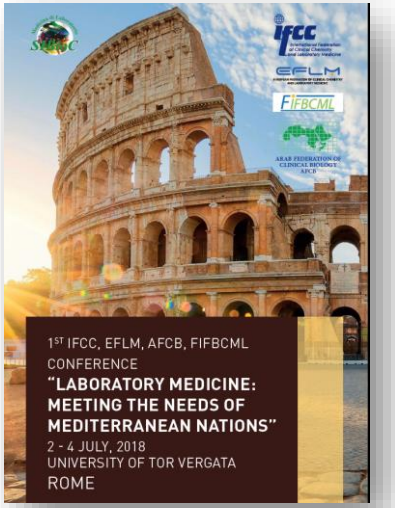
Policies for Standardization of Clinical Laboratory Management in the Mediterranean Countries: Differences from EU members



Sedef YENICE

1ST IFCC, EFLM, AFCB, FIFBCML CONFERENCE

"LABORATORY MEDICINE: MEETING THE NEEDS OF MEDITERRANEAN NATIONS"

2 - 4 JULY, 2018

UNIVERSITY OF TOR VERGATA

ROME

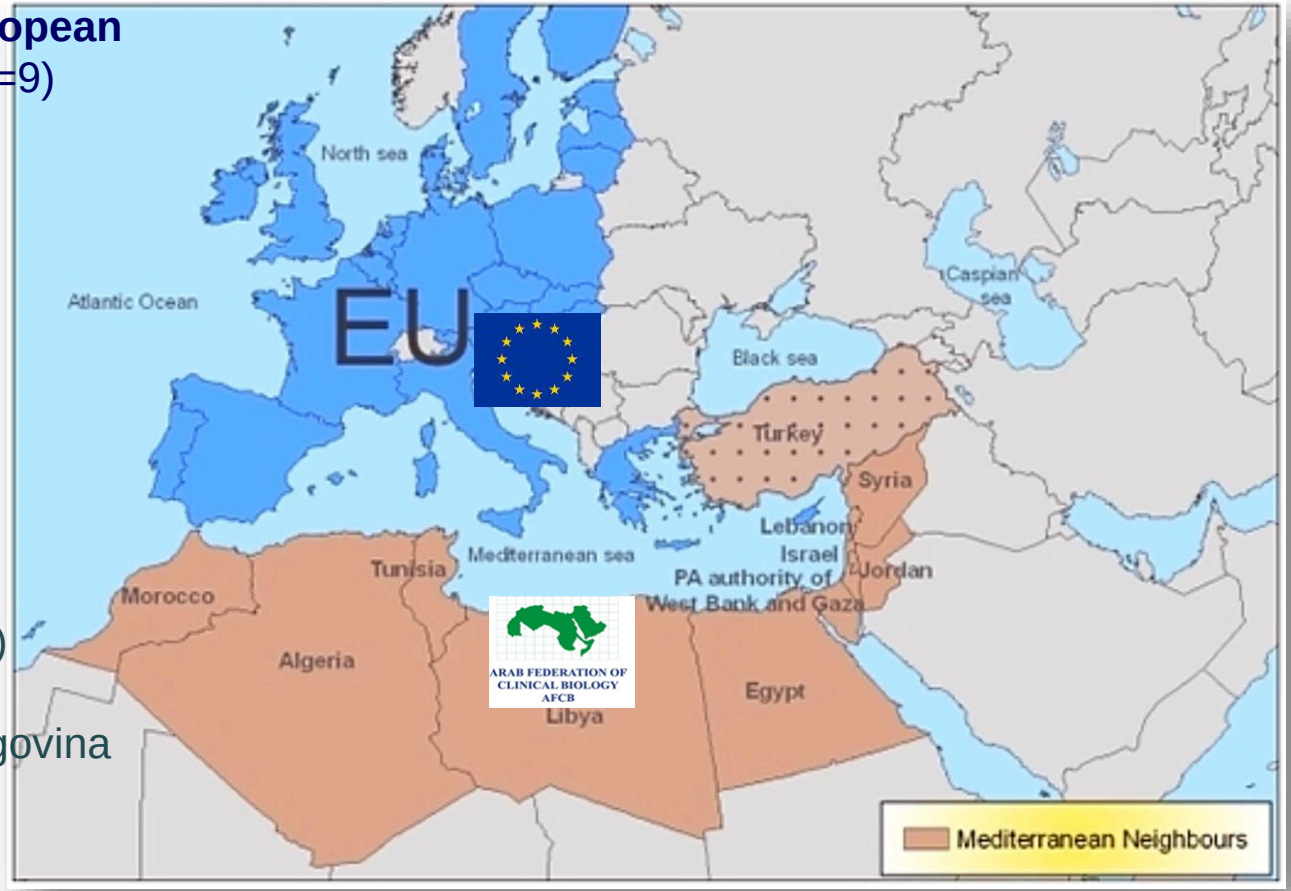
Presentation Outline

- Introduction of Mediterranean Countries by memberships
- Definition of Clinical Laboratory and Fundemental Aspects of Clinical Laboratory Management
- Regulatory Requirements and Standards
- National Accreditation Bodies and Authorities on GLP in Mediterranean Countries
- Differences from EU Members
- Challenges

Mediterranean Countries (n=23)

Southern European Coast - EU (n=9)
Croatia
Cyprus
France
Greece
Italy
Malta
Slovenia
Spain
Gibraltar

NON-EU (n=5)
Albania,
Bosnia-Herzegovina
Monaco
Montenegro
Turkey



Levantine Coast (n=4)
Israel
Lebanon
Palestine
Syria

Northern African Coast (n=5)
Algeria
Egypt
Morocco
Libya
Tunisia

https://www.schengenvisainfo.com/eu-countries/

Arab Federation of Clinical Biology (AFCB)

ARAB FEDERATION OF CLINICAL BIOLOGY
AFCB

The Arab Federation of Clinical Biology (AFCB) was established in 1974 in Egypt.

The twelve countries that currently form the AFCB are:

Mediterranean Nations
Algeria, Egypt, Lebanon, Libya, Morocco, Palestine, Syria, Tunisia

Non-Mediterranean Nations:
Jordan, Saudi Arabia, Sudan, and Yemen

- http://www.ifcc.org/executive-board-and-council/regional-federations/afcb-arab-federation-of-clinical-biology/
- www.ipclm-10.ps/content/about-afcb

International Federation of Clinical Chemistry and Laboratory Medicine

Advancing excellence in laboratory medicine for better healthcare worldwide

Education and Management

Committee on Clinical Laboratory Management (C-CLM)

Target Groups

All laboratory professionals wishing to develop good clinical laboratory leadership and management skills. While focus will be on the needs of developing countries, developed materials will be applicable and useful to all levels of management and leadership experience.

Definition of Terms

By **"clinical laboratory"** we mean a facility for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in the body. Facilities restricted to collection and/or preparation of specimens; or only serving as a mailing service, but not performing testing; only performing POCT (point of care testing); or providing only direct-to-consumer testing (DTCT) are not considered clinical laboratories.

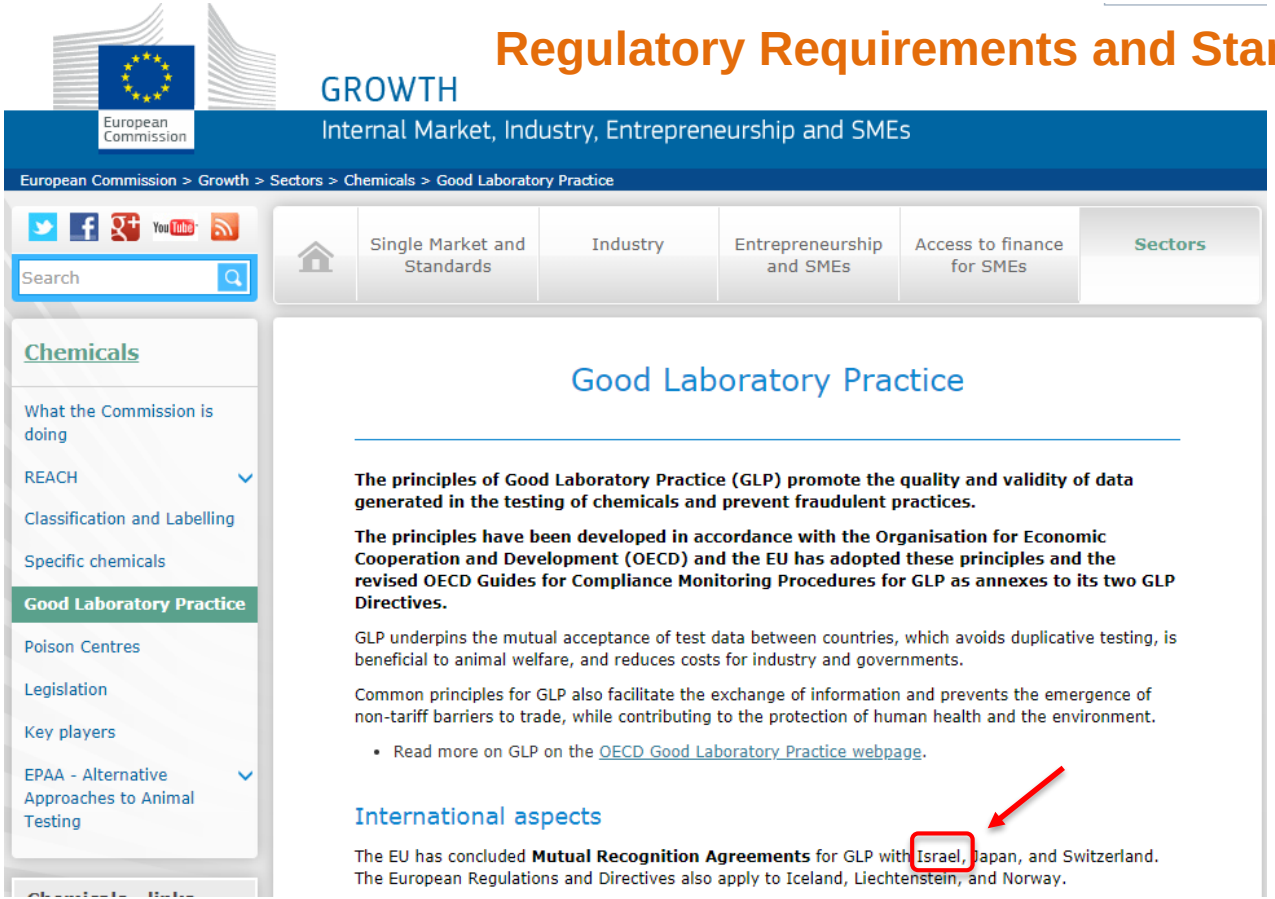
http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/

Fundamental and Administrative Issues of Clinical Laboratory Management

- Leadership and Management
  - Strategic Planning
  - Organizational Skills
  - Staff management
  - Technical Skills
- Professionalism – professional quality
  - Communication Skills
  - Corrective Actions
  - Team management
- Quality System Management
  - Planning Quality Assurance
  - System Process
  - Proactive Systems
  - Continous Quality Improvement
  - Management by Fact
- Laboratory Regulations
  - Legislation
  - Accreditation
  - Biosafety
  - Hazard and Chemicals Management
- Financial Management
- Laboratory Information Systems
- Resource Management – Instruments, etc.
- Problem Solving
- Delivery of Education

http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/

Regulatory Requirements and Standards



The term **Good Laboratory Practice** or GLP was first introduced in 1970's in Denmark and New Zealand. Soon after that, it was used by the Federal Drug Administration (FDA) and the Organisation for Economic Co-operation and Development (OECD), referring to a quality system of regulation and management practices or requirements in research laboratories.

Good Laboratory Practice embodies different principles which are designed to ensure and promote consistency, quality, safety, reliability and integrity of chemicals during non-clinical and laboratory testing.

Nevertheless, GLP isn't limited to chemicals only. Quite often, it also addresses medical devices, food additives, food packaging, color additives and other non-pharmaceutical products or ingredients.

- http://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en
- https://crotraining.co.uk/what-is-the-importance-of-good-laboratory-practice/

GOOD LABORATORY PRACTICE

Ref. Ares(2015)5384581 - 26/11/2015

EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Chemicals

Archives - Implementation of the GLP Directives in the European states

This section gives a brief overview on the application of the GLP Directives in the European Union. All Member States have transposed the GLP Directives and here you have a quick overview of the situation by country.

The Member States listed below have established functioning national GLP compliance monitoring programmes. Norway has transposed GLP Directives 87/18/EEC and 88/320/EEC which are an integral part of the EEA Treaty, and they also have an operational monitoring authority.

Austria

- The Federal Ministry for Agriculture and Forestry, Environment and Water Management, department I/3 is the GLP monitoring authority for all chemicals except medicinal products and veterinary drugs. The Austrian Federal Office for Safety in Health Care (BASG) is the competent monitoring authority for substances relevant in medicinal products. Inspections are performed on its behalf by the Austrian Agency for Health and Food Safety (AGES).
- Routine inspections take place every 2-3 years.
- GLP monitoring programme started in 1989 (industrial chemicals) and 1991 (pesticides).

Belgium

- The Federal Department of Public Health, the Food Chain Safety and Environment is in charge of the GLP monitoring authority, Scientific Institute of Public Health, which is responsible for all chemical products
- The test facilities in the national monitoring programme work on a wide range of chemical products: industrial chemicals, medicinal products, veterinary drugs, phytopharmaceuticals, food additives and cosmetic products.
- Laboratories are inspected every 2-3 years.
- The GLP monitoring programme started in November 1988.

Cyprus

This section gives a brief overview on the application of the GLP Directives in the European Union. All Member States have transposed the GLP Directives and here you have a quick overview of the situation by country.

The Member States listed below have established functioning national GLP compliance monitoring programmes. Norway has transposed GLP Directives 87/18/EEC and 88/320/EEC which are an integral part of the EEA Treaty, and they also have an operational monitoring authority.

EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Chemicals

Version January 2017

NATIONAL MONITORING AUTHORITIES ON GLP

Designated in accordance with Directive 2004/9/EC, Article 3

EU Member States				
MS	**Sectors**	**Competent authority**	**Contact person**	**Contact details**
Austria	Industrial chemicals	**Federal Ministry of Agriculture, Forestry, Environment and Water Management** *(Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft, BMLFUW)*	Dr Susanna Schragner	Abteilung V/3 Stubenbastei 5 1010 Wien Tel. (+43-1) 515 22 23 48 Fax (+43-1) 513 16 79 14 81 E-mail: susanna.schragner@bmlfuw.gv.at
	Human and veterinary medicinal products	**Austrian Agency for Health and Food Safety (AGES)** *(Agentur für Gesundheit und Ernährungssicherheit GmbH)* Institute Surveillance	Dr Ronald Bauer	Traisengasse 5 1200 Wien Tel. (+43-50) 555 36400 E-mail: inspektionen@ages.at http://www.basg.gv.at/inspektionen/good-laboratory-practice/
Belgium	All products	**Scientific Institute of Public Health (WIV-ISP)** *(Wetenschappelijk Instituut Volksgezondheid, WIV; Institut scientifique de la santé publique, ISP)* GLP monitorate	Mr Guido Jacobs	Juliette Wytsmanstraat / Rue Juliette Wytsman 14 1050 Brussel / Bruxelles Tel. (+32-2) 642 51 86 / 642 53 56 Fax (+32-2) 642 52 27 E-mail: glp@wiv-isp.be
Bulgaria	All products	**Bulgarian Accreditation Service** *(Българска служба за акредитация)*	Ms Milena Dimitrova	52 A "Dr. G. M. Dimitrov" Blvd. 1797 Sofia m.dimitrova@nab-bas.bg http://www.nab-bas.bg/en/dlp
Croatia	Medicinal products	**Ministry of Health** *(Ministarstvo zdravlja)* Directorate for Inpatient Health Care and Inspections, Service for Pharmaceutical Inspections *(Uprava za stacionarnu zdravstvenu zaštitu i inspekcijske poslove, Služba farmaceutske inspekcije)*	Dr Gordana Gregorović	Ksaver 200a HR - 10000 Zagreb Tel. (+385) 1 4607 528 Fax (+385) 1 4607 105 E-mail: Gordana.Gregorovic@miz.hr http://www.zdravlje.hr

Regulatory Requirements and Standards

The categories of laboratories practices and the corresponding requirements/industry standards

APPLICABLE LABORATORTY PRACTICE	LABORATORY CATEGORY	APPLICABLE STANDARD AND GUIDANCE
Good Clinical Laboratory Practice - GCLP	Clinical/Medical Laboratory	• CLIA – 42 cfr 493 (US Mandate) • CAP • **ISO 15189** • MHRA GCP for Clinical Labs (UK Guidance) • CPA (UK mandated for NHS Laboratories)
Good Laboratory Practice	Non-Clinical Laboratory	• 21 CFR 58 – Good Laboratory Practice for Non-Clinical Laboratories • International Organization for Economic Cooperation and Development (OECD) - Principles of Good Laboratory Practice and Compliance Monitoring
Bioanalytical Laboratory Practices	Bioanalytical Laboratory	• US-FDA – FDA Guidance for Industry, bioanalytical method validation • **European Medicines Agency (EMA) Draft Guideline on Validation of Bioanalytical Methods**

Source: Tobin C.Guarnacci. http://www.appliedclinicaltrialsonline.com/gclp-industry-perspective

ILAC (The **I**nternational **L**aboratory **A**ccreditation **C**ooperation) is the international organization for accreditation bodies operating in accordance with ISO/IEC 17011, was established in 1977 and is involved in the accreditation of conformity assessment bodies including:

- **calibration** laboratories (using ISO/IEC 17025),
- **testing** laboratories (using ISO/IEC 17025),
- **medical testing** laboratories (using ISO 15189) and
- **inspection** bodies (using ISO/IEC 17020).

The international arrangements are managed by **IAF** in the fields of management systems, products, services, personnel and other similar programs of conformity assessment.

https://ilac.org/about-ilac/
https://www.iaf.nu/

ILAC works closely with the regional co-operation bodies involved in accreditation

https://ilac.org/about-ilac/

- **EUROPE**

http://www.european-accreditation.org/

- **AFRICA**

http://www.intra-afrac.com/

- **ARAB REGION**

http://www.arac-accreditation.org/

https://www.iaf.nu/

notably EA in Europe, APLAC in the Asia-Pacific, IAAC in the Americas, AFRAC in Africa, SADCA in Southern Africa, and ARAC in the Arab region.

EUROPEAN ACCREDITATION

Publication Reference **EA-INF/03: 2018**

Signatories

to the EA Multilateral

and Bilateral Agreements

PURPOSE

The document lists the signatories to the EA Multilateral Agreement (EA MLA) and EA Bilateral Agreements.

8th June 2018 rev 04 Page 1 of 8

Harmonization in accrediting medical labs the main task of the healthcare committee within EA.

The European National accreditation bodies are united in European Accreditation (EA) and have policies that applies to all European ISO 15189 accreditations. EA members have signed a multilateral agreement for the mutual recognition of their accreditations.

	CALIBRATION LABORATORIES	TESTING LABORATORIES	MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION AND VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
SLOVAKIA - **SNAS**	√	√	√	√	√	√	√	√	
SLOVENIA - **SA**	√	√		√	√	√	√	√	
SPAIN - **ENAC**	√	√	√	√	√	√	√	√	√
SWEDEN - **SWEDAC**	√	√	√	√	√	√	√	√	√
SWITZERLAND - **SAS**	√	√	√	√	√	√		√	
TURKEY - **TURKAK**	√	√	√	√	√	√		√	√
UNITED KINGDOM - **UKAS**	√	√	√	√	√	√	√	√	√

(http://www.european-accreditation.org).

The European National accreditation bodies are united in European Accreditation (EA) and have policies that applies to all European ISO 15189 accreditations. EA members have signed a multilateral agreement for the mutual recognition of their accreditations.

A.1 EA MULTILATERAL AGREEMENT SIGNATORIES

	CALIBRATION LABORATORIES	TESTING LABORATORIES	MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION AND VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
ALBANIA - DPA		√				√		√	
AUSTRIA - AA	√	√	√	√	√	√	√	√	
BELGIUM - BELAC	√	√	√	√	√	√	√	√	√
BULGARIA – BAS	√	√	√	√	√	√	√	√	
CROATIA - HAA	√	√	√	√	√	√	√	√	
CYPRUS – CYS-CYSAB	√	√	√					√	
CZECH REPUBLIC - CAI	√	√	√	√	√	√	√	√	√
DENMARK - DANAK	√	√	√	√	√	√	√	√	√
ESTONIA - EAK	√	√	√	√	√	√	√	√	
FINLAND - FINAS	√	√	√	√	√	√	√	√	√
FRANCE – COFRAC	√	√	√	√	√	√	√	√	√
FYROM - IARM	√	√	√	√				√	
GERMANY - DAkkS	√	√	√	√	√	√	√	√	√
GREECE - ESYD	√	√	√	√	√	√	√	√	√
HUNGARY – NAH	√	√	√	√	√	√	√	√	
IRELAND - INAB	√	√	√	√		√		√	
ITALY - ACCREDIA	√	√	√	√	√	√	√	√	√
LATVIA - LATAK	√	√	√	√	√	√	√	√	
LITHUANIA - LA	√	√	√	√	√	√		√	
LUXEMBURG - OLAS	√	√	√	√		√		√	
MALTA – NAB-MALTA	√	√						√	
NETHERLANDS - RvA	√	√	√	√	√	√	√	√	√
NORWAY - NA	√	√	√	√	√	√	√	√	√
POLAND - PCA	√	√	√	√	√	√	√	√	√
PORTUGAL - IPAC	√	√	√	√	√	√	√	√	
ROMANIA - RENAR	√	√	√	√	√	√	√	√	√
SERBIA - ATS	√	√	√	√	√	√		√	

8th June 2018 – rev 64 (http://www.european-accreditation.org). Page 6 of 8


EA EUROPEAN ACCREDITATION

Publication Reference EA-INF/03: 2018

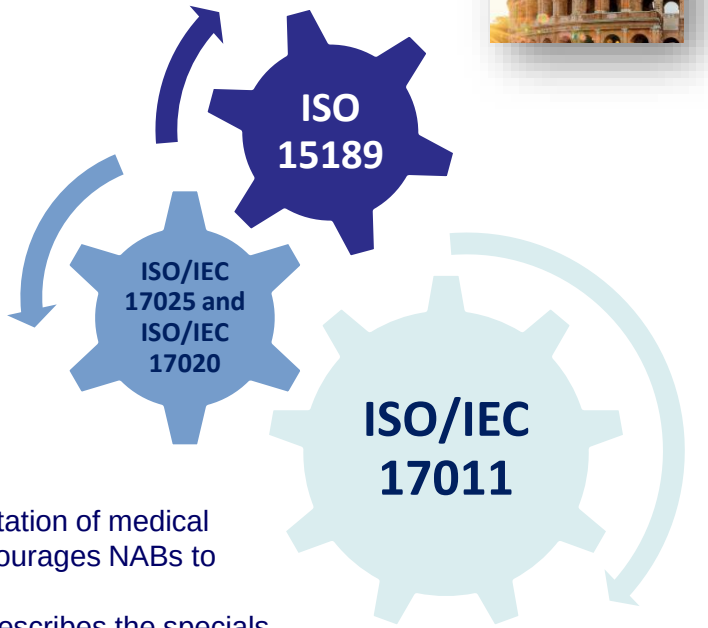
Signatories

to the EA Multilateral

and Bilateral Agreements

Flexible Scope for ISO 15189 Accreditation

The scope of accreditation describes for which laboratory services the accreditation is granted. According to ILAC and EA regulations, the description of the scope may be either fixed or flexible.
A **fixed scope** states every single test or service in every medical field in every type material.
A **flexible scope** does not mention individual tests or services, but coherent groups of services within a medical field and with identical technical principle with provision of all applicable materials (or products or matrices such as serum, plasma, blood cultures etc) (1).



Fixed vs Flexible

- ILAC has a policy on the formulation of scope (2).
- EA has two policies to the topic of scope of accreditation.

EA-4/17: EA position paper on the description of scopes of accreditation of medical laboratories clearly promotes the use of the flexible scope and encourages NABs to promote its use (3).
EA-2/15: EA requirements for the accreditation of flexible scopes describes the specials points of attentions that are needed when assessing a laboratory with a flexible scope (4).

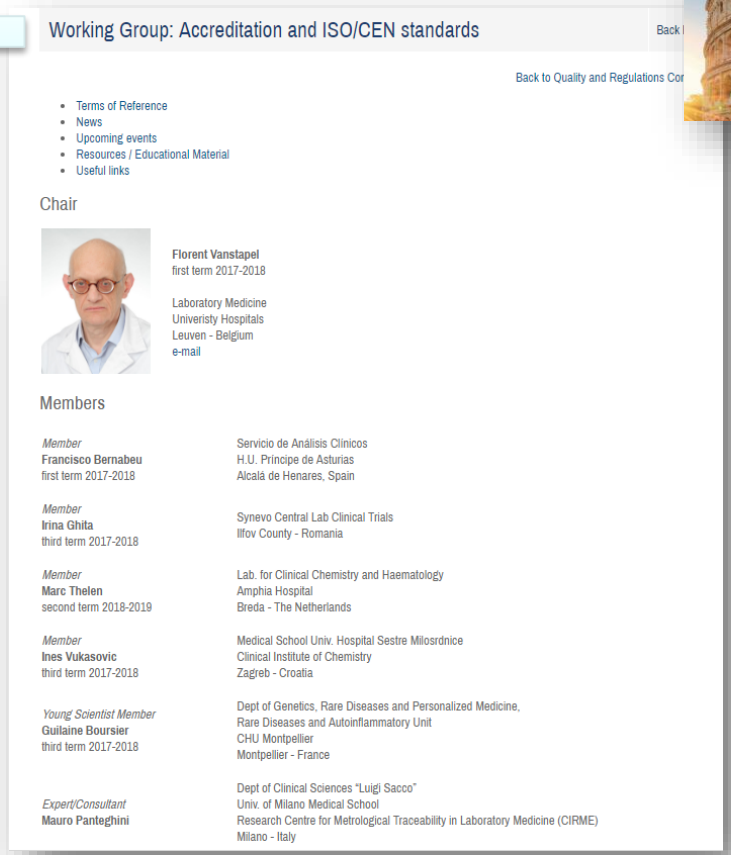
1. Thelen. MHM. J Lab Precis Med 2017;2:84.
2. Guideline for the Formulation of Scopes of Accreditation for Laboratories. ILAC-G18:04/2010. http://www.nab.lt/Files/ILAC_G18_04_2010.pdf
3. EA position paper on the description of scopes of accreditation of medical laboratories. Available online: http://www.european-accreditation.org/publication/ea-4- 17-m-rev00-december-2008-rev
4. EA-2/15. EA requirements for the accreditation of flexible scopes. Available online: http://www.europeanaccreditation.org/publication/ea-2-15-m

Terms of Reference

1.To represent EFLM and the interest of European laboratories in EA, ISO TC212 and CEN TC140 & EU regulatory frameworks (EU IVD directive, EU Health Care Focus Group)

2.To harmonize accreditation in Europe

1. By carrying out international surveys on current practices
2. By developing guidance documents for laboratories which support the translation and implementation of accreditation standards in practice
3. By educating and training Specialists in Laboratory Medicine and assessors of accrediting bodies on the application of specific professional standards of ISO 15189



https://www.eflm.eu/site/page/a/1125

https://www.eflm.eu/site/page/a/1142

Surveys on Accreditation of medical laboratories in the European countries and in the EU

Clin Chem Lab Med 2007;45(2):268–275 © 2007 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2007.037

Accreditation of medical laboratories in the European Union

Wim Huisman[1,*], A. Rita Horvath[2], David Burnett[3], Victor Blaton[4], Rózsa Czikkely[5], Rob T.P. Jansen[6], Anders Kallner[7], Desmond Kenny[8], Pika Mesko[9], Mario Plebani[10], José Queralto[11], Gerhard Schumann[12], Luděk Šprongl[13], Dalius Vitkus[14], Hans Wallinder[15] and Simone Zerah[16]

- April 2005, 19/25 NS replied
- Accreditation is carried out on a test-by –test basis
- Harmonization is needed.

Clin Chem Lab Med 2012;50(7):1147–1152 © 2012 by Walter de Gruyter • Berlin • Boston. DOI 10.1515/cclm-2011-0586

Review

European medical laboratory accreditation. Present situation and steps to harmonisation

Wim Huisman*

Medical Centre Haaglanden, Department of Clinical Chemistry, Den Haag, The Netherlands, and Chair of EFCC WG on Accreditation and ISO/CEN Standards

of medical laboratories in Europe. A recent questionnaire organised in 2011 by ENAC, the Spanish accreditation body, confirms this (Table 1). However, the percentage of laboratories which are actually accredited is still low in most countries (Table 2).

- March 2014, 39 EFLM NS
- 29/39 NS replied
- ISO 15189 Acc.project has been widely adopted.

DE GRUYTER Clin Chem Lab Med 2016; 54(4): 545–551

Guilaine Boursier*, Ines Vukasovic, Pika Mesko Brguljan, Maria Lohmander, Irina Ghita, Francisco A. Bernabeu Andreu, Edward Barrett, Duilio Brugnoni, Christos Kroupis, Ludek Sprongl, Marc H.M. Thelen, Florent Vanstapel, Tatjana Vodnik, Willem Huisman and Michel Vaubourdolle, on behalf of the Working Group Accreditation and ISO/CEN standards (WG-A/ISO) of the EFLM

Accreditation process in European countries – an EFLM survey

SURVEY RESULTS OF EFLM 2014* and ENAC 2011**

Country in Mediterranean Region	Number of Medical Labs accredited	% of the Overall Labs	#of Labs working toward accreditation	Status of Accreditation by EFLM 2014	Standard used for accreditation based on a survey by ENAC 2011	POCT, ISO 22870
ALBANIA	One Hospital Clinical Chemistry Lab	< 1	Not provided	Not offered by NAB, by Greek A.		
BOSNIE-HERZEGOVINA	Not provided	< 1	8			
CROATIA	7	3	4	per service	ISO 15189	
CYPRUS	25	15	5		ISO 15189	
FRANCE	268	25	410	Mandatory/ all fields of lab m/flexible approach largely used	ISO 15189, ISO17025	Included in the scope
GREECE	45	3	100		ISO 15189	
ITALY	One Microbiology Lab	< 1	5		ISO 15189	
SLOVENIA	1	< 1	Not provided	Not offered by NAB, by Croatia		
SPAIN	45	2	12	per test	ISO 15189	Med.Labs.
TURKEY	24 (at present)	< 1	13	Not mandatory, per test	ISO 15189	Not mandatory

*) Boursier G. Clin Chem Lab Med 2016; 54(4):545-551.

**) Huisman W. Clin Chem Lab Med 2012; 50(7):1137-1152.

NATIONAL ACCREDITATION BODIES AND AUTHORITIES ON GLP IN EU MEMBER MEDITERRANEAN COUNTRIES

- http://www.oecd.org/chemicalsafety/testing/linkstonationalwebsitesongoodlaboratorypractice.htm
- http://ec.europa.eu/docsroom/documents/26123
- file:///C:/Users/aidata1/Downloads/national-authorities-glp_en-updated_Jan2017_clean.pdf
- https://www.iaf.nu//articles/IAF_MEMBERS_SIGNATORIES/4

COUNTRY	BODY	NATIONAL MONITORING AUTHORITIES ON GOOD LABORATORY PRACTICE
Croatia	HAA:Croatian Accreditation Agency http://www.akreditacija.hr/EN	Ministry of Health (Ministarstvo zdravlja) Directorate for Inpatient Health Care and Inspections, Service for Pharmaceutical Inspections https://zdravstvo.gov.hr/
Cyprus	CYS-CYSAB: Cyprus Organization for the Promoting Quality	Cyprus Organisation for Promoting Quality (CYS-CYSAB) http://www.mcit.gov.cy/mcit/cys/cys.nsf/index_en/index_en?OpenDocument
France	CONFRAC: Comite Francais d'Accreditation https://www.cofrac.fr/	French National Agency for Medicines and Health Products Safety (Agence nationale de sécurité du médicament et des produits de santé, ANSM) http://ansm.sante.fr/
Greece	ESYD: Hellenic Accreditation System http://www.esyd.gr/portal/p/esyd/	General Chemical State Laboratory, National Organization for Medicines-EOF http://www.eof.gr/
Italy	ACCREDIA: Italian Accreditation Body; Regions https://www.accredia.it/en/	Ministry of Health (Ministero della Salute, Direzione Generale della Prevenzione) http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1080&area=buona%20pratica%20laboratorio&menu=vuoto

NATIONAL ACCREDITATION BODIES AND AUTHORITIES ON GLP IN EU MEMBER MEDITERRANEAN COUNTRIES

- http://www.oecd.org/chemicalsafety/testing/linkstonationalwebsitesongoodlaboratorypractice.htm
- http://ec.europa.eu/docsroom/documents/26123
- file:///C:/Users/aidata1/Downloads/national-authorities-glp_en-updated_Jan2017_clean.pdf
- https://www.iaf.nu//articles/IAF_MEMBERS_SIGNATORIES/4

COUNTRY	BODY	NATIONAL MONITORING AUTHORITIES ON GOOD LABORATORY PRACTICE
Malta	NAB-Malta: National Accreditation Board https://nab.gov.mt/en/Pages/Welcome-Page.aspx	National Accreditation Board
Slovenia	Ministry of Health: SA: Slovenska Akreditacja	Chemicals Office of the Republic of Slovenia (CORS) (Urad RS za kemikalije (URSK) http://www.uk.gov.si/
Spain	ENAC: Entidad Nacional de Accreditacion https://www.enac.es/	Spanish Agency of Medicines and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios, AEMPS) https://www.aemps.gob.es/industria/inspeccionBPL/listadoLab-BPL.htm

BENEFITS OF ACCREDITATION

What are the benefits of accreditation?

Accreditation brings business benefits and other advantages to many groups of people.

For Government:

Accreditation is the preferred mechanism for ensuring public confidence in the reliability of activities that impact on health, welfare, security and the environment. Accreditation is used, therefore, to identify Competent Bodies for the implementation of governmentpolicies and regulations

For Economy

- Accreditation can provide a competitive advantage and facilitates access to export markets within Europe and beyond - with the

FOREIGN ASSISTANCE

Albanian Directorate of Accreditation was assisted by the European Co-operation of Accreditation (EA) and by the CARDS 2001 project " Support for the standards and certification sector". This project has assisted the implementation of the legal framework in this area and the training of the directorate's staff.

During 2005, Albanian Directorate of Accreditation was assisted by the following projects:

- CARDS 2003 "Support to standardization, certification, and accreditation".
- Regional CARDS 2002 " Quality Infrastructure.

European co-operation for Accreditation

dav
Drejtoria e Akreditimit

ALBANIAN DIRECTORATE of ACCREDITATION

وزارة الصحة والسكان
خدمات نقل الدم القومية
National Blood Transfusion Services

ARAB REPUBLIC OF EGYPT

MINISTRY OF HEALTH & POPULATION

NATIONAL BLOOD POLICY

Managing Quality in State of Palestine

A directory of services for SMEs

International Trade Centre

PTB

Law No. 572

Establishment of the Lebanese Accreditation Council

CONSEIL LIBANAIS D'ACCREDITATION (COLIBAC)

standards may be requested under agreement between the concerned parties.
The conformity assessment may be conducted whether during the manufacturing of products, the provision of service, performance of the work or thereafter.

- Certificate of competence (for individuals).
- Certificate or statement issued by a specific authority proving that the holder thereof has received the necessary training and experience and has the necessary competence to carry out a specific work under particular conditions.
- Conformity Mark/Label: A special mark/label denoting the conformity of a specific product, service, work or production system with particular national standard specifications in a permanent manner. The mark/label is owned by a specific body

Website: Yes	GLP Manual	
Page 1 of 23	Procedure number 1-200000	Version number 13

ISRAC
הרשות הלאומית למסמכת מעבדות

Israel Laboratory Accreditation Authority

Valid from
15/05/2012

Effective from
01/01/2013

GLP Manual

Procedure Number 1-200000

zed by:

	Name	Date	Signature
Monitoring Unit Manager	Zahava Nizri		
Manager	Muriel Cohen		
Manager	Etty Feller		

The authorized copies of this document are those on ISRAC computer network and the master copy held by the QA. All other copies are uncontrolled and are only valid on the date printed. Printed on May 29, 2012

Accreditation based on 15189 is widely accepted in the medical labs of non-EU member Mediterranean countries

NATIONAL ACCREDITATION BODIES AND AUTHORITIES ON GLP IN NON-EU MEMBER MEDITERRANEAN COUNTRIES

COUNTRY	BODY	NATIONAL MONITORING AUTHORITIES ON GOOD LABORATORY PRACTICE
Albania	General Directorate of Accreditation (DPA) http://www.dpa.gov.al/	
Bosnia and Herzegovina	Institute for Accreditation of Bosnia and Herzegovina (BATA) http://www.bata.gov.ba/O_nama/default.aspx?id=17&langTag=en-US	
Israel	Israel Laboratory Accreditation Authority http://www.israc.gov.il	Israel National Good Laboratory Practice (GLP) Monitoring Unit within the Israel Laboratory Accreditation Authority (ISRAC) i.e. Israel National Good Laboratory Practice Monitoring Authority (IL-GLP-MA).
Montenegro	ATCG: Accreditation Body of Montenegro http://www.akreditacija.me/	
Turkey	TURKAK: Turkish Accreditation Agency http://www.turkak.org.tr/TURKAKSITE/Default.aspx	Ministry of Health, Department of Inspection and Diagnosis Services, Regulations on Service and Quality Standards and Requirements for the Medical Laboratory http://www.laboratuvar.saglik.gov.tr/

https://www.iaf.nu//articles/IAF_MEMBERS_SIGNATORIES/4

ARAB FEDERATION OF CLINICAL BIOLOGY AFCB

NATIONAL ACCREDITATION BODIES AND AUTHORITIES ON GLP IN AFCB MEMBER MEDITERRANEAN COUNTRIES

COUNTRY	BODY	MEMBERSHIPS	NATIONAL MONITORING AUTHORITIES ON GOOD LABORATORY PRACTICE
Algeria	Algerian Accreditation Body https://www.algerac.dz/	Arab Accreditation Cooperation – ARAC Full Member of ILAC since Oct.2017	
Egypt	Egyptian Accreditation Council - EGAC http://www.egac.gov.eg	African Accreditation Cooperation – AFRAC Arrangement Member	National Blood Regulatory Authority (NBRA) for the Blood Banks
Lebanon	Lebanese Accreditation Council - CONSEIL LIBANAIS D'ACCREDITATION (COLIBAC) https://www.unescwa.org/lebanese-accreditation-council	LIBNOR: International Organization for Standardization (ISO), the Codex Alimentarius Commission and the Arab Industrial Development and Mining Organization (AIDMO) and an affiliate member of the European Committee for Standardization (CEN)	Lebanese Standards Institution (LIBNOR), Ministry of Public Health
Libya	Libyan Accreditation Unit LIBAC		

http://www.intra-afrac.com/, http://arac-accreditation.org/fullmember

NATIONAL ACCREDITATION BODIES AND AUTHORITIES ON GLP IN AFCB MEMBER MEDITERRANEAN COUNTRIES

COUNTRY	BODY	MEMBERSHIPS
Morocco	Moroccan Accreditation Service (SEMAC) http://accreditation.newsweaver.co.uk/ilac/xxj1aiu93qs?a=1&p=51735384&t=28643616	Associate member, to ILAC since 2005, EA since 2012, ARAC since 2011 and IAF since 2015.
Palestine	Palestinian Accreditation Laboratory Committee PALAC, State of Palestine Standards Institution	Full member of ARAC
Syria	SASMO, the Syrian Arab Organization for Standardization and Metrology http://www.sasmo.org.sy/en/search_standards	AIDMO: Arab Industrial Development and Mining Organization ISO: International Organization for Standardization IEC: International Electrotechnical Commission FAO: Food and Agriculture Organization of the United Nations. OIML: International Organization of Legal Metrology
Tunisia	TUNAC National Accreditation Council http://www.tunac.tn/	African Accreditation Cooperation – AFRAC and ARAC Full Member

Joint Commission International

JCI identifies, measures, and shares best practices in quality and patient safety with the world.
surveys the laboratory based on the **Accreditation Standards for Laboratories** and as part of an overall healthcare facility survey.

Laboratory Standards include:
•Benchmarks for individual laboratories
•Best practices standards in a recognized format
•Quality management systems requirements

JCI has as many sets of standards approved and endorsed by the International Society for Quality in Health Care (ISQua).

COLLEGE of AMERICAN PATHOLOGISTS

CAP accredits laboratories based on the ISO 15189 standard for technical competence and quality management in medical laboratories. Laboratories must be appropriately licensed to perform testing when required by law.

The laboratory accreditation program is available for laboratories in the United States and for international laboratories.

CAP has accredited 54 laboratories under its ISO 15189 program since it launched in 2008.

1) https://www.jointcommissioninternational.org/about-jci/jci-accredited-organizations/ Accessed June 28, 2018.
2) http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=accrlabsearch_page&hideNavFrame=Y Accessed June 28, 2018.

JCI ACCREDITED ORGANIZATIONS WORLD WIDE

Joint Commission International

There are healthcare organizations and medical laboratories accredited by JCI in eight Mediterranean countries.

https://www.jointcommissioninternational.org/about-jci/jci-accredited-organizations/https://www.jointcommissioninternational.org/about-jci/jci-accredited-organizations/

LIST OF CURRENT JCI-ACCREDITED ORGANIZATIONS BY COUNTRY/TERRITORY AND BY ACCREDITATION/CERTIFICATION

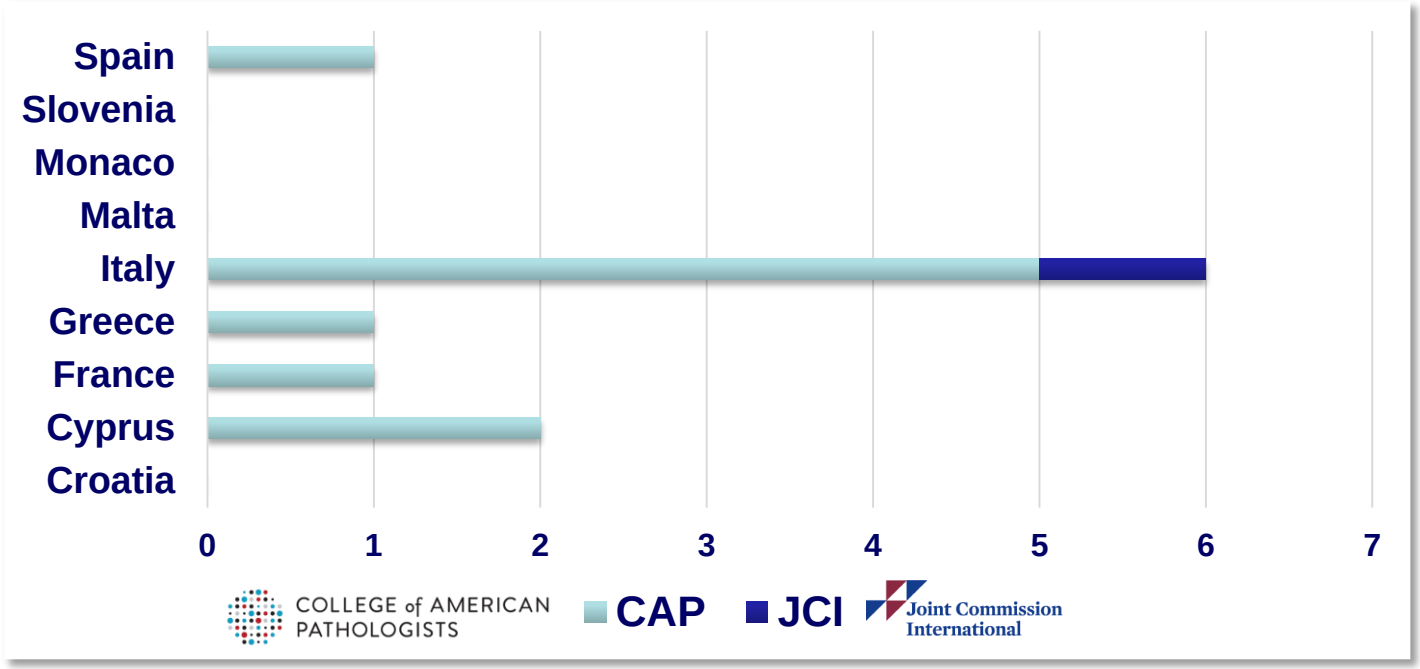
Joint Commission International

EU MEMBER MEDITERRANEAN COUNTRIES

COUNTRY	NUMBER OF ORGANIZATIONS	HOSPITAL PROGRAM	LABORATORY PROGRAM
GREECE	1	1	0
ITALY	23	12	1
SLOVENIA	3	*Ambulatory Care Program	0
SPAIN	31	13	0
None in CROATIA, CYPRUS, FRANCE, and MALTA			

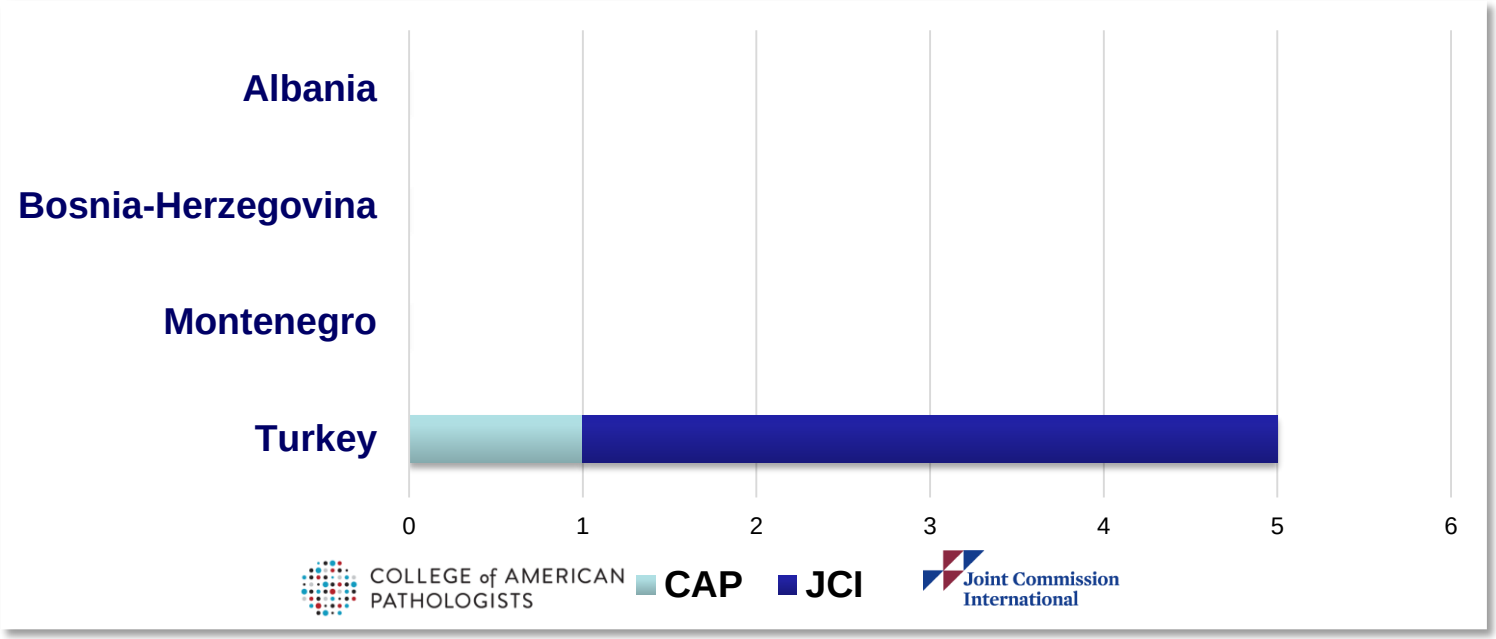
https://www.jointcommissioninternational.org/about-jci/jci-accredited-organizations/Accessed June 25, 2018.

LABORATORY ACCREDITATION PROFILE OF EU MEMBER MEDITERRANEAN COUNTRIES (n=9)



1) https://www.jointcommissioninternational.org/about-jci/jci-accredited-organizations/ Accessed June 28, 2018.
2) http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=accrlabsearch_page&hideNavFrame=Y Accessed June 28, 2018.

LABORATORY ACCREDITATION PROFILE OF NON-EU MEMBER MEDITERRANEAN COUNTRIES IN EUROPE (n=4)



1) https://www.jointcommissioninternational.org/about-jci/jci-accredited-organizations/ Accessed June 28, 2018.
2) http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=accrlabsearch_page&hideNavFrame=Y Accessed June 28, 2018.

LIST OF CURRENT JCI-ACCREDITED ORGANIZATIONS BY COUNTRY/TERRITORY AND BY ACCREDITATION/CERTIFICATION

AFCB MEMBER MEDITERRANEAN COUNTRIES

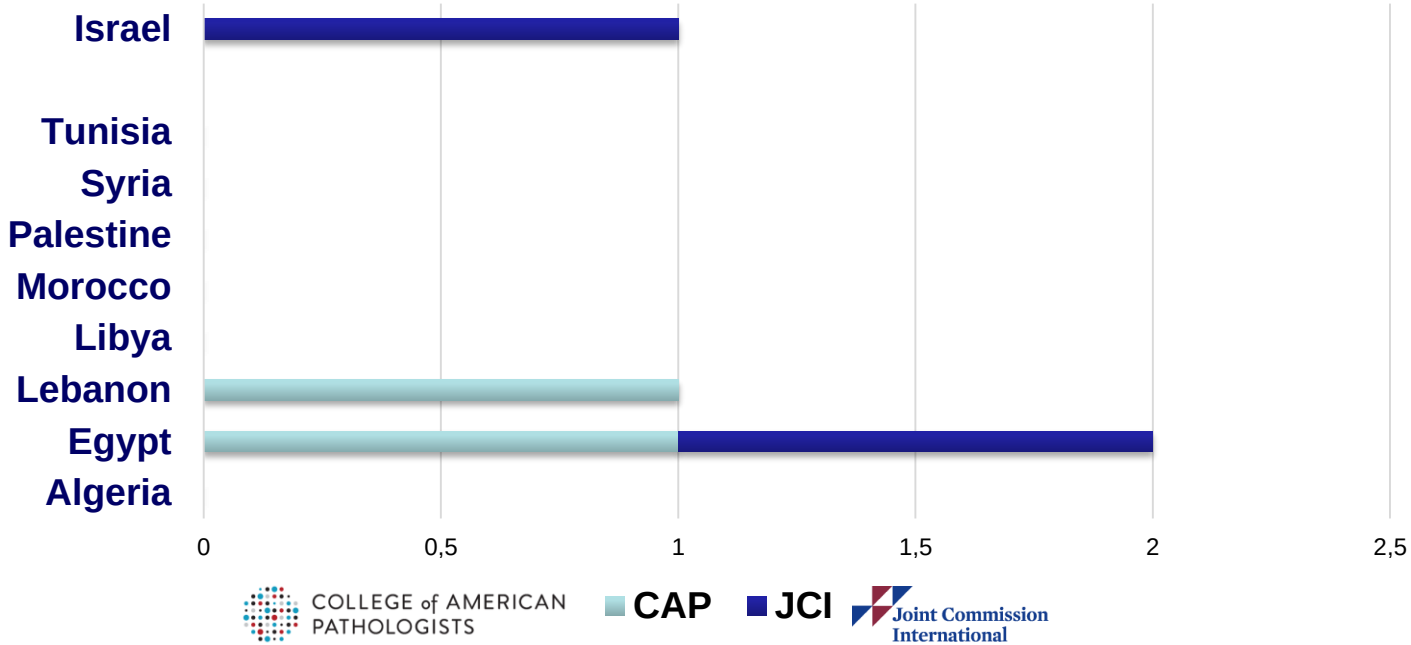
COUNTRY	NUMBER OF ORGANIZATIONS	HOSPITAL PROGRAM	LABORATORY PROGRAM
EGYPT	10	8	1
LEBANON	5	3	0
None in ALGERIA, LIBYA, MOROCCO, PALESTINE, SYRIA and TUNISIA			

OTHER NON –EU MEMBER MEDITERRANEAN COUNTRIES

COUNTRY	NUMBER OF ORGANIZATIONS	HOSPITAL PROGRAM	LABORATORY PROGRAM
ISRAEL	31	13	1
TURKEY	46	33	4

https://www.jointcommissioninternational.org/about-jci/jci-accredited-organizations/Accessed June 25, 2018.

LABORATORY ACCREDITATION PROFILE OF AFCB MEMBER AND OTHER MEDITERRANEAN COUNTRIES (n=9)



1) https://www.jointcommissioninternational.org/about-jci/jci-accredited-organizations/ Accessed June 28, 2018.
2) http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=accrlabsearch_page&hideNavFrame=Y Accessed June 28, 2018.

Differences as per the Progress in EU – (1)

REGULATIONS	Mediterranean Countries in Europe, EU and non –EU members/ EA (European organization for accreditation)	Other Countries in the Mediterranean Region/ Regional Accreditation Bodies AFRAC, ARAC
Accreditation of Medical Labs based on ISO 15189	The number of accredited labs is relatively high according to ISO 15189. Accreditation of medical laboratories in the countries of the EU is mostly accrued in cooperation with national accreditation bodies. These national accreditation bodies work together in a regional cooperation, the European Cooperation for Accreditation (EA).	National Accreditation Bodies (NAB) for medical labs were established in each country and work together in a regional cooperation: AFRAC, ARAC. Labs are accredited by National Accreditation or the government authorities. All aspects of ISO 15189 have been incorporated in their requirements. A uniform deployment of ISO 15189 in the region or nation wide?
Flexible Scope for ISO15189* and Harmonization of Flexibility	EA promotes the flexible approach, in most countries the majority of scope is fixed. EA has issued two relevant papers on scopes: EA-2/15 and 2. EA-4/17:	Any progress towards If those countries are in the process of adopting to a flexible scope for ISO15189 accreditation? The member societies of the regional accreditation bodies may be in the process of finding a harmonized viewpoint on the optimization of scope elements that are part of the source scope of more than one society.
	EFLM has published a guidance document to stmulate the use of a flexible scope – Thelen MH, et al. Working Group Accreditation ISO/CEN standards (WG-A/ISO) of the EFLM. 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	Efforts of WGs towards the harmonization of flexibility?

*) Thelen MHM. J Lab Precis Med 2017;2:84, Thelen et al. Clin Chem Lab Med 2015; 53(8): 1173–11, Fernandez-Calle, P. *et a*l. Biochemia Medica 2013;23(1):83–95

Differences as per the Progress in EU – (2)

REGULATIONS	Mediterranean Countries in Europe, EU and non –EU members/ EA (European organization for accreditation)	Other Countries in the Mediterranean Region/ Regional Accreditation Bodies AFRAC, ARAC
GLP Compliance	Implementing a risk-based GLP Quality Assurance (QA) programme. A document provided guidance to GLP test facilities on risk-based quality assurance programmes. The document was discussed by the EU GLP Working Group on 17 March 2016 and adopted by the EU GLP Working Group on 23 February 2017. **Guidance for GLP facilities on the implementation and maintenance of a risk-based Quality Assurance programme** Document date: 27/03/2017 - Created by GROW.DDG1.D.1 - Publication date: 28/03/2017	GLP is well implemented. But GCLP? Initiatives to adopt a risk-based GLP quality assurance programme?
Accreditation of POCT (1)	1. Standard ISO 15189, Medical laboratories. Requirements for quality and competence 2. Standard ISO 22870, Point-of-care testing (POCT). Requirements for quality and competence 3. In Vitro Diagnostic Medical Devices Directive 98/79/EC In France, POCT is in the scope of accreditation. Project in progress to give the responsibility to medical labs in the European countries. EFLM Quality and Regulations Committee,WG:Accreditation and ISO/CEN Standards is involved in discussion w regulatory bodies on POCT outside medical labs	Deployment of ISO 22870 in lab accreditation? Full compliance to ISO 22870? Despite the fact that accreditation is the best option, if it concerns the quality system only, certification according to ISO 9001 is also appropriate in some countries.

1) Boursier G. Clin Chem Lab Med 2016; 54(4):545-551

2) Simundic AM. Accreditation of Clinical Laboratories in Europe. The EFLM perspective. Presentation at the 49th Congresso Nazionale SIBioC-Medicina di Laboratorio, 16-18 October 2017, Firenze

Differences as per the Progress in EU – (3)

REGULATIONS	Mediterranean Countries in Europe, EU and non –EU members/ EA (European organization for accreditation)	Other Countries in the Mediterranean Region/ Regional Accreditation Bodies AFRAC, ARAC
Accreditation of Phylebotomy Services (1)	The differences exist in the way assessment for medical laboratories is practiced in the European countries. Not only in frequency of assessment and surveillance visits, but also in the hours spent by the assessment team. This became clear in a questionnaire sent to all European NABs in 2009. The pylebotomy services is under supervision of the medical lab in Spain.	Not in common. No accreditation is required. But any Surveillance activities?
House Developed Tests (HDT)	New IVD Directive published on May 5, 2017. The new IVD regulation of the EU requires ISO 15189 for the waiver of CE labeled in house developed tests. Effective in 5 years and another 2 years for selling IVD from the bench. EFLM is involved (2).	Any regional or national regulations towards the way of implementing HDT?

1) Huisman W. Clin Chem Lab Med 2012;50 (7):1147–1152

2) Simundic AM. Accreditation of Clinical Laboratories in Europe. The EFLM perspective. Presentation at the 49th Congresso Nazionale SIBioC-Medicina di Laboratorio, 16-18 October 2017, Firenze

Differences as per the Progress in EU – (4)

Clinical Laboratory Management	Mediterranean Countries in Europe, EU and non –EU members/ EA (European organization for accreditation)	Other Countries in the Mediterranean Region/ Regional Accreditation Bodies AFRAC, ARAC
Reference Intervals	Recommendation for the review of biological reference intervals in medical laboratories (1) EFLM WG-A/ISO/CEN Standards working on prorocol for determining reference limits, review of reference intervals and plans multicenter studies to determine the ref intervals. https://www.eflm.eu/site/page/a/1142	Any group activity within the member national societies?
Laboratory Leadership (2)	IFCC C-CLM is currently involved in developing a training program and published the PPTs of the 6 modules of training on basic leadership skills in 2017 and performed a survey on March 2018. http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/7-c-clm-publications-and-survey-reports/	The University of Washington, USA, created the Certificate Program in Laboratory Leadership and Management in partnership with WHO Regional Office for the Eastern Mediterranean, and implemented it with 17 participants and 11 mentors from clinical and public health laboratories in 10 countries [**Egypt**, Iraq, Jordan, **Lebanon, Morocco**, Oman, Pakistan, Qatar, Saudi Arabia, and Yemen] in 2014.

1) Henny J. Clin Chem Lab Med 2016;54 (12):1893–1900.

2) Perrone LA. Implementation of a mentored professional development programme in laboratroy leadership and management in the Middle East and North Africa. East Mediterr Health J. 2017 Feb 1;22(11):832 – 839.

Challenges

Quality issues remain the greatest challenge for the standardization of clinical laboratory management particularly in the non-EU member Mediterranien countries.

	Primary challenges are in general:
Organization	• Quality Management issues remain to be standardasized. • There are a variety of government authorities and non-government organizations that directly or indirectly impact on laboratory operations . • Undetermined responsibilities and authorities – quality specialist, quality manager, or quality management committee • Inadequate communications – lab w clinical pharmacy, etc.
Implementation	• Regional legislation/regulations on GCLP? • Inefficient implementation of GCLP or GLP, internal and external auditing nation wide? • Lack of validation and verification • Inefficiency in managing the QA level • Gaps in the management of regulations, eg. Lack of IQA, EQA
Training	• Requirement of qualified asessors and providing a uniform training for the assessors – extent and content of the training, frequency of the training are diverse – ISO 10011, ILAC G3 or EAL G7 • Inadequate organizational or institutional asessments and surveillance, differs from country to country
Resources	• Inadequate investment • Maintaining a high level of quality in a clinical laboratory is expensive. Accreditation fees, proficieny testing, quality control, internal auditing, sentinel event investigations, collecting quality metrics, and implementing QI initiatives all cost money. • ISO 15189 accreditation is voluntary and can be costly for some of the countries.
Discipline	• Lack of a culture of quality and compliance – Quality as a department vs as a responsibility • Demotivating environment
Top Management Support	• Sporadic and inconsistent implementations • Attitude/motivation • Management Education • Time management

Other Challenges

- **Serious geopolitical tensions** will remain, and exacerbated by a number of ongoing intraregional diplomatic rifts and their spillover effects. Such factors will further amplify **persistent challenges in fragile economies, including by worsening refugee crises, conflicts, and political instability; harming investor confidence; slowing private sector development; and clouding growth prospects.**

- However, despite mixed performances in the external environment and the challenges facing the Arab region, **a gradual improvement in the region's economic outlook is anticipated**: gross domestic product (GDP) growth is forecast at 2.9 percent for 2018 and at 3.1 percent for 2019. Such projections reflect a series of policy reforms, fiscal adjustments and improvements in the life sciences, along with an expected reduction in geopolitical tensions in the future.

- Notwithstanding the daunting challenges ahead for policymakers in the Arab region, most countries are now implementing their own ambitious national development strategies. The regional outlook, therefore, hinges upon their capacity in **minimizing those uncertainties while maximizing their transformative potential in view of the recent infrastructure development initiatives**.

https://www.unescwa.org/sites/www.unescwa.org/files/publications/files/perspectives-digital-economy-arab-region-english_0.pdf
https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/WESP2018_Full_Web-1.pdf
https://www.iom.int/sites/default/files/about-iom/publications_en.pdf
http://www.oecd.org/eco/outlook/economic-outlook/

Useful Links and Further Readings

- https://www.oecd-ilibrary.org/docserver/5jz18gs5fckf-en.pdf?expires=1530257621&id=id&accname=guest&checksum=D1A456E8005177FCB603FD78D6C8A450
- https://www.unescwa.org/sites/www.unescwa.org/files/publications/files/perspectives-digital-economy-arab-region-english_0.pdf
- https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/WESP2018_Full_Web-1.pdf
- https://www.iom.int/sites/default/files/about-iom/publications_en.pdf
- http://www.oecd.org/eco/outlook/economic-outlook/
- https://www.oecd-ilibrary.org/economics/oecd-economic-policy-papers_2226583x

The Fourth Industrial Revolution: How the Mediterranian Nations respond?

https://www.weforum.org/agenda/2016/01/the-fourth-industrial-revolution-what-it-means-and-how-to-respond

The world will always need human brilliance, human ingenuity and human skills.

Brad Keywell
Co-founder and CEO, Uptake

WORLD ECONOMIC FORUM

Thank you


Merci
ХВала Ти
Ви благодарам
Hvala
Grazie
Hvala ti
Grazzi
Faleminderit
Gracias
Teşekkürler
Ευχαριστώ
תודה
شكرا لكم