



Checklist for Assessor's pack ISO 15189

Issue No. 1
Revision No. 4
Date: August 2021

F1.17

Name of Medical Laboratory	
Assessment type	Preliminary Visit <input type="checkbox"/> Initial Assessment <input type="checkbox"/> Assessment <input type="checkbox"/> Re-assessment <input type="checkbox"/> Other(s), specify:
Name of Assessment Team members & fields to be assessed	
Date of assessment	

Please use ticks (✓) to fill in

Assessment Forms/Documents for Medical Laboratories	TL	A				TE	MS	Mentor	Observer
Declaration of Impartiality F1.23									
Quality Manual									
Relevant Procedures for Mgt Req <i>(Please list Procedures provided)</i>							<i>(if TL mentored)</i>		
Complaints, Internal Audit and Management Review reports							<i>(if TL mentored)</i>		
Relevant Procedures for Tech Req <i>(Please list Procedures provided)</i>							<i>(if A/TE mentored)</i>		
Assessment Plan									
Preliminary Visit findings or Accreditation Report									
Acknowledge Receipt									



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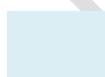
Assessment Forms/Documents for Medical Laboratories	TL	A				TE	MS	Mentor	Observer
Declaration of Confidentiality F1.02									
Attendance Sheet F1.03									
Agenda Opening Meeting F1.01							(if TL mentored)	(if observing TL)	
Agenda Closing Meeting F1.04							(if TL mentored)	(if observing TL)	
Accredited scope									
Scope for extension (if applicable)									
Assessor/Technical Expert Monitoring Checklist F1.10									
Team Leader Monitoring checklist, F1.28							(if TL mentored)		
Briefing meeting with Assessors/ Technical Experts F1.15									(if observing TL)
Preliminary Visit Findings Form F1.20	(applicable for preliminary visit only)								
Latest Proficiency Testing Plan F1.24									
MAURITAS Regulations (R1-R4)									
Feedback from assessment F1.21									
Acknowledge Receipt									

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Assessment Forms/Documents for Medical Laboratories	TL	A				TE	MS	Observer
Assessment of Management Requirements – ISO 15189:2012 F3.20								
Assessment of Technical Requirements – ISO 15189:2012 F3.21								
Vertical Assessment ISO 15189 F3.17								
Witnessing F3.04								
Latest Proficiency Testing Plan, F1.24								
Non-Conformity Form F3.07								
Recommendation Report F3.09								
Summary of Non-Conformities ISO 15189 F3.14								
Previous Non-Conformity Forms F3.07								
Finance Form F2.16	<i>(if external)</i>							
Test Methods or Standard Operating Procedures								
Acknowledge Receipt								

To be taken into consideration when planning for Initial Assessments, Extension of scopes and assessments for reinstating accreditation, where relevant

Assessment Forms/Documents for Medical Laboratories	A				TE	MS
Validation Data & Uncertainty of Measurement calculations						
Acknowledge Receipt						

 Shaded areas represent the forms that need to be provided in the assessor's pack during a full assessment for the respective assessor

TL – Team Leader

A – Assessor

TE – Technical Expert

MS – MAURITAS Staff