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| Application Form for Medical Laboratories |
| NABAF01/M |
| EN ISO 15189:2012 |



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| Logo Small | **NATIONAL ACCREDITATION BOARD - MALTA** |
| **APPLICATION FOR MEDICA LABORATORY ACCREDITATION**  **NABAF01/M** | |
| Instructions  1. This application should be completed in detail and returned duly signed to:   **The Director,**  **National Accreditation Board Malta,**  **Mizzi House,**  **National Road,**  **Blata l-Bajda HMR9010,**  **Malta**     1. This application and the requested documents shall be submitted in digital format. Documents are to be submitted in WORD, EXCEL or PDF format in the folder structure provided. 2. This application, except for original signatures, **shall be typed** and shall be submitted in WORD format either via email or in any other digital format. Handwritten applications shall not be accepted. A scanned copy of the application form with original signatures shall also be submitted. 3. All information provided will be treated in confidence. 4. Additional information may be obtained by contacting the NAB-MALTA at the above address or Tel: (+356) 23952510, e-mail: [info@nabmalta.org.mt](mailto:claudio.boffa@msa.org.mt) 5. Please ensure that you have read all the relevant standards, publications, and other normative documents (especially those listed in **ATG18**) relevant to your application. The accreditation scheme criteria, regulations and policies are available from the NAB-MALTA website [www.nabmalta.org.mt](http://www.nabmalta.org.mt), the EA website [www.european-accreditation.org](http://www.european-accreditation.org) and the ILAC website [www.ilac.org](http://www.ilac.org). 6. Incomplete applications will result in a delay in process, therefore, ensure that all the information required is available before submitting to the NAB-MALTA. 7. The term “Conformity Assessment Body” and its abbreviation “CAB” will be used in this form to signify the applicant organisation i.e., the laboratory. | |

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| SECTION A |

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| 1. BASIC DETAILS CONFORMITY ASSESSMENT BODY (CAB) *(Please ensure that the specific entity seeking accreditation and the legal entity are precisely identified. Please also state legal entity and trading name if different.)* | |
| Name of the Conformity Assessment Body | |
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| Main address | |
| Company Registration No.: | VAT No.: |
| Telephone Number: | E-Mail: |
| Website: | |
| ***Note****: These details will be used by the NAB-MALTA on the NAB-MALTA databases, certificates, etc...* | |

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| 2. INVOICING DETAILS *(If different to No.1 above)* | |
| Invoicing Contact Name | |
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| Address | |
| Company Registration No.: | VAT no.: |
| Telephone number: | e-mail: |

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| 3. LEGAL STATUS OF THE CONFORMITY ASSESSMENT BODY (CAB) | | |
|  | Yes/No | Documentary evidence |
| 3.1 Owned by an individual |  |  |
| 3.2 Private company or partnership |  |  |
| 3.3 Public limited company |  |  |
| 3.5 Academic institution |  |  |
| 3.7 Public entity / Authority |  |  |
| 3.8 Another category? If so, please specify: |  |  |
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| The applicant is to list here any other activities it, its parent company and/or related companies carries out and not subject to this application for accreditation. | | |

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| **4. CAB PART OF A LARGER ORGANISATION** |
| If the CAB is part of a larger organisation, what is the relationship to that organisation?  *Notes: - For CABs part of Government please define the relationship within Government.*  *- Provide the name and other contact details of the parent organisation if any* |

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| 5. LOCATIONS COVERED BY THIS APPLICATION*Notes:* *(1) The location details will be used by the NAB-MALTA on the NAB-MALTA database, certificates, etc.* *(2) Also include any virtual sites* | | | | |
| 5.1 Does the CAB operate from multiple sites? *If yes, complete the details hereunder as appropriate. Site numbering is to start with A1.* | | | Yes: | No: |
| Site no. | Site Location (Address) and total working area | Activities performed at this site | Contact details | |
| A1 |  |  |  | |
| A2 |  |  |  | |
| A3 |  |  |  | |
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| 6. OTHER EXTERNAL EVALUATIONS/AUDITS | | | |
| Has your organisation been evaluated or audited (e.g., accreditations, certifications, audits by regulatory authorities) by other external organisations in the past 5 years? If so, please fill in the table below | | | |
| **Name and address of**  **evaluation organisation** | **Type of evaluation (refer to applicable criteria)** | **Date of evaluation** | **Recognition granted if any** |
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| **7. HUMAN AND TECHNICAL RESOURCES**  *(List here the resources which will be utilised to cover the scope of accreditation sought)* | | |
| **7.1 Total number of employees in relation to scope of accreditation:** | | |
| **7.2 Distribution of employees in relation to scope of accreditation:** | **Full-time** | **Others (specify relationship for e.g., individually contracted)** |
| Employees with University education |  |  |
| Employees with technical education |  |  |
| Employees specially trained as laboratory assistants |  |  |
| Employees specially trained as technicians |  |  |
| Employees trained in quality management |  |  |
| Other (incl. secretarial and support staff) |  |  |

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| **8. MANAGEMENT REPRESENTATIVE**  *Name and position (director level) of the CAB’s representative with authority to commit the CAB to the requirements for accreditation.* |
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| e-mail: |

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| 9. MAIN CONTACT*Name, position, and address of CAB’s main contact with the NAB-MALTA* *Note: This is the person to whom all correspondence from the NAB-MALTA will be addressed.* |
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| e-mail: |

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| 10. DEPUTY CONTACT*Name, position, and address of CAB’s deputy contact with the NAB-MALTA* |
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| e-mail: |

| **11. INFORMATION ABOUT KEY PERSONNEL**  *(For Point 11.1 to 11.4 please identify the following personnel and briefly describe their competence giving the technical qualifications and experience. Professional C.V. to be submitted.)* |
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| 11.1 Laboratory Manager |
| 11.2 Deputy Laboratory Manager |
| 11.3 Person/s responsible for the quality management system |
| 11.4 Deputy/ies of the person/s responsible for the quality management system |

| SECTION B |
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| 12. ACCREDITATION SCOPE | | | | | | | |
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| **Notes:**   1. A clear description of the examinations undertaken by the laboratory, and a list of standards, methods, or procedures (SOPs), for which accreditation is being sought is to be given in this section. **Refer to document EA-4/17 M:2022 when filling this section.** 2. Applicants referring to regulations/legislation in the scope of accreditation they are applying for are to clearly indicate where such regulatory documents refer to conformity assessment activities. Such conformity assessment activities shall be clearly defined and clearly related to an accreditation standard. If such information is not submitted, the accreditation for that activity cannot continue. 3. Add as many rows as necessary to cover the full scope of accreditation to be covered by this application. 4. In column “FREQ” indicate the frequency with which the CAB performs the examinations. Use the following codes:   d = daily one to several times  w = weekly one to several times  m = monthly one to several times  i = infrequent (one to a few times per year)   1. In column “LOC” indicate whether the examination will be carried out in the laboratory or in some other location. Use the following codes:     A = Examination is carried out in the laboratory *(If the laboratory operates from multiple sites the use of A1, A2, A3, etc is to be made, refer also to Section 5.1 of this application form*)  B = Examination is carried out at an offsite location not belonging to the laboratory | | | | | | | |
| **No.** | **Materials/System/Matrix** | **Analyte / Parameter** | **Technique** | **Equipment/**  **Method/**  **Procedure Reference** | **Loc** | **Freq.** | **No. of examinations in the past 12m** |
| *e.g.,* | *Serum* | *IgM anti-Toxoplasma antibodies* | *ECLIA* | *Name of IV-MD (device)*  *SOP Ref. XX* | *A* | *m* | *100* |
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| 13. APPLICATION FOR FLEXIBLE SCOPE OF ACCREDITATION *Notes*   1. *This applies only when the laboratory is applying for a flexible scope.* 2. *Before applying for flexible scope make sure you have read NAB-MALTA Policy ATG16* | | | | | |
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| 13.1 Is the laboratory applying for a flexible scope? | | | | YES | NO |
| If YES to 13.1, answer the following questions: | | | | | |
| 13.2 Kindly indicate which of the below best identifies the flexible scope which the laboratory is applying for(refer to NAB-MALTA Policy ATG16): | | | | | |
| Modification of existing methods (Category 1) | | | | YES | NO |
| Inclusion of technically equivalent standard methods (Category 2) | | | | YES | NO |
| Inclusion of revised standard methods (Category 3) | | | | YES | NO |
| 13.3 For the accreditation scope applied for, kindly indicate the flexible scope categories which are being requested for each test discipline: | | | | | |
| *Material/System/ Matrix* | *Analyte/parameter* | *Technique* | *Equipment/Method/*  *Procedure Reference* | | *Flexible Scope Category required*  *(Cat 1,2,3, or n/a) \** |
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| *\*If Category 1 is identified, kindly provide an explanation of the flexibility boundaries which the laboratory would like to apply for (e.g., different matrix, different test method, different range of measurement, etc)* | | | | | |
| ***Note:*** *Add as many rows as necessary to cover the full scope of accreditation to be covered by this application.* | | | | | |
| 13.4 Please state justification for applying for a flexible scope: | | | | | |
| **Note:** Accreditation with a flexible scope may be not possible in some technical sectors. | | | | | |

| SECTION C |
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| **14. INFORMATION ABOUT THE CONFORMITY ASSESSMENT BODY** | | |
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|  | **Yes/**  **No** | All boxes shall be completed with the necessary information.  Enter references from the CAB’s quality management system (reference to a document number/s is sufficient) and any other applicable information as necessary. |
| 14.1 Does the applicant legal entity have full control and autonomy over its quality management system? |  |  |
| 14.2 For how long the quality management system has been in operation?  (Note: According to regulations RAB01, the system must have been in operation for at least 3 months. This means that records should be available to show that the system has been in operation). |  |  |
| 14.3 Has a complete cycle of internal audits been carried out? If no, please specify date by when a complete cycle will be carried out.  (Note: According to regulations RAB01, a complete cycle of internal audits covering the full system of the applicant must be completed prior to the initial assessment.) |  |  |
| 14.4 Are there legally enforceable agreements for ensuring the management and confidentiality of all information obtained or created during performance of laboratory activities? |  |  |
| 14.5 What is the laboratory’s policy in relation to reporting opinions and interpretations? |  |  |
| **For applicants applying for Flexible Scopes of Accreditation** |  |  |
| 14.6 Does the laboratory keep an updated list of accredited examination methods**, on form NABG34?** |  |  |
| 14.7 Are the responsibilities for the management of the flexible scope established and documented? |  |  |
| 14.8 Does the laboratory have a procedure to ensure that all requests, tenders, and contracts are carefully reviewed to determine the requirements of the client and whether the required parameters fall within the agreed boundaries of the laboratory’s flexible scope of accreditation? |  |  |
| 14.9 Has the process of reviewing and accepting/authorising methods under a flexible scope been incorporated into the internal audit programme? |  |  |
| **Note:** Accreditation with a flexible scope may be not possible in some technical sectors. | | |

| **SECTION D** | | |
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| **15. Documents and records to be submitted** | | |
| **Notes:**  *(1) The following documents must be submitted in electronic format with the application in the provided folder structure. NAB-MALTA will not process the application until all the items listed below have been received.*  *(2) If any of the documents are included as part of a quality management system manual or other documentation, please quote either the manual section or document reference number in the space provide next to the tick box.*  *(3) Documents submitted are to be in the English or Maltese language.*  *(4) If an application refers to legislation/regulations and such documentation is not in English or Maltese, then an official translation of such legislation/regulation shall be submitted* | | |
|  |  | In the box below, tick as necessary and write any necessary references. If not applicable, explain why. |
|  | An index and numbered list of the attachments *(use the folder structure provided)* |  |
|  | Cross-reference table  *(Note: This should allow a complete and effective identification of the correspondence between the clauses and sub-clauses of the applicable standard/other relevant accreditation criteria (Refer to* ***ATG18****) such as guidance documents (e.g., EA/ILAC publications) and the parts of the Applicant Laboratory documentation (QM, Procedures, etc) where such requirements are addressed; the non-applicable requirements must be properly identified and not simply omitted; (exclusions must be justified).* |  |
|  | NAB-MALTA accreditation contract, duly signed by authorised company representative *(this document is to be requested from the NAB-MALTA)* |  |
|  | Master list of documents controlled in the management system, including version and validity date. |  |
|  | All documentation describing the management system according to EN ISO 15189 (e.g., Quality Manual, procedure instructions, work instructions, SOPs, applicable standards) – |  |
|  | **Structure** - Proof of legal status of the laboratory and declaration of ownership (e.g. copy of MFSA certificate, Memorandum and Articles of Association) |  |
|  | **Structure** - Information on the structure of the laboratory (include organisation chart with names, functions, etc).  *Note: Any relationships with a related organisation should be clearly showed or explained*. |  |
|  | **Structure** - Site plan to scale showing the examination areas. This plan should include dimensions. |  |
|  | **Personnel** - Competence criteria and description of responsibilities (job descriptions) of staff members |  |
|  | **Personnel** - Professional C.V. and proof of the relevant qualifications of the Laboratory Manager and his/her deputy, the person responsible for the quality management system and his/her deputy. |  |
|  | **Personnel** – List of staff members who are responsible for approving/issuing examination reports (name, title, function) for the scope of accreditation sought. |  |
|  | **Equipment -** List of equipment (including loaned equipment and used working standards, if applicable)  **Required information**: inventory number, location, measurand (for which a proof of measurement traceability must be present), indication of equipment/type of equipment/item, manufacturer, calibration interval, indication of the proof of measurement traceability, whether calibration is done in-house or by an external provider.  Optional information: examination procedure, serial number, responsible person for the equipment, etc... |  |
|  | **Equipment -** If applicable, list of certified reference materials in use and proof of metrological traceability. |  |
|  | **Process** – Examination procedure validation data and validation summary |  |
|  | **Process** - Uncertainty measurement budgets |  |
|  | **Process -** Sample of a report (without patient data) for each examination field applied for accreditation. |  |
|  | **Proficiency Testing -** Summary report containing proof of participation in proficiency testing and interlaboratory comparisons **(NABG32 to be completed and returned with this application form***)* |  |
|  | **Management system** - Explanation of the risk management process within the laboratory |  |
|  | **Management system -** Copy of the internal audit programme |  |
|  | **Management system** - Copy of the minutes of the latest management review |  |
|  | **Flexible scope -** If this application includes a flexible scope, submit:   * Flexible Scope Master List form - **NABG34** * Responsibilities for the management of the flexible scope established and documented * Criteria for defining the competence of laboratory personnel for the purposes of developing, reviewing, validating, and authorising new and/or modified methods within the boundaries of the flexible scope. * Records of qualifications, experience and training of laboratory personnel authorised to review and authorise new and/or modified methods within the boundaries of the flexible scope. * The documented process that the laboratory will follow on receipt of applications for examinations within the flexible scope. * The documented verification process that the laboratory will follow on receipt of applications for examinations within the flexible scope. * Records related to a practical example of a completed flexible scope design process, for each area the laboratory has applied for. * Evidence of the laboratory’s own internal audit completed as evidence of conformity with this policy document. |  |

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| **SECTION E** | |
| **16. STATEMENT BY APPLICANT CONFORMITY ASSESSMENT BODY (the “CAB”)**  The CAB identified below (details of which are set out on paragraphs 1 and 2 of Section A of this application form) hereby applies to the NAB-MALTA to assess the CAB for its eligibility to be accredited as competent to provide the services specified in this application, having regards to relevant accreditation criteria and any other normative documents, conditions or factors that the NAB-MALTA considers to be relevant to or to affect the CAB’s competence for the specified services.  The CAB acknowledges that it has read and signed the NAB-MALTA terms and conditions and the relevant NAB-MALTA policies and regulations and agrees to comply at all times, during the currency of the application made herein and any resulting accreditation, with the NAB-MALTA terms and conditions as the same may be substituted, amended, supplemented, or varied by the NAB-MALTA after the date of this application.  The CAB undertakes to pay all fees due to the NAB-MALTA. The CAB declares that it has the necessary resources to undertake accreditation for the scopes requested.  The CAB hereby confirms that it has a right to supply the data and information contained in this application or which it otherwise gives to the NAB-MALTA, and gives its own consent and confirms that it has obtained all properly informed consents from any individuals in respect of whom the Organisation is giving data or information to the NAB-MALTA to enable the NAB-MALTA to lawfully receive such data and information and make use thereof for the purposes of its functions (having particular regard to, but not limited to, applicable data protection legislation) and also confirms that all such data and information is complete, accurate and correct and that it will promptly provide any such further information and data as may be required by the NAB-MALTA to assess and process this application.  The Organisation also accepts that the NAB-MALTA might need to consult with the appropriate regulator should an application be according to the requirements of specific European or national legislation. The Organisation also accepts that the NAB-MALTA assessment team may be accompanied either by representatives from the European Co-operation for Accreditation (EA) or any other representative from specific regulators or competent authorities. | |
| **17. Data Protection Declaration**  The NAB-MALTA ("the Controller") will process your personal data in accordance with the relevant provisions of the General Data Protection Regulation (GDPR), the Data Protection Act (Chapter 586 of the Laws of Malta) and other regulations made thereunder. The Controller will process your personal data for assessment and administrative purposes and to comply with its legal obligations. For further information on how your personal data will be processed refer to the Controller’s privacy policy.  I, the data subject, hereby consent to having the NAB-MALTA collect and process my personal information from this application. | |
| **Signed for and on behalf of**  *(enter name of organisation and preferably a rubber stamp)* | |
|  | |
| **Company Representative** | |
| **Position:** | |
| **Signature** | **Date** |