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Accreditation process in European countries – an EFLM survey

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Abstract

Background: Accreditation is a valuable resource for medical laboratories. The development of quality systems based on ISO 15189 has taken place in many laboratories in the European countries but data about accreditation remain scarce. The EFLM Working Group "Accreditation and ISO/CEN standards" conducted a survey that reviews the current state of the accreditation process in European countries.

Methods: An on-line questionnaire was addressed to delegates of 39 EFLM scientific societies in March 2014. One answer by country was taken into account. The survey was dealing with mandatory status, number of accredited medical laboratories in each country, possibility of flexible scope and concerned medical fields. The status of point-of-care testing (POCT) in each country was also studied.

Results: Twenty-nine responses (74%) were registered. All the assessed countries (100%) have begun an accreditation process in various ways. All the national accreditation bodies (NAB) offer or are working to offer an ISO 15189 accreditation. The accreditation process most often concerns all phases of the examination and various medical fields. Medical laboratories are responsible for POCT in 20 (69%) countries. The accreditation process for POCT, according to ISO 15189 and ISO 22870, is also developing.

Conclusions: While there are several variations in the approaches to accreditation of medical laboratories in the European countries, the ISO 15189 accreditation project has been widely accepted. The use of a unique standard and the cooperation among countries due to scientific societies, EFLM, accreditation bodies and EA enable laboratory professionals to move toward uniform implementation of the accreditation concept.

Keywords: accreditation; EFLM; ISO 15189; national accreditation body.

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Introduction

Accreditation is a valuable resource for medical laboratories and the development of quality systems based on ISO 15189 has taken place in many laboratories in

the European countries. Also in this field there are large differences between countries [1, 2]. The accreditation of medical laboratories in the European countries is mostly carried out in cooperation with national accreditation bodies (NAB). These NAB work together in a regional cooperation, the European Cooperation for Accreditation (EA). The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group Accreditation and ISO/CEN standards (WG-A/ISO) on the behalf of the Quality and Regulations Committee (C-QR) aims to represent the interest of medical laboratories within EA, International Organization for Standardization's Technical Committee 212 (ISO/TC 212) and European Committee for Standardization's Technical Committee 140 (CEN/TC140) and to harmonize accreditation of medical laboratories. Its purpose is also to educate and train assessors of NAB on the application of the specific requirements of ISO 15189-in cooperation with EFLM Education and Training Committee (C-ET)-and to develop guidance documents for laboratories which support the translation and implementation of accreditation standards in practice [3].

The WG-A/ISO conducted a survey on the accreditation process of medical laboratories by NAB. Among the medical laboratory professionals, a growing interest exists in the establishment of a quality management system to their own practice and we supposed that it mainly involves NAB. Consequently it is interesting to review the current state of the accreditation process in European countries.

Materials and methods

An on-line questionnaire was addressed to delegates of 39 EFLM scientific societies in March 2014 (see Supplementary Material). One answer by country was taken into account. The questionnaire included 26 questions addressing the following items: mandatory status, estimated number of accredited laboratories, possibility of flexible scope, concerned medical fields and point-of-care testing (POCT). Accredited laboratories were defined as exclusively having received a certificate of accreditation by a NAB. Institutional approval mandatory for reimbursement or working license delivery by Ministry of Health were not taken into account. Flexible scope was defined as scope for which laboratories can make some modifications to their scope without prior evaluation.

Results

Among 39 countries, 29 (74%) responses were registered: Albania, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, Luxembourg, the Netherlands, Norway, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the UK. The answers were communicated by EFLM National Representative (41%) or by president (24%) or members (35%) of the scientific societies.

Description of the accreditation process in European countries

All the societies declared there is an existing accreditation process for medical laboratories by a NAB in their country (29/29, 100%). In 3/29 (10%) countries, accreditation for laboratory medicine is not yet offered by their NAB and they declared to ask to a foreign NAB: Albania declared to ask for Greek accreditation body, Iceland declared to ask for Swedish accreditation body and Slovenia declared to ask for Croatian accreditation agency.

Only 5/29 (17%) countries declared that accreditation is mandatory (Belgium, France, Hungary, Ireland and Lithuania) and only 2/29 (7%) countries declared having mandatory accreditation for all the fields of laboratory medicine: France (2016) and Hungary (2017). Belgium, Ireland and Lithuania (2020) have a partial mandatory accreditation (Belgium for molecular biology tests, Ireland for immunohematology and blood transfusion, and Lithuania for biochemistry and hematology). The Ministry of Health studies on mandatory accreditation program in Turkey. Romania, Germany and Italy declared that an institutional approval is mandatory if laboratories want to make a contract with National Health Insurance Houses and/or retribution of costs but this is not an accreditation by a NAB.

All responding countries (29/29, 100%) declared the accreditation process is according to ISO 15189 standard. However, 12/29 (41%) countries are also using ISO 17025 as additional standard. In some countries, NAB are also using other national or international standards as Joint Commission International (JCI) in Turkey, Clinical Pathology Accreditation (CPA) in the UK and Ireland or CCKL Code of Practice in the Netherlands. An exception is made for Serbia, where Agency for accreditation Health Care Institutions, which is not the NAB, accredits laboratories as part of the health care institution in accordance with national standards, based on the International Society for Quality in Healthcare (ISQUa) standards and ISO standards.

The declared numbers of already accredited medical laboratories or medical laboratories in the process of accreditation are shown in Table 1. Only 6/26 (23%)

Table 1: Declared number medical laboratories having received a certificate of accreditation or working toward accreditation by a NAB.

Country	Number of medical laboratories already accredited	Percentage of the overall laboratories	Number of medical laboratories working toward accreditation
Albania	One hospital clinical chemistry laboratory	<1%	Not provided
Belgium	70	50%	Not provided
Bosnie-Herzegovina	Not provided	<1%	8
Bulgaria	3	<1%	2
Croatia	7	3%	4
Cyprus	25	15%	5
Czech Republic	184	40%	30
Estonia	11	24%	2
Finland	35	95%	1
France	268	25%	410
Germany	424	Not provided	Not provided
Greece	45	3%	100
Hungary	5	<1%	2
Iceland	1	5%	7
Ireland	60[b]	100%	Not provided
Italy	One microbiology laboratory	<1%	5
Lithuania	4	3%	Not provided
Luxembourg	8	40%	4
Netherlands	269[b]	78%	5
Norway	100	Not provided	Not provided
Romania	907	Not provided	Not provided
Serbia	19	15%	50
Slovak Republic	34	20%	40
Slovenia	1	<1%	Not provided
Spain	45	2%	12
Sweden	28[a]/78	88%[a]	Not provided
Switzerland	120	80%	18
Turkey	17	<1%	13
UK	240[a]/1000[b]	80%[a]	60[a]

Institutional approval mandatory for reimbursement or working license delivery by Ministry of Health were not taken into account. [a]These numbers/percentages refer only to clinical biochemistry laboratories. [b]Previous accreditation by a National Accreditation Body in a process of transfer from a national or international standard to ISO 15189 was taken into account (The Netherlands/CCKL Code of Practice, Ireland and UK/Clinical Pathology Accreditation).

countries (Finland, Ireland, the Netherlands, Sweden, Switzerland and the UK) declared there are more than 50% of medical laboratories already accredited in their country, followed by Belgium which declared above 50% of already accredited medical laboratories. Previous accreditation by a NAB in a process of transfer from a national or international standard to ISO 15189 was taken into account (The Netherlands/CCKL Code of Practice, Ireland and UK/CPA). The French society declared that above all (100%) not accredited medical laboratories are working toward ISO 15189 accreditation because ISO 15189 accreditation is mandatory. The repartition of the estimated percentage of medical laboratories in process of accreditation and/or already accredited is displayed in Figure 1.

A flexible scope is offered in 19/29 (65%) countries. The 10/29 (34%) countries where flexible scope is not proposed or not yet started for the ISO 15189 accreditation process are Albania, Belgium, Bulgaria, Croatia, Cyprus, Greece, Hungary, Lithuania, Slovak Republic and Turkey.

Hospital laboratories are involved in the accreditation program in all the countries (100%) followed by general physician laboratories in 17/29 (59%) countries, teaching center in 12/29 (41%) countries, then private laboratories, managed care and primary care laboratories, each one above 30% of the countries (respectively 31%, 31% and 28%).

Topics and fields evaluated in the accreditation process in European countries

The laboratory management system, phases of the examination (method, performance of the method) and the

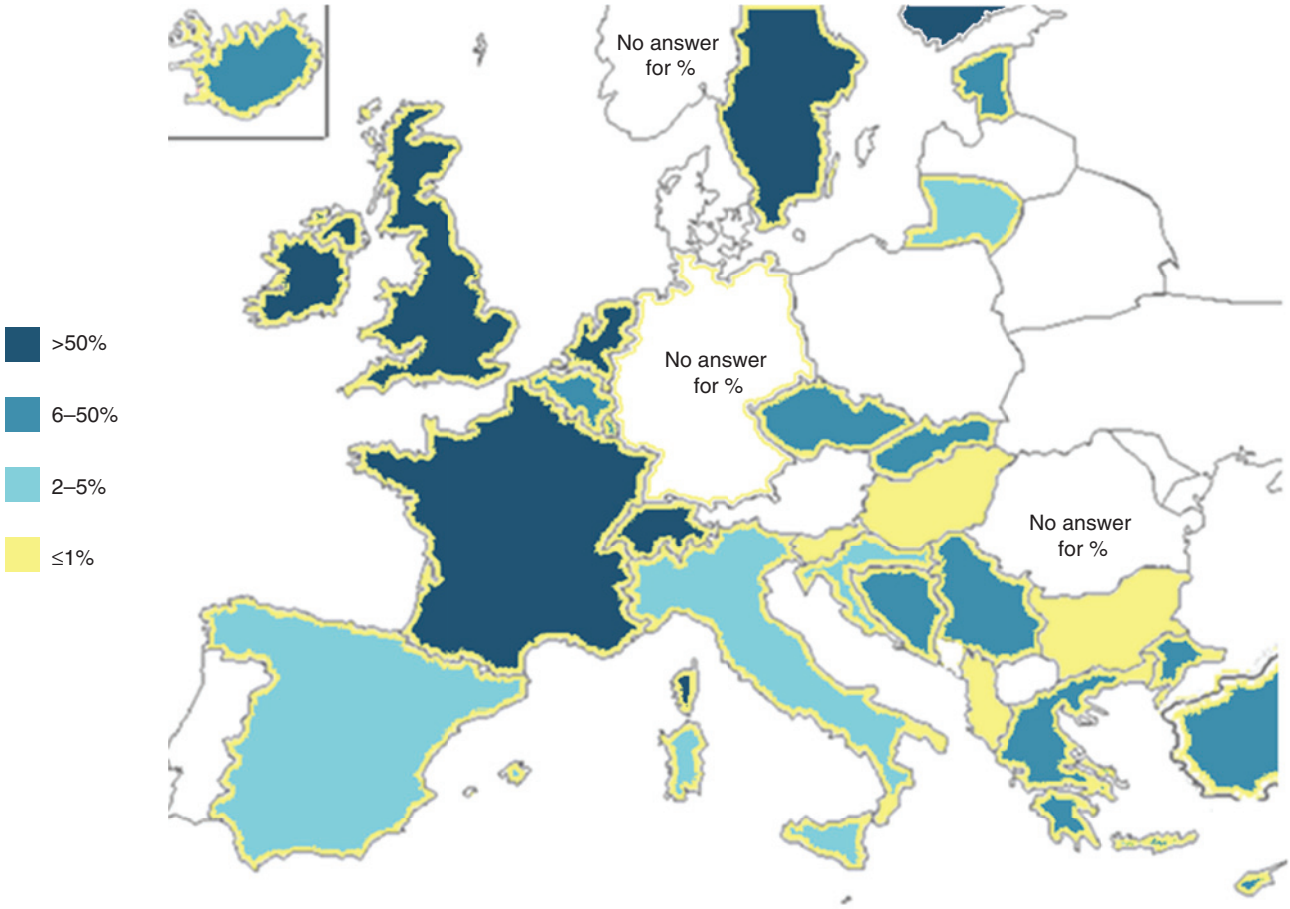

Figure 1: Repartition of the declared percentages of already accredited medical laboratories or working toward accreditation. Uncolored countries are non-responders countries. For the UK and Sweden, the percentage refers only to clinical biochemistry. The CPA accreditation which is replaced by INAB in Ireland and CCKL accreditation in the Netherlands were taken into account.

release of results are audited in all the countries (29/29, 100%). The sample collection and the transport to the laboratory of the pre-analytical phase are also involved in the accreditation process in all the countries except in the Slovak Republic (28/29, 96%) where only the transport to the laboratory is included in the audited processes. But the medicalized steps about test's selection advices, use and interpretation of results are not audited in all the countries. The fractions of countries where medicalized steps are included in the audited processes are shown in Figure 2.

Clinical chemistry, hematology and microbiology are part of audited medical fields in all the countries (29/29, 100%). There is an exception for Bosnia-Herzegovina, where hematology, and Albania and Lithuania, where microbiology, are fields that are not covered by the accreditation process. Genetics and molecular biology are not in the scope of accreditation in 4/29 (14%) countries (Albania, Bosnia-Herzegovina, Bulgaria and Lithuania), pathology in 9/29 (31%) countries (Albania, Bosnia-Herzegovina, Bulgaria, Croatia, Hungary, Italy, Lithuania, Luxembourg and Serbia), blood banking and immunohematology in 7/29 (24%) countries (Albania, Bosnia-Herzegovina, Bulgaria, Hungary, Italy, Lithuania and Turkey) and clinical toxicology in 7/29 (24%) countries (Albania, Bosnia-Herzegovina, Bulgaria, Italy, Lithuania, Turkey and the UK).

Focus on point-of-care testing

POCT is mainly (20/29, 69%) under the responsibility of medical laboratories. Medical laboratories are not responsible for POCT in Albania, Bulgaria, Cyprus, Czech Republic, Greece, Iceland, Romania, Serbia and Slovakia. It must be noted that medical laboratories are never responsible for patients self-testing and over-the-counter tests.

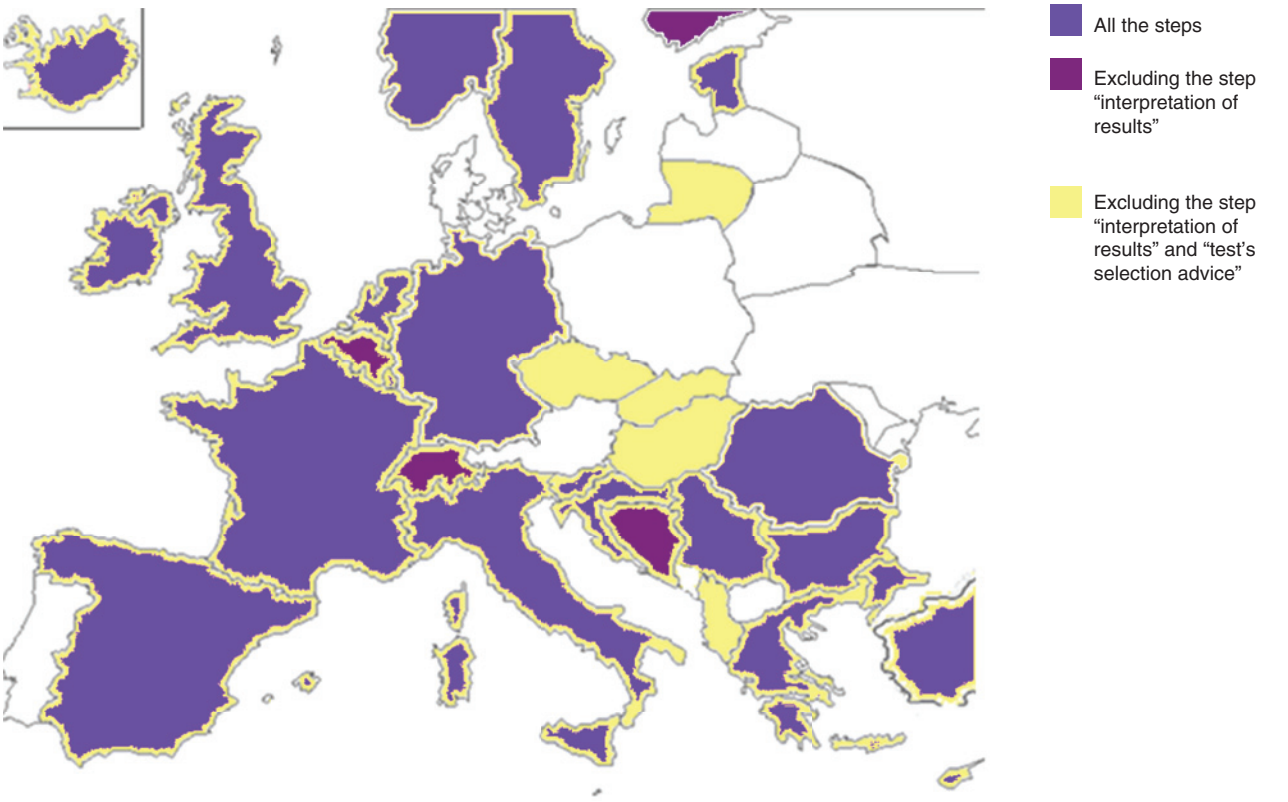

Figure 2: Countries where medicalized steps of laboratory testing are included in the audited processes.
All the steps means: laboratory's management system, test's selection advice, sample collection, transport to the laboratory, method and performance of the method, release of results, reporting back to the clinician and interpretation of results by requesting physician. In the Slovak Republic, only the transport to the laboratory is included in the audited processes. Uncolored countries are non-responding countries.

Among the 20 countries where POCT is under the responsibility of medical laboratories, seven (35%) countries have POCT in the scope of the accreditation process (Belgium, Finland, France, Germany, Ireland, the Netherlands and the UK) and 8 (40%) countries are working on it (Croatia, Estonia, Hungary, Italy, Norway, Slovenia, Spain and Sweden). All of those countries are using ISO 22870 as standard but ISO 15189 and 17025 are also used by Finland, Germany and Sweden.

Discussion

ISO accreditation project is mature and advanced in Europe. In contrast to the situation of just a decade ago [4], NAB are clearly identified and accreditation programs are effective or under development in the European countries.

In a few countries, accreditation may be accelerated by Public Authorities which are working on mandatory accreditation. At the time of the discussion, 3 countries have a mandatory accreditation project for all the fields of laboratory medicine: France (2016), Hungary (2017) and Lithuania (2020). It will be interesting to review its implementation in these countries in terms of flexible scope, training for assessors or duration of auditing processes.

In countries where the NAB does not offer accreditation, national law could replace it as in Slovenia where medical laboratories have to be mandatory licensed by the Ministry of Health. Indeed, an institutional approval was often mandatory for reimbursement or as working license. Some countries made the choice to have a mandatory ISO accreditation only for some medical fields or type of laboratories as in Belgium (molecular biology), Ireland (immunohematology and blood transfusion) but also in Germany (new born screening), the Czech Republic and Serbia (genetics), and Greece (private laboratories providing healthcare services) [1].

ISO 15189 and ISO 22870 are now the most recognized standards in Europe

This recognition is a strong evolution as compared to one decade ago and was already reported [1, 5, 6]. It may be

the result of the recent EA Multilateral Agreement (MLA) between NAB in Europe. However, in some countries ISO 17025 is widely used or can be obliged by health insurance, or national regulations may exist [1]. Some national or international standards are used as CPA standards in the UK and Ireland or CCKL Code of Practice in The Netherlands, which have adopted essential contents of ISO 15189.

Numbers and percentages of accredited medical laboratories are disparate

Despite the aspirations of the development of accreditation, the data provided showed that the number of accredited laboratories varies between European countries. Some countries have already reached an almost complete implementation of accreditation as Finland, Ireland, The Netherlands, Sweden, Switzerland and the UK. But other countries are still at the beginning of this development. Among the anchor countries in the implementation of accreditation, UK was one of the first where accreditations were noted (1992) and which was moving towards the ISO 15189 standard with Sweden (1992) and Belgium (1993) [5]. Consequently, it is not surprising to find that the highest rates of accredited laboratories were found in these countries.

The main shortcoming of this survey is inability to express the real total number of medical laboratories in each country. Indeed, there is no authority in each country responsible to give the total number.

The registry is in some country divided according to the medical fields and major stakeholders of professional activities. However, the numbers of accredited laboratories have to be weighted according to the country size and the multi-site accreditation status. In Sweden, in Finland or in France, the low number of accredited medical laboratories is probably the result of a dominant multi-site accreditation in a context of restructured network of medical laboratories. On the contrary, the high number of accredited laboratories in Belgium, Romania, Switzerland or United-Kingdom may be associated to few fusions of laboratories [2]. A network with multi-site laboratories should facilitate the implementation of accreditation but it is not evidenced in this study where high rates of accredited laboratories were found in countries with few multi-site laboratories as in others.

Flexible scope is another existing tool in almost two thirds of the countries, to facilitate the advancement of accreditation process. Among the countries with more than 50% of accredited laboratories, accreditation with flexible scope is largely used in France, the Netherlands and Sweden conversely to Finland, Ireland, Switzerland and the UK [2]. The WG-A/ISO had recently given some recommendations about flexible scope [7]. After a risk-based approach, a gradual transition towards flexible scopes may be used by laboratories that have no or limited track record in accreditation and by laboratories that have already demonstrated within a fixed scope that they have a validation/verification procedure that justifies the trust that comes with a flexible scope.

Hospital labs are always involved in accreditation process

The data also showed that all types of laboratories seem to be yet involved in accreditation considering that each type of laboratories are under the scope of accreditation in at least one third of European countries. Medical laboratory professionals are increasingly interested in attaining accreditation status for their services and the compulsory accreditation by national regulations may reinforce this trend.

"Medicalized steps" are not always included in accreditation process

The main advantage of working toward accreditation is the potential for more effective management of the laboratory and indeed the laboratory management system is examined in the accreditation in all the European countries as well as the phases of examination, including pre-analytical phase. However, medicalized steps, including test's selection advice and interpretation of results, are not always included in accreditation process. The repartition of the clinical fields which are under the scope of accreditation are also various. Even a majority of clinical fields are involved in the process, the data showed some heterogeneity between countries especially about genetics and pathology.

Point-of-care testing are also involved in accreditation process

The role of POCT has constantly increased in laboratory medicine in order to provide immediate results for clinician and the quality of these results are important as well. The data showed that laboratory professionals are responsible for POCT in the majority of European countries but not for patients self-testing and over-the-counter tests. With the aim to have confidence in POCT results,

a formal connection with an accredited medical laboratory is needed [6] but few European countries have yet POCT in the scope of the accreditation. Interestingly, these countries (Belgium, Finland, France, Germany, the Netherlands and the UK) are mostly those with a high rate of accredited laboratories. In these countries, ISO 22870 standard, which is strongly related to ISO 15189, is the predominant standard for accreditation of POCT. However, the data revealed that almost one half of the European countries are working on a project to give POCT under the responsibility of medical laboratories.

In conclusion, our survey has revealed that, while there are several variations in the approaches to accreditation of medical laboratories in the European countries, the ISO 15189 accreditation project has been widely adopted. The use of a unique standard and the cooperation among countries promoted by scientific societies, EFLM, accreditation bodies and EA enable laboratory professionals to move toward uniform implementation of the accreditation concept. Accreditation is the best option to assure quality for medical laboratories services and the choice of a mandatory accreditation seems to help progressing more quickly to complete accreditation. This is a first step which permits us to have a better picture of the state of the accreditation process in European countries. In the future, it would be interesting to assess and evaluate direct or indirect costs and benefits of such a large project.

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References

1. Oosterhuis WP, Zerah S. Laboratory medicine in the European Union. Clin Chem Lab Med 2015;53:5–14.
2. Mehay H, Boursier G, Vaubourdolle M. European Network for Accreditation of medical labs: update on the EFLM and EA surveys. 21st Joint EFLM-IFCC EuroMedLab congress, 24th 2015 June.
3. Huisman W. European communities confederation of clinical chemistry working group on accreditation: past, present and future. Clin Chim Acta 2001;309:111–4.
4. Huisman W, Horvath AR, Burnett D, Blaton V, Czikkely R, Jansen RT, et al. Accreditation of medical laboratories in the European Union. Clin Chem Lab Med 2007;45:268–75.
5. Blaton V. Accreditation and postgraduate training in European countries: an FESCC survey. Federation of European Societies of Clinical Chemistry. Clin Chim Acta 2001;309:115–20.
6. Huisman W. European medical laboratory accreditation. Present situation and steps to harmonisation. Clin Chem Lab Med 2012;50:1147–52.
7. Thelen MH, Vanstapel FJ, Kroupis C, Vukasovic I, Boursier G, Barrett E, et al. Flexible scope for ISO 15189 accreditation: a guidance prepared by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group Accreditation and ISO/CEN standards (WG-A/ISO). Clin Chem Lab Med 2015;53:1173–80.

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