# Information & Instructions for completing an Application Form

- The applicant laboratory shall undertake to carry out its testing activities in such a way as to meet the requirement of ISO 15189:2012, NABL specific criteria, other relevant requirements of NABL and the regulatory authorities, as applicable at all times.
- 2. Applicant laboratories are advised to ensure that the latest versions of NABL documents are available with them.
- 3. The application fee and other necessary charges related to accreditation process is given in NABL document NABL 100 'General Information Brochure' under NABL Finance and NABL Fee Structure'. NABL 100 is available on NABL website.
- 4. Laboratories are advised to familiarize themselves with NABL 100 'General Information Brochure', NABL 201 'Procedure for dealing with Changes in Accredited Conformity Assessment Body's Operations', NABL 216 'Procedures for Dealing with Adverse Decisions' and NABL 131 'Terms and Conditions for Obtaining and Maintaining Accreditation' before filling up this form.
- 5. The applicant laboratory shall provide photocopy of appropriate document(s) in support of the legal status claimed (eg. Registration Certificate under Indian companies Act, Limited Liability Act, Partnership Act, Registration of Business as Sole Proprietor, Indian trust Act, Societies Registration Act, Any Government notification in support of establishment of institution/ laboratory or any approval from local or regulatory bodies etc.) The name of the organization / laboratory shall not be different from the name given in the proof of legal identity certificate. If it is different, valid reasons for the same shall be furnished.
- 6. The applicant laboratory shall intimate NABL about any change in the information provided in this application such as scope applied for accreditation, personnel, and location etc. within 15 days from the date of changes.
- 7. NABL expects applicant laboratories that are to be accredited to follow the test methods as mentioned in the current National or International standards and as stipulated by regulatory bodies. Where such methods do not exist, other validated methods are acceptable. In case laboratory uses in-house validated methods the validation data should be submitted along with the application.
- 8. The applicant laboratory must participate satisfactorily in the Proficiency Testing program / EQAS conducted by APLAC or NABL any other national or international accredited/ recognized PT provider. For participation in PT, refer NABL document NABL 163.
- 9. The laboratory shall also inform NABL in advance about any reservation regarding appointment of Lead Assessor/ Assessor for the assessment.
- 10. The applicant laboratory shall be given due notice of any intended changes relating to NABL accreditation criteria and will also be given such time, as in the opinion of NABL is reasonable to carry out the necessary adjustments to its procedure(s). The laboratory shall inform NABL when such adjustments have been completed.
- 11. The application must be filled up carefully to provide required information in such a manner that further correspondence for seeking clarifications are not required. Particularly the scope of accreditation shall be complete to indicate unambiguously:

- a. materials or items tested
- b. specific tests or types of tests performed
- c. specification, standard (method) or technique used
- d. range of testing/ limit of detection for each test (as applicable)
- e. % CV (or) uncertainty of measurement (MU) for each test (wherever applicable) at a confidence probability of 95%.
- 12. The laboratory locations, tests, which the laboratory intends to cover, vide NABL accreditation must be listed clearly. The tests those are performed at site should be clearly identified in the scope of accreditation.

Note: Multilocation laboratory: A laboratory with more than one location in the same city with same legal identity and with overlapping scopes in different locations. The details of each location shall be explicitly mentioned in application form. In events where the laboratory operates from different city/ state, each laboratory shall apply separately for accreditation except those cases where safety or regulatory requirements are there for operation of the laboratory. In such cases, the laboratory shall provide the proper justification.

- 13. The laboratory shall offer the NABL or its representative cooperation in:
  - a. undertaking any check to verify testing capability of the laboratory.
  - b. the laboratory shall unambiguously provide names of all authorized signatories who are responsible for authenticity and issue of test certificates and reports.
  - c. offering access to relevant areas of the laboratory including primary sample collection centres for witnessing the activity being performed.
  - d. examination of all relevant documentation and records.
  - e. interaction with all relevant personnel.
- 14. The laboratory shall discharge all non-conformities raised during the assessment within the stipulated time. The same shall be verified to the satisfaction of NABL. The final decision on accreditation shall rest with NABL.
- 15. The application shall be kept confidential by NABL and information obtained during the processing of application, assessment visit and grant of accreditation shall be safeguarded and dealt with impartiality *until required by Law*. The procedure for processing of application for accreditation is given in NABL 100.

# User Manual

**National Accreditation Board for Testing** and Calibration Laboratories (NABL)

Type of Application: Medical

Creation Date: 16<sup>th</sup> Dec, 2017

Last Updating Date: 29<sup>th</sup> Jan, 2018

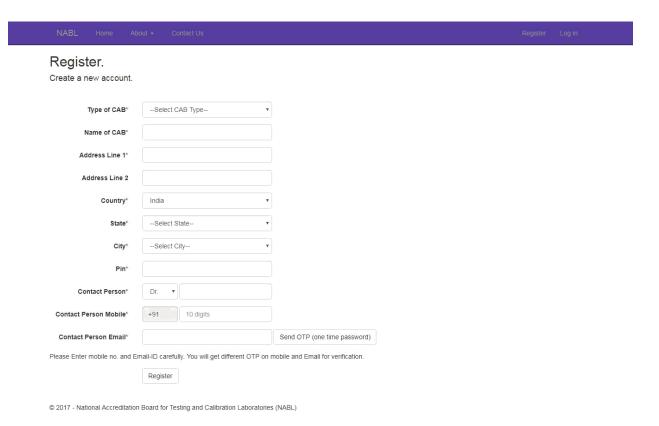
Version: 1.3

# **Table of Contents**

- 1. Registration of CAB
- 2. Login by CAB
  - Laboratory Details
  - Location Details
  - Discipline Details
  - Scope of accreditation
  - Organization
  - **Equipment**
  - Reference Materials
  - **4** Quality Control Activity
  - **List** Enclosure List
  - **♣** Payment Process

# 1. Registration of CAB:

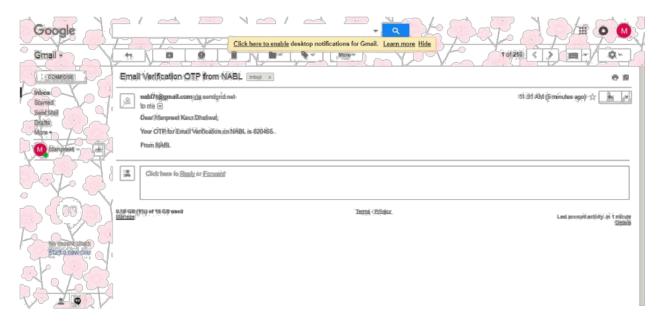
Open the URL <a href="http://nablwp.qci.org.in/Account/Register">http://nablwp.qci.org.in/Account/Register</a>. It opens registration form for different types of users.



For Type of CAB, there are five types of CAB, select Medical.

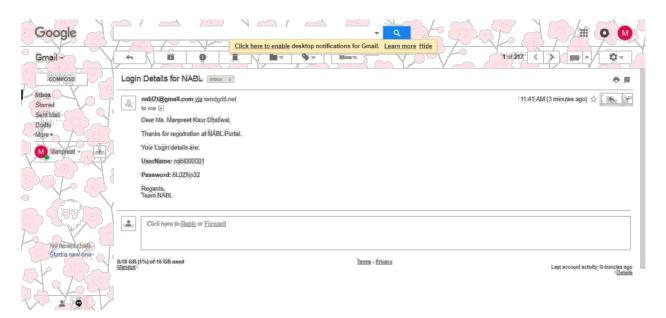
Enter all the details with valid mobile number and email id.

You will get OTP on your mobile number and email id. You have to validate your mobile number and email id using OTP.



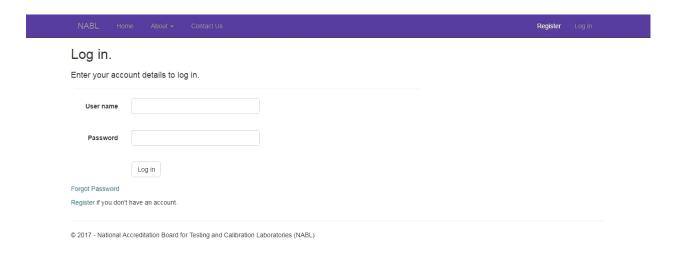
After entering OTP, Your Mobile number and Email ID will be validated and thereafter registration can be done.

After successful registration, you will receive Username and password on your email id.



# 2. Login by CAB:

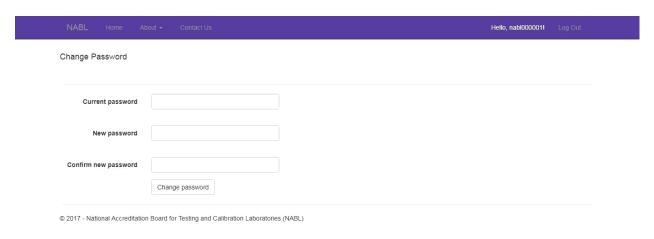
Open the URL <a href="http://nablwp.qci.org.in/Account/Login">http://nablwp.qci.org.in/Account/Login</a>. It will redirect you to login form.



Enter the credentials you receive in your email id.

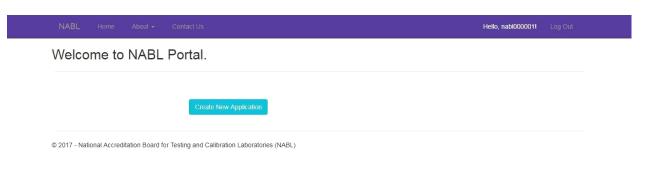
After submitting the credentials you will be redirected to change password screen.

It is mandatory for first time user to change the password.

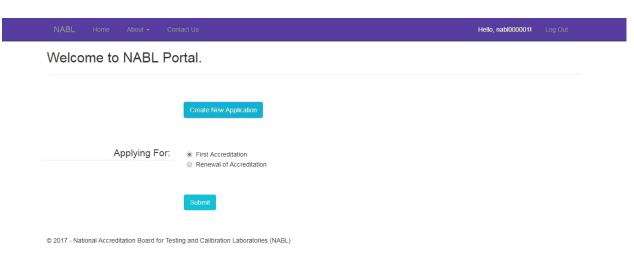


New Password should have minimum 8 characters with at least one special character, one number, one uppercase letter and one lowercase letter.

After changing password, it opens a new page with button Create New Application.



Click on create new application, it shows the options "Applying for". Select any one.





### **Laboratory Details:**

After submitting the option, you will be redirected to Laboratory details page.

#### Discipline Details Scope Of Accreditation Organization Equipment Reference Materials Quality Control Activity **Enclosure List** Laboratory Details Name of the Laboratory MEDICAL Note: Indicate name of the Laboratory will be appear on the Certificate Type of Laboratory' --Select Type of CAB--**GSTIN** GSTIN Country \* India State ! Punjab City \* Balachaur Address' CHANDIGARH District District Pin Code \* 894589 Mobile No\* Mobile No Landline no Landline No

#### **Medical Laboratory Details**

Complete the laboratory details with all the mandatory details.

If you want to proceed further, it is necessary to fill laboratory details first.

STD.C

Email

Fax No.

Fax No.

E-mail\*

For category of facility, it is mandatory to select at least one facility. For legal identity details, select legal identity options available and upload documents.

In Lab details, if you click Yes for "Does accreditation sought for different locations", it will add new tab "Location details" where you can add multiple locations.

After saving the form, click Next and you will be redirected to new tab.

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# **Location Details:**

In new tab location details, it shows a default location. This is the location which user has added in laboratory details.

User can add more locations by clicking on button "Click here".

#### **Laboratory Details** Discipline Details Scope Of Accreditation Organization Equipment Reference Materials **Quality Control Activity Enclosure List Location Details** Click Here To Add Location **Location Details** Sr. No. Update Delete **Location Name** Address Line 1 District Pin Code Contact No **FAX No** E-mail CHANDIGARH 894589 8734878743 man@gmail.com Location 1 Balachaur

#### **Medical Laboratory Details**

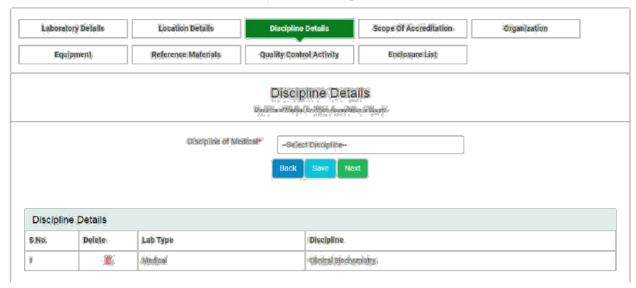
When user clicks on Click here to add location, it opens a form for adding location.

After adding location, it will be redirected to discipline details page.

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# Discipline details:

For discipline details page, select the Discipline of Medical testing from the dropdown.

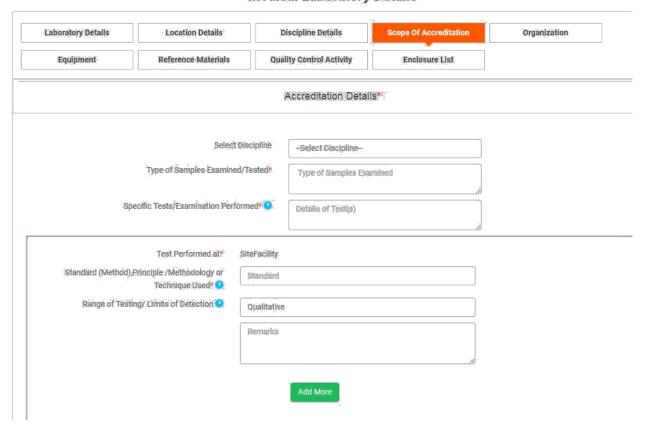




# Scope of Accreditation:

After adding Discipline Details, you will be redirected to Scope of Accreditation tab.

#### **Medical Laboratory Details**



In this form, for location, it shows those values in dropdown which you have added in second tab location details.

For selecting discipline, it shows those disciplines in dropdown which you have added in third tab Discipline Details.

In the Type of Samples examined/ Tested lab to provide the exact material used for testing.

In the Specific tests/ examination performed CAB to provide the Specific test performed in the above material of testing.

In the Standard (method), Principle /Methodology or technique used – CAB to specify the exact the methodology or Principle.

In the range of testing/ Limit of detection – CAB need to provide the range of testing of the equipment only. In cases of Specialized tests CAB may provide limit of detection

For Qualitative parameters CAB to specify the reporting pattern in the remarks Ex: Positive/ negative, Absent/ Present etc.

In %CV/MU – CAB to provide the highest %CV of last six months up to one place decimal Ex: 2.6, 3.0, 5.2, 15.1

Save the details and click Next.

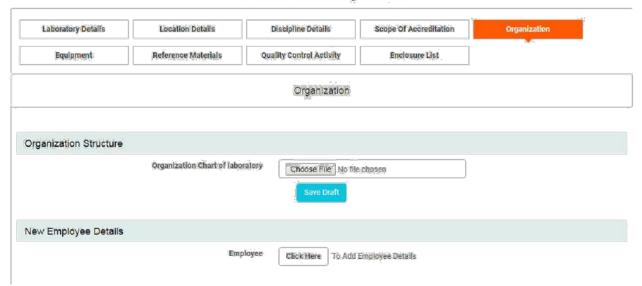
Note: If you are adding scope of accreditation for all the locations, then you will have to add organization, equipment, reference materials and quality control activity for all locations.

#### **Important Information:**

We understand that filling the scope of accreditation may appear as time consuming but it has been consciously designed in such a manner to overcome the issues related to scope of accreditation. The tests, test methods, Range of testing & amp; MU (wherever applicable) is required to be filled for each parameter as per the designed format. This is also a one-time activity wherein laboratory has to fill the requisite information initially and the information will be pre-fetched in future. The laboratory is required to fill the requisite information correctly and consciously as it an important part of accreditation. The laboratory is held responsible for the information provided in the application irrespective of the person who is filling the information. Any incorrect or insufficient information provided intentionally while filling the requisite information is treated as "Misleading/ Malpractice/ Fraud" and actions as per NABL 216 will be initiated which may also lead to calling off assessment.

# Organization:

To add organization chart, scope of accreditation must be filled initially.



In organization form, once you upload the relevant documents, it opens a separate section for filling the employee details.

Fill the employee details as required.

In case of Quality Manager, 4 days training course on "Laboratory Management system & internal auditing as per ISO 15189:2012" is mandatory and training certificate for the same to be uploaded.

# Note: While adding employee details, it is mandatory to add details for all employee types and for all locations which have been selected by scope of accreditation.



Equipment:

After completing the organization details, click on equipment and enter the all details as required.

If CAB is using one equipment for multiple parameters, then it has to tick the boxes in the parameters.

CAB to provide major and minor equipments used in the testing.

UID of equipment: Unique Identification number generated by the laboratory on its own for each & every equipment individually under scope of accreditation.

If the equipment is calibrated externally, the name of calibration agency along with the location to be specified in the box provided.

UID of equipment: Unique Identification number generated by the laboratory on its own for each & every equipment individually under scope of accreditation.

If the equipment is calibrated externally, the name of calibration agency along with the location to be specified in the box provided. If the equipment is calibrated in-house, the traceability details of the master equipment/ reference standard used for calibration to be specified in the box provided.

#### **Medical Laboratory Details**

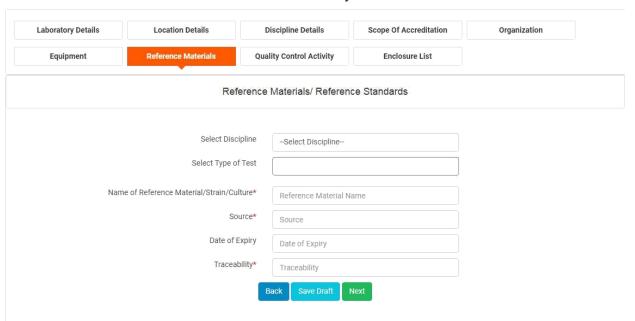
Laboratory Details	Location Details	Di	scipline Details	Scope Of Accreditation	Organization	
Equipment	Reference Materials	Qual	ity Control Activity	Enclosure List		
Equipment						
	Select Disc	ipline	Select Discipline			
Select Type of Test						
UID of Equipment * ③		UID Of Equipment				
	Name of Equipment*		Equipment Name			
		ial No	Serial No			
Model *		Model				
	Year of N	1ake* ∕Iake*	name of manufacturer			
Receipt date & date placed in Service*		2018  Reciept Date				
Range and Accuracy*		Range and Accuracy				
	Calibration	date*	Calibration Date			
he laboratory to decide the calibrati	Calibration Du		Due On			
	Calibrat	ed by	OInhouse OExternal			
		В	ack Add more N	lext		

>

#### Reference Material:

After completing the equipment details, click on "Next" tab. It opens the form for reference materials.

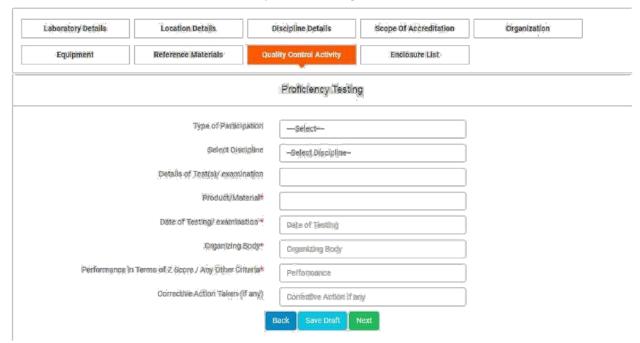
#### **Medical Laboratory Details**



# Quality control Activity:

After completing the details of reference materials, click on "Next" tab.

It opens the form for quality control activity.



# Enclosure List:

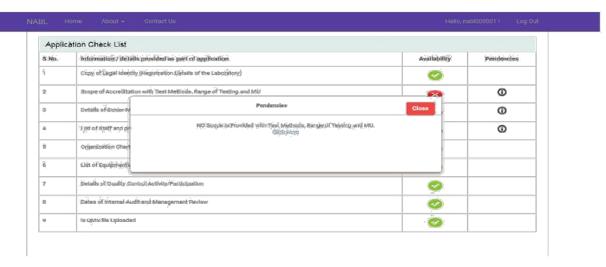
When whole form is completed, click on enclosure list.

If there is any detail which is missing, then it will be shown under pendency's.

If it meets with all the details, then it will show green tick in front of it under availability column.

Labora	atory Details	Location Details	Discipline Details	Scope Of Accreditation	Organiza	tion
Eg	ulpment	Reference Materials	Quality Control Activity	Enclosure List	ļ	
			Upload Quality manual D			
		Upload Quality o	choose File No file	e chosien		
			Application Form- Che	ck List		
Applica	ation Check List					
S No.	Information / det	tails provided as part of applicat	ion:		Availability	Pendencies
Copylof Legal Identity (Registration Details of the Laboratory):					<b>Ø</b>	
2. Scope of Accreditation with Test Methods, Range of Testing and MU				0		
8	Details of Senior Management with Designation and Contact Details				8	©
4 List of Staff and proposed Authorized Signatories			<b>Ø</b>			
22.	Organization Charl Enclosed			<b>©</b>		
List of Equipments / Reference Material used with details of Traceability			8	0		
Ź.	Details of Quality Control Activity Paintolpsillon				8	0
8	Dates of Internal Audit and Management Review					
9:	ts (this file Uploided)				<u> </u>	0

To add the details which are pending, click on icon under pendency, it opens a pop up.



It opens a pop window with click here button, Click on that button and complete the pending points.

When whole form is complete, it will show green tick in front of it and declaration form will be visible with Terms and conditions.

Equipment Reference Materials Quality Control Activity Enclosure List Declaration	Laboratory Details	Location Details	Discipline Details	Scope Of Accreditation	Organization
	Equipment	Reference Materials	Quality Control Activity	Enclosure List	

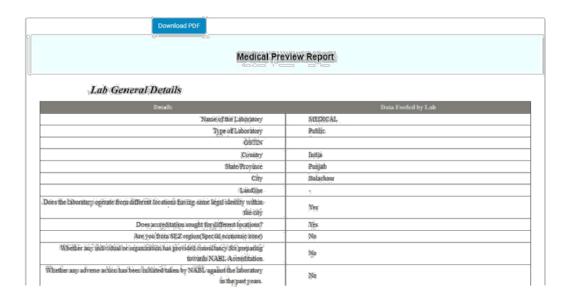
#### Terms & Conditions for Obtaining and Maintaining NABL Accreditation (NABL 131)

#### Terms and Condition

The Conformity Assessment Bodies (Testing including Medical / Calibration Laboratories / Proficiency Testing Providers PTP / Reference Material Producers RMP) that are applicant / accredited by NABI. shall be required to fulfill the following terms and conditions:

- 1. The Conformity Assessment Bodies (CABs) shall carry out its testing / calibration / medical / PTP / RMP activities in spice, a way as to meet the requirements of ISO/IEC. 17025:2005 or ISO 15189-2012 or ISO/IEC 17043:2010 or ISO 15189-2012 or ISO/IEC 17043:2010 or ISO 15189-2012 or ISO/IEC
- 2. The CAB shall have a valid legal identity.
- 3. The CAB shall meet the requirements of regulators in relevant field.
- 4. The CAB shall identify and define various activities which they are involved in, and ensure that it does not lead to any potential conflict of interest.
- 5. The CAB shall have adequate qualified and trained manpower for stated scope including NABL approved authorized signatory who meets the requirements of relevant NABL specific criteria for each field / discipline of accreditation.
- 6. The designated Quality Manager for CAB laboratory shall successfully undergo 4 day training on ISO/IEC 17025:2005 or ISO 15189:2012 whichever is relevant from a reputed training institute. For PTP / RMP, the Quality Manager shall preferably undergo either 4-days training on ISO/IEC 17043:2010 / ISO 3010de 34:2009 or at least 4 day training on ISO/IEC 17025:2005 or ISO 15189:2012 as the case may be.
- 7. The CAB, where applicable, shall participate in one inter laboratory comparison / proficiency. Testing program in at least one parameter / type of test per discipline prior to gaining accreditation and after obtaining accreditation for all groups included in the accredited scope of each discipline at least once every four years. Requirements specified in NABL 163 shall be followed for PT participation.
- 8. CAB shall submit the completed application for renewal of accreditation six months prior to the expiry of accreditation and also agree to undergo assessment as per the schedule proposed by NABL to maintain continuity in accreditation cycle:
- 9. The CAB shall offer cooperation to NABL or its representative in:
  - . Undergoing assessments in stipulated time intervals / whenever NABL considered it as required.
  - Access to all CAB areas of operations including subcontractor premises; wherever relevant and applicable.
  - . Undertaking any check / inspection to verify the capability of the CAB for the applied / accredited scope.
  - · Witnessing the activities being performed relevant to accreditation.
  - Assessing the competence of the staff (including staff working in shift operations / at site) during assessment:
  - · Access to all relevant information and documentation.
  - Access to those documents that provide insight into the level of independence and impartiality to the GAB from its related bodiles; if applicable.
  - · Access to all records pertaining to relevant personnel;
  - · Providing names of all authorized signatories who are responsible for authoriticity and issue of test / calibration / PTR / RMP reports.
  - · Investigating any complaints against the CAB.

There is also preview report button. Clicking on that button shows the report.



After completing all the information/ previewing the application Click

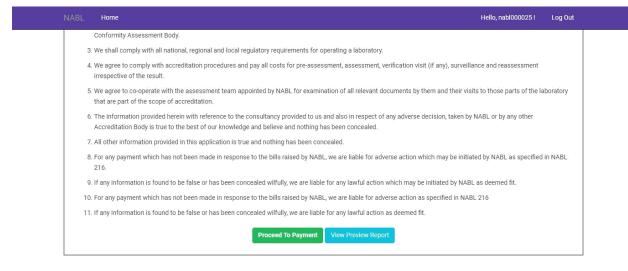
"submit". It will ask password for submission of application. Once the password entered by the user the application will be finally submitted. After final submission, it shows View report button. Clicking on it opens the preview from where you can download the form also.

Download PDF						
Medical Preview Report						
Lab General Details						
Details		Data Feeded by Lab				
Name of the Laboratory	MEDICAL					
Type of Laboratory	Public					
GSTIN						
Country	India					
State/Province	Punjab					
City	Balachaur					
Landline	2					
Does the laboratory operate from different locations having same legal identity within the city	Yes					
Does accreditation sought for different locations?	Yes					
Are you from SEZ region(Special economic zone)	Ne					
Whether any individual or organization has provided consultancy for preparing towards NABL Accreditation	No					
Whether any adverse action has been initiated taken by NABL against the laboratory in the past years.	No					



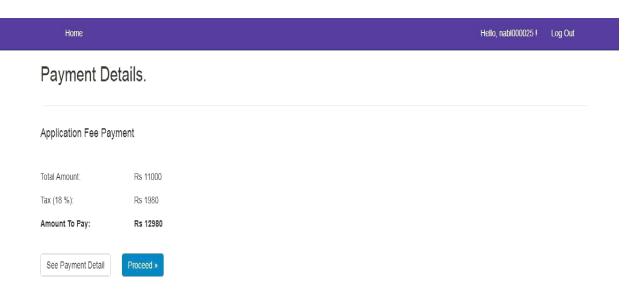
# Payment Process:

At the bottom of Terms and conditions it shows Proceed to payment option.

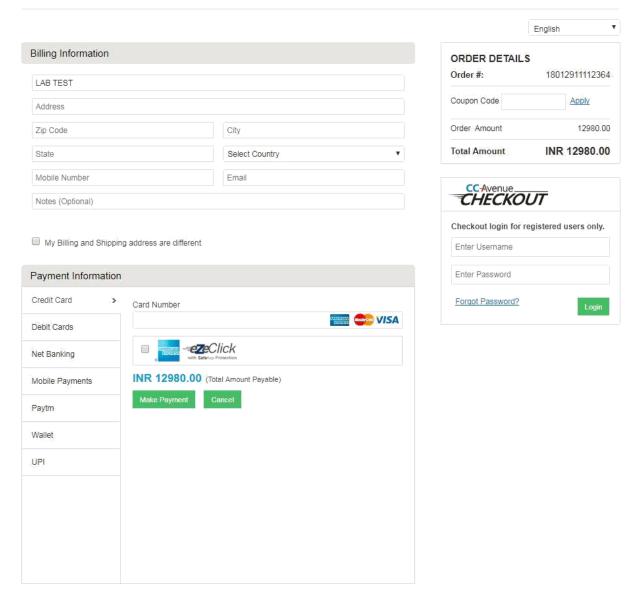


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After clicking on Proceed to payment, it shows the payment details.



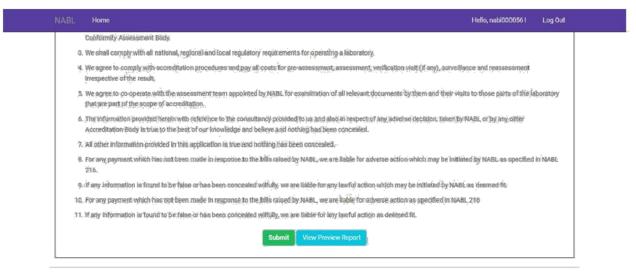
After clicking on proceed, it will redirect to the CC payment gateway.



On Payment gateway, user can select any type of card or can pay via different payment options like Pay tm, Wallet, etc.

After making payment, the application will be redirected to the declaration of the form.

At the bottom, it shows submit button. Click on submit button and it will ask for password.



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Once correct password is inputted, the application is submitted successfully.

#### General Note:

Click on "Save draft" option given at all places to remain in the same tab which enables the user to fill the complete details in the respective tab at the same time. For eg: In case of equipment, fill the details on one equipment as required. Now, if the details of second

equipment needs to be filled, then click on "Save draft" option to continue filling the details of second equipment and so on.

Click on "Next" option given at all the places enables the user to go to another tab. The user is required to click on "Next" tab after completing all the required details in that particular section.