Procedure for Recognition of Sample Collection Centre/ Facility declared by Medical Laboratories (CABs)
<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Page No.</th>
<th>Clause No.</th>
<th>Date of Amendment</th>
<th>Amendment</th>
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<th>Signature QM</th>
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<td></td>
</tr>
</tbody>
</table>
## CONTENTS

<table>
<thead>
<tr>
<th>Sl.</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amendment Sheet</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Content</td>
<td>2</td>
</tr>
<tr>
<td>1.</td>
<td>Procedure</td>
<td>3</td>
</tr>
<tr>
<td>2.</td>
<td>Flow-diagram (Applicant CABs-FA/RA)</td>
<td>5</td>
</tr>
<tr>
<td>3.</td>
<td>Flow-diagram (Accredited CABs)</td>
<td>6</td>
</tr>
<tr>
<td>4.</td>
<td>Procedure for Adverse decision</td>
<td>7</td>
</tr>
</tbody>
</table>
1. **PROCEDURE**

NABL recognizes sample collection centres/facility(ies) declared by its associated medical CABs. Assessment process of SCFs shall be an ongoing activity for the entire accreditation cycle. Each declared sample collection centre/facility (SCF) of a medical CAB shall be assessed once in its accreditation cycle.

**SCFs of applicant CABs**

SCFs shall be assessed on sample basis (at least 5%) initially on or before the schedule of final or renewal assessment and decision shall be taken for all declared SCFs with the assessment report of CAB declaring these SCFs. All declared SCFs shall be considered recognised SCFs of CAB. *(Refer Flow-diagram).*

**SCFs of accredited CABs**

All declared SCFs not assessed during initial assessment shall be assessed in subsequent months of accreditation cycle. At all time, the SCFs shall maintain compliance to requirements and recognition is co-terminus with accreditation cycle of CAB. *(Refer Flow-diagram).*

**Digitalisation of Process**

Mobile & Web based Applications has been developed for automation of application process and processes of assessment, corrective action, and recognition. These applications have provision for CABs to upload details of sample collection centres/facilities for which recognition is to be done, provision for assessor and for NABL users to assign assessors to these SCFs and review the assessment report. The mobile application will facilitate field assessment, marking location of assessors and laboratories/SCFs. Further, it will involve geo-tagging of sample collection centres/facilities which will help the CAB user/patients to find these facilities to get quality services. The web based application can be accessed from NABL website.

Till this above process becomes operational, NABL will be starting process as per current procedure.

**Web based Application: Key features**

- Manage lab, Sample collection centre/facility details and Assessor Data.
- Map based and Dashboard based view of Data of different entities.
- Review of Assessment data of sample collection centres.
- Upload of corrective action and follow-up action.
- User Management to provide access to different modules.

**Mobile application for on-site assessment of collection centres: Key features:**

- Facility for Collection centre and Assessors to update their profile and mark their location.
- Questionnaire-based Assessment of collection centres along with pictorial evidence.
- Mark NC’s for non-compliances.
Recognition of Sample Collection Centre/ Facility

NABL shall issue an annexure to the accreditation certificate containing ‘Recognised sample collection centres/ facilities’ with the following details –

<table>
<thead>
<tr>
<th>ID of Sample Collection Centre/ Facility</th>
<th>Name of Sample Collection Centre/ Facility</th>
<th>Address of Sample Collection Centre/ Facility</th>
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Based on this annexure, the accredited medical CAB may issue certificate of recognition to its declared SCFs as stated follows –

![Certificate of Recognition](Image)

MC-XXXX

CERTIFICATE OF RECOGNITION

**ABC SCF, ADDRESS** is a recognized Sample Collection centre/ Facility of **XYZ laboratory** with certificate no. **MC-XXXX and validity (Issue date 00/00/0000 - Valid date 00/00/0000)** and is authorized to collect, prepare, handle, transport patient sample collected for this laboratory.

Name and Signature

(Signature of Laboratory Director)  

Date
2. **Flow-diagram** (Applicant CABs-Final Assessment/ Reassessment)

Receipt of application. Information on Sample Collection Centre / Facility (SCF) will be taken in 1.9, Annexure to Application NABL 153

Initially at least 5% of declared SCF will be assessed (on sample basis) either before the FA/RA or during FA/RA either by different or same assessment team appointed for CAB.

- Is centre/facility recommended?
  - Yes: Decision will be informed to CAB, Records will be updated; Invoices will be generated for respective SCFs. CAB can re-apply for such SCF along with applicable fee
  - No: 30 Days time will be given to address the NCs, if any.

  - Is centre/facility recommended?
    - Yes: Assessment report will be evaluated by NABL for further decision
    - No: Decision will be informed to CAB, Records will be updated; CAB can re-apply for such SCF along with applicable fee

Recommendation/Decision on Sample collection centres / facilities shall be informed along with decision on the accreditation of CAB

- Invoices (AAFEE and other Charges) will be generated
- Annexure to Certificate shall be issued to CAB

On decision, CAB will claim to have recognized sample collection centres/ facilities declared by CAB as per application. It will have list of such recognized centres / facilities either on their website or display board for its end-users.

Further, CAB will issue a ‘CERTIFICATE OF RECOGNITION’ to authorize its centres /facilities to claim recognition (as per controlled template of CERTIFICATE) Enclosed

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**National Accreditation Board for Testing and Calibration Laboratories**

Doc. No: NABL 111 | Procedure for recognition of Sample Collection Centre/Facility declared by Medical Laboratories

Issue No: 01 | Issue Date: 20-Jun-2018 | Amend No: 00 | Amend Date: 00 | Page No: 5 of 7
3. **Flow-diagram** (Accredited CABs)

Rest of centres / facilities shall be assessed according to due activities or otherwise. Each Centre/facility shall be assessed once during accreditation cycle of the CAB

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Is centre/facility recommended?

Yes

Decision will be informed to CAB, Records will be updated; Invoices will be generated for respective SCFs. CAB can re-apply for such SCF along with applicable fee

No

30 Days time will be given to address the NCs, if any. Assessment report will be evaluated by NABL for further decision

Is centre/facility recommended?

Yes

Decision will be informed to CAB, Records will be updated; Invoices will be generated for respective SCFs

No

Decision shall be informed & concerned centre/facility will be Derecognised and delisted.

CAB will stop all claims related to concerned SCF; de-list the concerned centre/facility. However CAB can re-apply for its SCF along with applicable fee

CAB will ask concerned centre/facility to remove certificate of recognition from all places, to avoid inadvertent claim by its centre, till its re-enrolment and re-assessment.

If CAB continues to claim or fails to stop claim of recognition by centre, adverse decision will be initiated against the CAB

Adverse decision shall be taken as per NABL 216 for ABEYANCE
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4. Procedure for Adverse decision

When lab is not able to close the issues of complaints pertaining to SCFs and not taking corrective action on the NCs after initial recognition, the CAB shall stop NABL claim or use of NABL symbol for concerned SCFs and return its original annexure. NABL shall issue revised annexure to the medical CAB for others SCFs. Lab shall de-list such concerned centre/ facility from all places, to avoid inadvertent claim. Similarly lab will ask its centre/ facility to stop claiming recognition, till its re-enrolment by re-application and assessment.

Negative recommendation in Assessment report

CAB will address complaints from patients/ users of centre/ facility as per its procedure

If lab fails to resolve the complaint received by them

NABL will provide 30 Days time for resolution, then recommendation will be given to CABs according to outcome

Is centre/facility recommended?

Yes

No Adverse decision

No 30 Days time to CAB for Corrective action

No satisfactory Corrective Action or inadequate Corrective Action

CAB will delist such concerned centre/facility from all places, to avoid inadvertent claim. Similarly CAB will ask its centre/ facility to stop claiming recognition, till its re-enrolment by re-application and assessment

Failure to do so will call for adverse decision against the CAB (Abeyance)
National Accreditation Board for Testing and Calibration Laboratories (NABL)

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