A Transformative Journey Toward ISO 15189:2022 Accreditation at Cardinal Rugambwa Regional Referral Hospital Laboratory: Implementation, Milestones and Outcomes

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INTRODUCTION

Achieving ISO 15189:2022 accreditation is critical for ensuring diagnostic accuracy, patient safety and healthcare quality, yet it remains challenging in resource-limited settings.

Cardinal Rugambwa Regional Referral Hospital Laboratory began a structured quality improvement journey to strengthen its systems. This piece describes the laboratory's pathway toward accreditation despite the limited resources, highlighting key strategies and their role in enhancing diagnostic reliability and clinical decision-making.

METHODS

1 Framework
ISO 15189:2022 standards and the SLIPTA framework

2 Interventions
Four key interventions launched, 2020–2025

3 Monitoring
Continuous monitoring and corrective actions

4 Assessment
External assessment by SADCAS

Key interventions

- **Capacity building**
- **QMS strengthening**
- **Equipment & infrastructure**
- **Internal audits**

Data were entered, cleaned and analysed in Microsoft Excel; frequencies, percentages, tables and charts summarised the findings.

RESULTS

2020 Initiation of quality improvement

2022 Baseline SLIPTA assessment (2-star)

2023 SLIPTA reassessment (4-star)

2024 Accreditation readiness achieved

Jul 2025 SADCAS assessment & gap closure

Nov 2025 Accreditation certificate received

BLOOD TRANSFUSION — 3 Tests
- ABO Blood Grouping
- Rhesus Typing
- Compatibility Testing

CLINICAL CHEMISTRY — 9 Tests
- Alanine aminotransferase (ALT)
- Aspartate aminotransferase (AST)
- Creatinine
- Urea
- High Density Lipoprotein (HDL)
- Triglycerides
- Total Cholesterol
- Albumin
- Total Protein

SEROLOGY — 4 Tests
- Hepatitis B surface Antigen (HBsAg)
- Hepatitis C Antibody (HCV)
- Syphilis
- Rapid HIV

PARASITOLOGY — 2 Tests
- Malaria Rapid Diagnostic Testing (RDT)
- Malaria Microscopy – Giemsa Staining

Outcomes: improved turnaround time, reduced diagnostic errors, enhanced staff competency, and stronger patient care and service delivery. SADCAS assessment (July 2025) and closure of nonconformities led to accreditation.

CONCLUSION

Trustworthy data
Structured data management and simple, reliable analytical tools worked well in a resource-limited setting; consistent evaluation improved accuracy and decisions.

People and process
Continuous monitoring, teamwork and capacity building were essential for sustaining quality improvements.

Looking ahead
Strengthen data systems, routine analysis and staff competency to ensure long-term compliance with accreditation standards.

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