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| For PNAC Use only |  |  |  |  |  |

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|  | PNACPakistan National Accreditation Council 1-Constitution Avenue, Opposite Prime Minister Office, G-5/2,  Islamabad, **Pakistan.**  Tel: 051-9206044, 9209507, 9205509  Fax: 051-9209510, 051-9222312 | **F- 01/ 09**  **Issue Date: 25/ 01/2021**  **Rev No: 04** |

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| --- |
| **Application For Medical Laboratory Accreditation (ISO 15189)** |

|  |  |
| --- | --- |
| **Please type or use BLOCK LETTERS** | |
| Organisation **Address of Medical Laboratory** |  |
|  |
|  |
|  |
| Postcode |
| Tel: |
| Fax: |
| Person to whom enquiries about this application should be directed |
| **Name of Contact:** |
| **Designation:** |
| **Address:** |
|  |
| Postcode |
| Tel: |
|  | Fax: |
|  | E-mail: |
|  | Mobile |

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| --- |
| **Fields of Medical Testing**\***:** This application is for (tick appropriate boxes)  ⁭Clinical Chemistry ⁭Haematology⁭Histopathology  ⁭Immunology ⁭Microbiology⁭Molecular Biology  ⁭Other (Please describe)  \* ISO 15189:2012 is the standard for Medical Laboratories (examination of material derived from the human body) |

|  |
| --- |
| **For new accreditation only:** I enclosed (tick boxes)  A copy of the laboratory's Quality Manual  A copy of the laboratory's Standard Operating Procedures (Management & Technical)  Participation in recognised PT scheme (F-2/31)  Plan of PT participation (F-2/33)  Agreement (F-01/04)  Filled form (F-2/18)  Applicant fee-see note below |
| **Before completing the rest of this form, please read the following notes** |

**Notes on completing this form**

|  |  |
| --- | --- |
| This form is divided into 6 parts, which must be completed as follows:  **Part 1-** About yourselves All new applicants  **Part 2 -** About your staff All new applicants  **Part 3 -** Scope of application: All new applicants  **Part 4 -** About your quality system All new applicants  **Part 5 -** Other approvals All new applicants  **Part 6 -** Declaration All applicants  **PNAC accredited laboratories applying for extension of scope need to complete**  **Part 3 and part 5 only**. | |
| **For more information from PNAC Please contact on** | Telephone: 051-92223336-13  Fax: 051-9222312-13 | |
| **PNAC criteria documents** | You should study these documents, included in the applicant pack:   * Applicants Guide for Laboratories * Agreement between PNAC and an accredited Laboratory * Fee schedule * Guidelines on Specific Criteria for Medical labs | |
| **Need more space** | Give additional information on separate sheets of paper, indicating clearly the questions to which the information refers. | |
| **Applicant fee** | Remember to enclose your applicant fee with this form. Fee is applicable in all cases such as first time application, scope extension and renewal etc. Please make cheques payable to PNAC. The application fee is non-refundable. | |
| **Confidentiality** | All information given by lab will be confidential | |

**Part 1 - About yourselves:**

Please type or use BLOCK LETTERS

* 1. **Name and position (Director level) of person authorising this application**

|  |  |
| --- | --- |
| Title Name | |
| Name |  |
| Position |  |

**1.2 Name and address of the parent organisation (if different from the laboratory address given at page1)**

|  |  |
| --- | --- |
| Organisation |  |
| Address |  |
|  |
|  |
| Postcode |
|  | Tel: Fax: |

**1.3 Address for invoicing (if different from the laboratory’s address on page 1)**

|  |  |
| --- | --- |
| Organisation |  |
| Address |  |
|  |
|  |
| Postcode |
| Tel: Fax: |

**1.4 Information about ownership: please tick the appropriate box.**

|  |
| --- |
| Owned by an individual Owned by public hospital  Owned by a private company/partnership Owned by a private hospital Part of an academic institution  Other: Please describe |

**Note: (Please give registration No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, if applicable)**

**1.5 Is testing the main activity of the parent company?**

|  |
| --- |
| Yes No: describe the main activities of the parent company |

**1.7 Do you conduct Testing in the following category (if yes, please clearly mention the scope of accreditation, Part of this application)**

A. Permanent facility. ⁭Yes. ⁭No.

B. Sample Collection Centre. ⁭Yes. ⁭No.

If yes attach list of sample collection centres.

C. Temporary Facility (when a facility is created temporarily). ⁭Yes. ⁭No**.**

D. Mobile Laboratory. ⁭Yes. ⁭No

**Part 2 - About your staff**

Please type or use BLOCK LETTERS

**2.1 Please list the names, technical qualifications and relevant experience of the following staff**

1. **Technical Management** (if more than three members please attach extra sheet)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **S. No** | **Laboratory/**  **Department/**  **Section** | **Name &**  **Designation**  **of Signatory** | **Qualification with Specialisation** | **Experience in years related to present work** | **Relevant Training** | **Authorised for which specific area of testing** | **Specimen Signature** |
|  |  |  |  |  |  |  |  |
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1. **Quality Manger**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name & Designation** | **Qualification with Specialisation** | **Experience in years related to present work** | **Relevant Training** | **Specimen Signature** |
|  |  |  |  |  |

1. **Laboratory Staff.**

Laboratory Staff are the personnel who make critical evaluation of test results and whom is responsible for the adequacy of results. Please provide the list of Laboratory Staff and also provide their CV’s/Job Description’s. (Use extra sheets if necessary).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Section:** |  | | | |
| **Name of section leader/**  **Designation** | **Qualification with Specialisation** | **Experience in years related to present work** | **Relevant Training** | **Authorised for which specific area of testing** |
|  |  |  |  |  |

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| --- | --- | --- | --- | --- |
| **Name of Section:** |  | | | |
| **Name of section leader/**  **Designation** | **Qualification with Specialisation** | **Experience in years related to present work** | **Relevant Training** | **Authorised for which specific area of testing** |
|  |  |  |  |  |

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| --- | --- | --- | --- | --- |
| **Name of Section:** |  | | | |
| **Name of section leader/**  **Designation** | **Qualification with Specialisation** | **Experience in years related to present work** | **Relevant Training** | **Authorised for which specific area of testing** |
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| --- | --- | --- | --- | --- |
| **Name of Section:** |  | | | |
| **Name of section leader/**  **Designation** | **Qualification with Specialisation** | **Experience in years related to present work** | **Relevant Training** | **Authorised for which specific area of testing** |
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**Part 3 - Scope of application:**

**3A**. As far as possible, quote standard specifications in the third column. These may include specifications issued by companies and other organisations, both Pakistan and foreign, as well as national and international standards. Give reference numbers and dates of specifications quoted.

In the absence of standard specifications, documented in-house procedures may be quoted: cross-refer to your laboratory's Quality Manual/Procedures Manual.

(Use of photocopy of this page, if the space given is found insufficient)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sample Type/ Matrix** | **Types of test/**  **Properties measured** | **Range of measurement** | **Minimum detection limit** | **Uncertainty of Measurement** (where applicable)  MU (±) | **Standard specification/**  **Techniques/**  **equipment used** | **\*Quality Control Measures** |
|  |  |  |  |  |  |  |

\*Mention all measures in practice for quality control

1. Proficiency Testing
2. Inter Lab Comparison
3. Use of CRM/SRM
4. Repeatability / Reproducibility
5. Control Charts

**3B** **List the major items of equipment currently used for the types of test listed in 3A**

(Use extra sheet, if the space given is found insufficient)

|  |  |  |  |  |  |  |  |
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| **S. No.** | **Name of Equipment** | **Model/Type/year of make** | **Working Range/capacity of equipment** | **Minimum detection limit** | **Last date of calibration** | **Calibration due date** | **Test for which used and other relevant information** |
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**3C. List of Reference Standard/Material.**

**(Use extra sheet, if the space given is found insufficient)**

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| --- | --- | --- | --- | --- | --- |
| **S. No.** | **Name of Equipment** | **Source/Supplier’s name** | **Date of expiry/validity** | **Traceability** | **Purpose of use** |
|  |  |  |  |  |  |
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**3D: Proficiency Testing:**

Participation in recognised proficiency testing (for further details and requirements please refer to ISO/IEC 17043, PNAC Guide 02/13.

**(Use extra sheet, if the space given is found insufficient)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **S. No.** | **Product / Material/Sample Type** | **Details of Test(s)/examination** | **Date of testing/examination** | **Organizing body** | **Performance in term of Z -score or any other criteria** | **Corrective actions taken (if required)** |
|  |  |  |  |  |  |  |
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**Part 4 - About your quality system**

Please fill the PNAC form F-02/18 and answer the following question, adding comments as necessary

**A. Equipment and calibration**

|  |  |  |
| --- | --- | --- |
|  | **Yes No** | **Quality Manual reference/other comment** |
| 1. Does a fully documented calibration program exist to ensure that the accuracy of equipment is adequate for the service operated by the laboratory? |  |  |
| 2. Is a record maintained for test equipment, including calibration results? |  |  |
| 3. Are adequate facilities and environments provided for calibration, handling, control, storage and maintenance of all testing & measuring equipment? |  |  |
| 4. Are there documented procedures for internal calibration (if any) of all equipments and reference standards which cover the method of calibration and maximum, intervals between calibrations? |  |  |
| 5. Are the internal laboratory reference standards, and the calibration of key testing equipment traceable to national standard through: |  |  |
| * PNAC accredited |  |  |
| * Other bodies (specify)? |  |  |
| 6. Do you perform in-house calibration of your instruments? (if yes) |  |  |
| a. Have you identified source of  uncertainty measurement? |
| b. Do you incorporate uncertainty of measurement in your calibration? |

**B. Compliance with ISO 15189:2012 and PNAC Accreditation Requirements**

|  |  |  |
| --- | --- | --- |
|  | | **Yes No** |
| 1. Do you consider that your laboratory complies with ISO 15189:2012 and PNAC accreditation requirements? (Pls. see PNAC’s website for policies). | |  |
|  | **Area of non-compliance** | **Rectified by (date)** |
| If "No" in which specific areas it does not comply, and when do you expect non-compliance is rectified? |  |  |
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**Part 5 - Other approvals (certifications/ accreditations)**

Please detail current accreditation/approval held by your laboratory's testing facility

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| --- | --- | --- | --- |
| **Name & address of approval body** | **Scope of accreditation/approval and number of certificate (if any)** | **Period of accreditation/approval** | |
|  |  | Start | Expiry Date |
|  |  |  |  |
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**Part 6 - Declaration**

This declaration should be made by the person named in Section 1.1

|  |
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| 6.1 The laboratory applies to PNAC for accreditation for (please tick appropriate boxes)  Clinical Chemistry ⁭Haematology⁭Histopathology ⁭Immunology ⁭ Microbiology⁭Molecular Biology  ⁭Other (Please describe)  6.2. The organisation/laboratory agrees to conform, upon accreditation, with PNAC  requirements as detailed in the Agreement [F-01/04].  6.3 The organisation/lab comply fully with ISO 15189: 2012 for accreditation of  Medical testing laboratories.  6.4. I enclose a copy of Quality Manual and Quality Procedures (see Note below)  6.5 I understand PNAC policies and procedures for Assessment, surveillance and  Re-assessment.  6.6. I enclose a cheque (payable to PNAC) for the Applicant fee of \_\_\_\_\_\_\_\_. I  understand that this fee is non-refundable. (see Note below).  6.7. I understand the manner in which the accreditation system functions.  6.8. I declare that the information given in this form is correct to the best of my knowledge and belief  Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Note:** PNAC will not process your application until it has received your Quality Manual and Quality & Technical Procedures and application fee. |
| **When completed, return this Form to:**  (Please mention type/field of Laboratory on the right corner of the envelope such as microbiology/histopathology medical lab**)** ToThe Director General **Pakistan National Accreditation Council**  1-Constitution Avenue,  Opposite Prime Minister Office, G-5/2,  Islamabad, **Pakistan.**  Tel: 051-9206044, 9209507, 9205509  Fax: 051-9209510  051-9222312 |

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| **For PNAC use only:**  **Application and Resource Review:**  Resources are available to conduct timely assessment according to PNAC policies, competence and availability of suitable assessor/experts.  YES  No  Remarks (if any): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      Reviewed By: Sign & Date |