HELLENIC
ACCREDITATION
SYSTEM

APPLICATION FOR THE ACCREDITATION OF MEDICAL LABORATORIES ACCORDING TO EN ISO 15189:2022

Please type or print using CAPITAL LETTERS

Part 1 Organization

1.0

Name of Organization *: **Year Founded:** **Legal Form:**
Address: **Zip code:** **Phone number:** **Fax number:** **Email address:** **VAT No:** **Revenue Office:**
Name of person in charge for contacts with ESYD:

***** *The complete description of the structure to which the laboratory belongs is stated, i.e., Biochemistry Department/Laboratories Division/General Hospital "ABC"*

1.1 Name and position of person authorized for this application

First name:	**Surname:**
Position	

1.2 Name and address of parent organization (if different from entries of table 1.0)

Name:	
Address:	
Tel.:	**Facsimile:**

1.3 Address where invoice is to be sent and contact person (if different from the address of the organization and the person in charge for contacts with ESYD in table 1.0)

Name: **Address:** **Tel. :** **Facsimile:**

Part 2 Personnel

2.1 Please state the name, technical qualifications and relevant experience of the following personnel:

Scientific-Technical Manager/s appointed by the Management regarding technical responsibility (in the case of multiple scopes or fields and multiple managers please state multiple managers)

Name	
Technical Qualifications	
Relevant Experience	
Position within the organization	

Quality Manager/s appointed by the Management regarding responsibility for the management system

Name	
Technical Qualifications	
Relevant Experience	
Position within the organization	

Part 3 Scope of Application: Testing

3.1 State all the measurement parameters for which accreditation is sought. For each field of measurement use a photocopy of this page (**If you apply for the accreditation of more than one, sites, please add a table for each site with a reference to the address of the site)**

Field of testing (see table 3.3):
Laboratory Site (address):

Laboratory Equipment	Materials/ products to be Checked (Description)	Test Description / Measurand / Property **(c)**	Standards/ Methods Applied	Measurement Range	Measurement Uncertainty (**a**) **(b)**

a: where applicable, for level of confidence not less than 95%

b: state the corresponding confidence interval

c: in case of an extension of the scope, state if it refers to a new test or a modification / substitution of an existing test

3.2 In case the laboratory includes primary sample collection in the activities of its accreditation scope, please state the (one or more) primary sample collection sites (even if they reside inside the premises of the laboratory) which are under the control of the management system of the laboratory

Primary Sample Collection (e.g. venipuncture)	**Primary Sample Collection Site** (address)

3.3 TESTING FIELD	
Clinical chemistry	Point of Care (POCT)
Haematology	Other (please define)
Immunology	
Microbiology	
Histocompatibility	
Molecular genetics	
Cytogenetics	
Anatomical pathology	
Cytology	
Molecular biology	
Pharmacology	
Clinical toxicology	

3.3 MEDICAL IMAGING TASKS
RADIOLOGY DEPARTMENT:
X-ray images
Portabe X-ray images
Fluoroscopy procedures
DENTAL X-ray DEPARTMENT
Intraoral X-ray images
X-ray panoramic images
X-ray cephalometric images
Bone Density scan (DEXA)
COMPUTED TOMOGRAFPHY (CT) DEPARTMENT
Head CT scan
Sinus CT scan
Chest CT scan
Abdominal and Pelvic CT scan
Pelvis CT scan
Angiography CT scan
CT guided biopsy
MAGNETIC RESONANCE IMAGING (MRI) DEPARTMENT
MRI scans
Magnetic Resonance Angiography (MRA)
MAMMOGRAPHY DEPARTMENT
Film mammography
Digital mammography
Digital breast tomosynthesis
Mammography guided biopsy
ULTRASOUND DEPARTMENT
Ultrasound imaging
Transvaginal ultrasound imaging
Ultrasound breast imaging
Thyroid ultrasound imaging
Pediatric ultrasound imaging
Obstetric ultrasound imaging
Triplex ultrasound imaging
Ultrasound guided biopsies
Portable ultrasound images
Ultrasound guided prostate biopsies
Transrectal ultrasound imaging
Other examinations (specify)

Part 4 Available Quality System

Please answer each question adding comments where necessary (reference to **the paragraphs of EN ISO 1518:2022)**

4.1 MANAGEMENT REQUIREMENTS

A. Organization – Quality management system	Yes	No	Description of Activities / References in the QMS / Other comments
1. Does the laboratory make use of the option of paragraph 8.1.2 of the Standard EN ISO 15189:2022 for a Quality Management System (QMS) in accordance with the requirements of ISO 9001?			
2. Does the laboratory meet the EN ISO 15189:2022 requirements concerning laboratory organization and management?			
3. Does the Quality Management have the responsibility and authority to detect quality related problems and promote effective solutions?			
4. Does the Laboratory have a Quality Manual which is updated according to the Standard EN ISO 15189:2022?			
5. Does the QMS determine • The organization structure of the laboratory? • Its place in any parent organization?			
6. Does the Laboratory document the scope of its activities (plus laboratory activities outside its main location, e.g. POCT or primary sample collection) in the QMS, according to the paragraph 5.3.1 of the Standard EN ISO 15189:2022?			
7. Is the Quality System Documentation communicated, understood and applied by the personnel?			
8. Are the Objectives and Policies of the Laboratory documented according to the requirements of the Standard EN ISO 15189:2012?			

9. Has a study to address risks been prepared for the impartiality of laboratory activities?			
10. Are provisions made for the confidentiality of information and requirements regarding patients in accordance with the Standard EN ISO 15189:2022?			
11. Does the laboratory have Continuity and Emergency Preparedness Planning?			

B. Risk Management	Yes	No	Description of Activities / References in the QMS / Other comments
1. Are there procedures for the identification of risks and opportunities related to the tests and activities of the laboratory? Have these procedures been focused on patient care?			
2. Have actions been developed for the continuous improvement based on the risks and opportunities identified?			
3. Is the effectiveness of the above actions evaluated and reviewed based on real data that the laboratory collects?			

C. Document control	Yes	No	Description of Activities / References in the QMS / Other comments
1. Does the laboratory have document control procedures for documents created by internal or external sources and consisting part of the quality system?			
2. Does the laboratory have documented procedures for controlling changes in documents maintained in a computerized system?			

D. Service agreements	Yes	No	Description of Activities / References in the QMS / Other comments
1. Does the laboratory have documented policy and procedures for the establishment and review of requests, offers and contracts (POCT contracts are included)?			
2. Does the laboratory maintain records of requests, offers and contracts?			

E. Examination by referral laboratories	Yes	No	Description of Activities / References in the QMS / Other comments
1. Do you use a referral laboratory for second opinion?			
2. Does the laboratory have a policy for selecting and evaluating referral laboratories?			
3. In case of subcontracting is the customer kept informed by the laboratory? Does the laboratory seek the customer's consent?			
4. Is there a register of all these laboratories, are requests and results of all samples referred recorded, is the customer notified about the identity of the referral laboratory according to the requirements set by ELOT EN ISO 15189:2022?			

F. Externally Provided Products and Services	Yes	No	Description of Activities / References in the QMS / Other comments
1. Does the laboratory have a documented policy for the selection and purchasing of external services and supplies that affect the quality of its service?			
2. Does the laboratory keep records of the compliance of suppliers, but also of the supplied reagents and consumables, with the defined requirements?			
3. Does the laboratory keep records of suppliers' evaluation?			

4. Are actions taken following the suppliers' evaluation?			

G. Advisory services	Yes	No	Description of Activities / References in the QMS / Other comments
1. Does the laboratory provide advisory services? If yes, do they meet the needs of patients and users?			
2. Are there properly trained and authorized personnel for the provision of advisory services?			
3. Has the laboratory established specific criteria for personnel appropriateness and for the evaluation of training effectiveness?			
4. In case of hospital laboratories, is there systematic communication between laboratory staff and clinical staff?			

H. Users feedback, complaints, control of non-conformities, corrective actions, continuous improvement	Yes	No	Description of Activities / References in the QMS / Other comments
1. Does the Laboratory accept co-operation with users?			
2. Does the Laboratory have a documented procedure for the management / resolution of complaints?			
3. Do you keep records of all complaints submitted to the Laboratory, investigations and corrective actions taken?			
4. Are there policies and procedures in place for cases where any laboratory work or its results do not conform to the laboratory's own procedures or requirements agreed with the client?			
5. Does the Laboratory have a policy and procedure for implementation of corrective actions, following root cause analysis?			
6. Does the Laboratory monitor the effectiveness of the corrective actions taken? Is the risk assessment simultaneously updated?			

7. Has the Laboratory developed an action plan for continuous improvement?			

I. Control of records	Yes	No	Description of Activities / References in the QMS / Other comments
1. Are technical and quality records kept, maintained and stored in a way ensuring their integrity, safety and confidentiality?			
2. What is the time period the Laboratory maintains technical and quality records?			
3. Is there a procedure for the protection of Electronic records against unauthorized access?			
4. Do technical records include initial observations, data and all relevant elements required?			

J. Quality audits, reviews and quality indicators	Yes	No	Description of Activities / References in the QMS / Other comments
1. Is there a predetermined program for audits conduction, that emphasizes on identified risks?			
2. Is there a procedure for auditing laboratory's activities?			
3. How often are quality audits conducted?			
4. Does the Laboratory keep records of quality audits, findings and corrective actions taken?			
5. Does the Laboratory monitor the implementation and the effectiveness of corrective actions taken, deriving from internal audits?			
6. Does the Laboratory conduct reviews of the Laboratory management system, periodically and according to a planned program?			
7. Does the management review include the necessary subject matters?			
8. Does the Laboratory monitor the implementation of corrective actions, deriving from management reviews?			

9. Has the Laboratory established measurable quality indicators?			

4.2 TECHNICAL REQUIREMENTS

A. Laboratory personnel	Yes	No	Description of Activities / References in the QMS / Other comments
1. Does the management of the laboratory ensure the competence of all those performing tests and signing test reports?			
2. Are personnel that are undergoing training adequately supervised?			
3. Are there job descriptions for all personnel participating in managerial and technical processes?			
4. Are there training programs and records of authorizations for specific duties, training, competence, qualifications and experience?			
5. Is the technical competence of personnel evaluated on a regular basis?			
6. Is contracted personnel used?			
7. Is personnel trained and committed to keep patient records confidentiality?			
8. Does the laboratory director fulfill the standard's requirements?			

B. Accommodation and environmental conditions	Yes	No	Description of Activities / References in the QMS / Other comments
1. Is the environment in which tests are conducted appropriate for the correct performance of examinations?			
2. Does the laboratory monitor and record the environmental conditions in areas where calibrations / testing is conducted?			
3. Is access to work areas controlled?			
4. Is the national legislation for waste management applied?			

C. Equipment	Yes	No	Description of Activities / References in the QMS / Other comments
1. Do you keep records of the calibration/ testing equipment, including the results of their calibration, adjustment, maintenance or repair?			
2. Are adequate calibration and traceability requirements specified to ensure reliability of test results?			
3. Is the calibration of the laboratory's critical equipment traceable to the national standards through, • Accredited laboratories by E.SY.D. • Other bodies (refer)			
4. Are cases of out-of-control calibrations effectively handled?			
5. Does the laboratory verify that the equipment conforms to specified acceptance criteria before it is put into service or returned from maintenance?			
6. Are there procedures for equipment use and scheduled maintenance and/or calibration according to the manufacturer's instructions?			
7. Does the laboratory management ensure that the requirements of this International Standard are met, in case the laboratory uses equipment outside its permanent control?			

D. Pre-examination process	Yes	No	Description of Activities / References in the QMS / Other comments
1. Is the laboratory information sufficiently detailed as required by the standard to provide users with a comprehensive understanding of the scope of activities and its requirements?			
2. Does the laboratory have established specific sampling plan and procedures?			
3. Does the laboratory have established procedures for recording sampling data?			
4. Has the laboratory established documented procedures for the proper transportation, reception, collection and handling of primary samples?			

5. Are acceptance - rejection criteria for samples and recording of rejections documented?			
6. Has the laboratory established documented procedures for the reception and handling of emergency samples?			
7. Has the laboratory established documented procedures for the handling of requests for additional examinations?			

E. Methods, procedures and method validation, measurement traceability, quality assurance of testing results	Yes	No	Description of Activities / References in the QMS / Other comments
1. Are all the testing methods and procedures documented and validated? Are they ensured to be clinically appropriate for the requests received?			
2. Are the performance specifications for each test method related to its intended use and impact on patient care?			
3. Does the laboratory verify the correct implementation of standard methods? Does it evaluate the uncertainty of the methods?			
4. Does the laboratory use non-standard methods (e.g. documented laboratory-developed methods)?			
5. When customer doesn't specify the test method, does the laboratory select the appropriate method?			
6. Are biological reference intervals periodically reviewed, and does it communicate them to the users of its services?			
7. Does the laboratory have established procedures and keep records about quality control (IQC) and methods validation surveillance?			
8. Has the laboratory selected an IQC material fit for its intended purpose for each test?			
9. a) Do you participate in interlaboratory comparison or proficiency testing programs (EQA) and do you evaluate them?			
b) Have you set up a 4-year program to			

participate in EQA?			
c) Are EQA service providers assessed according to the requirements of ESYD PDI?			
10. a) Do you use reference materials for quality control purposes?			
b) If yes, is their compliance with the requirements of ILAC P10 and ESYD GA2 examined?			
11. Do you carry out an equivalence / comparability check of test results on similar methods or similar analytical systems?			
12. A) Is critical equipment calibrated? State whether checking is performed other than calibration.			
B) Do you perform internal calibrations?			
C) Do calibration service providers meet the criteria of ILAC P10 and ESYD GA2?			

F. Post-examination processes	Yes	No	Description of Activities / References in the QMS / Other comments
1. Is the review and release of the results done by specialized personnel?			
2. Are panic values and critical result values documented? Are they communicated as required by the standard?			
3. Does the laboratory have an automated system for review and release of results?			

G. Reporting of results	Yes	No	Description of Activities / References in the QMS / Other comments
1. Do laboratory reports include all the information that is required according to the Standard EN ISO 15189:2022?			
2. Does the laboratory follow the terminology requirements?			
3. Does the laboratory fulfill the standard's requirements about results communication?			

H. Laboratory Information System - LIS	Yes	No	Description of Activities / References in the QMS / Other comments
1. Does the laboratory ensure that only authorized and appropriately trained personnel are using the laboratory information system?			
2. Does the laboratory use an LIS that is appropriate for the collection, processing, recording, storage or retrieval of laboratory's data according to the requirements of the Standard EN ISO 15189:2022?			
3. Is the laboratory developed software documented and appropriately validated?			

4.3 Conformity with the Accreditation Standard EN ISO 15189:2022 and the Regulations ESYD RA and ESYD G-CLINLAB

Do you consider that your laboratory fulfils the Accreditation Standard EN ISO 15189:2022 and the Regulations ESYD RA and ESYD G-CLINLAB?

YES ☐ NO ☐

If not, which points are in non-agreement and when do you anticipate correcting the non-conformity?

Points of non-conformity	Corrective action (date)

Part 5 Other Approvals

Please state in detail recent approvals received by your laboratory with regard to its competence in testing.

Name and address of Approval Body	Scope of accreditation / approval and certificate number (if such exists)	Accreditation period	
		Begin	End

Part 6 Declaration

6.1 The organization is applying for accreditation to ESYD for:
(please check appropriate boxes)

Initial accreditation	
Extension of the scope of existing accreditation	
Extension of the scope of existing accreditation in other location	

6.2 I accept the performance of a **pre-assessment*** according to ESYD PA YES • NO •

**A pre-assessment is not mandatory and is carried out before the assessment after the documented acceptance of the applicant. The pre-assessment is strongly recommended for avoiding further problems during the assessment*.

6.3 After accreditation, the organization / laboratory is bound to continue fulfilling the requirements of ESYD which are stated in detail in the documents EN ISO 15189:2022, ESYD RA, and ESYD G-CLINLAB as well as, in any other specific publication.

6.4 The following documentation which concerns the Quality Management System – QMS, is submitted in duplicate (one electronic copy and one hard copy):

7.4.1 Quality Manual	•	Risk Assessment	•
7.4.2 Standard Operating Procedures	•	Number of SOPs	•
7.4.3 Other Documentation	•	Operating license (if required)	•

……

6.5 I understand the manner by which the accreditation system functions.

6.6 I declare that the information presented within this document is correct.

6.7 I shall provide the assessment team with any information and shall facilitate the conduct of the assessment.

6.8 I assume the payment of all fees to ESYD, in accordance with the catalogue of fees of ESYD DENHMER, independently of the granting or not of accreditation and declare that we will defray the surveillance fees for maintaining accreditation status.

6.9 I enclose the **application fees.**

Signature_____ Date_____