ASSESSMENT CYCLE MATRIX FOR MEDICAL LABORATORIES – ISO 15189:2022

Organization Name:					
SADCAS Accreditation No:					
Team Leader					

Dates																
Types of assessment (Initial, Periodic on-site assessment, Re-assessment, Extension, Re-instatement, …)																**Total No NCs/ Cycle**
Extent of assessment: **F**: Full assessment of the clause **P**: Partial assessment of clause **N**: Not assessed	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	
SADCAS Publications																
Previous Corrective Action(s) cleared																
4.1 Impartiality																
4.2 Confidentiality																
4.3 Requirements regarding patients																
5.1 Legal Entity																
5.2 Laboratory Director																
5.3 Laboratory Activities																
5.4 Structure and Authority																
5.5 Objectives and Policies																
5.6 Risk Management																
6.1 Resource Requirements																
6.2 Personnel																
6.3 Facilities and environmental conditions																
6.4 Equipment																

Dates																Total No NCs/ Cycle
Types of assessment (Initial, Periodic on-site assessment, Re-assessment, Extension, Re-instatement, …)																
Extent of assessment: **F**: Full assessment of the clause **P**: Partial assessment of clause **N**: Not assessed	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	
6.5 Equipment calibration and metrological Traceability																
6.6 Reagents and Consumables																
6.7 Service Agreements																
6.8 Externally provided products and services																
7.1 Process Requirements																
7.2 Pre-examination Processes																
7.3 Examination Process																
7.4 Post Examination process																
7.5 Nonconforming work																
7.6 Control of data and information Management																
7.7 Complaints																
7.8 Continuity and emergency preparedness planning																
8.1 General Management system Requirements																
8.2 Management System Documentation																
8.3 Control of Management System Documents																
8.4 Control of Records																
8.5 Actions to address Risks and opportunities for Improvement																
8.6 Improvement																

Dates																
Types of assessment (Initial, Periodic on-site assessment, Re-assessment, Extension, Re-instatement, …)																**Total No NCs/ Cycle**
Extent of assessment: **F**: Full assessment of the clause **P**: Partial assessment of clause **N**: Not assessed	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	Extent: F/P/N	Major	Minor	
8.7 Nonconformities and Corrective Actions																
8.8 Evaluations																
8.9 Management Reviews																

SCOPE COVERAGE OF TESTS OVER THE ASSESSMENT CYCLE

Please note: The coverage of tests over the accreditation cycle must include tests on the scope of accreditation

INITIAL ASSESSMENT : Date and Type of Assessment: | **Technical Assessor:**

TESTS: VERTICAL ASSESSMENTS	TESTS WITNESSED	PERSONNEL WITNESSED	COMMENTS/NEW TESTS ADDED/ ISSUES FOR FOLLOW-UP

ASSESSMENT 1: Date and Type of Assessment: | **Technical Assessor:**

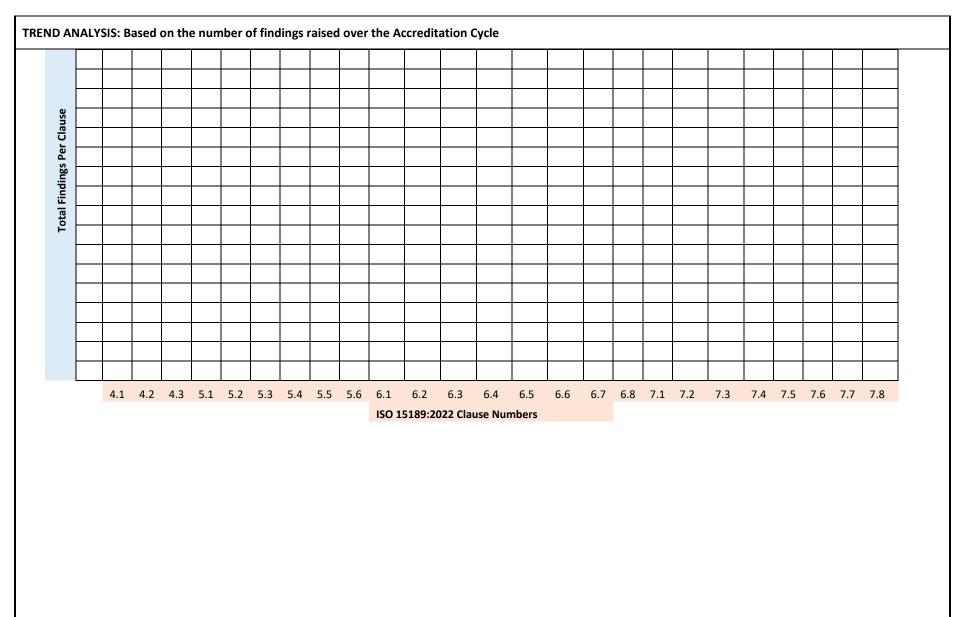| TESTS: VERTICAL ASSESSMENTS	TESTS WITNESSED	PERSONNEL WITNESSED	COMMENTS/NEW TESTS ADDED/ ISSUES FOR FOLLOW-UP

SCOPE COVERAGE OF TESTS OVER THE ASSESSMENT CYCLE

Please note: The coverage of tests over the accreditation cycle must include tests on the scope of accreditation

ASSESSMENT 2: Date and Type of Assessment: | **Technical Assessor:**

TESTS: VERTICAL ASSESSMENTS	TESTS WITNESSED	PERSONNEL WITNESSED	COMMENTS/NEW TESTS ADDED/ ISSUES FOR FOLLOW-UP

ASSESSMENT 3: Date and Type of Assessment: | **Technical Assessor:**

TESTS: VERTICAL ASSESSMENTS	TESTS WITNESSED	PERSONNEL WITNESSED	COMMENTS/NEW TESTS ADDED/ ISSUES FOR FOLLOW-UP

ASSESSMENT 5: Date and Type of Assessment:			
TESTS: VERTICAL ASSESSMENTS	TESTS WITNESSED	PERSONNEL WITNESSED	COMMENTS/NEW TESTS ADDED/ ISSUES FOR FOLLOW-UP

TREND ANALYSIS: Based on the number of findings raised over the Accreditation Cycle

Total Findings Per Clause

| 4.1 | 4.2 | 4.3 | 5.1 | 5.2 | 5.3 | 5.4 | 5.5 | 5.6 | 6.1 | 6.2 | 6.3 | 6.4 | 6.5 | 6.6 | 6.7 | 6.8 | 7.1 | 7.2 | 7.3 | 7.4 | 7.5 | 7.6 | 7.7 | 7.8 |

ISO 15189:2022 Clause Numbers

TREND ANALYSIS: Based on the number of findings raised over the Accreditation Cycle

8.1	8.2	8.3	8.4	8.5	8.6	8.7	8.8	8.9

Total Findings Per Clause (y-axis label)

RECOMMENDATIONS/COMMENTS:

Signed by: _____   **Name:** _____   **Date:** _____