EUROPEAN ACCREDITATION

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Description of scopes of accreditation for medical laboratories

PURPOSE

This policy document is intended for national accreditation bodies (NABs) that assess medical laboratories. The aim of this document is to update and replace the policy document EA 4/17 M:2008 and give a description of the accreditation scopes of medical laboratories, in an extensive definition: clinical biology included point-of-care testing (POCT), anatomical pathology, medical imaging and other medical examinations. The scope of this document extends to the following: Medical laboratories including both private institutions and government entities who provide medical examination within the boundaries of their own organisation and for third parties.

Authorship

This document has been prepared by EA Laboratory Committee Working Group on Healthcare.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

Further information

For further information about this publication, please contact the Secretariat.

Please check our website for up-to-date information http://www.european-accreditation.org

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CONTENTS

1 INTRODUCTION

As the flexible scopes of accreditation are developing in Europe in the field of testing and considering the particularities of the examinations carried out by medical laboratories, the EA WG Healthcare, Laboratory Medicine, which is composed of national accreditation body (NAB) representatives and stakeholders, had intensive discussions on the description of scopes of accreditation.

This mandatory document is intended for NABs to help the harmonization in the description of scopes of accreditation and the development of flexible scope of accreditation. It should be noted that it is not mandatory for EA members to accredit flexible scopes, although EA encourages EA members to provide this as a service to their customers. Furthermore, it can contribute to facilitate work and reduces administrative measures for both, accredited laboratories and NABs.

The document describes principles how to develop scopes of accreditation that are used by the NAB to illustrate the frame of competence of each accredited medical laboratory in a as far as possible harmonized way. Furthermore, it recognizes that different degrees of flexibility may be introduced to meet the needs of the implemented national accreditation system and the medical laboratories when demonstrating the competences in laboratory examinations.

It is important to specify the scope of accreditation of medical laboratories clear enough to determine which services are provided (e.g. which analyte in which material/organic matrix is determined by which technique described by which method) under accreditation. It is a combination of activities from medical and technical fields.

The scope of accreditation is, first of all, designed to clearly define the services for which the medical laboratory has committed to meet the requirements for accreditation. It shall be also designed to give enough information to the customers about the services which could be provided under accreditation.

It is recommended to design and standardize the presentation of the scope of accreditation at a national level with the involvement of scientific societies in each medical field covering all activities of medical laboratories. Where overlaps occur, the different medical fields should find common approaches to present the scope of accreditation in a uniform way. To increase transparency and readability of the scopes of accreditation, the applied terms and definitions should be first agreed upon and then applied in a consistent way for all listed activities in the scope.

2 TERMS AND DEFINITIONS

dd/mm/yyyy: example of format of the date (day/month/year)

Scope of accreditation: specific conformity assessment activities for which accreditation is sought or has been granted (ISO/IEC 17011 §3.6).

Flexible scope of accreditation: scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body as confirmed by the accreditation body (ISO/IEC 17011 §3.7).

Examination: set of operations having the object of determining the value or characteristics of a property.
Note: Laboratory examinations are also often called assays or tests. In the document the term test is used.

Method/procedure: can be considered synonymous with the term “measurement procedure” as defined in ISO/IEC Guide 99 (ISO/IEC 17025 §7.2.1.1 note).

Commercial procedure: procedure specified in the instructions for use of *in vitro* diagnostic medical devices (IVD-MD) (ISO 15189 §5.5.1.1 note).

Published procedure: procedure that has been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international consensus standards or guidelines, or national or regional regulations (ISO 15189 §5.5.1.1 note).

In-house method: laboratory-developed method

Test kit or testing kit: a discerning device used in a wide range of areas including medical diagnosis. In the document the term test kit is used.

Ref. XX, YY, ZZ, PPYY, PPZZ, IHM01: The reference of the method / procedure / instruction / SOP (Standard Operating Procedure) / test kit can be any unique combination of letters and numbers

Version code: The version code can be a number (including letters), a date or a combination of numbers, letters and dates. It is typically assigned to a specific release of a commercial procedure such as for an *in vitro* diagnostic medical device (IVD-MD). Version codes can also be used in the same way to designate the laboratory's own examination procedures as well as any other document in the management system.

<u>For point-of-care testing (POCT):</u>

Site: a building (e.g. such as a hospital), where POCT examinations are performed.

Delivery points: wards, clinics, and emergency care rooms etc. where POCT is delivered.

Cluster: a grouping of POCT delivery points such as wards and clinics, where critical variables such as IT interfaces, purpose of POCT (for example emergency care) are the same. A cluster could be over more than one site. However, the approach should ensure that all the sites are separately considered.

The following verbal forms apply in understanding how to implement the policy document:
- "shall" indicates a requirement

- "should" indicates a recommendation
- "may" indicates a permission
- "can" indicates a possibility or a capability

In the ISO/IEC Directives, Part 2, Seventh edition, 2016, 3.3.3, a requirement is defined as an "expression in the content of a document conveying objectively verifiable criteria to be fulfilled and from which no deviation is permitted if compliance with the document is to be claimed."

In the ISO/IEC Directives, Part 2, Seventh edition, 2016, 3.3.4, a recommendation is defined as an "expression in the content of a document conveying a suggested possible choice or course of action deemed to be particularly suitable without necessarily mentioning or excluding others."

3 GENERAL

In a scope of accreditation, the NAB lists in detail all relevant elements related to the particular examination method that the accredited medical laboratory is able to apply with proven appropriate competence.

For a flexible scope of accreditation, the information provided shall be equal to the information on the same examinations provided under a scope of accreditation, but a part of it may be maintained by the medical laboratory and may be subject to changes. A presentation of a scope of accreditation by introducing the concept of flexibility can reduce the details of information given by the scope depending on the number of implemented degrees of freedom; thereby, it makes the presented scope lighter and more readable by reducing details without at the end losing overall information for those, which may need it. Nevertheless, to this end, it is complemented by a detailed list of accredited activities, maintained by the medical laboratory and publicly available in order to be provided on request.

For all presentations of scopes of accreditation, it is important to note that the reader of a scope can assume that the accredited medical laboratory provides a full service for the listed examinations. This means, the reader can expect that the medical laboratory has demonstrated proper competence to cover all pre-examination, examination and post-examination aspects that are essential to provide for the particular examination an effective and efficient laboratory service to the clinicians, other health care professionals and the patients. Within this, it is also expected that a medical laboratory is able to demonstrate its competence in interpreting the results of its examinations performed. If one of the above is not or only in part guaranteed in accordance with NAB’s procedures, the NAB should indicate an appropriate limitation in the scope presentation to further describe the restriction.

The official publication of the scope of accreditation by the NAB reflects the competence of the medical laboratory to offer the activities and examinations which have been granted accreditation, as of the date of publication.

At a first level, the scope of accreditation should be defined as a “medical laboratory field”, such as Clinical Chemistry, Hematology, Immunology, Microbiology, Genetics, etc., and, if needed, also as a “medical laboratory sub-field”.

On a national level, the NAB and the corresponding medical laboratory profession can define such discipline and sub-discipline levels. If possible, these definitions should be in line with the common understanding in the particular medical domain in Europe.

In any cases, the scope of accreditation shall include examinations. The way in which description of the examinations are done depends on the flexibility allowed by the NAB in the presentation.

The NAB shall **have a clear policy to the possibilities it provides under the presentation of scopes of accreditation of different flexibility. Especially the possibilities what the AB allows the accredited medical laboratory to do in technical and organizational terms when choosing a particular scope presentation shall be stated.**

Examples of scopes of accreditation are given in annex.

4 PRINCIPLES OF A SCOPE OF ACCREDITATION

To fulfill this basic requirement taking into account the activity of medical laboratories and the frequent technological changes they are dealing with, especially with IVD-MD, the presentation of a non-flexible scope of accreditation of a medical laboratory shall state in every “medical laboratory field”, every individual method (examination) described with at least four parameters such as:

- Material and / or System and / or Matrix,
- Analyte and / or Parameter,
- Technique,
- Equipment and / or Method and / or Procedure reference.

In addition, the NAB shall provide information on the scope of accreditation that shall identify the locations (sites) of the medical laboratory and the activities performed at each location / site and covered by the scope of accreditation.

Note 1: The NAB can set in its policy the requirement for mentioning of valid version codes of equipment and / or method and / or procedure references in the presentation of the scope of the accreditation of the medical laboratory if it wants to determine in its accreditation system the most defined stage at the moment of the creation of the scope.
If the scope of accreditation contains no element of flexibility and if the mentioning of the valid version code in the scope of accreditation is not foreseen or possible in the applied policy, the NAB can state another way in its policy to clearly define how the medical laboratory informs the NAB of changes and the way how such changes will be assessed thereafter.

Note 2: Any change of information in the presentation of the scope of accreditation, including the locations where the examinations are performed, would be considered as an extension or reduction of the scope of accreditation of the medical laboratory.

Note 3: As many examinations performed by medical laboratories are identification and/or determination of concentration of analytes and/or parameters, the description of these analytes and/or parameters can be enough to describe also the corresponding examinations.

5 PRINCIPLES OF A FLEXIBLE SCOPE OF ACCREDITATION

Considering the activity of medical laboratories, use of a flexible scope of accreditation is preferred due to frequent changes to constantly answering the needs of the clinicians, other health care professionals, the patients, and to also keep abreast of technological development. Application of a flexible scope of accreditation allows more innovation. On the other hand, allowing such approaches implies that the NAB has clear procedures on how it addresses flexible scopes of accreditation. The presentation of a flexible scope of accreditation describes the boundaries of the flexibility of the scope of accreditation including the degrees of freedom.

As the flexible scope of accreditation will depend on the process of introduction of new or modified services, a risk-based approach shall be considered by the NAB to design these boundaries.

Different degrees of freedom to include medical examinations in the scope of accreditation can be established based on:

- flexibility concerning the material and/or system and/or matrix;
- flexibility concerning the analyte and/or parameter*);
- flexibility concerning the technique (same technical principle), e.g. changes in the performance of the method used for examination;
- flexibility concerning the equipment and/or method and/or procedure used for examination;
- a combination of two or more of these flexibilities.

*) The scope of accreditation covers a group of analytes and/or parameters. The flexibility consists in the addition of new analytes and/or parameters inside the group. For example, addition of individual vitamins inside a group “vitamins”.

When a medical laboratory is granted a flexible scope of accreditation, it is allowed to include additional activities in its scope of accreditation on the basis of its own verifications and validations without evaluation by the NAB prior to operation of the activity. The possibility of introducing new, modified or developed methods under flexible scope of accreditation does not include introduction of new technical principles not previously covered by the scope of accreditation.

The medical laboratory shall maintain a detailed list of accredited activities which forms part of its accreditation, including the locations / sites where the particular listed activities are performed. The scope of accreditation shall make reference to the list, regardless of the way the reference is made (either at the beginning or at the end of the scope presentation, by the use of appropriate sentences or coding referring clearly to the detailed list of accredited activities the medical laboratory shall manage and be able to provide on request). The

detailed list of accredited activities shall be made publicly available, in order to be provided on request.

This list shall contain at least the same information as required for the scope of accreditation and shall be maintained up-to-date according to principles of records control (e.g with an effective date of introduction / modification of activities). The NAB may further define all details in its procedures relevant for accreditation of medical laboratories to reach the desired uniform presentation of scopes of accreditation of its totality of accredited conformity assessment bodies. Every activity and examination stated on the list shall be validated and/or verified according to approved procedures and concepts.

Note: If there is no ambiguity in identifying examinations which are part of the scope of accreditation of the medical laboratory and which not, the detailed list can be part of a complete list, covering all the examinations performed by the medical laboratory. Consequently, the medical laboratory does not have to maintain two lists.

6 PRIMARY SAMPLE COLLECTION

If a medical laboratory is accredited for primary sample collection, this activity shall be identified by the NAB in the scope of accreditation.

The presentation of the scope of accreditation for primary sample collection follows the principles defined for a scope of accreditation (chapter 4) and for a flexible scope of accreditation (chapter 5), except the parameter “analyte and/or parameter” as primary sample collection is not dedicated to an analyte or parameter.

In addition, if primary sample collection is performed in particular sites in a multi-sites organization, these particular sites and the activity performed at each site are stated in the scope of accreditation.

Note: Usually, a flexible scope of accreditation is not needed for primary sample collection but in some special cases, defined by the NAB, a degree of flexibility might be useful and therefore introduced in the policy of the NAB.

7 POINT-OF-CARE TESTING

The presentation of the scope of accreditation for point of care testing follows the principles defined for a scope of accreditation (chapter 4) and for a flexible scope of accreditation (chapter 5).

Any change of information in the presentation of the scope of accreditation, including the sites and delivery points where the examinations are performed, would be considered as an extension or reduction of the scope of accreditation. A degree of freedom to include medical examinations in the scope of accreditation can be allowed by the NAB based on a flexibility concerning delivery points inside a cluster.

The NAB shall clearly distinguish, in the scope of accreditation, examinations undertaken by the medical laboratory responsible of managing the POCT activities. The information

concerning the accreditation of the medical laboratory shall refer to both standards, EN ISO 15189 and EN ISO 22870 as long as POCT is separately stated in the latter standard.

Note: The NAB can introduce in the scope of accreditation, instead of the direct mentioning of the delivery points or clusters, a reference to a separate publicly available list of delivery points and/or clusters covered by the scope of accreditation. This is particularly interesting when many delivery points or clusters, where POCT examinations are performed, are included in the scope of accreditation of the medical laboratory responsible of managing the POCT activities.

8 REFERENCES

8.1 Normative references

EN ISO/IEC 17011: 2017 “Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies”

EN ISO 15189: 2012 “Medical laboratories - Requirements for quality and competence”

EN ISO 22870: 2016 “Point-of-care testing (POCT) — Requirements for quality and competence”

EN ISO/IEC 17025: 2017 “General requirements for the competence of testing and calibration laboratories”

ISO/IEC DIR 2:2016 - ISO/IEC Directives Part 2 Principles and rules for the structure and drafting of ISO and IEC documents.

8.2 Other references

8.2.1 Mandatory documents

EA 2/15: 2019 “EA requirements for the Accreditation of Flexible Scopes”

8.2.2 Guidance documents

ILAC G18: 2010 “guideline for the formulation of scopes of accreditation for laboratories”

EA 4/20: 2020 “Guidance for the Assessment of Laboratories against EN ISO 15189 and EN ISO 22870 Point-of-Care Testing (POCT)”

9 ANNEX: EXAMPLES OF PRESENTATION OF SCOPES OF ACCREDITATION

The annex is informative and contains only examples. The location / site of the medical laboratory, where the activities are performed, are not mentioned in these examples. A scope of accreditation of a multisite medical laboratory needs an indication on which location / site the listed examinations are performed.

The presentation (number of columns, title of columns, version code, etc.) is not mandatory and can be chosen by the NAB to fit into its national accreditation system. Only the four parameters defined in chapter 4 are mandatory for the description of a scope of accreditation.

In case of a flexible scope of accreditation, the detailed list of accredited activities shall contain at least the same information as required for the scope of accreditation and shall be maintained up-to-date according to principles of records control (e.g with an effective date of introduction / modification of activities).

The scope of accreditation shall make reference to the detailed list of accredited activities. The way the reference is made, can be chosen by the NAB to best fit its need in the national accreditation system.

9.1 Examples in the field of microbiology

Used Terms and Abbreviations:

ECLIA: Electro-chemiluminescence immunoassay
ELIFA: Enzyme-linked immunofiltration assay
ELISA: Enzyme-linked immunosorbent assay

9.1.1 Example 1 - Scope of accreditation (4 columns format)

Scope presentation (established by the NAB)

	Material/System/Matrix	**Analyte/parameter**	**Technique**	**Equipment/Method/Procedure Reference**
a				
b	Serum	IgM anti-Toxoplasma antibodies	ECLIA	Name of IVD-MD (device) SOP Ref. XX
c	Serum	IgG anti-Toxoplasma antibodies	ECLIA	Name of IVD-MD (device) Test Kit YY Version code
d	Cord blood	anti-Toxoplasma antibodies	ELIFA	In-house method Ref. IHM01 Version code

9.1.2 Example 2 - Scope of accreditation (3 columns format)

Scope presentation (established by the NAB)

	Material/System/Matrix	Technique / Analyte/parameter	Equipment/Method/Procedure Reference
b	Serum	ECLIA IgM anti-Toxoplasma antibodies	Name of IVD-MD (device) SOP Ref. XX
c	Serum	ECLIA IgG anti-Toxoplasma antibodies	Name of IVD-MD (device) Test Kit YY Version code
d	Cord blood	ELIFA anti-Toxoplasma antibodies	In-house method Ref. IHM01 Version code

9.1.3 Example 3 – Flexible scope of accreditation - Flexibility concerning the material/system/matrix only

Scope presentation (established by the NAB)

	Material/System/Matrix	Analyte/parameter	Technique	Equipment/Method/Procedure Reference
b	**Body fluids**	anti-Streptococcus pneumoniae antibodies	Immunochromatography	IVD-MD instruction

The current detailed list of accredited activities is available from the medical laboratory / can be downloaded at http://www.medical-laboratory.xyz.

Detailed List of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

a	Material/ System/ Matrix	Analyte/parameter	Technique	Equipment/Method/ Procedure reference	Supplier / Manufacturer	External Quality Control (EQC)	Date of Validation and release	Remarks
b	**Serum**	anti-Streptococcus pneumoniae antibodies	Immuno-chromato-graphy	IVD-MD instruction (Ref. ZZ including version code)	Name of manufacturer	EQC1	15.03.2010	
c	**Urine**	anti-Streptococcus pneumoniae antibodies	Immuno-chromato-graphy	IVD-MD instruction (Ref. ZZ including version code)	Name of manufacturer	EQC1	15.03.2010	
d	**Cerebro-spinal fluid**	anti-Streptococcus pneumoniae antibodies	Immuno-chromato-graphy	IVD-MD instruction (Ref. ZZ including version code)	Name of manufacturer	EQC1	24.05.2015	

9.1.4 Example 4 – Flexible scope of accreditation - Flexibility concerning the analyte/parameter only

Scope Presentation (established by the NAB)

a	Material/System/Matrix	Analyte/parameter	Technique	Equipment/Method/Procedure Reference
b	Serum	**Specific Ag and Ac against infectious agents (bacteria, virus, parasites and fungi)**	ECLIA	IVD-MD instruction

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz.

Detailed List of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

	Material/System/Matrix	Analyte/ parameter	Technique	Equipment/Method/ Procedure reference	Supplier / Manufacturer	External Quality Control (EQC)	Date of Validation and release	Remarks
b	Serum	**IgM anti-Toxoplasma antibodies**	ECLIA	IVD-MD instruction (Ref. XX including version code)	Name of manufacturer	EQC1	15.03.2010	
c	Serum	**IgM anti-Rubeola antibodies**	ECLIA	IVD-MD instruction (Ref. XX including version code)	Name of manufacturer	EQC2	16.03.2013	

9.1.5 Example 5 – Flexible scope of accreditation - Flexibility concerning the technique and the examination equipment/method/procedure only

Scope presentation (established by the NAB)

	Material/System/Matrix	Analyte/parameter	Technical Principle	Equipment/Method/Procedure Reference
b	Serum	IgM anti-Toxo-plasma antibodies	**Immunoassays**	**Commercial methods/procedures**

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz.

Detailed List of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

	Material/System/Matrix	Analyte/ parameter	Technique	Equipment/Method/ Procedure reference	Supplier / Manufacturer	External Quality Control (EQC)	Date of Validation and release	Remarks
a								
b	Serum	IgM anti-Toxoplasma antibodies	**ECLIA**	**IVD-MD instruction (Ref. XX including version code)**	Name of manufacturer	EQC1	15.03.2010	
c	Serum	IgM anti-Toxoplasma antibodies	**ELIFA**	**IVD-MD instruction (Ref. YY including version code)**	Name of manufacturer	EQC1	17.07.2014	
d	Serum	IgM anti-Toxoplasma antibodies	**ELISA**	**IVD-MD instruction (Ref. ZZ including version code)**	Name of manufacturer	EQC1	19.10.2015	

9.1.6 Example 6 – Flexible scope of accreditation - Flexibility concerning the examination equipment/method/procedure only

Scope presentation (established by the NAB)

	Material/System/Matrix	Analyte/parameter	Technique	Equipment/Method/Procedure Reference
a				
b	Serum	IgM anti-Toxo-plasma antibodies	ECLIA	**Commercial methods/procedures, in-house methods**

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz

Detailed List of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

	Material/System/Matrix	Analyte/ parameter	Technique	Equipment/Method/ Procedure reference	Supplier / Manufacturer	External Quality Control (EQC)	Date of Validation and release	Remarks
a								
b	Serum	IgM anti-Toxoplasma antibodies	ECLIA	**IVD-MD instruction (Ref. XX including version code)**	Name of manufacturer	EQC1	15.03.2010	
c	Serum	IgM anti-Toxoplasma antibodies	ECLIA	**In-house method (Ref. IHM01 including version code)**	Literature / own method	EQC1	17.07.2014	

9.1.7 Example 7 – Flexible scope of accreditation - Flexibility concerning the material/system/matrix, the analyte/parameter, the technique and the examination equipment/method/procedure

Scope presentation (established by the NAB)

	Material/System/Matrix	Analyte/parameter	Technical Principle
a			
b	**Body fluids**	**Specific Ag and Ac against infectious agents (bacteria, virus, parasites and fungi)**	**Immunoassays**

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz.

Detailed list of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

a	Material/System/Matrix	Analyte/ parameter	Technique	Equipment/Method/ Procedure reference	Supplier / Manufacturer	External Quality Control (EQC)	Date of Validation and Release	Remarks
b	**Blood**	**IgM anti-Toxoplasma antibodies**	**ECLIA**	**IVD-MD instruction (Ref. XX including version code)**	Name of manufacturer	EQC1	15.03.2010	
c	**Blood**	**IgG anti-Toxoplasma antibodies**	**ELIFA**	**IVD-MD instruction (Ref. YY including version code)**	Name of manufacturer	EQC1	15.03.2017	Replaced automate (state the type and brand of the equipment)
d	**Blood / aqueous humor or vitreous**	**Goldman-Witmer coefficient**	**ECLIA / Nephelometry**	**Published procedure (Ref. PPZZ including version code)**	Literature	EQC2	24.05.2014	
e	**Blood / cord blood**	**anti-Toxoplasma antibodies**	**ELIFA**	**In-house method (Ref. IHM01 including version code)**	Literature / own Method	EQC1	21.11.2017	

9.2 Examples for primary sample collection

9.2.1 Example 1 - Scope of accreditation

Scope presentation (established by the NAB)

	Material/System/Matrix	Technique	Equipment/Method/Procedure Reference
a			
b	Blood	Venipuncture	SOP Ref. XX version code

9.2.2 Example 2 - Flexible scope of accreditation – Flexibility concerning the examination equipment/method/procedure only

Scope presentation (established by the NAB)

	Material/System/Matrix	Technique	Equipment/Method/Procedure Reference
a			
b	Blood	Venipuncture	SOP Ref. XX

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz

Note: As not only sample collection activities can be performed in particular sites in a multi-sites organization, the NAB may find useful, in a flexible scope approach, to identify also the preanalytical and postanalytical phases in the scope of accreditation.

9.3 Examples for point-of-care testing

9.3.1 Example 1 – Scope of accreditation

Scope presentation (established by the NAB)

	Site/delivery point	Material/System/ Matrix	Analyte/parameter	Technique	Equipment/Method/Procedure Reference
a					
b	Hospital A / surgical reanimation	Blood	Blood Gases: pH, pCO2	Potentiometric method	Name of device SOP Ref. XX
c	Hospital A / neonatal reanimation	Blood	Blood Gases: pH, pCO2	Potentiometric method	Name of device SOP Ref. XX
d	Hospital A / Emergency room 1	Urine	blood, glucose, ketone, protein, specific gravity, pH, urobiligen, bilirubin, ascorbic acid, nitrites and leucocytes	Dipstick	Name of device SOP Ref. YY

9.3.2 Example 2 – Flexible scope of accreditation - Flexibility concerning the material/system/matrix, the analyte/parameter, the technique, the examination equipment/method/procedure and the delivery points

Scope presentation (established by the NAB)

a

Material/System/Matrix	Analyte/parameter	Technical Principle	Equipment/Method/Procedure Reference
Body fluids	**Analytes in biochemistry**	**Standard chemical tests such as Electrochemistry, Spectrophotometry**	**Commercial methods/procedures**

b

c

d

e

Sites	Clusters
Hospital A (address)	**Reanimation services**
	Emergency rooms

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz.

Detailed list of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

		Site/delivery point	Material/ System/ Matrix	Analyte/parameter	Technique	Equipment/Method/ Procedure reference	Supplier / Manufacturer	Date of Validation and Release	Remarks
a									
b		**Hospital A / Surgical reanimation Neonatal reanimation**	**Blood**	**Blood Gases: pH, pCO2**	**Potentiometric method**	**IVD-MD instruction (Ref. XX including version code)**	Name of manufacturer	15.03.2010	
c		**Hospital A / Surgical reanimation**	**Blood**	**Hb**	**Spectrophotometry**	**IVD-MD instruction (Ref. XX including version code)**	Name of manufacturer	15.03.2010	
d		**Hospital A / Emergency room 1**	**Urine**	**blood, glucose, ketone, protein, specific gravity, pH, urobiligen, bilirubin, ascorbic acid, nitrites and leucocytes**	**Dipstick**	**IVD-MD instruction (Ref. YY including version code)**	Name of manufacturer	15.03.2017	

9.4 Other examples

9.4.1 Next-generation sequencing techniques in the field of Genetics

9.4.1.1 Example 1 - Scope of accreditation

Scope presentation (established by the NAB)

	Material/System /Matrix	Analyte/parameter	Technique	Equipment/Method/Procedure Reference
a				
b	Blood DNA	Detection of germline mutations in 23 genes associated with Limb-Girdle Muscular Dystrophy: ANO5 CAPN3 CAV3 DAG1 DES DNAJB6 DYSF FKRP FKTN ISPD LMNA MYOT PLEC POMGNT1 POMT1 POMT2 SGCA SGCB SGCD SGCG TCAP TRIM32 TTN	Next generation sequencing	Name of device SOP Ref. XX version code
c	Blood DNA	Non-invasive prenatal test (NIPT): Trisomie 21	Next generation sequencing	Name of device SOP Ref. YY version code

9.4.1.2 Example 2 - Flexible scope of accreditation - Flexibility concerning the analyte/parameter and the examination equipment/method/procedure

Scope presentation (established by the NAB)

	Material/System/Matrix	Analyte/parameter	Technique	Equipment/Method/Procedure Reference
a				
b	Blood DNA	**Detection of mutations**	Next generation sequencing	**Commercial methods / procedures, in-house methods**
c	Blood DNA	**Non-invasive prenatal test (NIPT)**	Next generation sequencing	**Commercial methods / procedures**

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz.

Detailed list of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

	Material/ System/ Matrix	Analyte/parameter	Technique	Equipment/Method/ Procedure reference	Supplier / Manufacturer	External Quality Control (EQC)	Date of entry in the list	Remarks
a								
b	Blood DNA	**Detection of germline mutations in 23 genes associated with Limb-Girdle Muscular Dystrophy:** **ANO5 CAPN3 CAV3 DAG1 DES DNAJB6 DYSF FKRP FKTN ISPD LMNA MYOT PLEC POMGNT1 POMT1 POMT2 SGCA SGCB SGCD SGCG TCAP TRIM32 TTN**	Next generation sequencing	**In-house method** **(Ref. IHM01 including version code)**	Literature / Own method	EQC1	15.03.2010	
c	Blood DNA	**Non-invasive prenatal test (NIPT):** **Trisomie 21**	Next generation sequencing (bioinformatics analysis outsourced to Name of the Company)	**IVD-MD instruction** **(Ref. YY including version code)**	Name of manufacturer	Exchange of samples	15.03.2017	

9.4.2 Anatomical pathology

9.4.2.1 Example 1 – Scope of accreditation

Scope presentation (established by the NAB)

	Material/System/Matrix	Technique / Analyte/parameter	Equipment/Method/Procedure Reference
a			
b	Biopsies of: - Breast - Lymph node	Macroscopic study and carving Processing Complementary technique (detail above see*) Microscopic study and diagnosis	Published procedure Ref. PPZZ Version code
c	Paraffin block	*Fluorescent In Situ Hybridization (FISH) - HER 2	Name of device SOP Ref. YY

9.4.2.2 Example 2 – Flexible scope of accreditation - Flexibility concerning the material / system / matrix, the analyte/parameter and the examination equipment / method / procedure

Scope presentation (established by the NAB)

	Material/System/Matrix	Technique / Analyte/parameter	Equipment/Method/Procedure Reference
a			
	Biopsies of human body tissues	Macroscopic study and carving Processing Complementary technique (detail above see*) Microscopic study and diagnosis	**Published methods / procedures**
b	**Paraffin block**	*Fluorescent In Situ Hybridization (FISH) **Detection of deletions and amplifications of gene sequences**	**Commercial methods / procedures**

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz.

Detailed list of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

a	Material/System/Matrix	Analyte/ parameter	Technique	Equipment/Method/ Procedure reference	Supplier / Manufacturer	Date of entry in the list	Remarks
b	**Biopsies of** **- Breast** **- Lymph node**	**/**	Macroscopic study and carving Processing Complementary technique (detail above see*) Microscopic study and diagnosis	**Published procedure** **(Ref. PPZZ including version code)**	Literature	24.05.2014	
c	**Biopsy of Liver**	**/**	Macroscopic study and carving Processing Complementary technique (detail above see*) Microscopic study and diagnosis	**Published procedure** **(Ref. PPYY including version code)**	Literature	24.05.2014	
d	**Paraffin block**	**HER 2**	*Fluorescent In Situ Hybridization (FISH)	**IVD-MD instruction (Ref. YY including version code)**	Name of manufacturer	24.05.2014	
e	**Paraffin block**	**p53**	*Fluorescent In Situ Hybridization (FISH)	**IVD-MD instruction (Ref. ZZ including version code)**	Name of manufacturer	24.05.2014	

9.4.3 Other medical examinations

9.4.3.1 Physiology

9.4.3.1.1 Example 1 – Scope of accreditation

Scope presentation (established by the NAB)

	Material/System/Matrix	Technique / Test	Equipment/Method/Procedure Reference
a			
b	Patient	Exercise test / Electro-cardiogram: treadmill	Name of device SOP Ref. XX version code
c	Patient	Pulmonary function tests: spirometry	Name of device SOP Ref. YY version code

9.4.3.1.2 Example 2 – Flexible scope of accreditation - Flexibility concerning the analyte / parameter, the technique and the examination equipment / method / procedure

Scope presentation (established by the NAB)

	Material/System/Matrix	Technical principle / Tests	Equipment/Method/Procedure Reference
a			
b	Patient	**Exercise test / Electrocardiogram**	**Commercial methods / procedures**
c	Patient	**Pulmonary function tests**	**Commercial methods / procedures**

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz.

Detailed list of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

	Material/ System/ Matrix	Test	Technique	Equipment/Method/ Procedure reference	Supplier / Manufacturer	Date of entry in the list	Remarks
a							
b	Patient	**Exercise test** **- treadmill** **- stationary bicycle**	**Electrocardiogram**	**Device instruction (Ref. XX including version code)**	Name of manufacturer	15.03.2010	
c	Patient	**Pulmonary function tests**	**- Spirometry** **- Lung plethysmo-graphy** **- Lung diffusion testing**	**Device instruction (Ref. YY including version code)**	Name of manufacturer	24.05.2014	

9.4.3.2 Medical imaging

9.4.3.2.1 Example 1 – Scope of accreditation

Scope presentation (established by the NAB)

	Material/System/Matrix	Technique / Examination	Equipment/Method/Procedure Reference
a			
b	Abdomen	X-Rays without contrast media	Name of device SOP Ref. XX version code
c	Breast	Mammography	Name of device SOP Ref. YY version code

9.4.3.2.2 Example 2 – Flexible scope of accreditation – Flexibility concerning the material/system/matrix and the examination equipment / method / procedure in Medical imaging

Scope presentation (established by NAB)

	Material/System/Matrix	Technique / Examination	Equipment/Method/Procedure Reference
a			
b	**Body**	Radiography with or without contrast media	**Commercial methods / procedures**
c	**Blood vessels**	Angiography with or without contrast media	**Commercial methods / procedures**
d	**Breast**	Mammography	**Commercial methods / procedures**

The current detailed list of accredited activities is available from the medical laboratory. / can be downloaded at http://www.medical-laboratory.xyz.

Detailed list of Accredited Activities dd/mm/yyyy for the above Scope Presentation (provided by the medical laboratory)

a	**Material/System/ Matrix**	**Examination**	**Technique**	**Equipment/Method/ Procedure reference**	**Supplier / Manufacturer**	**Date of entry in the list**	**Remarks**
b	**Abdomen**	Radiography	X-Rays without contrast media	**Device instruction (Ref. XX including version code)**	Name of manufacturer	15.03.2010	
c	**Abdomen**	Radiography	X-Rays with contrast media	**Device instruction (Ref. XX including version code)**	Name of manufacturer	15.03.2010	
d	**Bones**	Radiography	X-Rays without contrast media	**Device instruction (Ref. XX including version code)**	Name of manufacturer	15.03.2010	
e	**Arterial system**	Angiography	X-Rays with contrast media	**Device instruction (Ref. YY including version code)**	Name of manufacturer	15.03.2010	
f	**Venous system**	Angiography	X-Rays with contrast media	**Device instruction (Ref. YY including version code)**	Name of manufacturer	15.03.2010	
g	**Breast**	Mammography	X-Rays	**Device instruction (Ref. ZZ including version code)**	Name of manufacturer	24.05.2014	