



Accreditation Department

ASSESSMENT REPORT

ACCREDITATION CRITERIA ISO 15189:2012

PART 1: GENERAL INFORMATION

NAME AND ADDRESS OF THE APPLICANT LABORATORY

<input type="checkbox"/> Pre-Assessment	<input type="checkbox"/> Accreditation Assessment	<input type="checkbox"/> Surveillance
<input type="checkbox"/> Unannounced Visit	<input type="checkbox"/> Extension of Scope	<input type="checkbox"/> Re-Assessment

PART 2: ASSESSMENT TEAM DETAILS

LEAD ASSESSOR:

Name: _ Signature: Date

TECHNICAL ASSESSOR:

PART 3: ASSESSMENT DETAILS

STAFF INTERVIEWED:

S. No.: Name:

Position:

SCOPE COVERED AND COMMENTS:

CLA USE NO.	COMMENTS
4.1	•
4.2	•
4.3	•
4.4	•
4.5	•
4.6	•
4.7	•
4.8	•
4.9-4.13	•
4.14	•
4.15	•
5.1	•

5.2	•
5.3	•
5.4	•
5.5	•
5.6	•
5.7	•
5.8	•
5.9	•
5.10	•
PT PART ICIPATION	•

ASSESSMENT FINDINGS:

#	TYPE OF FINDINGS	STATEMENT	CLAUSE No.	FOLLOW UP REQUIRED	CORRECTIVE ACTION STATUS
1	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
2	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
3	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
4	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
5	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
6	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
7	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
8	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				

9	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
10	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
11	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
12	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
13	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
14	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
15	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				

PART 4: DETAILED RECOMMENDATIONS FOR SCOPE OF ACCREDITATION

Note:

- | | | | |
|---|---|---|---|
| A | Accredit the Test Method/ Continued Accreditation (surveillance/re-assessment), | B | Accreditation shall be granted/Continue only if corrective action is submitted and verified |
| C | Not Accredit/suspended Test Method. Finding/s observed detrimental to the final results | D | Pending Scope that was not assessed during this visit
CAB is conformity assessment body |

PART 5: CONCLUSION AND RECOMMENDATION OF LEAD ASSESSOR

<input type="checkbox"/> Accreditation shall be granted/ continue	<input type="checkbox"/> Accreditation shall be granted/ continue subject to acceptance of corrective actions evidence
<input type="checkbox"/> Accreditation shall be suspended	<input type="checkbox"/> Accreditation shall be withdrawn
<input type="checkbox"/> Scope shall be extended	<input type="checkbox"/> Scope shall be extended subject to acceptance of corrective actions evidence
<input type="checkbox"/> Re-witness	<input checked="" type="checkbox"/> Follow up visit is required
<input type="checkbox"/> CAB is ready for initial assessment	<input type="checkbox"/> CAB can be ready for initial assessment subject to closing the Pre- assessment findings

Comments:

Follow up visit is required to cover all the scope of accreditation, and all the ISO 15189 requirements.

Type of Task	Materials/Products	Task Name	Standard method	Recommendation	witnessed by

PART 6: RE-WITNESS / FOLLOW UP VISIT

DATE:

RE-WITNESS/FOLLOW UP FINDINGS (IF ANY):

#	TYPE OF FINDINGS	STATEMENT	CLAUSE NO.	FOLLOW UP REQUIRED	CORRECTIVE ACTION STATUS & DATE OF FOLLOW UP
	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
2.	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				
3.	<input type="checkbox"/> NCR <input type="checkbox"/> OBS				

PART 7: CONCLUSION AND RECOMMENDATION OF LEAD ASSESSOR

<input type="checkbox"/> Accreditation shall be granted/ continue	<input type="checkbox"/> Accreditation shall be granted/ continue subject to acceptance of corrective actions evidence
<input type="checkbox"/> Accreditation shall be suspended	<input type="checkbox"/> Accreditation shall be withdrawn

<input type="checkbox"/> Scope shall be extended	<input type="checkbox"/> Scope shall be extended subject to acceptance of corrective actions evidence
<input type="checkbox"/> Scope shall be reduced	<input type="checkbox"/> Re-witness / Follow up visit is required
<input type="checkbox"/> CAB is ready for initial assessment	<input type="checkbox"/> CAB can be ready for initial assessment subject to closing the Pre- assessment findings

LEAD ASSESSOR(UNDER OBSERVATION)

NAME:_ SIGNATURE: APPROVED ELECTRONICALLY DATE:

ASSESSMENT TEAM:

Name:_____ Role in assessment: Lead assessor

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1. TASK FORCE MEMBERS (IF APPLICABLE)

Name:_____ Recommendation:_____ Date:[Publish Date]
 Name:_____ Recommendation:_____ Date: [Publish Date]
 Name:_____ Recommendation:_____ Date: [Publish Date]

2. SUBMISSION OF FINAL REPORT FOR DECISION

Name:_____ Signature:_____ Date: [Publish Date]

3. DECISION REGARDING ACCREDITATION OF CAB:

HEAD OF SECTION:

Name:_____ Signature:_____ Date: [Publish Date]

4. APPROVAL OF ACCREDITATION BOARD DIRECTOR

Name: _____

Signature: _____

Date: [Publish Date]