

**CROATIAN CENTRE FOR QUALITY ASSESSMENT
IN LABORATORY MEDICINE**

Specifics and challenges of EQA in Croatia

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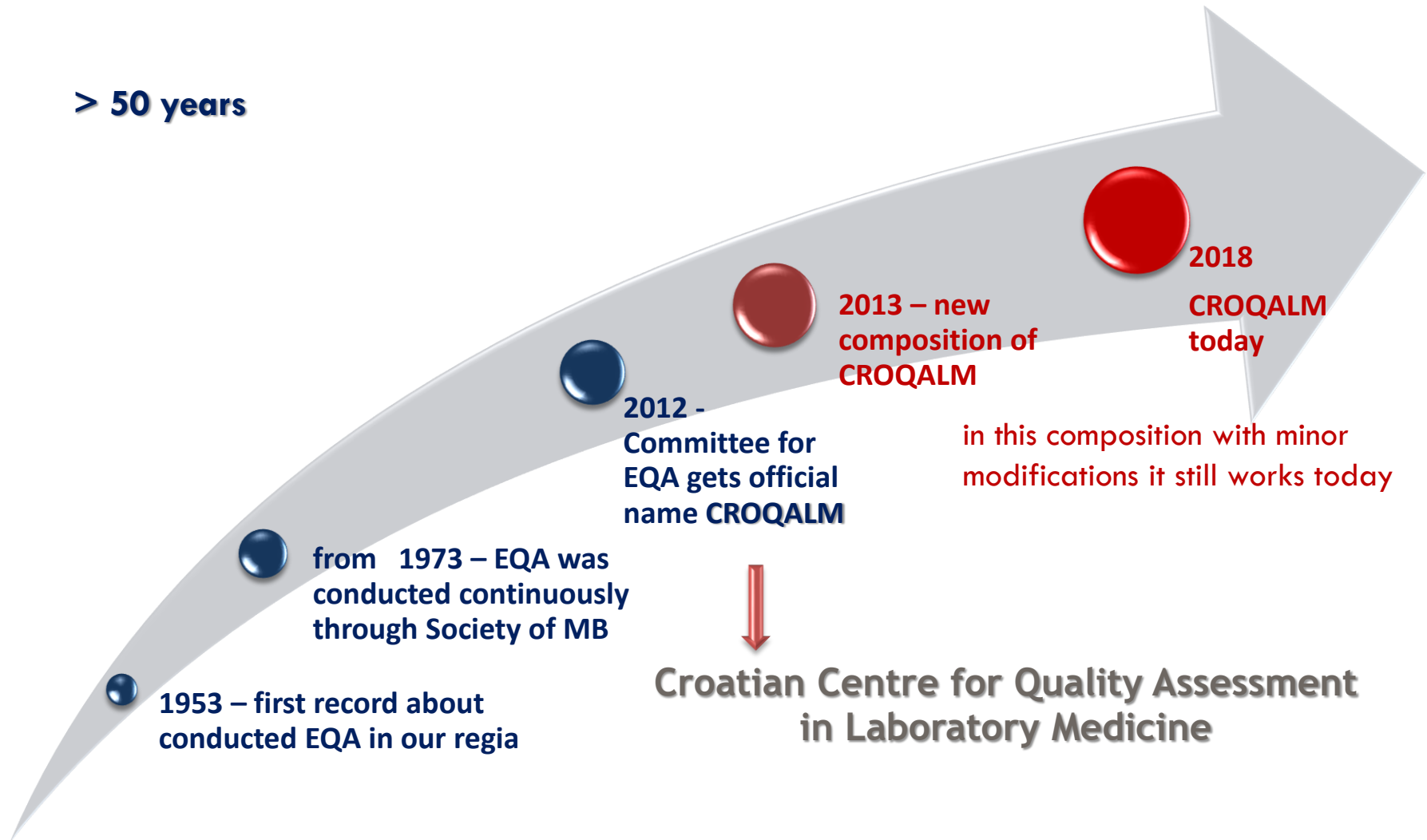
Presentation content

□ Overview:

- Why are we specific (different?)
- What are our major problems (challenges)
- Which activities of CROQALM Team are to be solved main problems in organizing and conducting EQA
- What are the benefits of national EQA (CROQALM)

Timeline of EQA in Croatia

> 50 years



Why are we specific?

HDMBLM

CCMB

- ✓ (2005) issued document: **Harmonization of laboratory test reports for general, special and high-differentiated medical biochemistry tests – application is mandatory** for all ML (refers to recommended methods, units, reference intervals)
ADVANTAGE
- ✓ According decision of CCMB (2013), **Croqalm EQAS is obligatory for all MLs in Croatia** (for each test that ML works and test is part of the CROQALM scheme). **ADVANTAGE/ DISADVANTAGE**
- ✓ (2012) issued document: **Requests for CROQALM**

ML

Number of registration ML in Croatia vary from 194 to 204

DISADVANTAGE

A large number of different analysers/
reagents

DISADVANTAGE

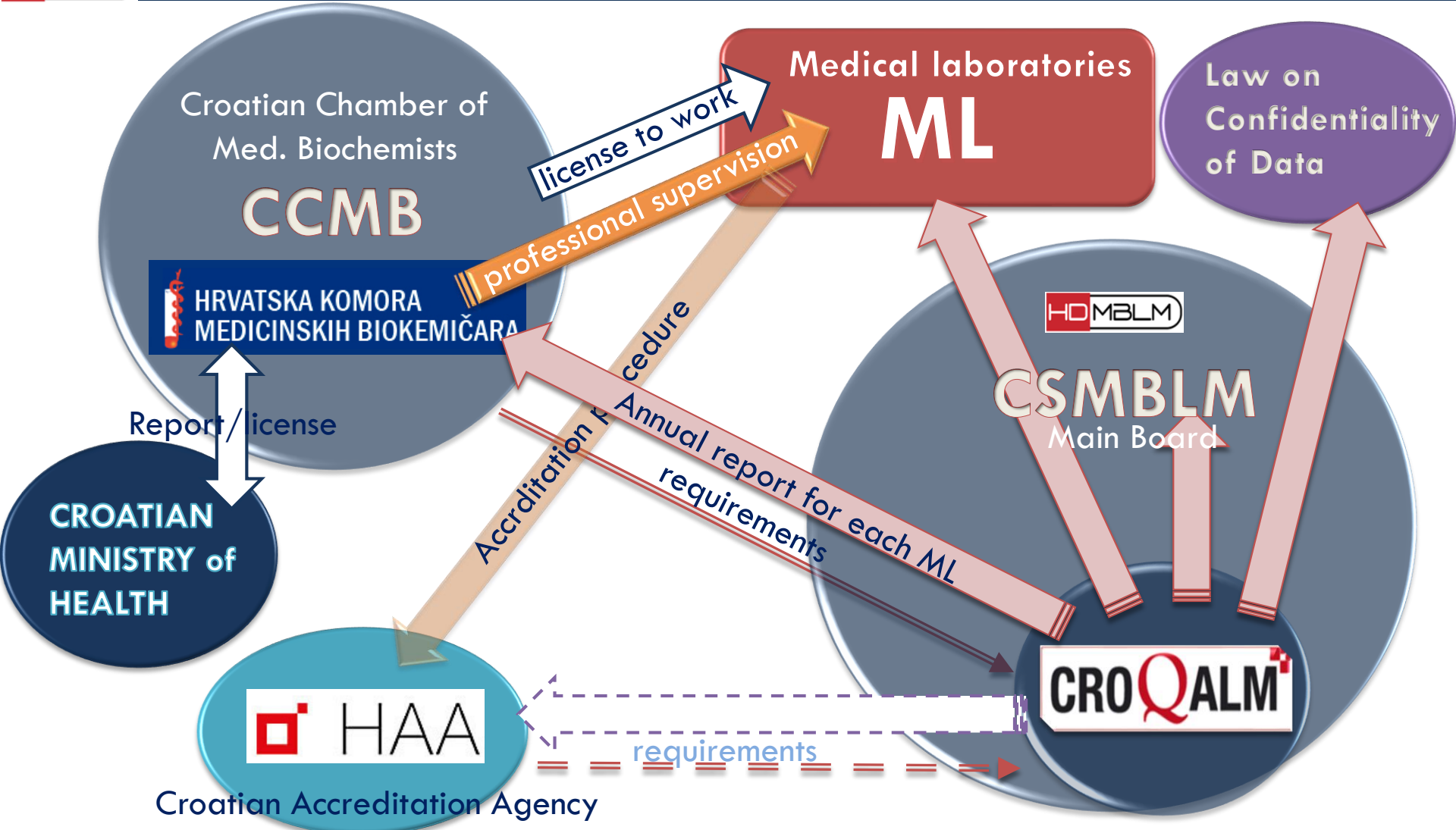
→ **resulting in**

- ✓ difficult choice of optimal (commutable) sample for a wide variety of analysers and reagents
- ✓ Small and numerous peer groups that can be statistically evaluated

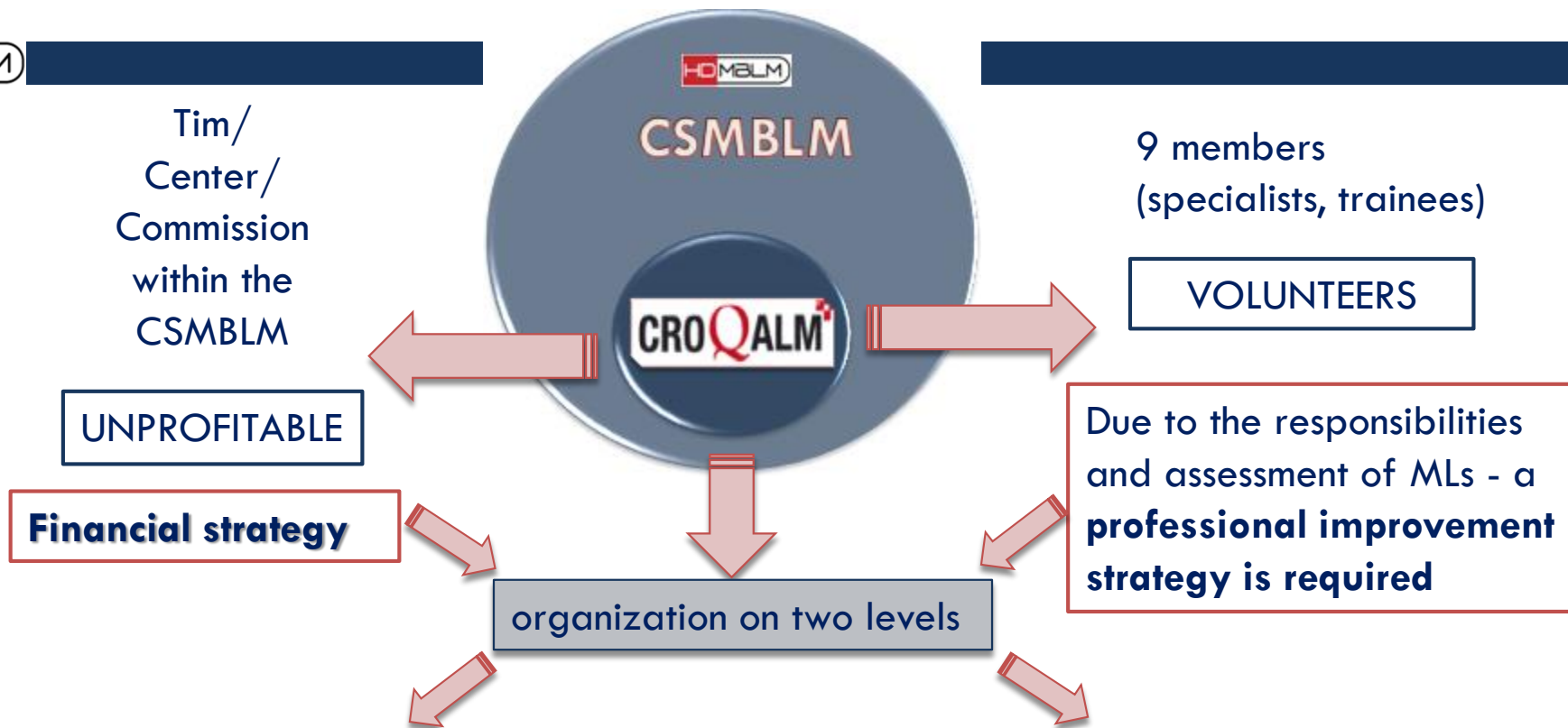
→ **our challenges**

Who is responsible to whom...

HD MBLM



How are we organized?



According modules (11 modules):

10 analytical modules (schemes)
and 1 for extra-analytical phase

Coordinators for modules

According to the working groups for :

- Making and work on web site
- Improving the quality of the sample
- improving the program for data evaluation
- Education

Where are we now?

External quality assessment (EQA) scheme in Croatia

- 10 analytical modules with different number and type of analytes per module
- The control samples distributed three times per year, depending on the participants' application and the module schedule

Module	Name of the module	No of round per year	Type of control sample	Number of participants (in 2018)
I	Biochemistry parameters	3	liquid frozen control sample (pool, WEQAS)	180
II	Specific proteins, CRP	3	Commercial human based control sample (lyophilized or liquid)	168
III	Laboratory haematology	3	Stabilized whole blood from blood donor	183
IV	Laboratory coagulation	3	Commercial control sample (lyophilized plasma sample)	164
V	Drugs	1	Commercial control sample (lyophilized)	17
VI	Urinalysis: urine test strip, sediment	3	Commercial human based sample (liquid)	178
VII	Analysis of pH, blood gases, electrolytes, glucose and lactate	3	Commercial control sample (liquid)	70
VIII	Hormones, vitamins, tumor and cardiac markers	2	Commercial human based control sample (lyophilized)	94
IX	Glycosylated hemoglobin A1c (HbA1c)	3	Commercial human based control sample (lyophilized)	151
X	Extra-analytical phase of laboratory testing	3	Questionnaire design: 1st and 2nd phase: Distributed samples (simulating errors)	168
XI	Sweat chloride test	3	Liquid control sample (home-made)	8

Education

Two levels:

Education of CROQALM members

- CROQALM workshop (2015; CSMBLM)
- DEKS (Danish Institute of External Quality Assurance for Laboratories in Health Care) education
- Active participation in EQALM (workgroups of EQALM, posters presentations)



- **Croatia - host country for EQALM Symposium 2018**

Education of participants (ML)

- Lectures/Seminar in regional centers
- E-seminar CSMBLM (sweat test)
- Poster presentations at national and international professional meetings (Sarajevo 2015, Dubrovnik Course 2015 EQALM 2015, 2016, Locus 2016)
- Publishing results (BM, CCLM)
- Organizing the Symposium: „National EQA: From sample to judgment”

bilingual (English/Croatian) web site

<http://croqalm.hdmblm.hr>

CROQALM

CROATIAN CENTRE FOR QUALITY ASSESSMENT
IN LABORATORY MEDICINE



HOME



ABOUT US



INSTRUCTIONS
FORMS



CALENDAR OF
EVENTS



MODULES
TESTS



RESULTS ENTRY



CONTACT



NOTIFICATION

Application for participation and results entry/evaluation

HDMBLM

is done through a web
interface



CROQALM

CROATIAN CENTRE FOR QUALITY ASSESSMENT
IN LABORATORY MEDICINE

- using inlab2*QALM software (IN2 Group Ltd., Zagreb, Croatia) as a program for the evaluation of quality in laboratory medicine



HOME



ABOUT US

INSTRUCTIONS
FORMSCALENDAR OF
EVENTSMODULES
TESTS

RESULTS ENTRY



CONTACT



NOTIFICATION N

Statistical evaluation of quantitative results

- at the end of each exercise
- for each peer group with five or more participants
- after outlier removal (Tukey), mean, standard deviation and coefficient of variation is calculated for each peer group.

- the data are further evaluated according to:
 - ▣ predefined allowable limits of performance
 - ▣ z-scores with graphical presentation

Analytical performance specifications

- In 2017 CROQALM defined analytical performance specifications according to:

Model 1: *Based on the effect of analytical performance on clinical outcomes*

- *Direct outcome studies*
- *Indirect outcome studies*

Model 2: *Based on components of biological variation*

Model 3: *Based on state-of-the-art*

(only where BV isn't possible)

- **absolute allowable deviation** from target value at low concentrations

Reports

(at the end of every exercises)



Each laboratory receives:

- ❑ Statistical analysis for every analyte
- ❑ Summary Report
- ❑ Scheme coordinator comments

HDMBLM Hrvatsko društvo za medicinsku biokemiju i laboratorijsku medicinu
Croatian society of medical biochemistry and laboratory medicine

CROQALM Hrvatski centar za vrednovanje kvalitete u laboratorijskoj medicini
Croatian Centre for Quality Assessment in Laboratory Medicine

Boškovićeva 18, 10000 Zagreb • Croatia • Tel/Phone & Fax: +385 1 48 28 133
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Stranica 01 / 5 / 20

MODUL: MODUL 1A - BIOKEMJSKE PRETRAGE

Pretraga	Rezultat	Mjera
GLUKOZA	4.5	mmol/L, Fotom Archit
UKUPNI BILIRUBIN	20	µmol/L, Fotom Archit
KREATININ	236	µmol/L, Nektar metod
UREJA	5.8	mmol/L, Fotom gluta
URATI	285	µmol/L, Fotom gluta
NATRIJ	148	mmol/L, Indira
KALIJ	4	mmol/L, Indira
UKUPNI KALCIJ	2.35	mmol/L, Fotom gluta
ANORGANSKI FOSFAT	1.2	mmol/L, Fotom gluta
KLORIDI	103	mmol/L, Indira
ŽELJEZO	38	µmol/L, Fotom gluta
KOLESTEROL	0.7	mmol/L, Fotom CHOC
TRIGLICERIDI	2	mmol/L, Fotom GPO
HDLKOLESTEROL	1.7	mmol/L, Homo Archit

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Stranica 01 / 2 / 20

ZBIRNO IZVJEŠĆE O REZULTATIMA VANJSKE PROCJENE KVALITETE

MODUL:	MODUL 1A - BIOKEMJSKE PRETRAGE	
Ukupan broj rezultata u modulu za laboratorij:		27
Broj prihvatljivih rezultata prema ciljnim vrijednostima bez obzira na metodu:		24
Postotak prihvatljivih rezultata prema ciljnim vrijednostima bez obzira na metodu:		89
Broj prihvatljivih rezultata prema ciljnim vrijednostima prema metodi:		25
Postotak prihvatljivih rezultata prema ciljnim vrijednostima prema metodi:		93
MODUL: MODUL 2 - SPECIFIČNI PROTEINI		
Ukupan broj rezultata u modulu za laboratorij:		9
Broj prihvatljivih rezultata prema ciljnim vrijednostima bez obzira na metodu:		9
Postotak prihvatljivih rezultata prema ciljnim vrijednostima bez obzira na metodu:		100
Broj prihvatljivih rezultata prema ciljnim vrijednostima prema metodi:		9
Postotak prihvatljivih rezultata prema ciljnim vrijednostima prema metodi:		100
UKUPNO:		
Ukupan broj rezultata u svim modulima za laboratorij:		97
Broj prihvatljivih rezultata prema ciljnim vrijednostima bez obzira na metodu:		86
Postotak prihvatljivih rezultata prema ciljnim vrijednostima bez obzira na metodu:		89
Broj prihvatljivih rezultata prema ciljnim vrijednostima prema metodi:		80
Postotak prihvatljivih rezultata prema ciljnim vrijednostima prema metodi:		94

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Stranica 01 / 2 / 8

REAGENS: Siemens
INSTRUMENT: Sysmex CS-2000
JEDINICA MJERE: 1

PROTROMBINSKO VRIJEME-ujaci (PV-ujaci)

Statistička obrada rezultata

Metoda	N	X	SD	KV (%)	Valj rezultat
Izvanje na metodu	125	0.18	0.014	7.93	
iBehring, Thrombost S	71	0.18	0.014	7.93	
iBehring, Innovin	57	0.18	0.008	4.40	0.18
smpbplasin 20	5	0.16	0.011	6.90	
sial, Thromboplastin-Si	8	0.17	0.020	11.80	
eplasin Plus	1	0.20			
sline Cj Plus	8	0.17	0.012	7.10	
smpbplasin	1	0.16			
smpbplasin R	10	0.18	0.009	5.00	
sialsin	3	0.20			
sial INR	1	0.16			

Pregled odstupanja prema z vrijednosti (z score)

Metoda	N	X	SD	X-2SD	X+2SD	Rezultat	z
Izvanje na metodu	125	0.18	0.009	0.16	0.20	0.18	0.00

Pregled prema dozvoljenim odstupanjima (ciljnim vrijednostima)

Metoda	N	X	Doz(A)	X-Doz	X+Doz	Rezultat
Izvanje na metodu	57	0.18	15 (0.03 do 0.5)	0.150	0.210	0.18 +

Doz(A) = % dozvoljenog odstupanja za (X-SD) (z vrijednost: z-score)
Doz = dozvoljeno odstupanje
KV = koeficijent varijacije
A = specifično odstupanje
B = broj laboratorija sudionika
U = pojedinačna mjerna nesigurnost (k=2)
Doz (%) = (Doz/DozRef)*100
Program vanjske procjene kvalitete mreže MBL
InizQALM-STATISTIČKA OBRADA



MODUL: MODUL 1A - BIOKEMJSKE PRETRAGE

ANALIZA REZULTATA

Broj uzebesnika: 184

MODUL 1A
Uzorak: Ioflizirani komercijalni kontrolni uzorak seruma humanog porijekla
MODUL 1B
Uzorak: svježi serum dobrovoljnog davatelja
MODUL 1C
Uzorak: sjepljeni serum dobrovoljnog davatelja

ANALIZA REZULTATA

Uzorci korišteni u ovom ciklusu planirani su na način da se za obradu rezultata i komercijalni kontrolni uzorak seruma (uzorak 1A), dok se uzorci 1B i 1C koriste odgovarajućim ogleđnim grupama.

Kontrolni komercijalni materijal pokazuje dobru komutabilnost (zamjenjivost) za većinu pretraga, s iznimkom kreatinina i alkaline

Annual Report

For:

- Participants (Certificate of participation with an indication of the scheme in which they participated)
- CCMB (report of acceptable results per exercise for each ML – used in professional supervision)

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POTVRDA
za sudjelovanje
u programu vanjske procjene kvalitete u 2014.

KLINIKA ZA DJEČJE BOLESTI
Biokemijsko-hematološki laboratorij
Dr.sc. Vesna Žižić, spec. med. biokem.

Klaičeva
10000 ZAGREB

MODULI:
MODUL 1 - BIOKEMIJSKE PRETRAGE
MODUL 2 - SPECIFIČNI PROTEINI
MODUL 3 - LABORATORIJSKA HEMATOLOGIJA
MODUL 4 - LABORATORIJSKA KOAGULACIJA
MODUL 5 - D-DIMERI I SRČANI BILJEZI
MODUL 6 - ANALIZA MOKRAĆE
MODUL 7A - POCT
MODUL 8 - HORMONI, LIJEKOVI, VITAMINI I TUMORSKI BILJEZI
MODUL 10 - PREDANALITIČKA FAZA LABORATORIJSKOG RADA
MODUL 11 - POSTANALITIČKA FAZA LABORATORIJSKOG RADA

Za CROQALM:
Dr.sc. Jasna Leniček Križić, spec.med.biokemije

Jasna Leniček Križić

What are benefits of our national EQA ?

or why to maintain and improve a small, national EQAS when there are available well-established international EQA providers?

Because:

1. Adapted to our system of professional legality
2. Have an acceptable price for our conditions

This is sustainable because:

- members are volunteers
- each participant (ML) also participates as a professional responsible person

CROQALM members...

HD MBLM

all members are:

EuSpLM and work in ML
(Hospital or Private ML)
and are
volunteers for
CROQALM and
CSMBLM)



THANK YOU!

HDMBLM



Have a
useful and
nice time
in Zagreb