

Request for Proposal # 2021-069

for

Consultancy Services to assist Five Laboratories in Private Sector in Obtaining NABL Accreditation for Assay (Purity) of Medical Grade Oxygen as per ISO/IEC 17025:2017

Response to Request for clarifications

S.No.	Query	Answer
1	Legal Identity : As per ISO/IEC 17025 and NABL requirement, it is important to define legal identity of testing lab organization . Such will have ultimate responsibility of technical validity of the reported results , and accreditation is granted to such organization only. In this RFP it is not clear, the legal relationship of PATH with five private sector labs .	All five labs will have individual legal identities.
2	Technical scope : Testing scope of various gases for medical application are covered under 'Chemical testing Field ' by NABL (Ref. NABL 120). However , it is not clear from RFP that, which specific standard specifications the Oxygen Assay (purity) tests are performed by these 5 said labs. Refer one sample scope of other NABL accredited lab , performs same test with different standards as EP 9.0 and USP42	The laboratories must perform the test for medical oxygen testing with any standards, but the testing standard should be recognised and approved by the NABL for accreditation.
3	Scope of services (Annexure E Section B Point No. 10) : 'Consultant shall be present during Pre-assessment and Final assessment by NABL'. Generally NABL do not permit the consultant to remain as a part of assessment , as it is an assessment for ensuring competency of lab staff. However, after completion of assessment lab staff can seek guidance / assistance to close N/cs, if any.	Attendance is recommended without any interference at the time of audit.

4	<p>Scope of services (Annexure E Section D) , Timelines for key deliverables :</p> <p>a. Timeline defined in RFP (No. of days) are total man days for the activity to be completed ? or time deadlines from workorder date ? If it is deadline from work order date, then for point No. 2 activity, 20 days are not sufficient for 5 labs together , as per our experience. It also needs involvement of lab staff.</p> <p>Generally role of consultant in such activity, is to develop technical competency with lab staff so that, they should work in compliance with ISO/IEC 17025 laboratory management system and NABL requirements. Such technical competency of lab staff is assessed by NABL assessors during assessment. During consultancy activity, we deliver these trainings to lab staff so that, for long term such trained persons can handle future NABL assessments on their own as well as provide most reliable test services to their customers.</p>	<p>A total of 120 days has been allocated for the overall project. The days mentioned for the activities can be re-shuffled to meet the on-time delivery. A vendor can use multiple consultants to deliver the project. Also, the mentioned location are tentative and may change after the PATH internal assessment.</p>
5	<p>After submission of application to NABL, each lab undergoes three assessments from NABL – Adequacy Audit, Pre-assessment, Final Assessment. The standard schedule of NABL to complete these assessment can be approximately 2 months , since availability of expert auditor with NABL for such specialized field is limited. Consultant do not have any control on these activities by NABL or can interfere in NABL process.</p>	<p>We expect the vendor should expedite the process by contacting NABL and making them understand the need for the assessment on an urgent basis. Any delay due to NABL will be considered.</p>
6	<p>Point No. 5 - After completion of final assessment and closer of all reported N/cs, grant of accreditation, and NABL certificate takes minimum 30 days ,again control is out of consultants scope.</p>	<p>Final certification to the laboratories will be considered as a closure to release any payment.</p>
7	<p>With above conditions and facts, RFP do not provide information about delay in handling of key deliverables and late delivery clause for the same. Please provide clarification.</p>	<p>Not Applicable</p>