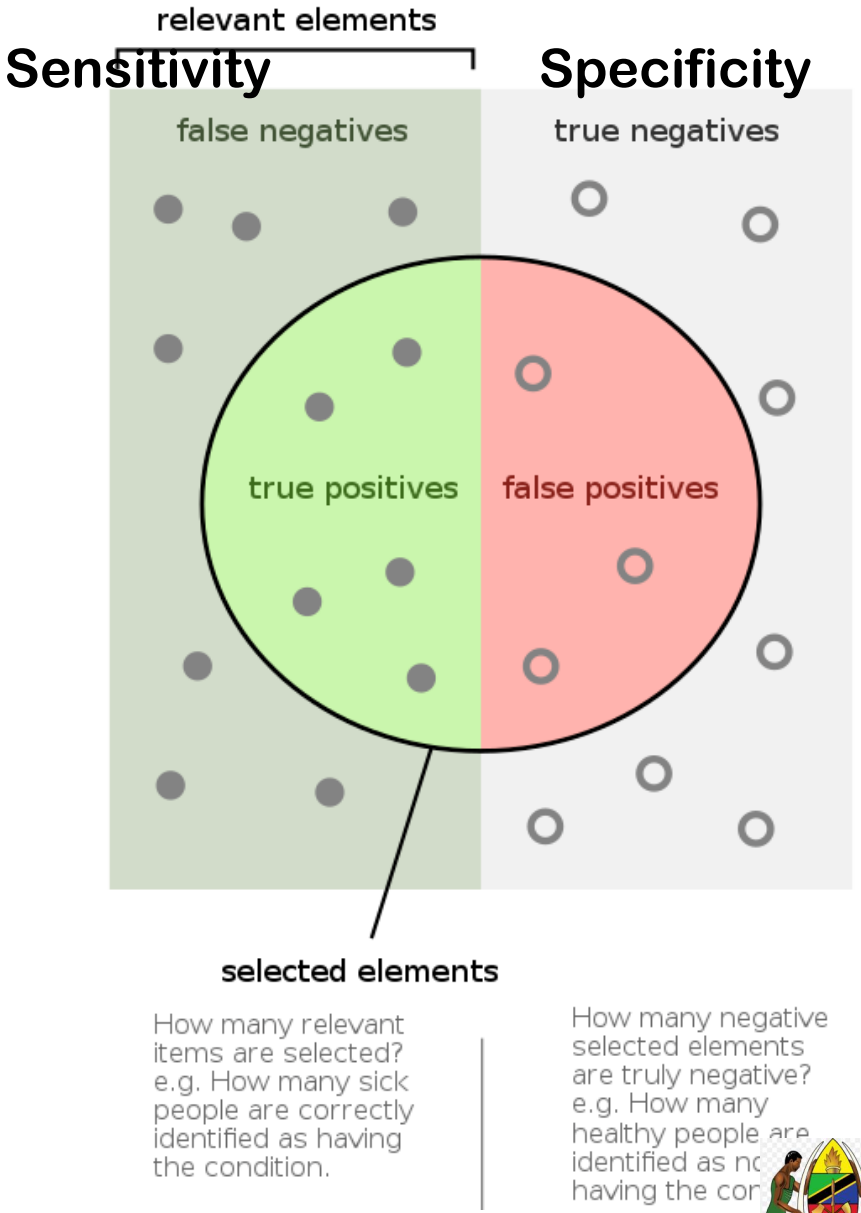


Fig 8: Sensitivity & Specificity-Qualitative Method Validation. Source: en.wikipedia.org

Quantitative

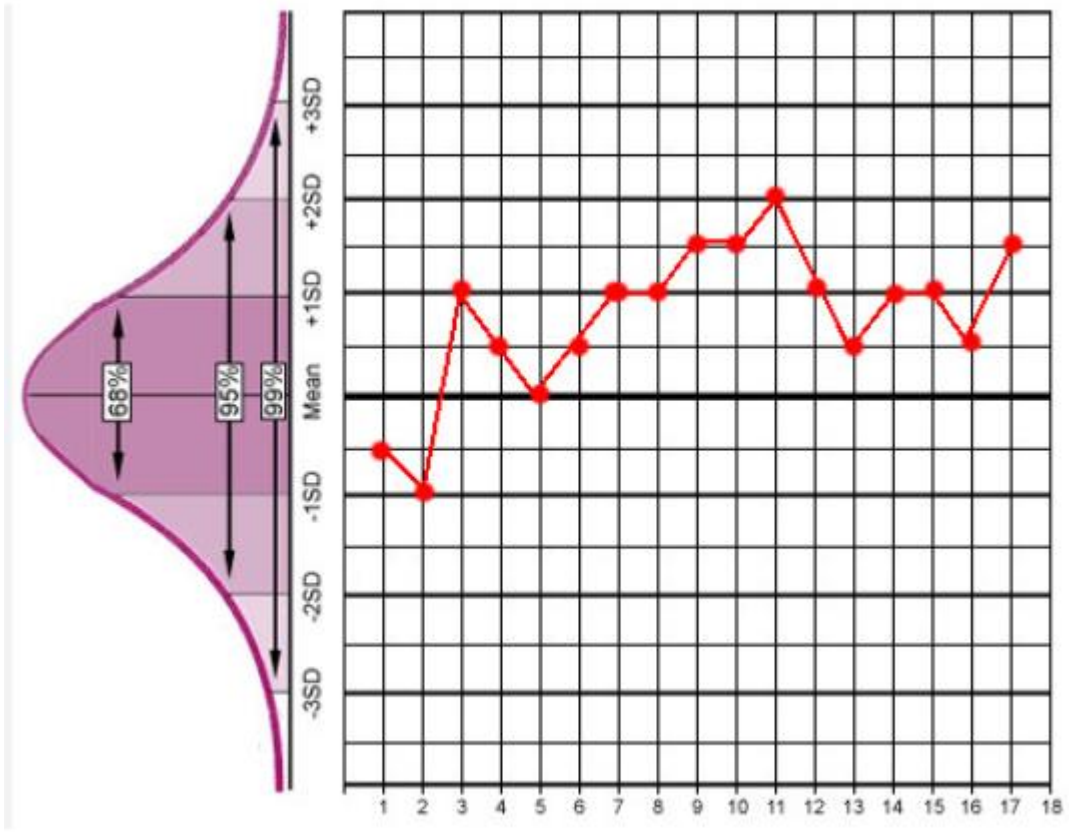


Fig. 9: Levy Jennings Chart Vs Standard Normal Distribution Curve
Source: www.science.org (Sep, 2023)

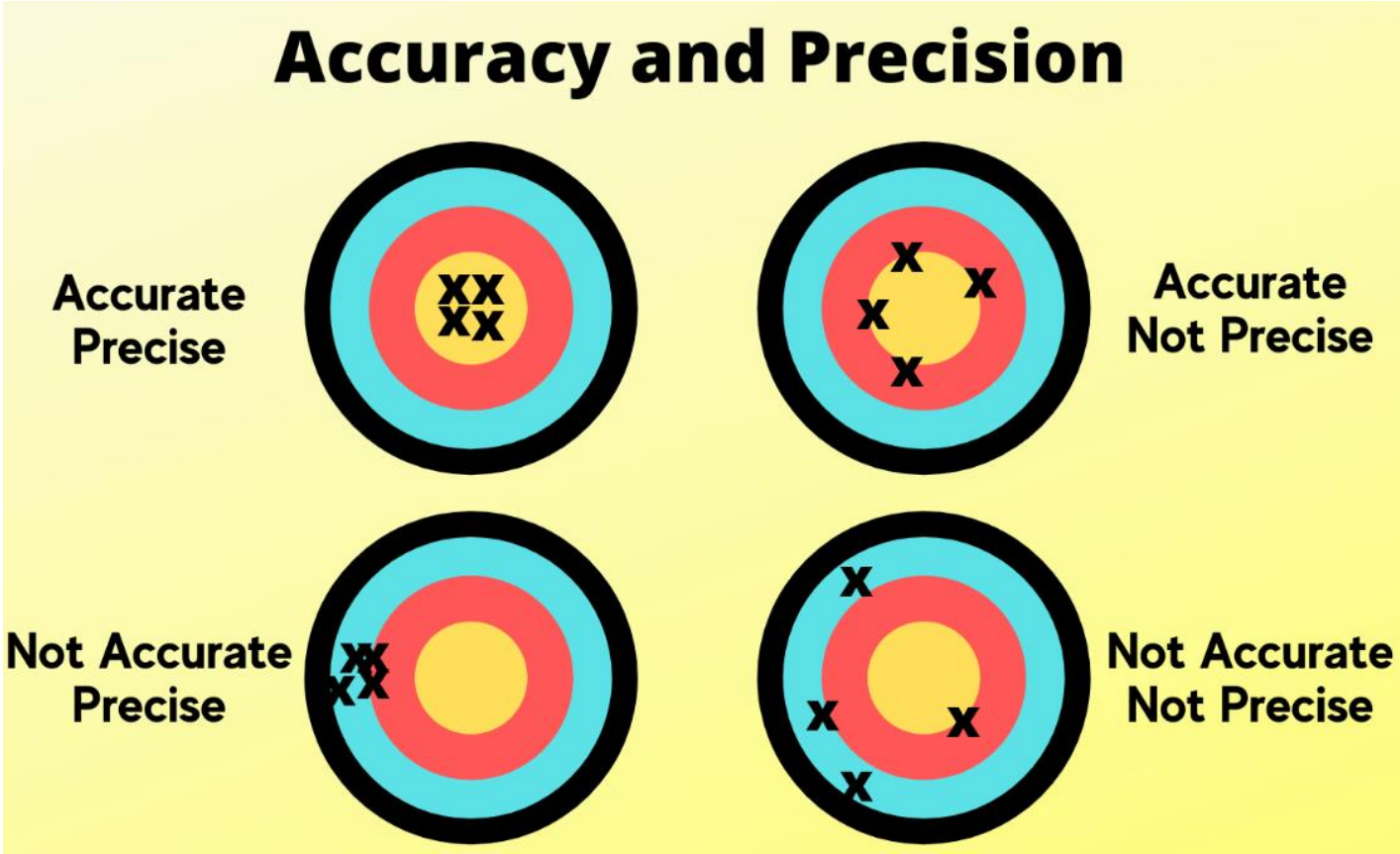


Fig. 10: Accuracy and Precision expressed in Target Diagram
Source: en.wikipedia.org (Sep, 2023)

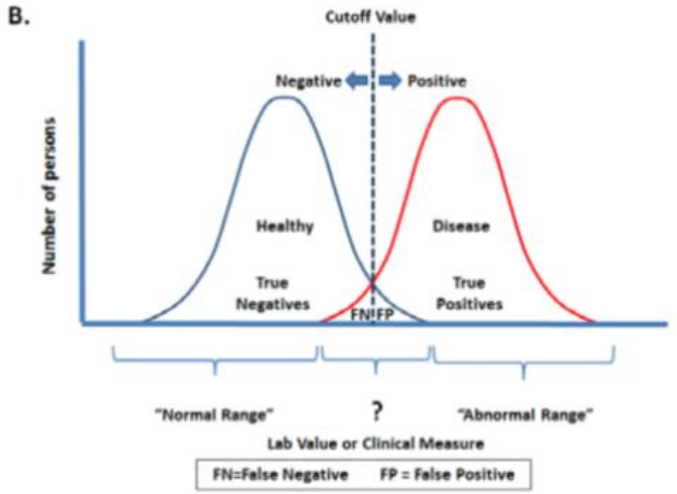
Qualitative

$$\text{Sensitivity} = \frac{TP}{TP+FN}$$

$$\text{Specificity} = \frac{TN}{TN+FP}$$

$$PPV = \frac{TP}{TP+FP}$$

$$NPV = \frac{TN}{TN+FN}$$



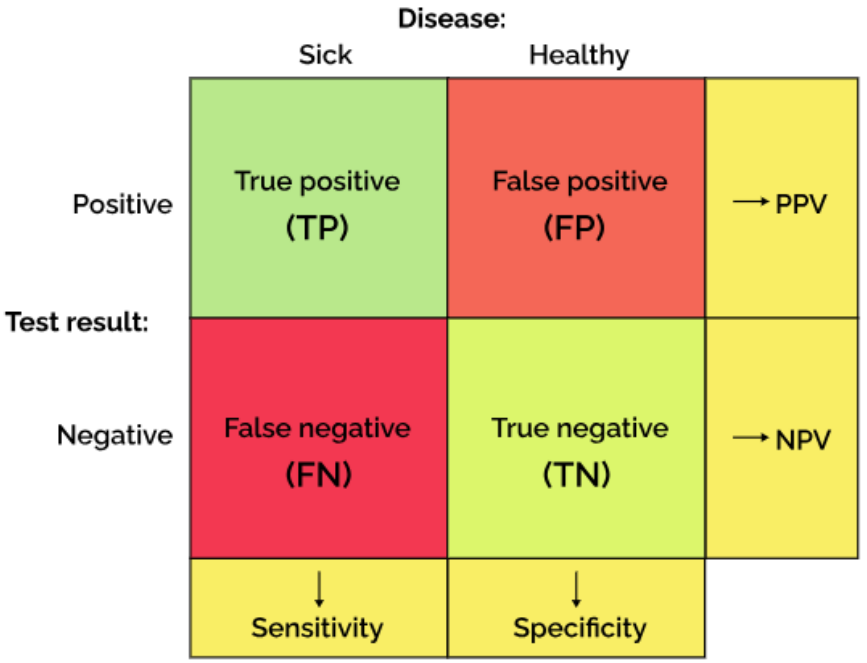


Fig.11: Sensitivity & Specificity in a 2x2 Table. https://www.omnicalculator.com/statistics

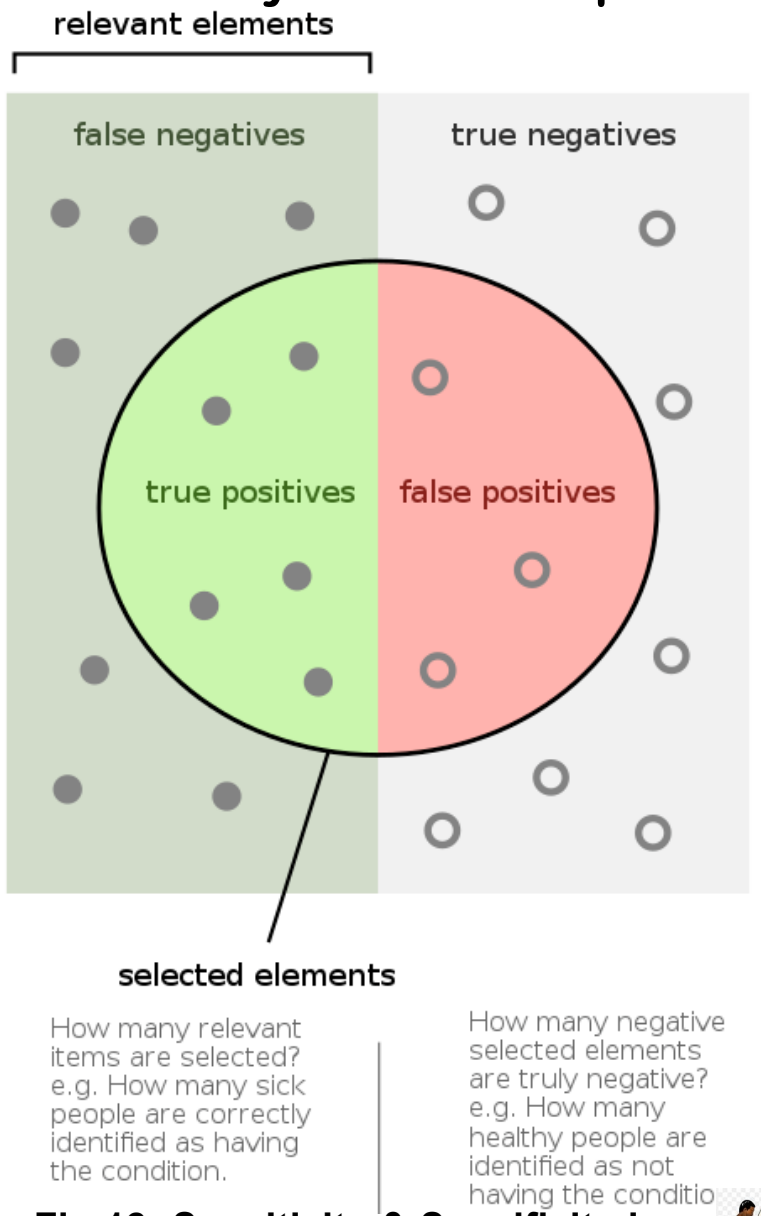


Fig 12: Sensitivity & Specificity in Venn diagram: en.wikipedia.org.

External Quality Assessment (EQA)

- External Quality Assessment
  - External Quality Assessment Schemes
  - Proficiency Testing
  - Repeat Testing
  - On site Testing

- Inter-laboratory Comparison
  - Accredited laboratory
  - Selection criteria
  - Memorandum of Understanding (MoU) between two laboratories

Example at MoH: EQA, PT

Internal and External Quality Control

Quality Control

- **Internal (IQC):**
  - In house: In build QC (e.g H&E Histology section staining of nucleus and cytoplasm); Locally prepared QC (e.g. Malaria positive blood smear)
- **External (EQC):**
  - Commercial: In build QC (e.g Rapid tests);
    Control Reagent (e.g. Hematology (Hgb); Cl/chemistry (Glucose)

- **MoH: In build QC; Control reagents (High and Low Concentration)**

Five basic laboratory requirements to ensure effective detection & diagnosis of diseases

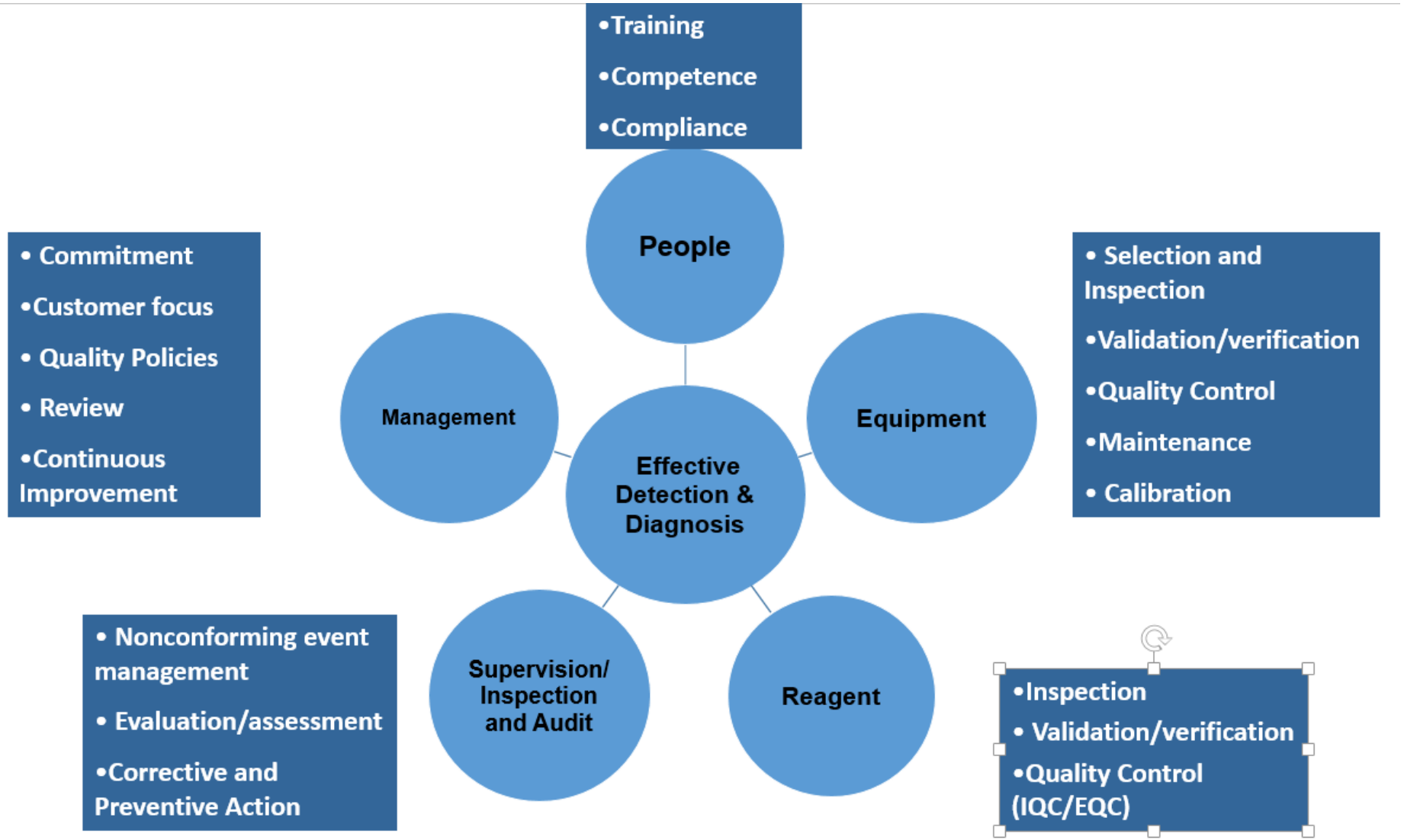


Figure 13: basic Laboratory requirements for effective detection and diagnosis

QMS Implementation & Laboratory Accreditation on ISO 15189 in Tanzania

- Laboratory accreditation is a procedure by which an authoritative body gives formal recognition of technical competence for specific tests/ measurements, based on third party assessment and following international standards (ISO 15189:2022).

- Laboratory accreditation on ISO 15189, is the hallmark of laboratory quality management system implementation

QMS Implementation & Laboratory Accreditation on ISO 15189 in Tanzania

- 2007: Started QMS Implementation and Roadmap to accreditation to 6 laboratories (National and Zonal Hospital Laboratories)
- 2010: Started SLMTA implementation to 12 laboratories (6 regional; 6 district laboratories)
- 2014: Four (4) Labs accredited on International Standards
- 2018: Twelve 12 Labs accredited on International standards
- 2022: 58 Laboratories accredited on International Standards.
- 2023: 61 Laboratories accredited on International Standards (Refer Figure 14)

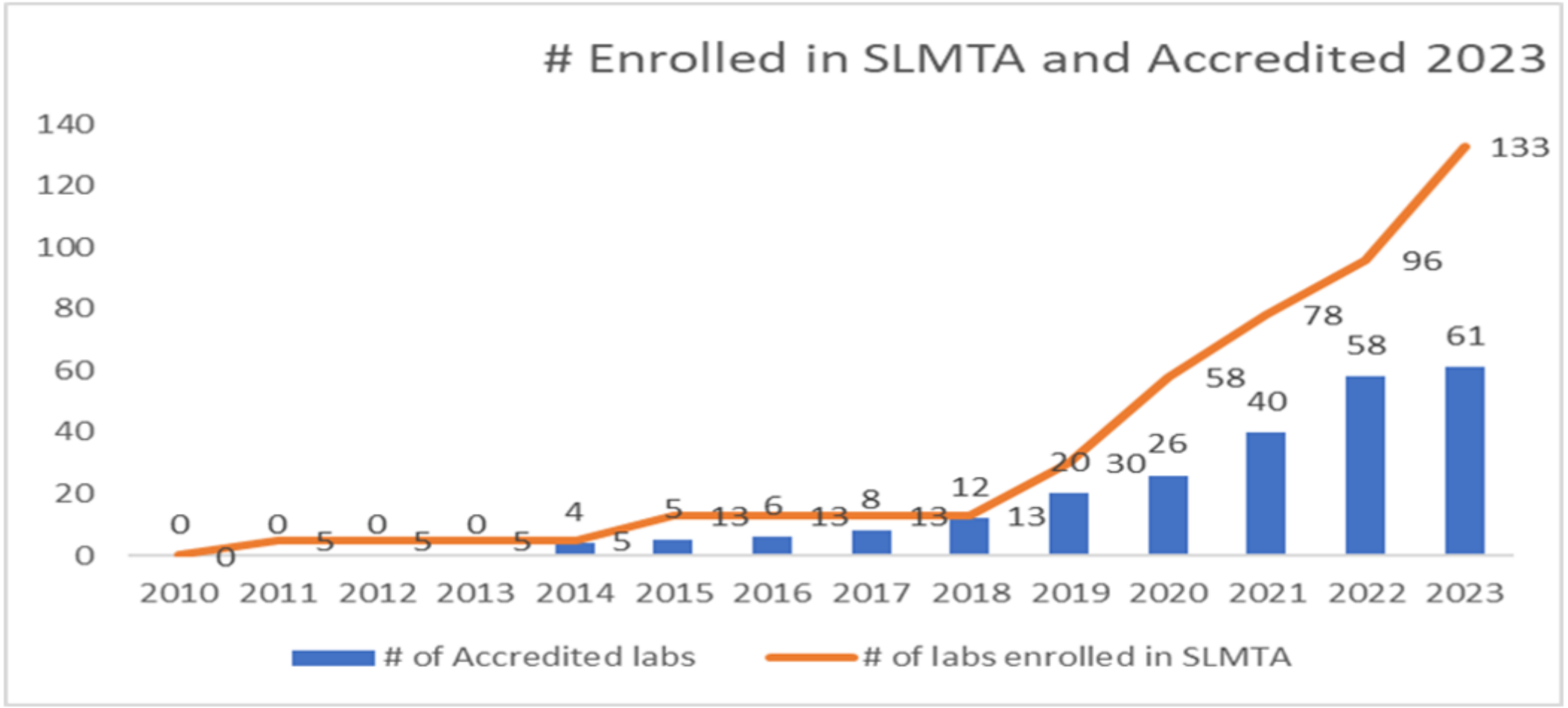


Figure 14: Health Laboratory Accreditation through SLMTA & Direct ISO 15189 Accreditation). Source: MoH June, 2023

QMS Implementation & Laboratory Accreditation According to Levels of the Health Laboratory Services by June, 2023

- All 3 (100%) National Level Laboratories are accredited
- Most 25 (89%) of Regional Referral Level Laboratories are accredited
- Over half 4(57%) of Zonal Level Laboratories are accredited
- Half 3(50%) of Specialized Level Laboratories are accredited
- Out of 184 District Level Laboratories, only 12 (7%) are accredited
- Out of 378 Health Centre Level Laboratories, only 2 (1%) are accredited
- Out of 1056 Faith Based Laboratories, only 12 (1%) are accredited ***(Refer Table 1)***

NOTE: Only 61 (3.6%) Health Laboratories from Health Centre to National Levels are Accredited on ISO 15189 Standard.

Table 1: Laboratory Accreditation According to Levels of the Health Laboratory Services

	National	Zonal	Specialized	Regional RH	District	HC	FBO & Private	Total
No of labs	3	7	6	28	184	378	1056	1662
Accredited	3	4	3	25	12	2	12	61
Accreditation program 2022	0	0	3	1	21	2	4	31
SLMTA Program 2022	0	0	0	1	13	3	0	17
Gap (No intervention)	0	3	0	1	139	371	1042	1556
Achievement	100%	57%	50%	89%	7%	1%	1%	4%

Source: MoH (June, 2023)

QMS Challenges

1. Inadequate or no health facility top management commitment
2. Inadequate or no competence assessment of laboratory personnel
3. Laboratory personnel not performing method validation or verification
4. Laboratory personnel not performing inspection or audit
5. Laboratory personnel not performing corrective action
6. Lack of planned preventive maintenance and equipment calibration
7. Frequent out of stock and unreliable supply of reagents and consumables.
8. Lack participation in EQA Schemes or Proficiency Testing
9. High cost of participating in EQA schemes
10. Lack of service provider for EQA schemes; or unavailability of EQA panels.

Recommendations

1. Create QMS awareness to Health Facility Top Management
2. Conduct personnel orientation and competence assessment prior to performing laboratory tests.
3. Perform method validation or verification for newly acquired equipment and/or reagents
4. Conduct inspections and/or audit
5. Perform corrective action or preventive action to non-conforming events
6. Perform planned preventive maintenance and calibration to laboratory equipment
7. Establish Inventory Management of reagents and consumables.
8. Participate in EQA Schemes or Proficiency Testing
9. Develop costed plan for QMS implementation
10. Establish National EQA Service provider (**ISO**/IEC **17043**:2010)

References

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Acknowledgement

1. APT
2. MoH
3. UDOM
4. CLSI
5. ASCP

Thank you!

Questions?

Comments?