SADCAS Ref. No:							

PROFICIENCY TESTING REQUIREMENTS
ISO 15189:2022 CLAUSE 7.3.7.3
AND SADCAS REQUIREMENTS

Date(s) of evaluation			
Assessor			
Laboratory		Area / Field of operation	
Laboratory Representative			

REQUIREMENTS & COMMENTS Compliance = C, Non-compliance = NC, Not applicable = NA Comment below on adequacy of how requirements have been addressed, documented and/or implemented	C NC NA
TECHNICAL REQUIREMENTS	
Has the laboratory established a procedure for EQA enrolment, participation and performance for examination methods used, where such programmes are available?	
Has the laboratory participated in EQA programmes appropriate to the examinations and interpretation of examination results? If the laboratory has not participated in EQA activities because EQA programme is either not available or considered not suitable, does the laboratory use alternative methodologies to monitor examination method performance? Does the laboratory justify the rationale for the chosen alternative and is evidence of its effectiveness provided?	
Provide details of EQA activity	
Is the amount and frequency of EQA Activity (or alternative activities) appropriate to the volume and associated risk for testing activities of the laboratory?	
Comment on frequency of EQA Activity	

Does the EQA programme(s) chosen by the laboratory, to the extent possible: 1) have the effect of checking pre-examination, examination, and post-examination processes? 2) provide samples that mimic patient samples for clinically relevant challenges? 3) fulfil ISO/IEC 17043 requirements?	
Provide details on selection of EQA programmes	
Are EQA samples processed by personnel who routinely perform pre-examination, examination, and post-examination procedures?	
Is the EQA data reviewed at regular interval with specified acceptability criteria, in a time frame which allow for a meaningful indication of current performance?	
Comment on review of EQA data	
Analysis of EQA Results Has the laboratory analyzed the results of EQA (or alternative methods) and have appropriate Corrective action been taken when EQA results fall outside specified acceptability criteria including an assessment of whether the non-conformance is clinically significant as it relates to patient samples? (e.g. SDI >2, or Z score > 2)	
Comments on analysis of results:	

If it is determined that the impact is clinically significant, does the laboratory review patient results that could have been affected. Are users advised as appropriate?	
SADCAS TR 08	
General requirements: Has the laboratory prepared and implemented an activity plan that indicates how and when EQA programmes and/alternative methodologies are to be implemented for at least 1 accreditation cycle (5 years).	
Does the activity plan cover all accredited activities listed on the laboratory's schedule of accreditation.	
Provide details of the activity plan	
Where the laboratory has participated in EQA programmes / Alternative methodologies, is a report available and does it address the following minimum information:	
• Identification of the participants	
• Identification of the examination method	
• Measurement result	
• Target value(s) and how these were established	
• Evaluation of the measurement results	
• An indication of the performance of individual participants	
• Minimum acceptance criteria	
• Conclusion	

Additional / General Comments *This space may also be used to expand on comments in specific sections*

Name: **Technical Assessor**		**Signature:**	**Date:**
Name: **Team Leader**		**Signature:**	**Date:**