



National Accreditation Board for Testing and Calibration Laboratories (NABL)

**Criteria for Obtaining and Maintaining Recognition under the
Integrated Quality Assurance Scheme
(For laboratories under NACO Network-Recognition Scheme)**

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AMENDMENT SHEET

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1. ABBREVIATIONS

ICTC	Integrated Counselling and Testing Centre
PPTCT	Prevention of Parent to Child Transmission
DSRC	Designated Sexually Transmitted Infection
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
NACO	National AIDS Control Organization
ISO	International Organization for Standardization
APAC	Asia Pacific Accreditation Cooperation
Global ACI	Global Accreditation Cooperation Incorporated
NRL	National Reference Laboratory
SRL	State Reference Laboratory
SACS	State AIDS Control Society
PT	Proficiency Testing
AMC	Annual Maintenance Contract
PPP	Public Private Partnership
ILC	Inter Laboratory Comparison
RSLs	Regional STI Laboratories
SSLs	State STI Laboratories
NACP	National AIDS Control Program

2. INTRODUCTION

This scheme is applicable only for the laboratories at Integrated Counselling and Testing Centres (ICTCs) / Prevention of Parent-to-Child Transmission (PPTCTs), Designated STI/RTI Clinic (DSRC) sites or equivalent facilities (hereafter referred as laboratories) of NACO network. These laboratories play crucial role in the prevention and control of HIV and Syphilis in India, through counselling and testing services.

This integrated scheme is:

- Joint initiative between NABL and NACO to verify the implementation of standardised quality at ICTCs/PPTCTs/DSRCs or equivalent facilities providing essential diagnostic services under NACP. This scheme is not applicable for SRLs and NRLs of NACO.
- An independent quality scheme of NABL and is not covered under ISO 15189 accreditation of APAC & Global ACI MRA.
- Recognition scheme for the quality and competency of the laboratory based on the requirements drawn from the National and International standards e.g. ISO 15189, WHO guidelines, etc.

3. RECOGNITION CRITERIA

- Applicant laboratory shall apply as per the scheme documents along with applicable fee and satisfactory performance preferably in the NABL accredited Proficiency Testing program (as per ISO/IEC 17043) (in last six months from the application date), else proficiency testing conducted by the higher tier laboratory – National/Regional STI Laboratories (NRLs/ RSLs). (Ref: National Guidelines on Quality Management System for Laboratories under National and STD Control Programme 2025).
- Scope to be covered in the Integrated scheme shall include rapid diagnostic tests for HIV and Syphilis under Infectious Disease Serology.
- The laboratories performing NACO mandated tests and are under Public Private Partnership with NACO/ SACS shall submit copy of PPP arrangement.

Note: Testing laboratories of NACO network are deemed to be Govt. entity (Public) as per NACO program.

- The laboratories applying first time or renewing recognition or extending scope of recognition under the scheme shall submit fee as per Annexure-I of this document.
- Tests which are not covered under the above Proficiency Testing (PT) program (ref. Point 1) shall be recognised under the scheme, based on satisfactory outcome of participation in inter laboratory comparison.
- The laboratory shall submit the documentary evidence of calibration of equipment used for the testing the parameters under the scope of recognition.

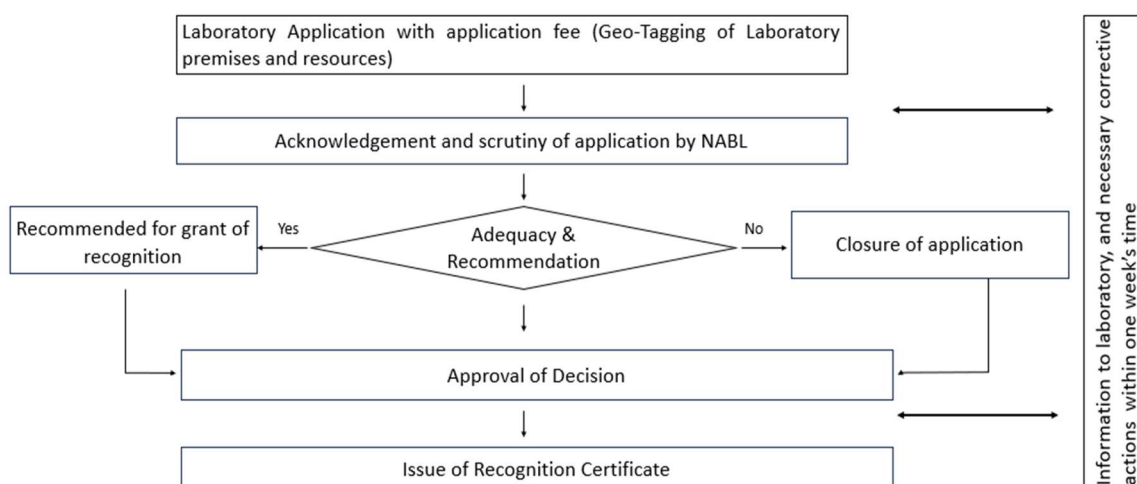
Note: Wherever possible, calibration from a NABL accredited laboratory is recommended.

- The laboratory shall at all times comply with all applicable regulatory and statutory requirements of the relevant national, regional, and local authorities.
- Recognition period shall be of three years for one cycle.

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4. RECOGNITION PROCESS

1. Laboratory shall apply in prescribed application form through NABL Portal or other acceptable mode.
2. Laboratory application shall be reviewed along with PT results and supporting information/ documents/ evidences.
3. Decision on recognition shall be taken on the basis of satisfactory PT performance in last six months from the date of submission of application.
4. Recognition certificate along with scope shall be issued by NABL.



5. SCOPE EXTENSION/ SCOPE REDUCTION

1. Laboratory may extend the scope of recognition during the recognition period by submitting scope extension fee, based on the satisfactory Proficiency Testing/ILC results, calibration of equipment used for the testing the parameter.
2. Scope of recognition may be reduced in this scheme, if PT/ILC performance is not satisfactory.

6. CHANGE OF PREMISES

1. Laboratory shall inform NABL for the change of premises and submit requisite declaration/information in the application for the change of premises along with applicable fee, within the 30 days of change.
2. Laboratory shall stop using recognition scheme symbol or claim of recognition on the test reports issued from changed premises until recognition decision from NABL for new premises is obtained.
3. NABL based on the satisfactory information submitted by the laboratories, shall issue recognition certificate for the change of premises, for the remaining period of recognition cycle.

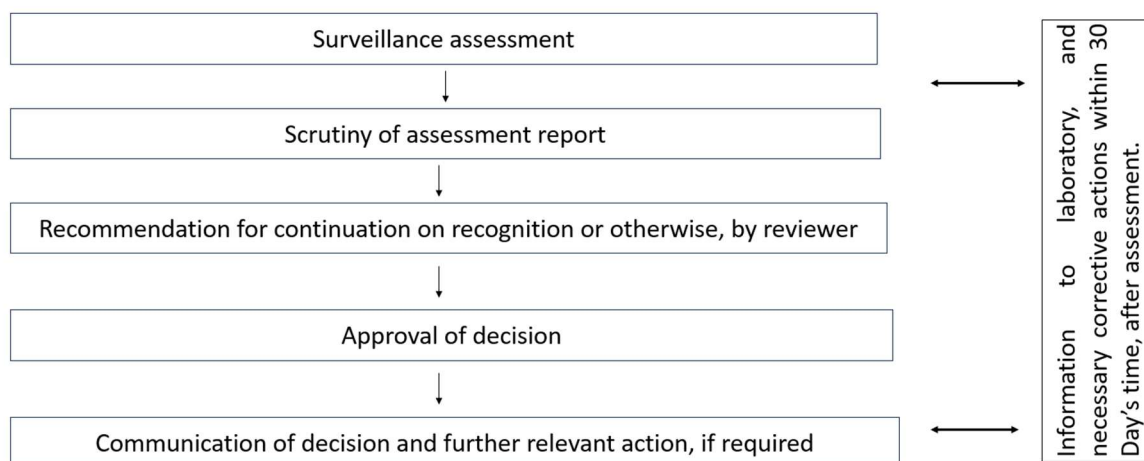
7. OTHER OPERATIONAL CHANGES

If PPP laboratory recognised under the scheme undergoes change in name and legal identity, laboratory shall inform NABL within 30 days. NABL shall review the request and impact on recognition and take appropriate action/decision.

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8. SURVEILLANCE ASSESSMENT

1. Surveillance assessment shall be conducted at least once in recognition period at any point of time to assess laboratory's operations and compliance to the requirements of recognition scheme.
2. NABL shall notify the laboratory and respective SACS for upcoming surveillance assessment three months prior to the assessment.
3. NABL shall schedule the surveillance assessment on the date, either provided by the laboratory or deemed appropriate by NABL, acceptable to the laboratory.
4. NABL shall assign appropriate assessor to conduct assessment as per defined checklist.
5. Surveillance assessment report shall be submitted directly to NABL.
6. Assessment report shall be reviewed and approved by NABL.
7. Based on the outcome of the surveillance assessment, decision on continuation of recognition or otherwise shall be communicated and necessary actions shall be taken.
8. Surveillance assessment logistics, transport and accommodation of assessors shall be made by respective laboratory through NACO/SACS arrangement, implying that all expenses related to the surveillance assessments shall be borne by the respective laboratory.
9. Administrative charges for the surveillance assessment shall be raised against the respective SACS with information to the respective laboratory and NACO soon after the assessment. Respective SACS on behalf of assessed laboratory shall make the payment within the stipulated period mentioned in the invoice.
10. After receipt of payment of administrative fee, NABL shall convey the outcome of surveillance assessment.



11. NABL may increase the frequency of surveillance assessment depending upon 1st surveillance report (if not satisfactory), feedback, inputs from users and outcome of unannounced assessment conducted as part of compliance monitoring.

9. UNANNOUNCED ASSESSMENT

1. NABL may conduct unannounced assessment, using independent assessor /NABL Officer on sample basis as per percentage decided by NABL.
2. Expenses related to unannounced assessment shall be borne by NABL.

10. TERMS AND CONDITIONS FOR OBTAINING AND MAINTAINING RECOGNITION

Applicant and recognised laboratories under the scheme shall require to fulfil the following terms & conditions:

1. Applicant and recognised laboratories during the recognition period shall meet the scheme criteria as defined in this document.
2. The laboratory shall offer cooperation to NABL or its representative during surveillance assessment or unannounced assessment on the following whenever NABL considers it as necessary:
 - a. Access to all laboratory areas of operations.
 - b. Undergoing any assessment to verify the capability of the laboratory for the applied scope.
 - c. Witnessing the activities being performed relevant to this scheme.
 - d. Assessing the competence of the staff during assessment.
 - e. Access to all relevant information, documentation and records.
 - f. Access to all records pertaining to relevant personnel.
 - g. Investigating any complaints against the laboratory.
3. The laboratory shall pay the applicable fee/ charges to NABL within stipulated time.
4. Laboratory shall ensure test results/ reports are reported by competent personnel as defined in NACO guidelines.
5. Laboratory shall undergo surveillance assessment proposed by NABL any time during recognition period.
6. Laboratory shall continue to participate in PT or ILC as per this document for applicable test during recognition period.
7. The laboratory shall not involve in any kind of activity(ies) which may bring NABL to disrepute.
8. The recognised laboratories can relinquish recognition through a written notice to NABL by clearing any outstanding payment and surrendering the certificate along with scope.
9. The laboratory shall respond promptly to the changes initiated by NABL as per this document. The laboratory shall inform NABL when such alterations under the agreed time frame have been completed.
10. Laboratory shall not claim recognition or use recognition symbol under this scheme, for premises which are not actually recognised, and for tests which are not recognised as per recognition scheme.
11. NABL absolves itself of any legal or financial liability arising out of activities of any of its laboratory covered under this scheme involving any accidental or consequential damages to personnel / equipment / products/ institution at any time.
12. It is the responsibility of laboratory to abide by the National/ Regional/ State/ Local regulatory requirements/Acts/ Rules/ Legal orders/ Court Decisions/ Orders issued by Government/ Statutory Bodies during recognition period as applicable and effective from time to time.
13. The Laboratory shall inform NABL within 30 days of significant changes affecting the Lab's activities and operations relevant to recognition, such as:
 - a. change in premises of laboratory
 - b. change in its name / legal identity, if laboratory is under Public Private Partnership
 - c. change in the recognised scope,
 - d. equipment (if applicable)
 - e. change in Laboratory In-charge
14. Laboratory recognised under this scheme shall not claim to be NABL accredited laboratory or make any reference of accreditation in its test reports/any document or imply having accreditation from NABL

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NABL reserves the right to take appropriate adverse action, including abeyance, de-recognition against the laboratory in case where irregularities are established without issuance of a Notice of adverse action & opportunity for a hearing under exceptional circumstances. Such action may be taken for reasons including but not limited to the noncompliance with the recognition criteria, applicable rules and regulations, or any other condition outlined in the terms of reference.

All disputes, arising out of NABL decisions that remain unresolved through mechanism provided by NABL are subject to the exclusive jurisdiction of the Courts at New Delhi and none other.

11. INSTRUCTIONS TO CLAIM RECOGNITION

Recognition Certificate shall be issued to the laboratories upon approval by NABL with Certificate No. along with certificate validity. The recognition logo with certificate number as represented below, shall be called as recognition symbol and the same shall be used by recognised laboratory on its test reports for the recognised scope at the premises approved by NABL.



Recognition Logo



NABLNACOMMYSCXXXX

Recognition Symbol

Also, Laboratory may write following statement to claim recognition under the scheme:

“Integrated Quality Assurance Scheme Recognised Laboratory vide NABLNACOMMYSCXXXX”

1. Recognised laboratory shall claim recognition for the recognised test parameters by using above image in test reports.
2. The image shall be legible and displayed only in the appropriate form and proportion.
3. Electronic reproduction of above image is permitted provided that the requirements of this document are met, integrity, orientation of above image is maintained and distortion of graphic is avoided.
4. Recognition under this scheme claim shall be related only for the specific laboratory premises which is covered under the recognised scope, and not with any other non-recognised premises.
5. Recognised laboratory shall not authorise the claim of recognition by their customers, subcontractors or any other third party. It is the responsibility of each recognised laboratory to describe their recognition status in a manner that does not imply recognition in areas that are outside their actual recognised scope and facilities not covered under scheme and to minimize the risk of a customer / general public being misled.
6. The claim of recognition shall be used by recognised laboratory during the period only when it

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holds valid recognition.

12. SITUATIONS WHEN CLAIM OF INTEGRATED QUALITY ASSURANCE SCHEME RECOGNITION IS NOT PERMITTED

1. Applicant laboratories shall neither claim recognition nor use any image related to NABL (i.e Accreditation Logo/ Symbol and Scheme Logo/Symbol) and/or NABL Recognition Programs.
2. When the laboratory is derecognized or under Abeyance, then laboratory shall neither claim recognition nor use any symbol related to NABL and/or NABL's Integrated Quality Assurance Scheme.

Note: Once derecognized or placed under Abeyance, the laboratory shall immediately cease to issue test report displaying the recognition status under this scheme in any form; and shall cease publishing and/or distribution of documents (including promotional & advertisement, website, letter head etc.) containing the recognition status to under this scheme.

13. ADVERSE DECISION

A. Inactive of Application

1. Conditions:
 - a) Not submitting application fee with application.
 - b) Not addressing the regulatory requirements.
2. Actions by NABL
 - a) The application will be placed in inactive category.
 - b) The decision will be formally communicated to the laboratory by NABL.
 - c) The laboratory application shall be made active based on the submission of satisfactory actions required to address the reasons for its inactive status.

B. Closure of Application

1. Condition:
 - a) Not addressing the inadequacies pertaining to application within 30 days maximum time from initial communication.
2. Actions by NABL
 - a) The application will be closed.
 - b) The decision will be formally communicated to the laboratory by NABL.

C. Abeyance

1. Condition:
 - a) When Integrated Quality Assurance Scheme recognised laboratory subcontracts a substantial or critical part of its recognised scope to another Integrated Quality Assurance Scheme recognised laboratory or NABL's ISO 15189 accredited laboratory due to temporary incapacity to perform testing under the scope & laboratory has not informed such arrangement to NABL within 30 days from the start of subcontracting.
 - b) When laboratory is unable to provide satisfactory corrective action evidences on non-conformities of surveillance assessment within stipulated time of 30 days.
 - c) When laboratory has not participated in the accepted PT/ILC Program for more than last six months from the date on which the data is submitted/sought.
2. Actions by NABL
 - a) NABL shall place the laboratory under Abeyance for a maximum of three months or until the validity of recognition, whichever is earlier.
 - b) NABL shall keep record of start and end dates of abeyance period.

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Laboratory shall inform the resumption of testing activity at the laboratory or and corrective actions on reason of Abeyance. Laboratory recognition shall be reinstated based on review by NABL and accordingly laboratory shall be allowed to claim recognition under Integrated Quality Assurance Scheme.

D. De-recognition of Laboratory

1. Conditions:

- a) PT performance is not satisfactory in two consecutive PT/ ILC participation.
- b) When laboratory has not submitted any corrective action against NCs raised during surveillance assessment within the stipulated time of 30 days.
- c) When laboratory has not paid the applicable fee within stipulated period mentioned in the invoice.
- d) When laboratory has not resolved conditions/reasons of abeyance within three months' time or until the validity of recognition, whichever is earlier.
- e) Any false claim under NABL accreditation in any form, instead of recognition under Integrated Quality Assurance Scheme.
- f) Any false claim under Integrated quality assurance scheme beyond recognised scope
- g) Any violation of terms and conditions.

2. Actions by NABL

- a) Outstanding is to be collected before issuing the decision.
- b) Laboratory will be de-recognised.
- c) The decision will be formally communicated to the laboratory by NABL.

Laboratory may apply afresh after taking satisfactorily taking actions on the reasons of de-recognition along with requisite fee applicable at that time.

14. Annexure I (Fee Structure)

Fee Structure applicable for this scheme is as follows:

Components	Fee / Charges
Application/ Renewal Fee	₹15,000/-
Administrative fee for Surveillance	₹5,000/-
Scope Extension/ Change in Premises	₹5,000/-

Note: In addition to the above-mentioned fee, GST (as applicable) is to be paid along with said charges/ fees.

Fee/charges paid is non-refundable.

15. COMPLIANCE CHECKLIST

Sl.	Requirements	Yes/ No	Evidence (To be checked during the assessment)	Remark on Compliance/ Non- Compliance
1.	Organization and Personnel			
a.	Is there a Medical Officer (designated Head / In-charge of laboratory) available and supervises the laboratory activities?			
b.	Is/Are adequate and qualified Staff (counsellor/s and laboratory technician/s) available as per NACO guidelines?			
c.	Is there an alternate arrangement for laboratory technician in case of leave/vacant position? Specify			
d.	Whether Personnel Files have documents for: 1. Staff Trainings-Induction and refresher 2. Education (e.g., degrees/certificates) 3. Personnel Health Data – (vaccination status, etc.)			
e.	Does the laboratory supervisor routinely perform review of all quality records? 1. Temperature monitoring log sheets? 2. Preventive Maintenance log sheets? 3. Specimen rejection logbook? 4. IQC Records across all test areas 5. PT/ILC Results? 6. Corrective actions, if any against PT outliers 7. Records of pre-test and post-test counselling			
2.	Facilities and Safety			
a.	Is signage displayed within and/or outside the facility containing all the required information as per the NACO guidelines? 1. Laboratory Display Board (Outside or on laboratory entrance) 2. Working hours 3. Turn Around Time			
b.	Does the equipment placement / layout facilitate optimum workflow			
c.	Is facility adequately ventilated?			
d.	Is facility adequately lit?			
e.	Is Universal standard safety precautions implemented?			
f.	Post-exposure prophylaxis register maintained by the facility			

g.	Does the laboratory have first aid and spill kit available and laboratory technician trained on spill management?			
3.	Space requirement			
a.	Are there separate provisions for counselling and laboratory operations (sample collection & testing) available at the ICTC and does the counselling areas support privacy?			
b.	Are patient samples stored separately from reagents and blood products in the laboratory refrigerators and freezers?			
4.	Legal or Statutory requirements as applicable			
a.	Declaration by Head / In-charge of laboratory regarding Handling of Biomedical Waste generated in the facility as per provisions of latest Biomedical Waste Management Rules. Or Valid service agreement with the authorised BMW collection agency.			
b.	Is/Are the fire safety device/s available, and the staff trained?			
5.	Documents & Records			
a.	Are informed consent, Medico legal records maintained, if applicable (as per NACO guidelines and applicable laws).			
b.	Are records retained as per NACO guidelines/OM of NCAO			
6.	Standards on basic processes			
a.	Is the Bio-medical waste (BMW) segregated as per latest BMW Management Rules.			
b.	Are BMW bins/bags filled not beyond two-thirds of their capacity and are disposed of within 48 hours?			
c.	Are Kit inserts/ authorised documented procedure used as SOPs for HIV and Syphilis			
d.	Are the Dry Blood Spot samples collected, stored and transported for Early Infant Diagnosis test as per the NACO guidelines			
e.	Does the laboratory have complaints redressal mechanism			
f.	Is the Laboratory technician aware of the procedure for handling and disposing of expired kits as per the NACO guidelines?			
7.	Equipment			
a.	Is refrigerator available and respective temperature monitoring equipment calibrated?			
b.	Is centrifuge available and calibrated?			

c.	Is/are pipettes available and calibrated_(if applicable)?			
8.	Quality Checks			
a.	Does the laboratory perform internal quality control as per the NACO guidelines			
b.	Does Laboratory technician use control while opening a new box of test?			
c.	Does the laboratory perform lot-to-lot verification of kits before placing them into use?			
d.	Does the laboratory follow the HIV and Syphilis test Algorithm as per the NACO guideline?			
e.	Are test kits labelled with date received and initialed (Signed)			
f.	Are test kits in use currently within their expiration dates?			
g.	Are the test reports verified against the worksheet and signed by authorized staff?			
h.	Does the lab participate in Proficiency Testing Program/ILC for HIV and Syphilis in every six months?			
9.	Inventory Management			
a.	Are adequate kits and consumable stocks available for HIV and Syphilis testing as per NACO guidelines			
b.	Are adequate kits and consumable stocks available for Dry blood spot sample collection, storage and transportation for Early Infant Diagnosis test			
c.	Is/Are the staff aware about the minimum stock level and First Expired, First Out			
10.	Data System			
a.	Does the laboratory use national data system - SOCH for program reporting as per NACO guidelines or Ministry of Health & Family Welfare			
b.	Does the laboratory use NACO Prayogshala to manage the PT program data			

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