

# Survey regarding accreditation of medical laboratories within EA – Mid 2019

*Survey sent to 34 ABs  
Received from 32 ABs (94 %)*





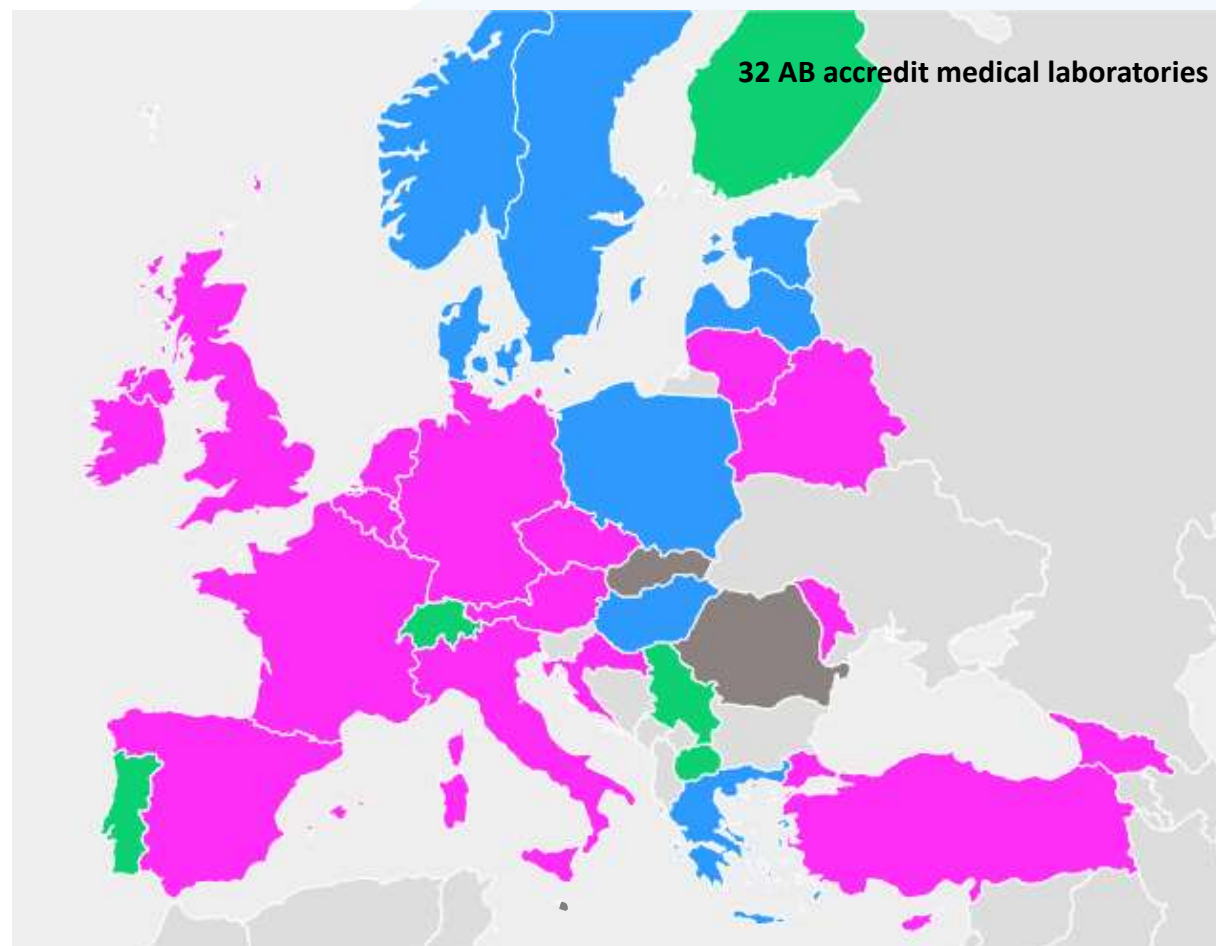
## Survey regarding accreditation of medical laboratories within EA

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### Standard used for accreditation for medical laboratories

ISO 15189 only	59%	(19)
Both standards but with preference of ISO 15189	25%	(8)
Both standards (ISO 15189 and ISO/IEC 17025) without any preference	16%	(5)
No answer		

NB: DAkkS - ISO/IEC 17020 for clinical pathology

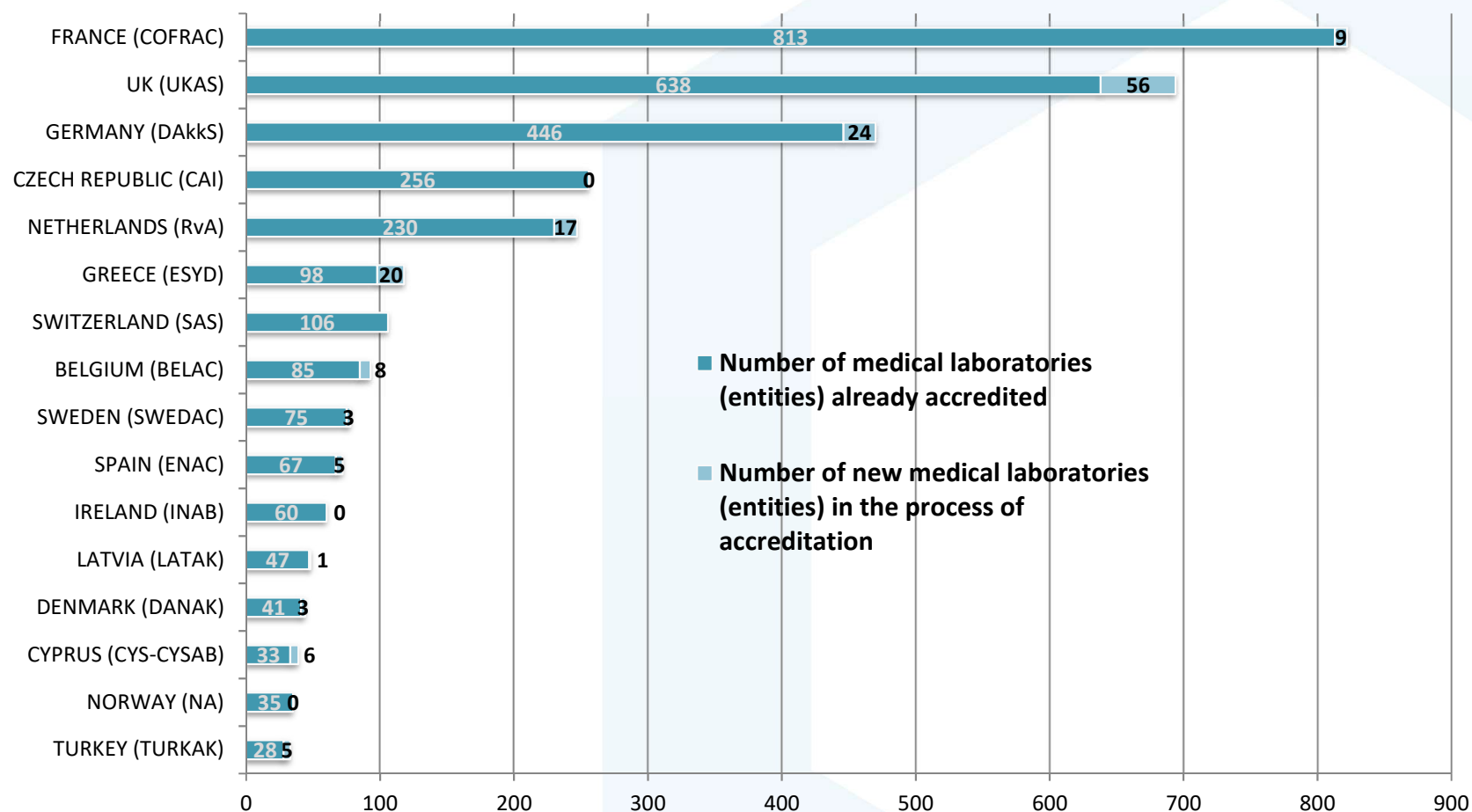




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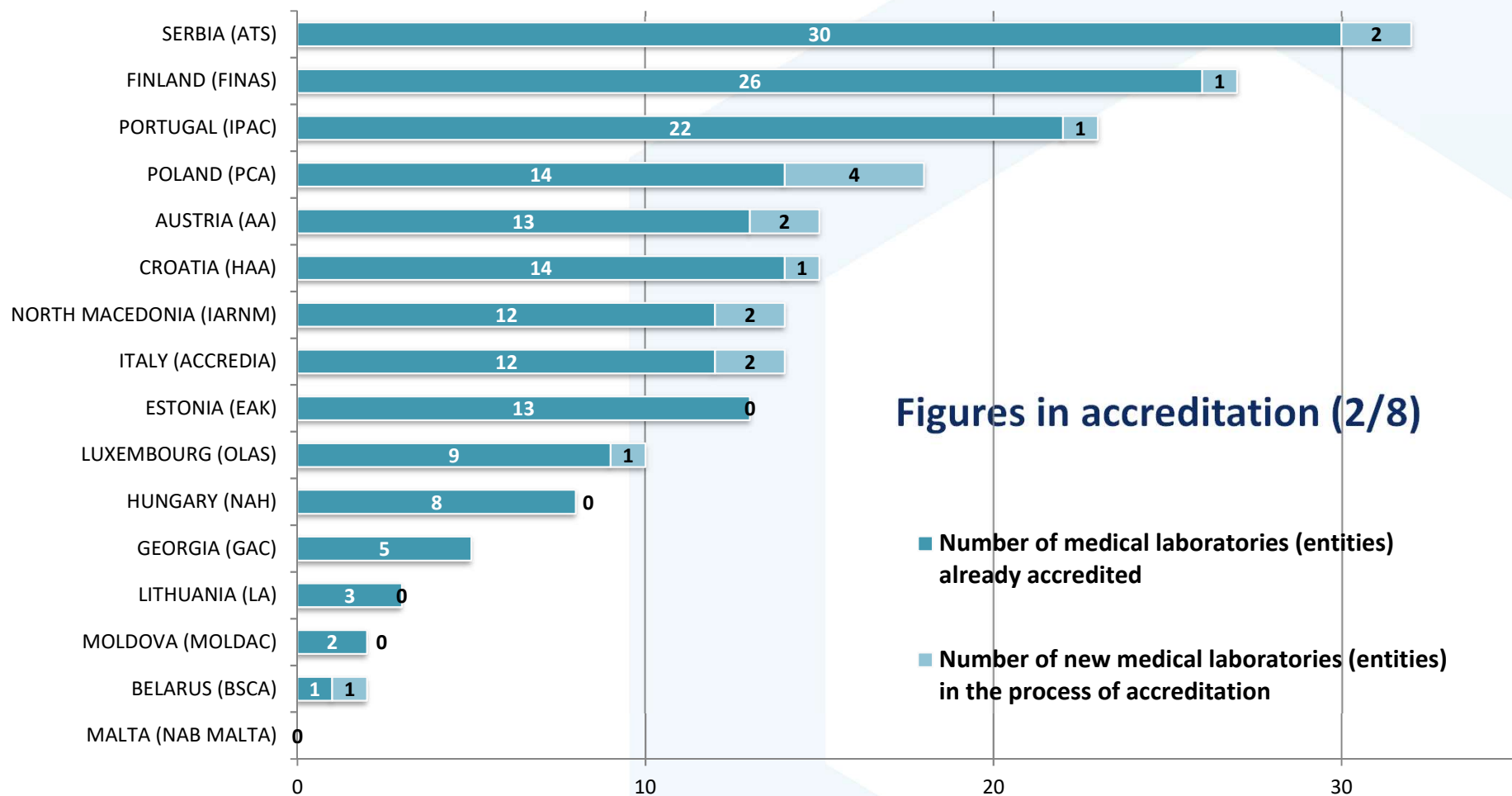
### Figures in accreditation (1/8)





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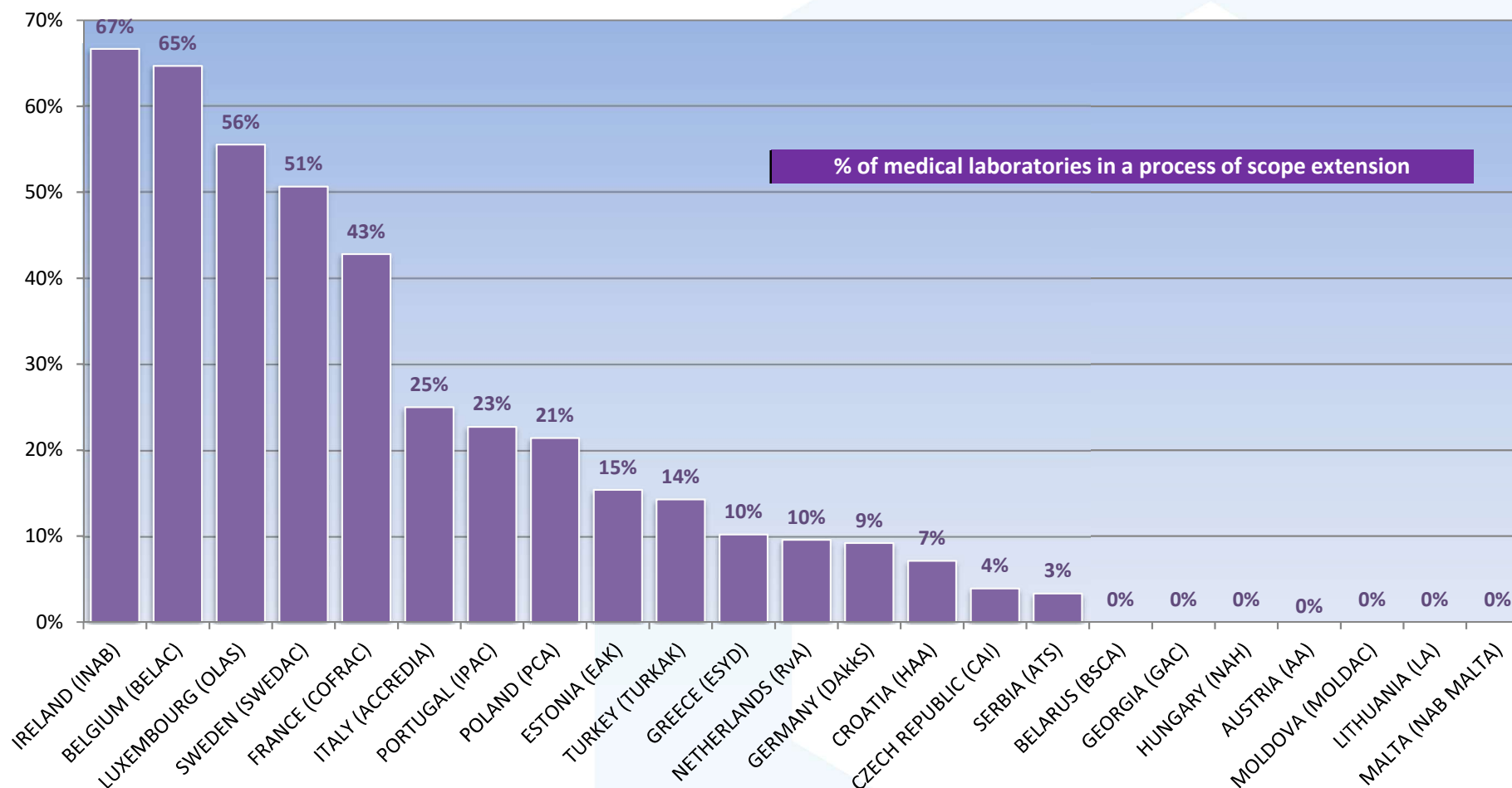


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### Figures in accreditation (3/8)

23 answers



## Figures in accreditation (4/8)

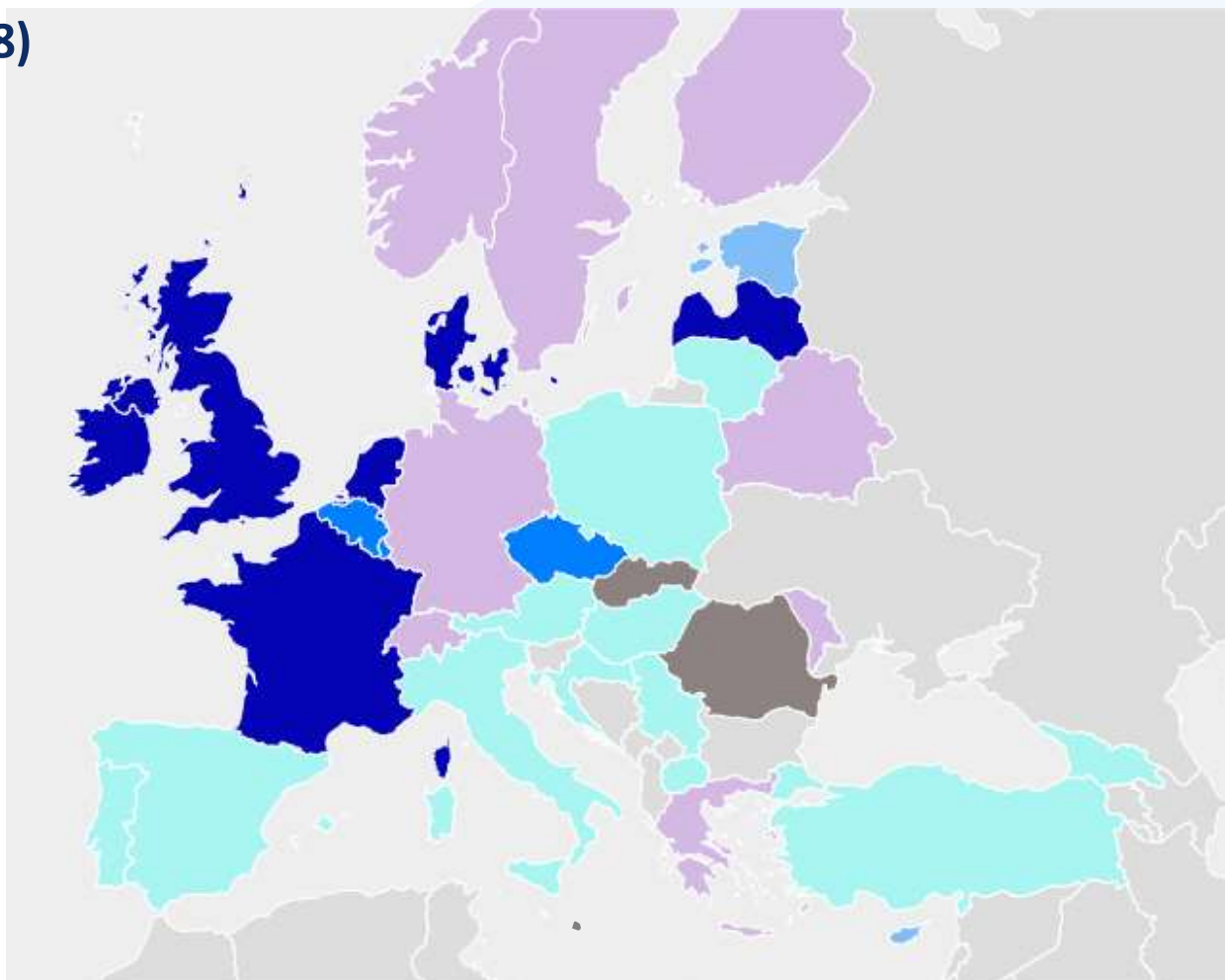
Percentage of accredited medical laboratories considering the total number of medical laboratories of the country
< 10% (12)
10% - 49% (2)
50% - 79% (3)
80%-99% (6)
100% (0)
I do not know (9)
No answer

### Remarks:

BELGIUM (BELAC): 39.4% of the pathology labs, 55.9% of the clinical biology labs and 100% of the genetic centers

DENMARK (DANAK): almost 100% for Biochemistry

FRANCE (COFRAC): 100% of the medical laboratories having a medical biology activity



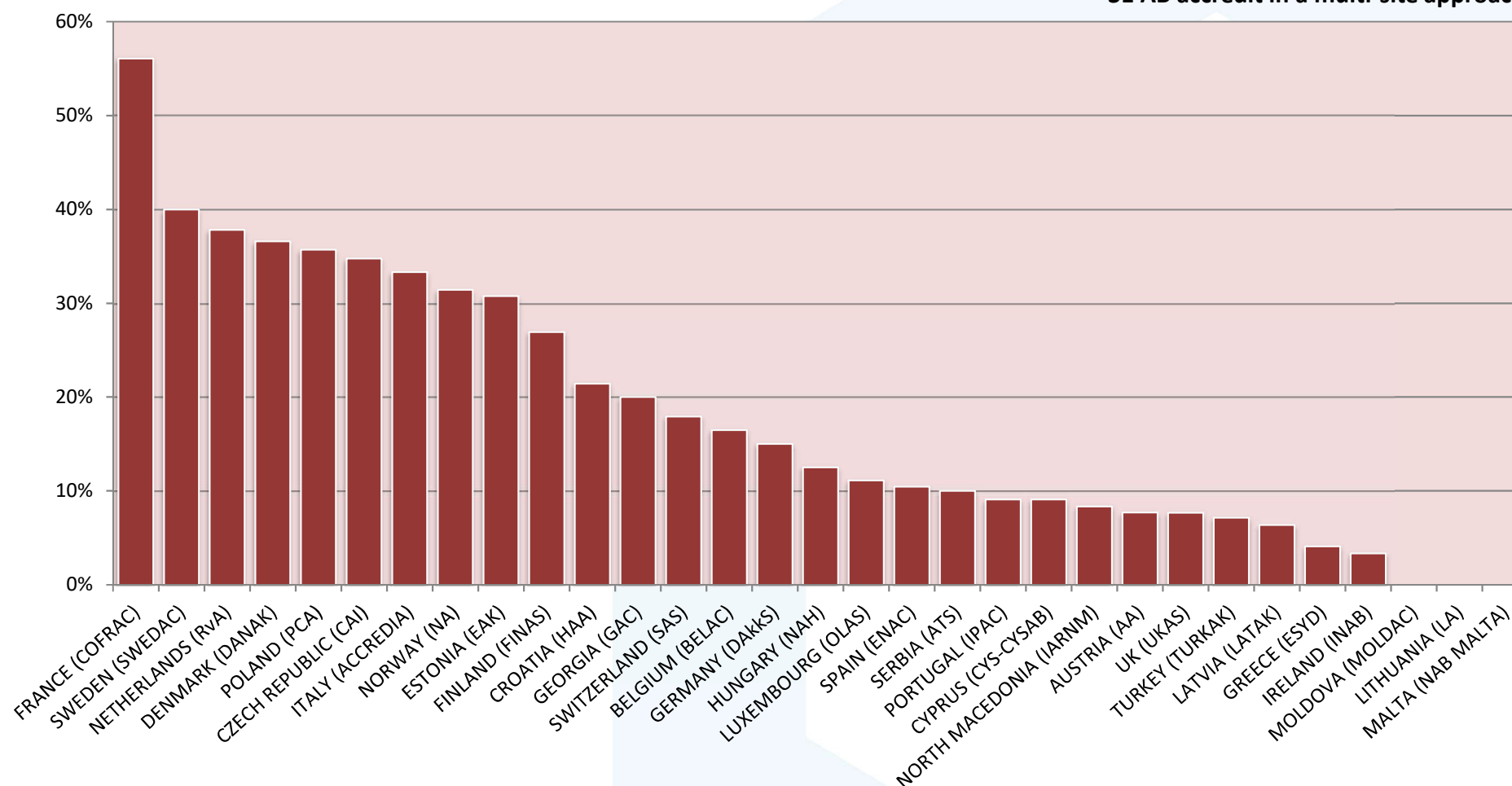


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### Figures in accreditation (5/8)

31 AB accredit in a multi-site approach





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### Figures in accreditation (6/8)

A site is a location belonging to the organization of a medical laboratory, under the same management and the same quality management system, **where all or part of examinations are carried out** : different building and/or different address.

Pre-analytical, analytical and/or post-analytical activities (15)	Only analytical activities (8)	Only pre-analytical activities (1)
Poland, North Macedonia, Belgium, France, Czech Republic, Greece, Cyprus, Latvia, Norway, Serbia, Turkey, Italy, Germany, Switzerland, Denmark	Croatia, Portugal, UK, Netherlands, Luxemburg, Spain, Estonia, Sweden	Georgia

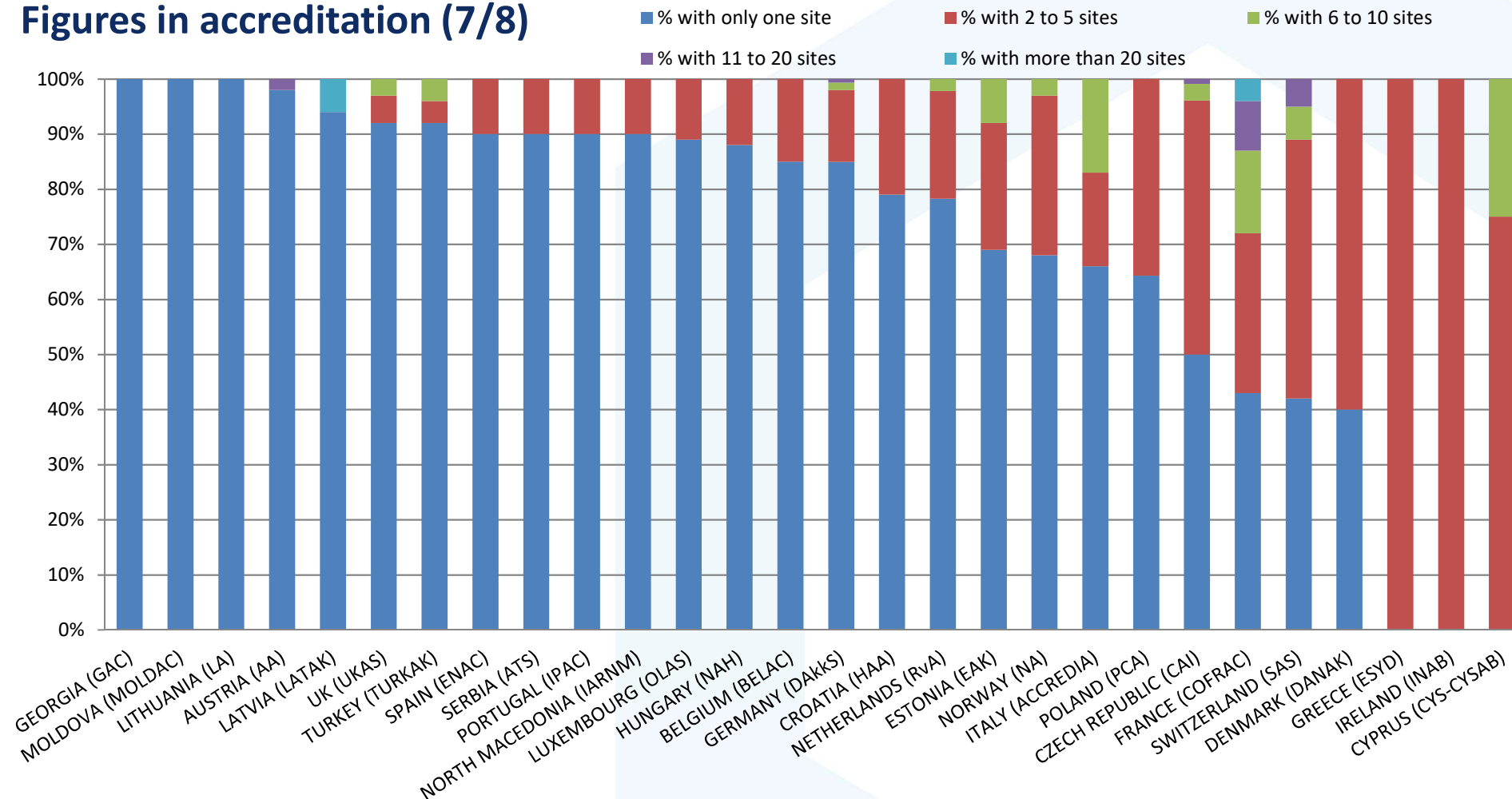




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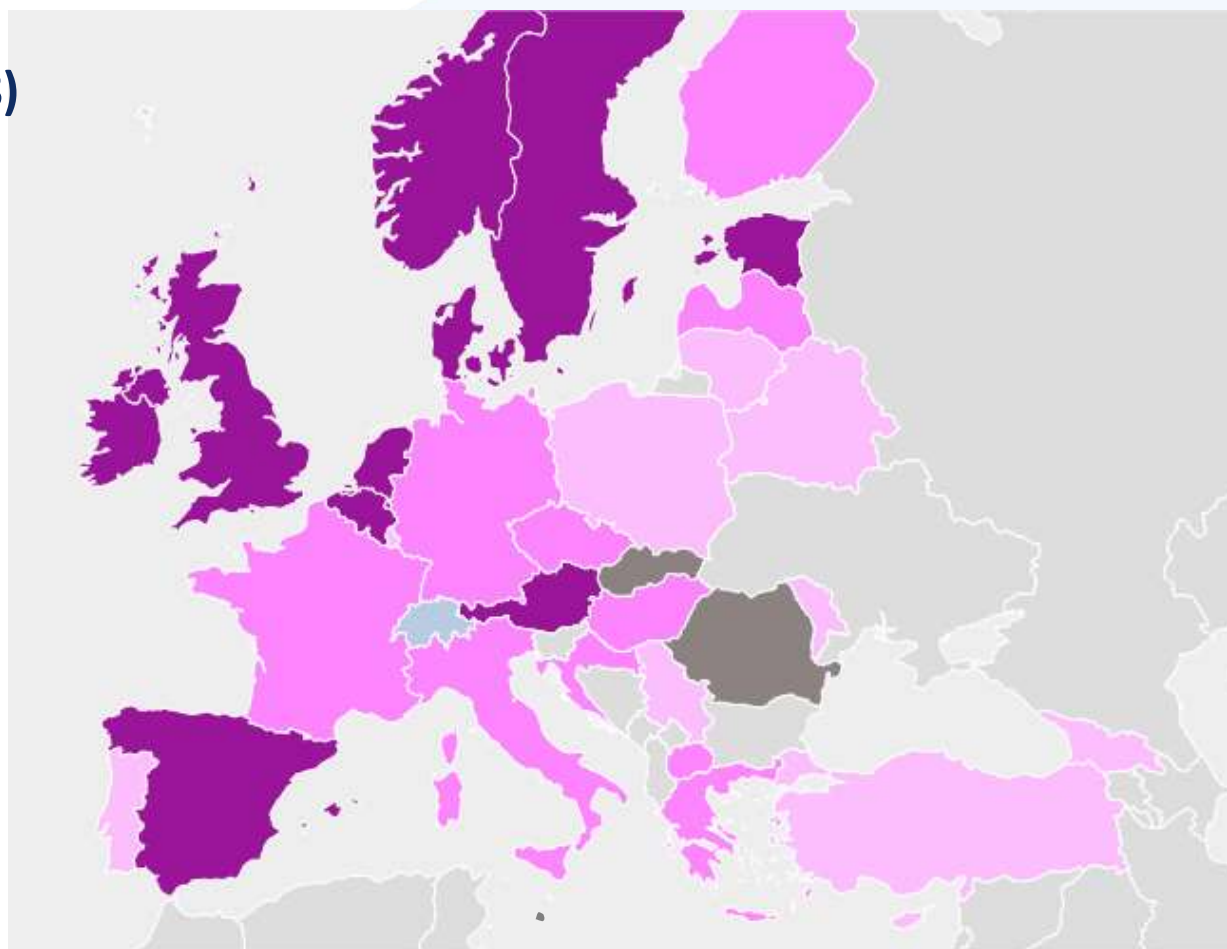
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### Figures in accreditation (7/8)



## Figures in accreditation (8/8)

Percentage of hospital medical labs in accredited medical labs	
<= 30% (11)	
31% - 60% (10)	
> 60% (10)	
No data (1)	
No answer	

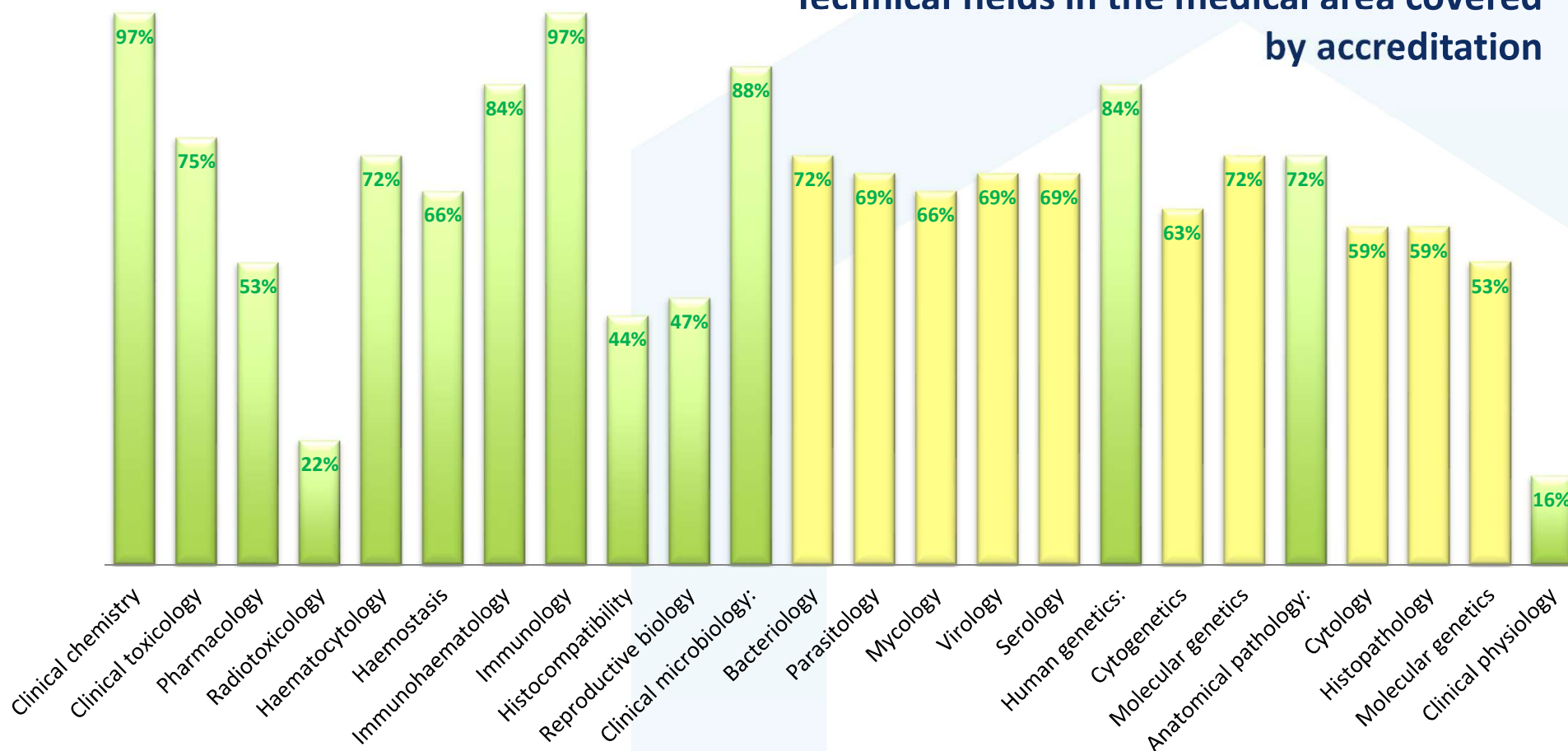




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### Technical fields in the medical area covered by accreditation

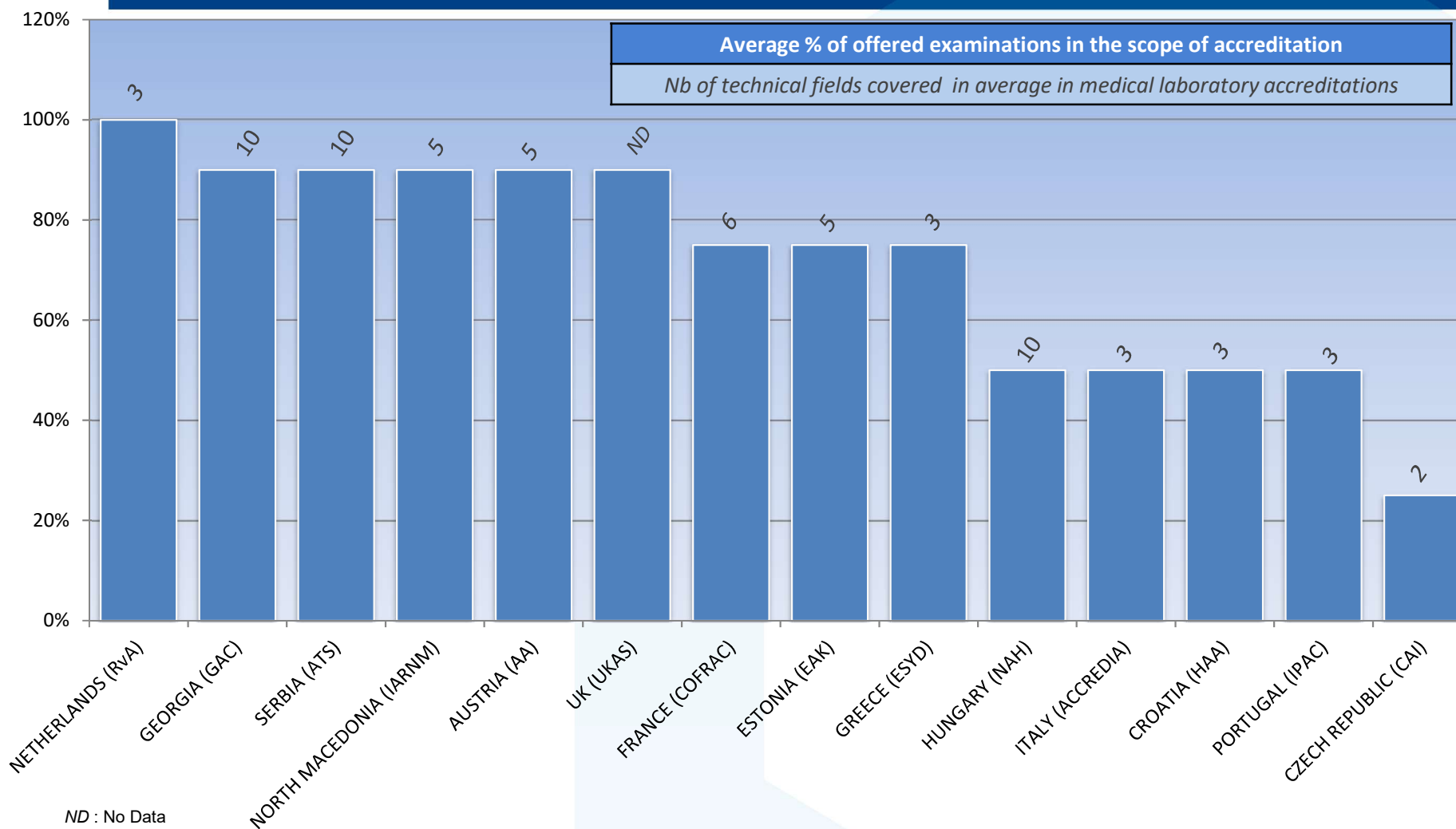


Others: Clinical neurophysiology, nuclear medicine, medical autopsy, detect the Lead in Blood and hear, Metabolic disorders, Prenatal and neonatal screening, Gasometry, Biometric activities and research



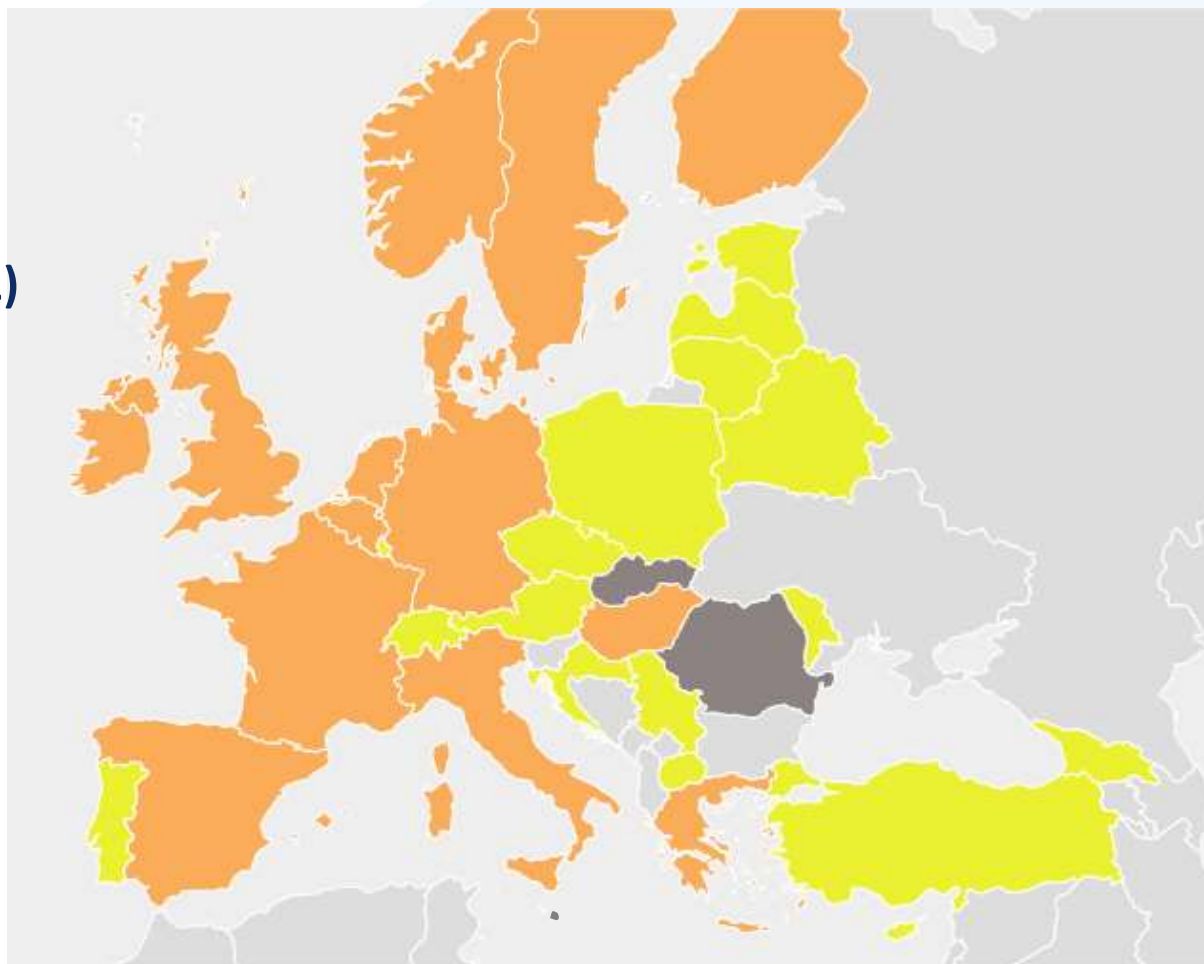
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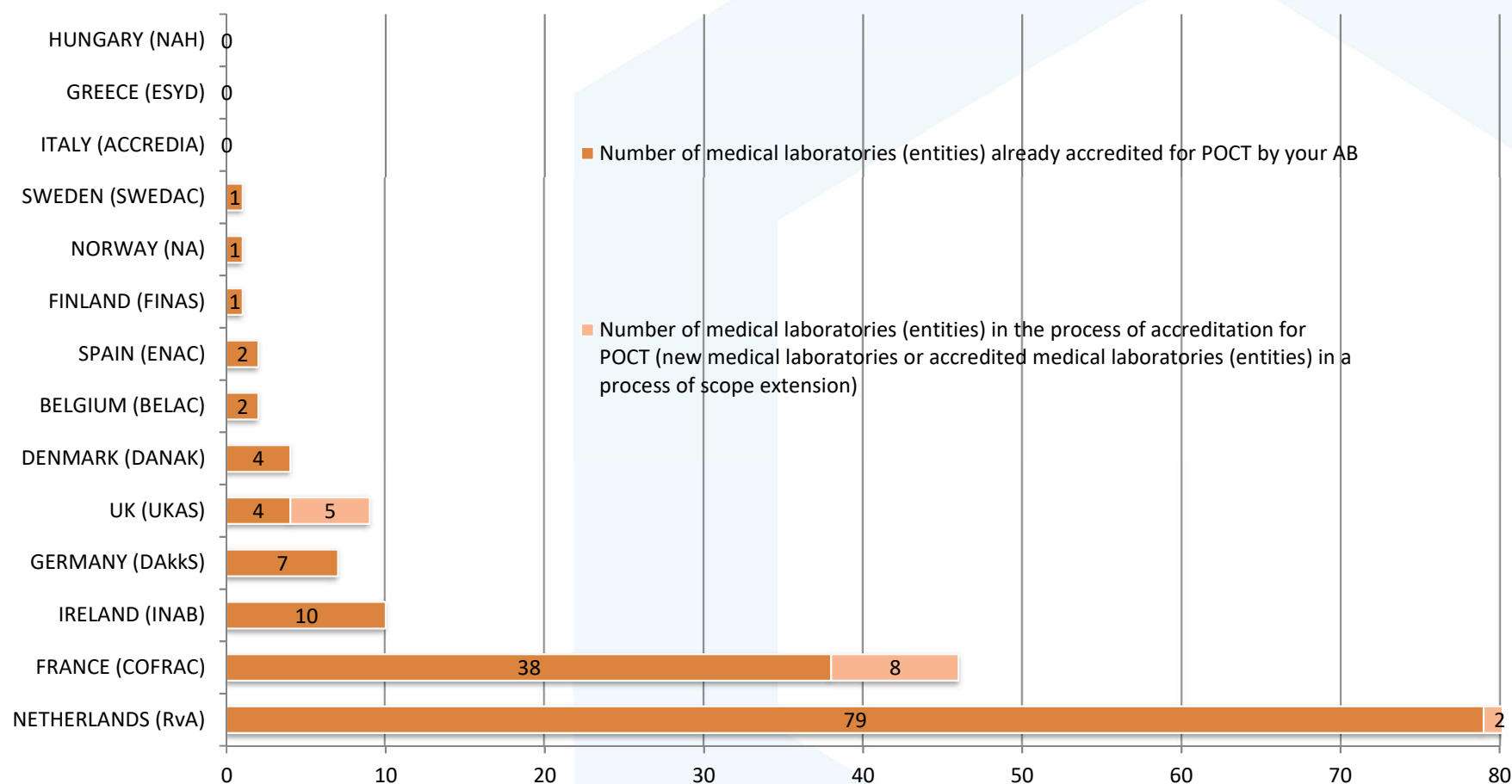


**Do AB accredit for  
Point of care testing (POCT)  
(according to ISO 22870)? (1/2)**

Yes	44%	(14)
No	56%	(18)
No answer		

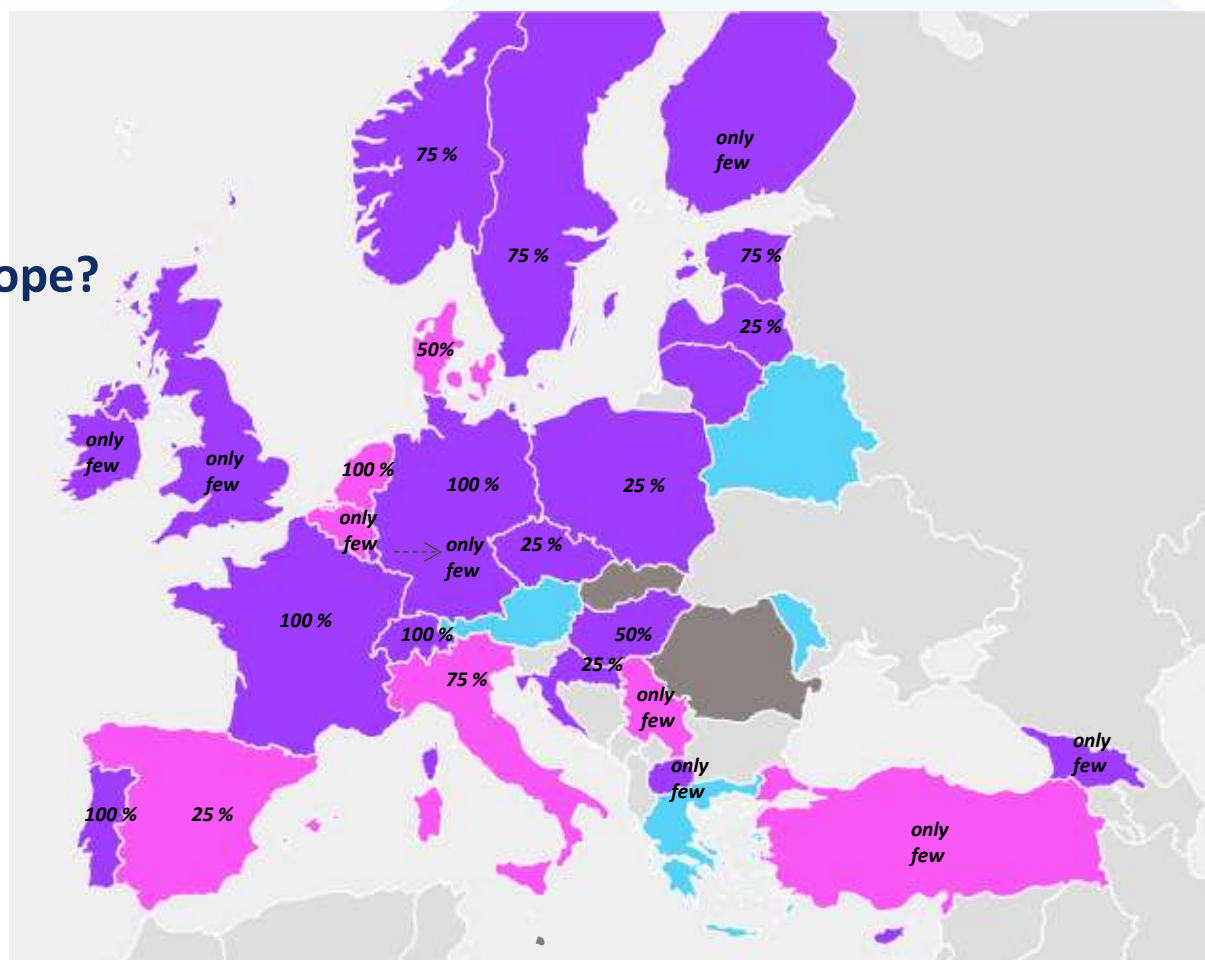


## Do AB accredit for Point of care testing (POCT) (according to ISO 22870)? (2/2)



## Do AB offer accreditation with flexible scope?

Yes, different types of flexibility	62%	(20)
Yes, only one type of flexibility	22%	(7)
No	16%	(5)
No answer		



Percentage of accredited medical laboratories with flexible scope are displayed





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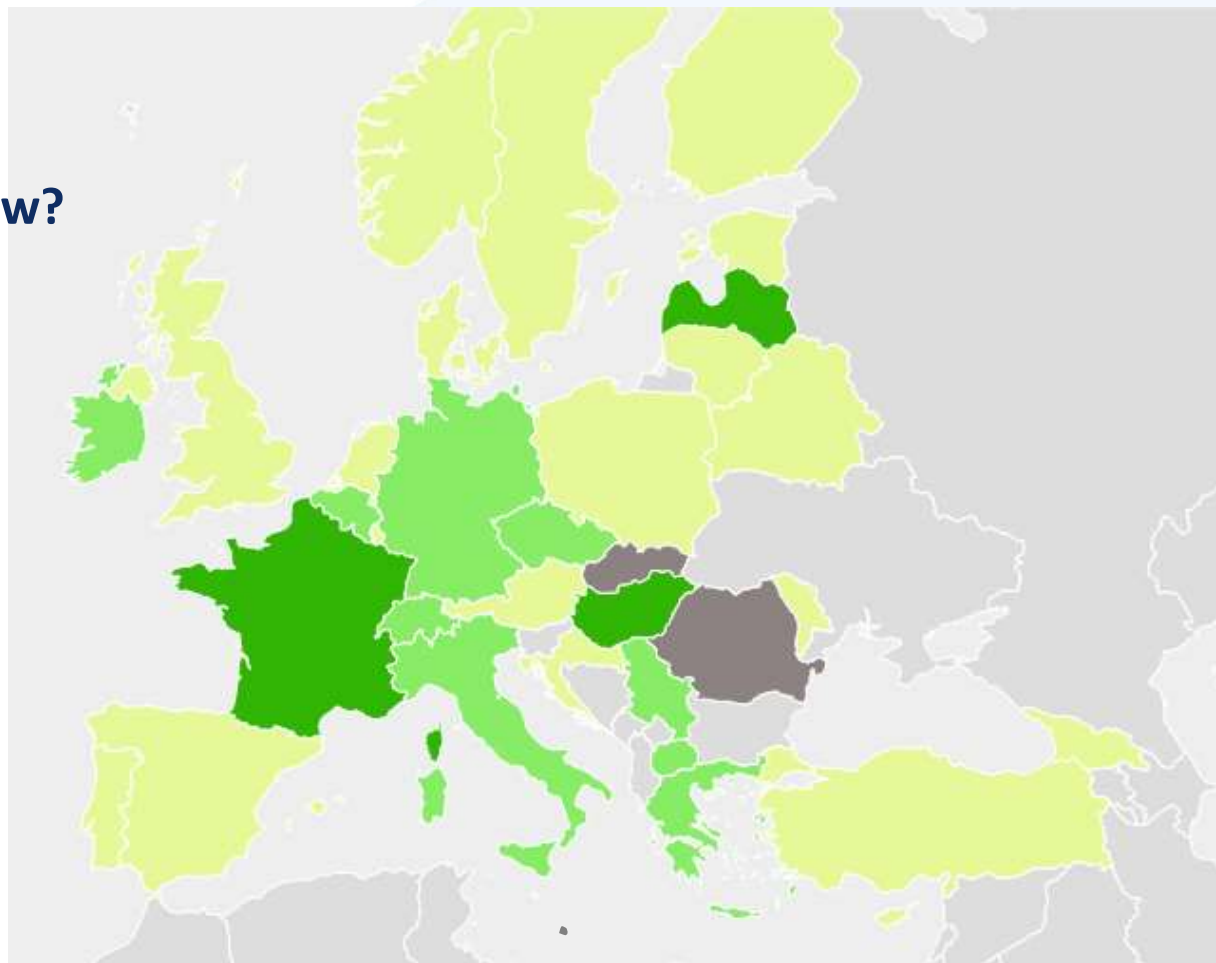
### For 34% of AB (11), there are specific requirements for the accreditation of medical laboratories:

FINLAND (FINAS)	The microbiological laboratories need to have a permission from the National Institute for Health and Welfare for the testing of infectious diseases (national law for infectious diseases).
SWITZERLAND (SAS)	<ul style="list-style-type: none"> <li>- There are several legal requirements (e.g. health, safety, PT participation, qualification of technical staff)</li> <li>- To perform medical testing in some special fields (e.g. hematology, serology, microbiology, genetics) the medical laboratories are obliged to get a governmental (federal) authorization (requirements are established in ordinances and periodically checked)</li> <li>- In genetics also accreditation can be used besides inspection by authorities in health care as a base to state necessary competency for federal authorization.</li> </ul>
GEORGIA (GAC)	subcontracting for sampling
IRELAND (INAB)	Clinical advice must be provided by medically trained staff according to standard set down by the Department of Health / HSE
BELGIUM (BELAC)	extra legal obligations NGS guidelines
FRANCE (COFRAC)	Management of the medical laboratory - Personnel qualifications - Subcontracting - Responsibility for the pre-analytical phase, even if the sample collection is not carried out in the laboratory by personnel from the laboratory - EQA
GREECE (ESYD)	ESYD's Guideline G-CLINLAB refers to procedures required for Accreditation of Medical Laboratories that apply, either approved standardized methods (CEIVD), which require verification by the Lab, or laboratory-developed tests (LDTs or else in-house methods) and modified approved methods, which require analytical validation and clinical verification.
CYPRUS (CYS-CYSAB)	External quality control - Verification of methods
NETHERLANDS (RvA)	Several professional societies have drafted additional requirements with regard to specific aspects of the technical field.
GERMANY (DAkks)	Quality management system, internal and external quality controls in RiLi-BÄK (Guidelines of Germans doctors chamber).
SWEDEN (SWEDAC)	There are Swedish regulations for subcontracting and how to refer to accreditation when using subcontractors



**Is accreditation of medical laboratories mandatory by law?  
(1/2)**

Yes	9%	(3)
Yes, partially	28%	(9)
No	63%	(20)
No answer		





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Accreditation of medical laboratories mandatory by law (2/2)	the types of laboratories/technical fields for which accreditation is mandatory	the deadlines to which accreditation is mandatory	the number of laboratories holding accreditation in this context	the number of laboratories seeking accreditation in this context
ITALY (ACCREDIA)	Only laboratory of the Province of Trento, except transfusion and Anatomy Pathology	End 2018	4	1
NORTH MACEDONIA (IARNM)	Before several years ago there was Governmental decision for obligatory accreditation of eight (8) medical laboratories within public hospitals in Macedonia	not clearly defined	1	1
SWITZERLAND (SAS)	Pre-implantation genetic diagnosis (PGD/PID)	5 years after application	3 to 5	3 to 5
IRELAND (INAB)	Blood Transfusion only	--	60	0
BELGIUM (BELAC)	mandatory accreditation for a number of molecular tests (NIPT, microbiology, pathology, oncology, ...) and 80% of all genetic testing	--	75	7
FRANCE (COFRAC)	All medical laboratories for all medical biology fields (all their medical biology activity)	1st November 2020	790	2
CZECH REPUBLIC (CAI)	genetics - only hereditary (not somatic changes in genes)	2011	62	0
GREECE (ESYD)	Private diagnostic laboratories providing services to other laboratories and/or healthcare organizations.	November 2013	--	--
HUNGARY (NAH)	Medical diagnostical laboratories, molecular genetical laboratories	01/01/2019	8	0 (other to come)
LATVIA (LATAK)	All medical laboratories, but fields are not clarified	31.12.2018.	47	1
SERBIA (ATS)	medical examination connected with the consequences of radioactivity (changes on chromosomes)	RADIATION PROTECTION AND NUCLEAR SAFETY LAW ("Fig. Gazette", Nos. 36/2009 and 93/2012	3	--
GERMANY (DAkkS)	newborn screening	before 2010	12	0



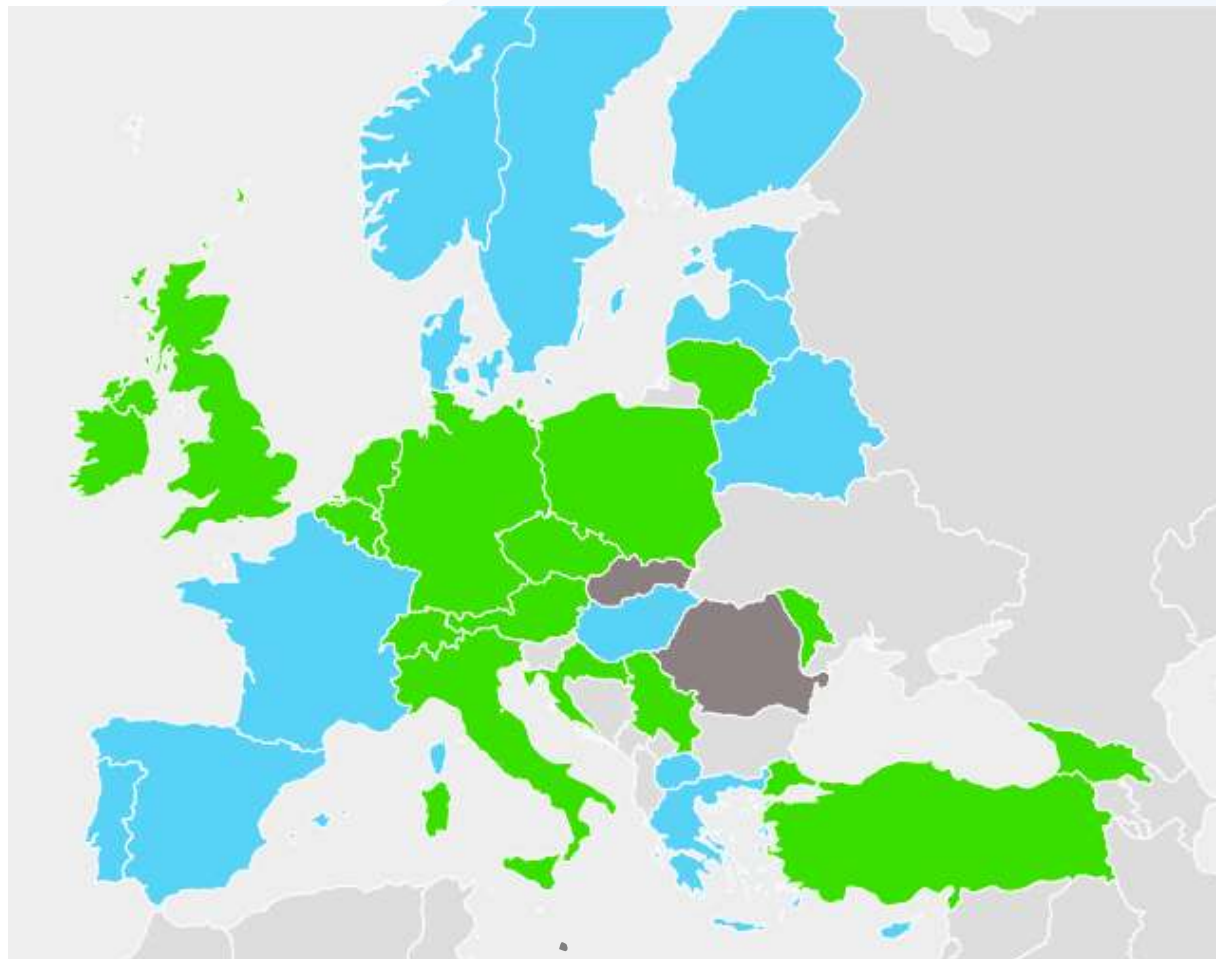
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Accreditation of medical laboratories mandatory, other than by law, in your country (reimbursement ...)	the types of laboratories/technical fields for which accreditation is mandatory	the context for which accreditation is mandatory (reimbursement ...)	the number of laboratories holding accreditation in this context	the number of laboratories seeking accreditation in this context
NETHERLANDS (RvA)	For most clinical laboratories accreditation is strongly recommended by the assurance companies with regard to reimbursements.	-	-	-
LUXEMBOURG (OLAS)	(1) medical laboratories in the non-hospital sector and (2) medical laboratories in the hospital sector, but only for analyses of ambulatory patients	reimbursement by the National Health Fund (CNS)	5	1

**Is there a specific quality monitoring scheme by your national healthcare system?  
(1/2)**

Yes	56%	(18)
No	44%	(14)
No answer		





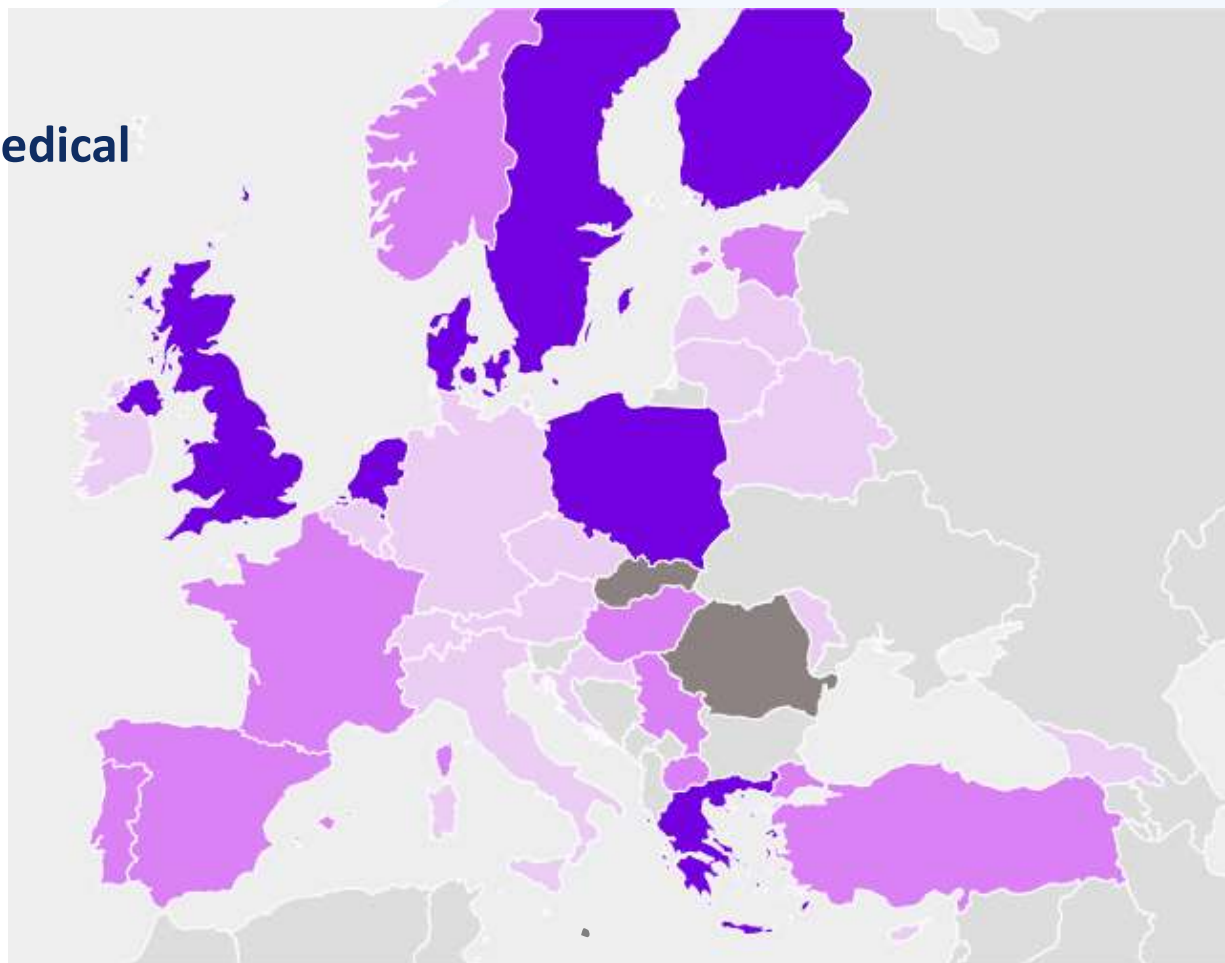
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(2/2)	Specific quality monitoring scheme by the national healthcare system
AUSTRIA (AA)	mandatory participation in PT-Programmes
BELGIUM (BELAC)	mandatory EQA participation / inspections by national healthcare system for recognition of medical laboratories
CROATIA (HAA)	professional audit of medical biochemistry labs by croatian chamber of biochemistry is mandatory
CZECH REPUBLIC (CAI)	The Czech Medical Society has own system for monitoring quality in medical laboratories. This system is based on ISO 15189.
GEORGIA (GAC)	regulation for monitoring ML
GERMANY (DAkkS)	Requirements of RiLi-BÄK (internal and external quality control) is checked in different parts of Germany (Länder) by different authorities on very different levels and frequencies.
IRELAND (INAB)	HIQA organisation that monitors hospitals.
ITALY (ACCREDIA)	Law 502/1992 (National Health System)
LITHUANIA (LA)	Minimum requirements for health care services quality control are established by the order of the Minister of Health of the Republic of Lithuania (No V-998, 5 December, 2007) "Description of the assessment of health care laboratories". For medical laboratories internal quality controls systems and participation in EQA schemes (including plans and results) are periodically overseen by the State Health Care Accreditation Agency under the Ministry of Health (Accreditation Agency) during supervision visits according to the annual inspections plan.
LUXEMBOURG (OLAS)	There is a quality monitoring scheme by the Ministry of Health, based on the participation in a list of mandatory PTs. This applies to all laboratories, regardless whether they are accredited or not.
MALTA (NAB MALTA)	Licensing of medical/clinical laboratories is under the control of the Ministry of Health.
NETHERLANDS (RvA)	This only accounts for fertility laboratories and donortest Laboratories as well as transplantation laboratories
POLAND (PCA)	ILC for microbiology examinations / ILC for clinical chemistry, hematology, coagulology
SERBIA (ATS)	Agency for accreditation medical institutions
SWITZERLAND (SAS)	PT participation /Qualification of technical staff
UK (UKAS)	Joint Working Group on Quality Assurance - monitors EQA performance
SWEDEN (SWEDAC)	The laboratory can choose any supplier of PT-programs.

Does your AB accredit for medical imaging?  
(1/3)

Yes	22%	(7)
No but it is planned	28%	(9)
No	50%	(16)
No answer		





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Yes: (2/3)	Standard(s) used for accreditation for medical imaging	Technical fields covered by accreditation for medical imaging	Number of organizations already accredited by your AB:	Number of new organizations in the process of accreditation:	Is accreditation mandatory for medical imaging?
FINLAND (FINAS)	Both ISO 15189 and ISO/IEC 17025	Nuclear imaging / clinical neurophysiology	1	0	no
POLAND (PCA)	ISO/IEC 17025	Radiography (incl. Angiography, Mammography) / CT	41	1	yes (Polish law: The Act of November 29, 2000 / Atomic law)
UK (UKAS)	Standard developed by Professional Bodies in UK	Radiography (incl. Angiography, Mammography) / Scan / Bone / densitometry / MR imaging / Ultrasound / Nuclear imaging	44	21	no
GREECE (ESYD)	Both ISO 15189 and ISO/IEC 17025	Radiography (incl. Angiography, Mammography) / Scan / Bone / densitometry / MR imaging / Ultrasound / Nuclear imaging	1	2	no
NETHERLANDS (RvA)	ISO 15189	Bone densitometry / MR Imaging / Ultrasound / Blood pressure measurement, ECGs, Fundusfotography, audiometry and wrist-arm index are occasionally covered by accreditation	6	0	no
SWEDEN (SWEDAC)	ISO/IEC 17025	Radiography (incl. Angiography, Mammography) / Scan / Bone densitometry / MR imaging / Ultrasound / Nuclear imaging	15	1	no
DENMARK (DANAK)	ISO 15189	Nuclear imaging	0	0	no



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**No but it is planned:**  
(3/3)

**Standard(s) planned to be used for accreditation for medical imaging**

NORTH MACEDONIA (IARNM)	Both ISO 15189 and ISO/IEC 17025
PORTUGAL (IPAC)	ISO 15189
FRANCE (COFRAC)	ISO 15189
HUNGARY (NAH)	-
NORWAY (NA)	ISO 15189
SERBIA (ATS)	-
SPAIN (ENAC)	ISO 15189
ESTONIA (EAK)	-
TURKEY (TURKAK)	ISO 15189



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### Reminder

