

ASSESSMENT CYCLE MATRIX FOR MEDICAL LABORATORIES – ISO 15189:2012

Organization Name:					
SADCAS Accreditation No:					
Team Leader					

Dates																Total No NCs/ Cycle
	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	
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																
SADCAS Publications																
Previous Corrective Action(s) cleared																
4.1 Organization and Management responsibility																
4.2 Quality Management System																
4.3 Document Control																
4.4 Service Agreements																
4.5 Examination by Referral laboratories																
4.6 External Services and Supplies																
4.7 Advisory Services																
4.8 Resolution of Complaints																
4.9 Identification & control of nonconformities																
4.10 Corrective Actions																
4.11 Preventive Action																
4.12 Continual Improvement																
4.13 Control of Records																

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	
4.14 Evaluation of Audits																
4.15 Management Review																
5.1 Personnel																
5.2 Accommodation and Environmental Conditions																
5.3 Laboratory Equipment, reagents and consumables																
5.4 Pre-examination processes																
5.5 Examination Processes																
5.6 Assuring Quality of Examination results																
5.7 Post Examinations Processes																
5.8 Reporting of Results																
5.9 Release of results																
5.10 Laboratory Information Management																

SCOPE COVERAGE OF TESTS OVER THE ASSESSMENT CYCLE			
<i>Please note: The coverage of tests over the accreditation cycle must include tests on the scope of accreditation</i>			
ASSESSMENT 1: Date and Type of Assessment:			Technical Assessor:
TESTS: VERTICAL ASSESSMENTS	TESTS WITNESSED	PERSONNEL WITNESSED	COMMENTS/NEW TESTS ADDED/ ISSUES FOR FOLLOW-UP
ASSESSMENT 2: 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			
<i>Please note: The coverage of tests over the accreditation cycle must include tests on the scope of accreditation</i>			
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 4: Date and Type of Assessment:			Technical Assessor:
TESTS: VERTICAL ASSESSMENTS	TESTS WITNESSED	PERSONNEL WITNESSED	COMMENTS/NEW TESTS ADDED/ ISSUES FOR FOLLOW-UP

