Title	***Application for Accreditation of Medical Laboratories***
Reference	***DA-08***
Revision	***01***
Date	***01-02-2016***

NOTE: The present document is the English version of the document under reference at the specified revision. In case of difference the Italian version prevails. To identify the revised parts reference must be made to the version in Italian only.

Preparation	Approval	Authorization	Application date
The Quality Manager	The Director of the Dept. of Testing Labs	The General Director	2016-02-15

1. NAME OF THE CAB

1.1 Address of the laboratory's operative location

2. ORGANIZATION

2.1 Full name and title [1] of the manager[2] of the applicant laboratory[3]

2.2 Full name and title [1] of the substitute manager of the laboratory[3]

2.3 Full name and title [1] of the quality manager of the laboratory[3]

2.4 Full name and title [1] of the substitute manager of the quality manager [3]

2.5 Full name of the person/s who review the results and who authorize the issuance of the report [3][4]

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1) Title means the abbreviation used in ordinary correspondence which the person wants placed before his/her name (e.g. doctor, prof, Ms, Mr etc.).
2) By Laboratory Manager ACCREDIA means the person responsible for the activities of the medical lab and assurance that the ACCREDIA rules are complied with (see UNI CEI EN ISO/IEC 15189 § 4.1.1.4).
3) The CV of the person in question, signed and dated, shall be attached to this application.
4) Report means the document with the results of the exams (paper or electronic) which the lab sends to the applicant. The information requested refers to point n) of § 5.8.3 of UNI EN ISO 15189:2013.

3. OTHER INFORMATION

3.1) The laboratory performs exams for:

internal ❑ YES ❑ NO

If YES indicate the approx. number of daily blood tests

external ❑ YES ❑ NO

If YES indicate the approx. number of daily blood tests

other laboratories ❑ YES ❑ NO

If YES indicate the approx. number of daily blood tests

NOTES:

3.2) For the performance of the visit, indicate which activities described in the quality manual are not carried out at the main site of the laboratory as stated in § 1.1 (e.g. blood tests, POC exams, storage of consumables, purchases) specifying were this is done (with particular reference to those requiring time and/or means of transport).

3.3) For the performance of the visit, indicate which quality and technical records (see § 4.13 of UNI EN ISO 15189:2013) are not available at the site of the lab indicated in § 1.1, specifying the place where they are carried out (with particular reference to those requiring time and/or means of transport).

3.4) Provide, if relevant/applicable, information regarding the incorporation of the lab within its organization, including relations with other structures (e.g. specify if the lab shares staff, equipment, areas with other structures, or if it uses materials or services provided by other units/departments, e.g. clinical engineering for the calibration of measuring instruments or for monitoring the temperature of fridges or incubators).

3.4) The list of documents stating the management procedures of the lab's activities (apart from exam procedures or procedures regarding the use of equipment and work instructions).

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	Enter more lines if necessary		

4. OTHER ATTACHMENTS TO BE SENT WITH THE APPLICATION FOR ACCREDITATION

❑	Chamber of Commerce profile or other document attesting the legal identity of the CAB and the identity of the legal representative:
❑	ACCREDIA document *DA-08 Annex. 1: List of the exams for which accreditation is sought and of the diagnostic systems*
❑	Quality manual of the lab in controlled distribution in pdf (in a single file) Reference:……Revision…….:
❑	Copy for updating with regard to the exam procedures deriving from methods designed or developed by the lab and related declarations of validation (see RT-35, § 5.5.1.3)
❑	CVs (dated, signed and with authorization for data processing) of persons indicated in § 2
❑	The procedure/s or other document/s of the lab describing the general criteria adopted for the estimate and the measurement uncertainties relating to the accredited exams
❑	Organization chart of lab staff (minimum: main positions)
❑	Only for first accreditation: report of the last management review containing all the information given in point 4.15 of UNI EN ISO 15189, and including the results of a complete cycle of internal audits
❑	For fixed accreditation exams: the results of the assessments obtained by comparison activities (VEQ) or evidence of the inclusion in circuits programmed in the ACCREDIA document *DA-08 Annex 1*. If not applicable, please specify, giving reasons

In cases of applications for accreditation in the flexible scope (see RT-26):

❑	Procedure for the management of evaluations obtained in External Quality Assessment (EQA)
❑	Results of External Quality Assessment (EQA)

Rev.: Date:

Stamp of the CAB
Name and signature of legal representative[5]

5) Legal representative or delegated legal representative.