National Accreditation Board for Testing and Calibration Laboratories (NABL)

Procedure for Recognition of Sample Collection Centre/ Facility declared by Medical Laboratories (CABs)
## AMENDMENT SHEET

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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 can be assessed in its accreditation cycle, to the extent possible.

SCFs of applicant CABs

SCFs shall be assessed on sample basis (at least 5%) initially on or before the schedule of initial 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 based on the assessment report of the assessed SCFs.

(Refer Flow-diagram).

SCFs of accredited CABs

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

Digitalisation of Process

Mobile & Web based Applications has been developed to ease the application process, assessment process, 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 to conduct assessment 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.

Web based Application: Key features

- Manage laboratory, Sample collection centre/facility details and Assessor Data.
- Map based and Dashboard based view of data of laboratories
- Review of Assessment data of sample collection centres.
- Upload corrective actions and follow-up action to close the non-conformities, if any.
- 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.
- Provision to raise non-compliances.
Recognition of Sample Collection Centre/ Facility

NABL shall issue an annexure along with the accreditation certificate of the CAB 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 –

To be printed on the CAB Letter head

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

Receipt of application. Information on Sample Collection Centre / Facility (SCF) will be taken in, 1.10 Annexure to Application NABL 153

At least 5% of declared SCF can be assessed (on sample basis) either before or during Initial assessment/ reassessment to the extent possible, either by different or same assessment team appointed for CAB.

- Is centre/facility recommended?
  - No
    - 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
  - Yes
    - 30 Days time will be given to address the NCs, if any.
      - Is centre/facility recommended?
        - No
          - Decision will be informed to CAB, Records will be updated; CAB can re-apply for such SCF along with applicable fee
        - Yes
          - Assessment report will be evaluated by NABL for further decision

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
3. **Flow-diagram** (Accredited CABs)

Rest of centres / facilities shall be assessed according to due activities or otherwise. Each declared sample collection centre/ facility (SCF) of a medical CAB can be assessed once in its accreditation cycle, to the extent possible.

- **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**
    - Decision shall be informed & concerned centre/facility will be Derecognised and delisted. Updated list of recognised SCFs to be issued to the laboratory.

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**
    - 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 against the laboratory as per NABL 216.
4. 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 claim of NABL recognition or use of NABL symbol for concerned SCFs and return its original annexure. NABL shall issue revised annexure to the medical CAB for other 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.

CAB will address complaints from patients/ users of sample collection 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 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.

Failure to do so will call for adverse decision against the CAB as per NABL 216.
National Accreditation Board for Testing and Calibration Laboratories (NABL)

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