

<b>EA Position Paper</b>				
<b>on the</b>				
<b>description of scopes</b>				
<b>of accreditation</b>				
<b>of medical laboratories</b>				

**PURPOSE**

The aim of this paper, which results from a comprehensive discussion within the EA WG Healthcare - Laboratory Medicine, is to give a description of the accreditation scopes of medical laboratories. It sets out some principles for the definition of such flexible or fixed scopes.

*Authorship*

The publication has been written by the EA Laboratory Committee working group on Healthcare – Laboratory Medicine.

*Official language*

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**CONTENTS**

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**Introduction..... 4**  
**Position on the description of scopes of accreditation of medical laboratories 4**  
**Example..... 5**

## **Introduction**

The EA WG Healthcare, Laboratory Medicine, which is composed of national Accreditation body representatives and stakeholders -, has for some time been considering the description of the scopes of accreditation for medical laboratories. This position paper results from extensive discussions.

## **Position on the description of scopes of accreditation of medical laboratories**

1. The scope of accreditation should normally cover a substantial majority of the overall service provided by the laboratory within a medical laboratory field (that is on a discipline level, see point 5 below).
2. It is recognized that the accreditation bodies (ABs) cannot enforce this and that accreditation also has educational aspects in that a laboratory may start with a limited scope to become acquainted with the accreditation process and requirements. Nevertheless, the ABs should encourage the laboratories to cover the relevant part of their examinations within each medical laboratory field in their scope.
3. The 'flexible' scope of accreditation is preferred. The laboratory shall maintain a list of all individual examinations which form part of its accreditation. This approach is fully in line with overall EA principles on flexible scopes as published in EA-2/15.
4. For each medical field, mentioned in the scope, it is expected that the laboratory provides a full service, which includes all pre-examination, examination and post-examination aspects that are essential to provide an effective and efficient laboratory service to the patients. Within this, it is expected that a medical laboratory is able to demonstrate its competence in interpreting the results of the examinations performed.
5. At a first level, the scope of accreditation shall be defined as a medical laboratory field, such as for example Clinical Chemistry, Haematology, Immunology, Microbiology, etc. It is accepted that on a national level the AB and the corresponding medical laboratory profession define such discipline levels.
6. At a second level, the scope must include the types of examinations / technical fields.
7. For the description of the scope of accreditation for a medical laboratory, the first and second levels are mandatory along with a description of the materials and products associated with these levels.
8. The flexible scope may include named examinations. For fixed scopes this is mandatory.

The format of the scope of accreditation can however be chosen on a national level in consultation between the AB and the medical laboratory profession.

## Example

An example of the description of a flexible scope of a medical laboratory is presented below.

<b>Medical laboratory fields</b>	<b>Types of examinations / Technical fields</b>	<b>Materials or products</b>
Clinical chemistry	Electrophoresis, Gel chromatography, HPLC, Photometry (reflection), Turbidimetry	Blood, Serum, Plasma, Urine
Haematology	Flow cytometry, Blood cell counting	Blood, EDTA-Blood, Citrat-Plasma
Immunology	Enzyme immuno assay, Particle agglutination	Serum, Urine, Liquor
Microbiology (bacteriology, mycobacteriology, mycology, parasitology)	PCR, ELISA, Microscopy	Body fluid, Serum, Sputum, Stool, Blood culture
Virology (is actually part of microbiology)	PCR, Enzyme immuno assay	Serum, EDTA-Blood, Plasma