



SADCAS Ref. No:							
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**PROFICIENCY TESTING REQUIREMENTS ISO 15189 CLAUSE 5.6
AND SADCAS REQUIREMENTS**

Date(s) of evaluation			
Assessor			
Laboratory		Area / Field of operation	
Laboratory Representative			
Clause	REQUIREMENTS & COMMENTS	Compliance = C, Non-compliance = NC, Not applicable = NA	C NC NA
	Comment below on adequacy of how requirements have been addressed, documented and/or implemented		
	TECHNICAL REQUIREMENTS		
5.6.4	Proficiency Testing: Has the laboratory participated in Proficiency Testing (PT) or Inter Laboratory Comparisons (ILC)? If the laboratory has not participated in PT activities either because PT is either not practical or because none exist, has the laboratory taken appropriate steps to assure the Quality of Test and Calibration Results? <i>(NB: The laboratory shall provide valid verifiable reasons of not participating in PT activities)</i>		
Provide detail of PT activity or where appropriate alternative methods (e.g. Inter/Intra laboratory comparisons; Use of reference materials) of assuring the quality of test and/or calibration results.			
5.6.3	Appropriateness of PT Activity: How are the following addressed/ implemented?		
	Is the amount of PT Activity (or alternative activities) appropriate to the volume and associated risk for the testing and/or calibration activities of the laboratory?		
Comment on Appropriateness			

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

5.6.7	Analysis of Results of PT Testing: <i>How are the following addressed/ implemented?</i>	C NC NA
	Has the laboratory analyzed the results of the PT/Interlaboratory results (or alternative) and have appropriate steps been taken when results are not satisfactory (En>1, or Z score > 3)	
Comments on analysis of results		
5.6	Is the laboratory experiencing any problems with participating in Proficiency Testing?	
Comment on the effectiveness of corrective and preventive action taken		
Medical Laboratories Only : SADCAS TR 08		
	<p>General requirements:</p> <p>Has the laboratory prepared and implemented an activity plan that indicates how and when Proficiency Testing and/or Inter Laboratory Comparisons activities are to be implemented for at least 2 accreditation cycles i.e. the activity schedule for the past accreditation cycle (where possible) and the plan for the subsequent accreditation cycle?</p>	
	Does the activity plan cover all accredited activities listed on the laboratory’s schedule of accreditation and in a period not exceeding 1 accreditation cycle	
	<p>Where the laboratory has participated in Proficiency Testing scheme / ILC activities, is a report available and does it address the following minimum information:</p> <ul style="list-style-type: none"> • Identification of the participants • Identification of the measurement standard or artefact • Measurement results • Reference value(s) and how these were established • Evaluation of the measurement results • An indication of the performance of individual participants • Minimum acceptance criteria • Conclusion 	
Comment on activity plan and/or ILC reports		
Signed : Team Leader/Technical Assessor		Date: