ISO 15189:2022 GAP ANALYSIS & TRANSITION PLAN

Name of Facility		Date of Submission	

CLAUSE	ISO 15189:2012	CLAUSE	ISO 15189:2022	EXTENT OF CHANGE	DETAILS OF CHANGES WITHIN YOUR MANAGMENT SYSTEM WHICH HAVE/WILL BE TAKEN TO ADRESS CHANGES	Timelines	SADCAS COMMENTS
	Forward		Forward				
	Introduction		Introduction				
1.	Scope		Scope				
2.	Normative References		Normative References				
3.	Terms & Definitions		Terms and Definitions				
4.	**Management Requirements**						
4.1	Organisation and Management Responsibility						
4.1.1	Organisation						
4.1.1.1	General	5.3.2	Laboratory Activities: Conformance with requirements	Structural			
4.1.1.2	Legal Entity	5.1	Legal Entity	Structural			
4.1.1.1.3	Ethical Conduct	4.1	Impartiality	Minor			
		4.2	Confidentiality	Structural			
4.1.1.4	Laboratory Director	5.2	Laboratory Director	Minor			
		5.6b	Risk Management	New			
4.1.1.4o	Contingency Planning	7.8	Continuity and Emergency Preparedness Planning	Minor			
		7.6.4	Control of data and Information Management:	Minor			

			Downtime plans				
4.1.2	Management Responsibility			N/A			
4.1.2.1	Management Commitment	8.2.3	Management system documentation: Evidence of Commitment				
4.1.2.2	Need of Users	4.3	Requirements for Patients	New			
4.1.2.3	Quality Policy	5.5	Objectives and Policies	Minor			
4.1.2.4	Quality Objectives	5.5	Objectives and Policies	Minor			
		8.1.3	Management system Awareness	New			
		8.2.2	Management system Documentation: competency and quality	New			
4.1.2.5	Responsibility, authority, interrelationships	5.4	Structure and authority	Minor			
4.1.2.6	Communication	5.4.1b	Structure and authority: General	Minor			
4.1.2.7	Quality Manager	5.4.2	Quality Management	Minor			
4.2	Quality Management system	8	Management System Requirements	N/A			
4.2.1	General Requirements	8.1	General Requirements	Minor			
4.2.2	Documentation Requirements	8.2	Management System Documentation	N/A			
4.2.2.1	General Documentation	8.2.1	Management System documentation: General	Minor			
		8.2.4	Management System documentation: Documentation	Structural			
		8.2.5	Management System documentation: Personnel Access	Minor			

4.2.2.2	Quality Manual	8.2.1	Management System documentation: General	Minor			
		8.2.4	Management System documentation: Documentation	Structural			
4.3	Document Control	8.3	Control of Management System documents	Minor			
		7.3.1c	Examination Process - General	Structural			
4.4	Service Agreements	6.7	Service Agreements	Minor			
4.5	Examination by Referral Laboratories	6.8	Externally provided products and Services	Minor			
		7.4.1.7c	Post – Examination processes : Result reporting: Additional Information	Minor			
4.6	External Services and Supplies	6.8	Externally provided products and Services	Structural			
		7.6.5	Control of data and information management: Offsite Management	Structural			
4.7	Advisory Services	5.3.3	Advisory Services	Minor			
4.8	Resolution of Complaints	7.7	Complaints	Minor			
4.9	Identification and Control of NCNs	7.5	Nonconforming work	Major			
4.10	Corrective Action	8.7	Nonconformities and Corrective Actions	Major			
4.11	Preventive Action	8.5	Action to address risks and opportunities	Major			
4.12	Continual Improvement	8.6	Improvement	Major			
4.13	Control of Records	8.4	Control of Records	Minor			
4.14	Evaluation and Audit			N/A			
4.14.1	General Evaluation	8.8.1	Evaluations: General	Minor			

4.14.2	Periodic Review of requests and suitability of procedures/samples	7.2.4.1	Primary sample collection and handling: General	Minor			
		7.3.1e	7.3 Examination Processes: General	Minor			
		4.3c	Requirements regarding patients	Minor			
4.14.3	Assessment of User Feedback	8.6.2	Laboratory user and personnel feedback	Minor			
4.14.4	Staff Suggestions	8.6.2	Laboratory user and personnel feedback	Minor			
4.14.5	Internal Audit	8.8.3	Internal Audits	Major			
4.14.6	Risk Management	5.6	Risk Management	Major			
		8.5	Actions to address risks and opportunities for improvement	Major			
		7.1	Process Requirements: General	Major			
4.14.7	Quality Indicators	5.5	Objectives and Policies				
		8.8.2	Quality Indicators				
4.14.8	Review by external organisations						
4.15	Management Review	8.9	Management Review	Minor			
5.	**Technical Requirements**						
5.1	Personnel	6.1	Resource Requirements: General	Minor			
		6.2.1	Personnel: General	Minor			
5.1.1	General			N/A			
5.1.2	Qualifications	6.2.2a	Personnel Competence Requirements	Minor			
5.1.3	Job Descriptions	6.2.5b					

5.1.4	Personnel introduction to the organisational environment			Structural			
5.1.5	Training	6.2.2a	Personnel: Competence	Minor			
		8.1.3	Management System Awareness	New			
5.1.6	Competence	6.2.2	Personnel Competence				
5.1.7	Appraisal			N/A			
5.1.8	CPD	6.2.4	Personnel: Continuing education and Professional Development	Minor			
5.1.9	Personnel Records	6.2.5	Personnel: Personnel Records	Minor			
5.2	Accommodation and Environment	6.3	Facilities and Environmental conditions	N/A			
5.2.1	General	6.3.1	General	Minor			
5.2.2	Laboratory and Office Facilities	6.3.2	Facility Controls	Minor			
5.2.3	Storage Facilities	6.3.3	Storage Facilities	Structural			
5.2.4	Staff Facilities	6.3.4	Personnel Facilities	Minor			
5.2.5	Patient sample Collection Facilities	6.3.5	Sample Collection Facilities	Minor			
5.2.6	Facility maintenance and environmental conditions	6.3.1	Facilities and Environmental conditions: General	Structural			
		6.3.2.b,c	Facilities and Environmental conditions: Facility Controls	Structural			
5.3	Laboratory equipment, reagents and consumables	6.4	Equipment	Minor			
			Equipment calibration and metrological Traceability	Minor			
5.3.2	Reagents and Consumables	6.6	Reagents and consumables	N/A			

5.3.2.1	General	6.6.1	Reagents and consumables: General	Minor			
5.3.2.2	Reagents and Consumables – reception and storage	6.6.2	Reagents and Consumables- Receipt and Storage	Minor			
5.3.2.3	Reagents and Consumables – acceptance testing	6.6.3	Reagents and Consumables – acceptance testing	Major			
5.3.2.4	Reagents and Consumables – inventory Management	6.6.4	Reagents and Consumables – inventory Management	Structural			
5.3.2.5	Reagents and Consumables – instructions for use	6.6.5	Reagents and Consumables – instructions for use	Structural			
5.3.2.6	Reagents and Consumables – adverse incident reporting	6.6.6	Reagents and Consumables – adverse incident reporting	Minor			
5.3.2.7	Reagents and Consumables – records	6.6.7	Reagents and Consumables – records	Structural			
5.4	Pre-examination Processes	7.2	Pre-examination Processes	N/A			
5.4.1	General	7.2.1	Pre-examination Processes - General	Minor			
5.4.2	Information for patients and users	7.2.2	Pre-examination Processes – Laboratory Information for patient and users	Minor			
5.4.3	Request form information	7.2.3	Pre-examination Processes – Requests for providing laboratory examinations	Major			
5.4.4	Primary sample collection and handling	7.2.4	Primary sample collection and handling	N/A			
5.4.4.1	General	7.2.4.1	Primary sample collection and handling - General	Minor			
		7.2.4.3	Primary sample collection and handling – Patient Consent	Minor			

5.4.4.2	Instructions for pre-collection activities	7.2.4.2	Primary sample collection and handling – Information for Pre-collection activities	Minor			
5.4.4.3	Instructions for pre-collection activities	7.2.4.4	Primary sample collection and handling – Information for collection activities	Minor			
5.4.5	Sample Transportation	7.2.5	Primary sample collection and handling – Sample transportation	Minor			
5.4.6	Sample Reception	7.2.6	Sample Receipt	Minor			
5.4.7	Pre-Examination handling, preparation and storage	7.2.7	Pre-examination handling, preparation and storage	Minor			
5.5	Examination Processes	7.3	Examination Processes	N/A			
5.5.1	Selection, verification and validation of examination procedures			N/A			
5.5.1.1	General	7.3.1	Examination Processes - General	Major			
5.5.1.2	Verification of Examination Procedures	7.3.2	Examination Processes – Verification of examination methods	Major			
5.5.1.3	Validation of examination procedures	7.3.3	Examination Processes – Validation of examination methods	Major			
5.5.1.4	Measurement Uncertainty of measured quantity values	7.3.4	Examination Processes – Evaluation of measurement uncertainty	Minor			
5.5.2	Biological Reference intervals and clinical decision values	7.3.5	Examination Processes - Biological Reference Intervals and Clinical decision limits	Minor			

5.5.3	Documentation of examination procedures	7.3.6	Examination Processes - Documentation of Examination procedures	Minor			
5.6	Ensuring quality of examination results	7.3.7	Ensuring the validity of examination results	N/A			
5.6.1	General	7.3.7.1	Ensuring the validity of examination results - General	Structural			
5.6.2	Quality Control	7.3.7.2	Ensuring the validity of examination results – Internal Quality Control (IQC)	Major			
5.6.2.1	General	7.3.7.2	Ensuring the validity of examination results – Internal Quality Control (IQC)	Major			
5.6.2.2	Quality Control Materials	7.3.7.2	Ensuring the validity of examination results – Internal Quality Control (IQC)	Major			
5.6.2.3	Quality Control Data	7.3.7.2	Ensuring the validity of examination results – Internal Quality Control (IQC)	Major			
5.6.3	Interlaboratory Comparisons	7.3.7.3	Ensuring the validity of examination results: External quality Control	Major			
5.6.3.1	Participation	7.3.7.3	Ensuring the validity of examination results: External quality Control	Major			

5.6.3.2	Alternative approaches	7.3.7.3	Ensuring the validity of examination results: External quality Control	Major			
5.6.3.3	Analysis of Interlaboratory comparison samples	7.3.7.3	Ensuring the validity of examination results: External quality Control	Major			
5.6.3.4	Evaluation of laboratory performance	7.3.7.3	Ensuring the validity of examination results: External quality Control	Major			
5.6.4	Comparability of examination results	7.3.7.3	Ensuring the validity of examination results: External quality Control	Major			
5.7	Post – Examination Processes	7.4	Post Examination Processes	Minor			
5.7.1	Review of results	7.4.1.2	Post Examination Processes – Result review and release	Minor			
		7.4.1.3	Post Examination Processes – Critical Results Report	Minor			
5.7.2	Storage, retention and disposal of clinical samples	7.4.2	Post -Examination handling of samples	Minor			
5.8	Reporting of results	7.4.1	Results Reporting	N/A			
5.8.1	General	7.4.1.1	Results Reporting : General	Minor			
		7.6.3 d	Information system Management	Minor			
		7.4.1.4	Results Reporting : Special Considerations for results	Minor			
5.8.2	Report Attributes			N/A			
5.8.3	Report Content	7.4.1.6	Results Reporting: Requirements for reports	Minor			
		7.4.1.7	Results Reporting: Additional Information for reports				

5.9	Release of results			N/A			
5.9.1	General	7.4.1.2	Results Reporting: Result and Review and release	Minor			
		7.4.1.3	Results Reporting: Critical Results Report				
5.9.2	Automated selection and reporting of results	7.4.1.5	Results Reporting: Automated selection, review, release and reporting of results	Minor			
5.9.3	Revised reports	7.4.1.8	Results Reporting: Amendments to reported results	Minor			
5.10	Laboratory Information Management	7.6	Control of data and information management	N/A			
5.10.1	General	7.6.1	Control of data and information management: General	Minor			
5.10.2	Authorities and Responsibilities	7.6.2	Control of data and information management: Authorities and responsibilities for Information Management	Minor			
5.10.3	Information System Management	7.6.3	Authorities and responsibilities for information Management: Information systems management	Minor			
	No direct equivalent Clause in 2012	4.3	Requirements regarding patients	New Clause			
	No direct equivalent Clause in 2012	5.3.1	Laboratory activities: General	New Clause			
	ISO 22870:2016			Minor			