SUPPLEMENTARY APPLICATION FORM
MEDICAL LABORATORIES

RvA-F004-2-UK

Name of applicant organisation	:	
Registration number (if applicable)	:	
Registered place of business	:	
Date of application	:	
Applicant name	:	

General

This form is to be used in case of:

- new applications for accreditation (RvA-F001a),
- applications for scope extension(s) with an activity or a location (RvA-F105).

Where applicable in this form a distinction is made between the requirements for an organisation that is not yet accredited against ISO 15189 and the requirements for an organisation requesting a scope or location extension.

1. Specification of the activities

For medical laboratories a flexible scope is preferred.
Accreditation is requested for the activities specified in the source scope (RvA-F004-3). The source scope contains the scope elements for which the scientific organizations came to an agreement.
Supplementary information about the formulation of scopes for medical laboratories can be found in the EA document EA-4/17 (see www.european-accreditation.org).

If also a scope in English is used, a proposal for such an English scope description must be provided.

EXPLANATION

In the source scope (RvA-F004-3), on the appropriate tab(s), you specify the field(s) for which you request accreditation. Further explanation about the use can be found on the first tab of the source scope.
In case of POCT, additional to ISO 15189, the requirements of the ISO 22870 are also applicable. In the source scope the actual POCT activities have to be specified.

2. Documents to be submitted with the application

Documents can be submitted digitally, accompanied by a clear table of contents and user instruction. The document titles need to reflect the numbering of documents below.
With this application the following documents must be submitted:

Documents to be submitted *(including the documents mentioned in F001a/F105)*	**New application for accreditation**	**Extension of an existing accreditation**	
		Within work field[1)]	**Outside work field[1)]**
1. Proof of Chamber of Commerce registration (not more than six months old);	√		
2. An organisational chart and description of your organisational structure;	√		√[2)]
3. Quality manual and general management system procedures;	√		√[2)]
4. The technical implementing rules for all the tests applied for, if applicable including POCT- - and R&D examinations;	√	√	√
5. Validation and verification reports for all the tests applied for;	√	√	√
6. A statement of the inter-laboratory comparison (Proficiency testing, etc.) tests in which your laboratory has taken part (see RvA-T030);	√	√	√
7. General procedures that have been developed or modified, which are not included in the quality manual;	√	√[2)]	√[2)]
8. A cross reference between the requirements of ISO 15189 and your quality system according to the model in Appendix 1;	√	√	√
9. Modified chapter 1 of the report part A for this accreditation;			√
10. An example of a anonymized report for the requesting doctor;	√	√	√
11. Report(s) of recent internal audit(s) including action plans (no older than 6 months);	√	√[3)]	√[3)]
12 internal audit planning (annual planning);			
13. Report of the most recent management review (no older than 6 months);	√	√[3)]	√[3)]
14. Farmatec permit/recognition;	√[4)]	√[4)]	√[4)]
15. A list of examination procedures traceable to the flexible scope elements under accreditation (see SAP M000);	√	√	√

1) see annex 1 of RvA-BR010 'Police rule for the field of activities' for the work fields
2) if applicable for this new activity. If you do not consider it applicable, this needs to be mentioned.
3) for this new activity
4) if applicable

APPENDIX 1: Model cross reference list NEN-EN-ISO 15189:2012

Clause		Documents of the body (name, code and date)
4	**Management requirements**	
4.1	Organisation and management responsibility	
4.1.1	Organisation	
4.1.1.1	General	
4.1.1.2	Legal entity	
4.1.1.3	Ethical conduct	
4.1.1.4	Laboratory director	
4.1.2	Management responsibility	
4.1.2.1	Management commitment	
4.1.2.2	Needs of users	
4.1.2.3	Quality policy	
4.1.2.4	Quality objectives and planning	
4.1.2.5	Responsibility, authority and interrelationships	
4.1.2.6	Communication	
4.1.2.7	Quality manager	
4.2	Quality management system	
4.2.1	General requirements	
4.2.2	Documental requirements	
4.2.2.1	General	
4.2.2.2	Quality manual	
4.3	Document control	
4.4	Service agreements	
4.4.1	Establishment of service agreements	
4.4.2	Review of service agreements	
4.5	Examination of referral laboratories	
4.5.1	Selection and evaluating referral laboratories and consultants	
4.5.2	Provision of examination results	
4.6	External services and supplies	
4.7	Advisory services	
4.8	Resolution of complaints	
4.9	Identification and control of non-conformities	
4.10	Corrective action	
4.11	Preventive action	
4.12	Continual improvement	
4.13	Control of records	
4.14	Evaluation and audits	
4.14.1	General	
4.14.2	Periodic review of requests, and suitability of procedures and sample requirements.	
4.14.3	Assessment of user feedback	

Clause		Documents of the body (name, code and date)
4.14.4	Staff suggestions	
4.14.5	Internal audit	
4.14.6	Risk management	
4.14.7	Quality indicators	
4.14.8	Review by external organisations	
4.15	Management review	
4.15.1	General	
4.15.2	Review input	
4.15.3	Review activities	
4.15.4	Review output	
5	**Technical requirements**	
5.1	Personnel	
5.1.1	General	
5.1.2	Personnel qualifications	
5.1.3	Job descriptions	
5.1.4	Personnel introduction to the organizational environment	
5.1.5	Training	
5.1.6	Competence assessment	
5.1.7	Reviews of staff performance	
5.1.8	Continuing education and professional development	
5.1.9	Personnel records	
5.2	Accommodation and environmental conditions	
5.2.1	General	
5.2.2	Laboratory and office facilities	
5.2.3	Storage facilities	
5.2.4	Staff facilities	
5.2.5	Patient sample collection facilities	
5.2.6	Facility maintenance and environmental conditions	
5.3	Laboratory equipment, reagents and consumables	
5.3.1	Equipment	
5.3.1.1	General	
5.3.1.2	Equipment acceptance testing	
5.3.1.3	Equipment instructions for use	
5.3.1.4	Equipment calibration and metrological traceability	
5.3.1.5	Equipment maintenance and repair	
5.3.1.6	Equipment adverse incident reporting	
5.3.1.7	Equipment records	
5.3.2	Reagents and consumables	
5.3.2.1	General	
5.3.2.2	Reagents and consumables – Reception and storage	
5.3.2.3	Reagents and consumables – Acceptance testing	

Clause		Documents of the body (name, code and date)
5.3.2.4	Reagents and consumables – Inventory management	
5.3.2.5	Reagents and consumables – Instructions for use	
5.3.2.6	Reagents and consumables – Adverse incident reporting	
5.3.2.7	Reagents and consumables – Records	
5.4	Pre-examination processes	
5.4.1	General	
5.4.2	Information for patients and users	
5.4.3	Request form information	
5.4.4	Primary sample collection and handling	
5.4.4.1	General	
5.4.4.2	Instructions for pre-collection activities	
5.4.4.3	Instructions for collection activities	
5.4.5	Sample transportation	
5.4.6	Sample reception	
5.4.7	Pre-examination handling, preparation and storage	
5.5	Examination processes	
5.5.1	Selection, verification and validation of examination processes	
5.5.1.1	General	
5.5.1.2	Verification of examination processes	
5.5.1.3	Validation of examination processes	
5.5.1.4	Measurement uncertainty of measured quantity values	
5.5.2	Biological reference intervals or clinical decision values	
5.5.3	Documentation of examination processes	
5.6	Ensuring quality of examination results	
5.6.1	General	
5.6.2	Quality control	
5.6.2.1	General	
5.6.2.2	Quality control materials	
5.6.2.3	Quality control data	
5.6.3	Interlaboratory comparisons	
5.6.3.1	Participation	
5.6.3.2	Alternative approaches	
5.6.3.3	Analysis of interlaboratory comparison samples	
5.6.3.4	Evaluation of laboratory performance	
5.6.4	Comparability of examination results	
5.7	Post-examination processes	
5.7.1	Review of results	
5.7.2	Storage, retention and disposal of clinical samples	
5.8	Reporting results	
5.8.1	General	
5.8.2	Report attributes	

Clause		Documents of the body (name, code and date)
5.8.3	Report content	
5.9	Release of results	
5.9.1	General	
5.9.2	Automated selection and reporting of results	
5.9.3	Revised reports	
5.10	Laboratory information management	
5.10.1	General	
5.10.2	Authorities and responsibilities	
5.10.3	Information system management	