Klinički značaj preanalitike u laboratorijskoj dijagnostici

Zorica Šumarac

"Prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone."

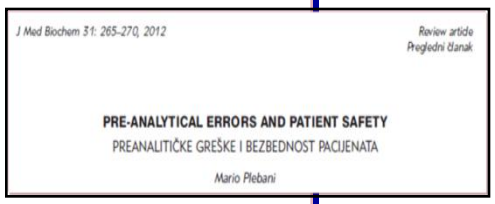
Hippocratic Oath, 4 th Century B.C

Primum non nocere ("first do not harm")

Greek physician treating a patient, ca. 480-470 BC (Louvre Museum, Paris, France)

70%-80% svih medicinskih dijagnoza postavlja se na osnovu laboratorijskih rezultata

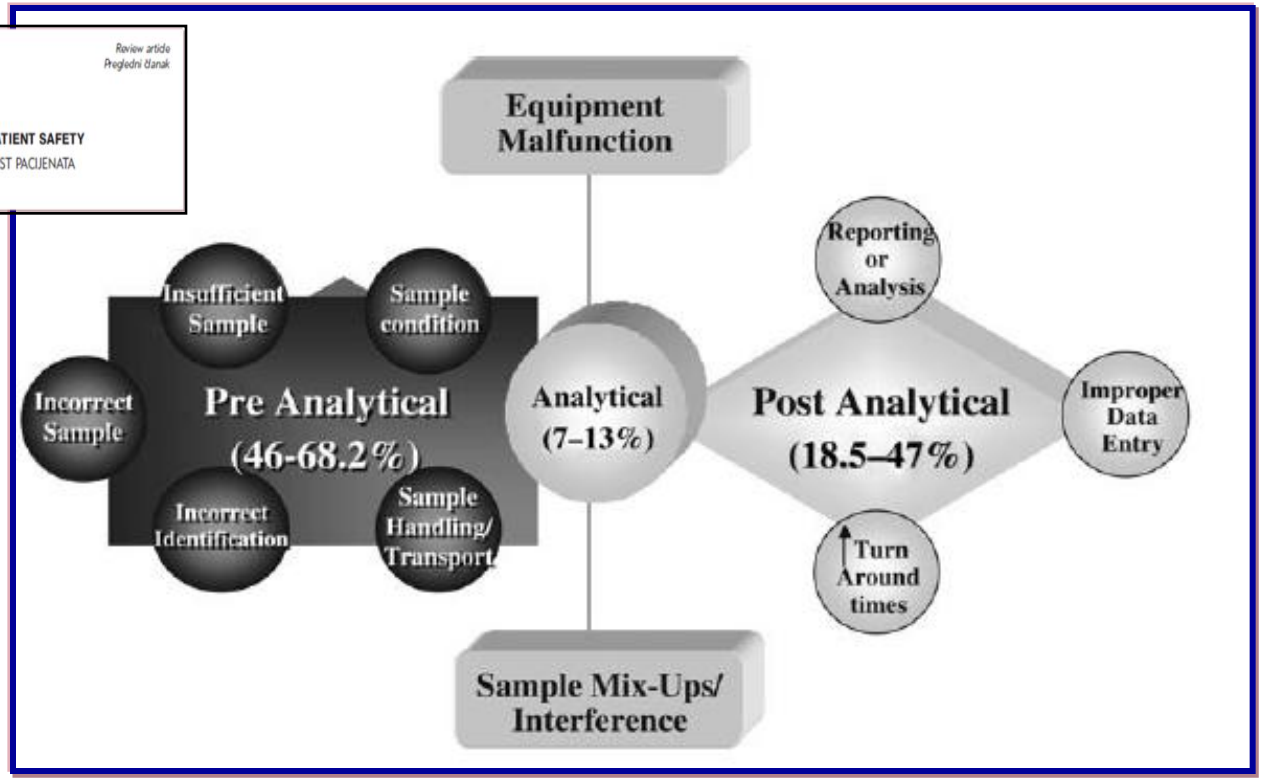
Maurice O'Kane. The reporting, classification and grading of quality failure in the medical laboratory. Clinica Chimica Acta 404 (2009) 28–31.


J Med Biochem 31: 265–270, 2012 Review article
Pregledni članak

PRE-ANALYTICAL ERRORS AND PATIENT SAFETY

PREANALITIČKE GREŠKE I BEZBEDNOST PACIJENATA

Mario Plebani



Mario Plebani. Errors in clinical laboratories or errorrs in laboratory medicine. Clin Chem Lab Med 2006;44(6):750-9.

Preanalytical variability: the dark side of the moon in laboratory testing

Preanalytical quality control program – an overview of results (2001–2005 summary)

Preanalytical conditions that affect coagulation testing, including hormonal status and therapy

Indikatori kvalitete

Preanalytical Variables in the Coagulation Laboratory

Governance of preanalytical variability: Travelling the right path to the bright side of the moon?

Preanalytical Issues in Hematology

Causes, consequences, detection, and prevention of identification errors in laboratory diagnostics

Risk management in the preanalytical phase of laboratory testing

Preanalytical errors in primary healthcare: a questionnaire study of information search procedures, test request management and test tube labelling

The beginning of the second decade of the era of patient safety: Implications and roles for the clinical laboratory and laboratory professionals

Lee H. Hilborne [a,b,c,*], Ira M. Lubin [d], Maren T. Scheuner [b]

The IFCC Working Group on laboratory errors and patient safety

...rio Plebani [a,b]

Analytical interferences and analytica...

Oswald Sonntag *

...diagnostics. It's time to think outside the box

Preanalytic

~ 370 000 radova

National survey on the pre-analytical ... a representative cohort of Italian labo...

...ka izvananalitičke faze laboratorijske dijagnostike ...u Hrvatskoj - presječno anketno istraživanje

Development and implementation of an automatic system for verification, validation and delivery of laboratory test results

Pre-analytical workstations: A tool for reducing laboratory errors

The Preanalytic Phase

An Important Component of Laboratory Medicine

Recommendations for detection and management of unsuitable samples in clinical laboratories

Pre-analytical variation of some haematological quantities

Quality indicators and specifications for the extra-analytical phases in clinical laboratory management

Towards quality specifications in extra-analytical phases of laboratory activity

Towards quality specifications in extra-analytical phases of laboratory activity

"Pre-pre" and "post-post" analytical error: high-incidence patient safety hazards involving the clinical laboratory

Preanalytical venous blood sampling practices demand improvement — A survey of test-request management, test-tube labelling and information search procedures ☆

Review

The Haemolytic, Icteric and Lipemic Sample
Recommendations Regarding their Recognition and Prevention of Clinically Relevant Interferences

Recommendations of the Working Group on Preanalytical Variables of the German Society for Clinical Chemistry and the German Society for Laboratory Medicine

Quality Assurance in the Preanalytical Phase

Physician's brain

Patient Community

Care Provider

Results Interpretation

Clinical Question

Care Provider

Pre-Analytic

Results Reporting

Post-Analytic

Test Selection

Report Review

Test Ordering

Analysis

Analytic

Patient/ Specimen Identification

Specimen Preparation

Patient's brain

Specimen Collection

Specimen Processing

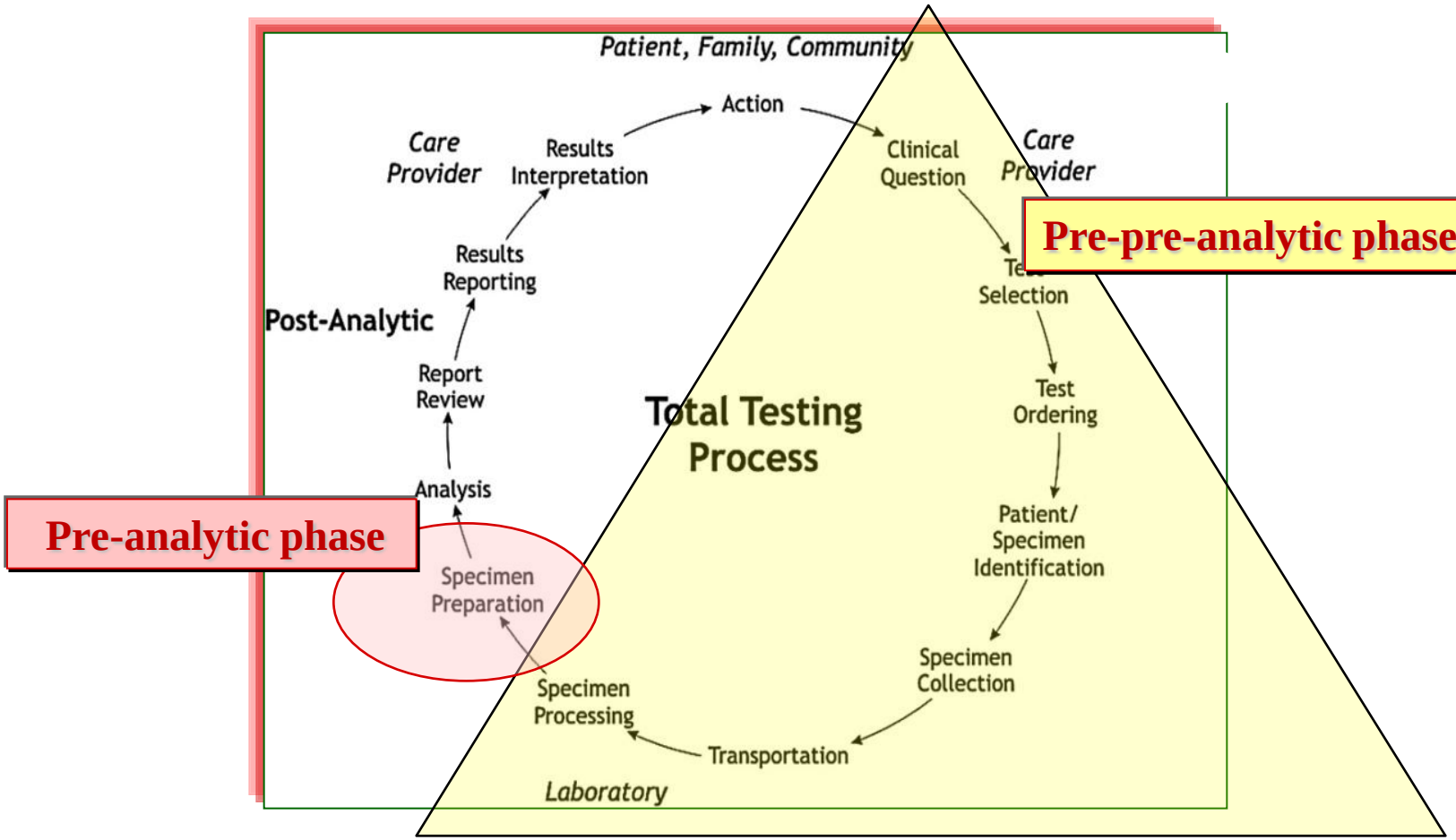
Transportation

Laboratory

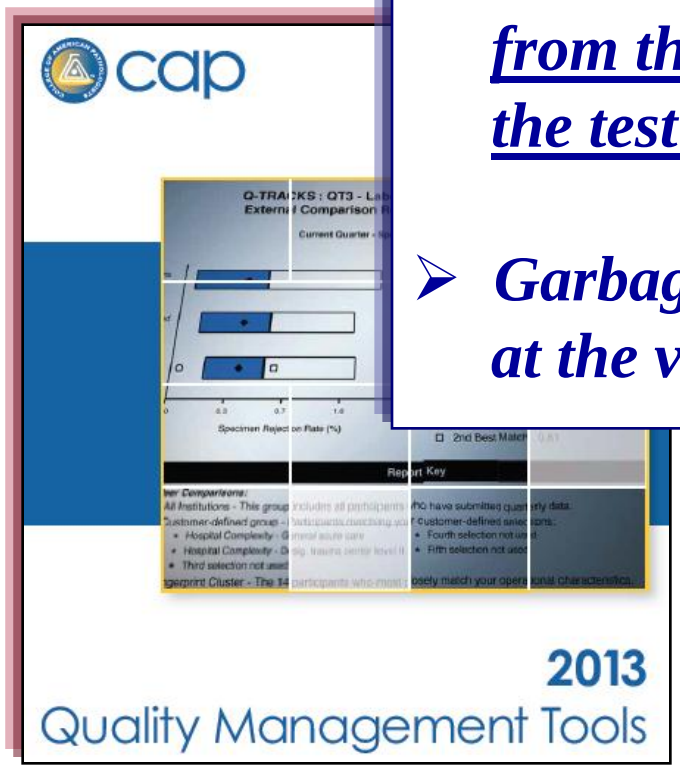
Laboratorian's brain

Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 2010;47:101-10.

"pre-pre-analytical phase"- including test requesting, patient and sample identification, blood collection and sample handling and transportation".



Where the story begins....



- ***Pre-analytical = factors affecting patient testing <u>from the time of the physician ordering the test to the test performance</u>.***
- ***Garbage in, garbage out – quality testing starts at the very beginning.***

PRE-PREANALITIČKA FAZA

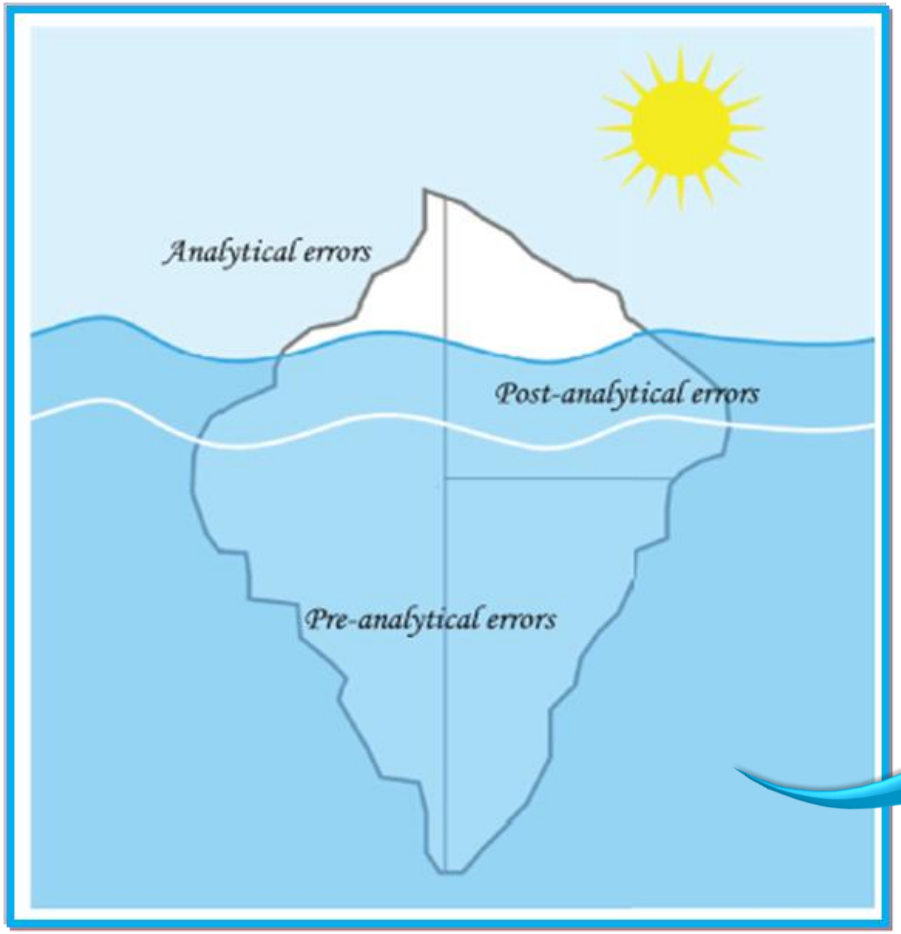
- klinička odluka lekara o izboru odgovarajućih analiza (izgled uputa)
- komunikacija sa pacijentima
- informisanost i priprema pacijenata za ispitivanja
- unošenje podataka u LIS/protokol
- identifikaciju pacijenata i uzoraka
- uzorkovanje biološkog materijala
- transport, čuvanje uzoraka, stabilnost

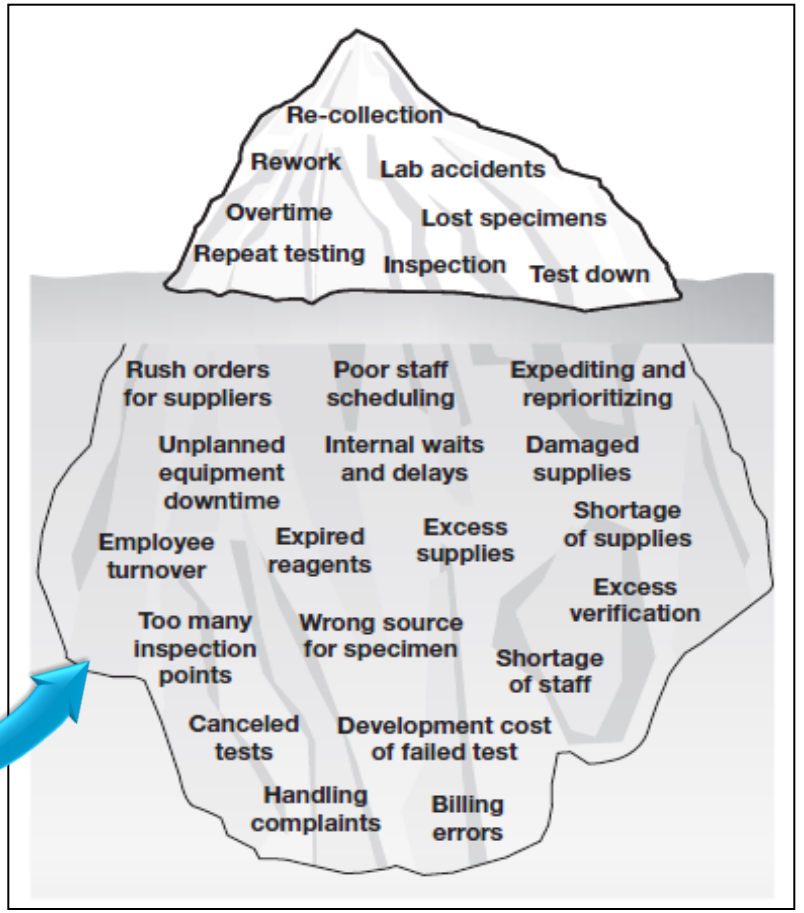
PREANALITIČKA FAZA

- rukovanje uzorcima (centrifugiranje)
- alikvotiranje, sortiranje
- upravljanje interferencijama
- upravljanje neprihvatljivim uzorcima

- praćenje kvaliteta rada
- dokumentacija
- praćenje incidenata,
- zadovoljstva korisnika

LABORATORIJSKE GREŠKE I BEZBEDNOST PACIJENTA





Exploring the iceberg of errors in laboratory medicine

M. Plebani / Clinica Chimica Acta 404 (2009) 16–23

Errors in laboratory medicine (review)

	Lapworth 1994	Goldschmidt 1995	Nutting 1996	Plebani 1997	Stahl 1998	Hofgartner 1999	
						Molecular genetic On site survey (2 labs)	Molecular genetic Questionnaire
Sector of the laboratory	Clinical Chemistry	Whole lab	Primary care	Stat lab	Whole Lab		
Data collection period	1 year	6 years	6 months	3 months	3 years	10 years	1 year
Numbers of tests	~997000	ND	ND	40490	676564	4234	88394
Numbers of patients	~249000	ND	160.714	ND	ND	ND	ND
N° of errors Frequency (%)	120 0.05% of patients	133	180 0,11% of patients	189 0.47% of test results	4135 0.61% of test results	16 0.38%of test results	293 0.33% of test results
- pre-analytical phase	31.6%	53%	55.6%	68.2%	75%*	44%	60%
- analytical phase	31.6%	23%	13.3%	13.3%	16%*	31%	19%
- post-analytical phase	30.8%	24%	30%	18.5%	9%*	12.5%	15%
- multiple phases	6%					12.5%	6%
Identification errors	41 (34%)	77 (58%)	ND	5 (2,6%)	ND	ND	ND
Impact on patients' outcome	ND						
-none		43%		74%			63.4%
-mild		23%	13%	19.6%		25%	20%
-moderate		26%	13%	6.4%		50%	10.2%
-severe		8%				25%	6.4%
-very severe		none					

Bonini PA et al;. Errors in Laboratory Medicine; Clin Chem; 2002;48:691-8

Nestandardizovane procedure, bez unutrašnje i spoljašnje kontrole!

Povećan fokus na bezbednost pacijenta, favorizuje potrebu standardizacije i kontrolisanja preanalitičke faze laboratorijskog rada.

SRPSKI STANDARD

SRPS ISO 15189

Januar 2008.

Identičan sa ISO 15189:2007

Medicinske laboratorije — Posebni zahtevi za kvalitet i kompetentnost

Medical laboratories — Particular requirements for quality and competence

I izdanje

ISO 15189

obavezuje ali ne preporučuje metod.

Potreba za:

- **međunarodnom standardizacijom**
- **definisanjem indikatora kvaliteta**
- **metodama za prikupljanje podataka**
- **prikazivanja i analize**
- **omogućavanja medjulaboratorijskog poredjenja**
- **definisanja "*state of the art*"**
- **promovisanja transverzalnog poredjenja lab (*benchmarking*)**
- **uvodjenja spoljašnje kontrole rada (*EQA*)**

H1-A5
Vol. 23 No. 33
Replaces H1-A4
Vol. 16 No. 13

Tubes and Additives for Venous Blood Specimen Collection; Approved Standard —Fifth Edition

This document contains requirements for venous blood collection tubes and additives, including technical descriptions of ethylenediaminetetraacetic acid (EDTA), sodium citrate, and heparin compounds used in blood collection devices.

A standard for national application developed through the NCCLS consensus process.

H21-A4
Vol. 23 No. 35
Replaces H21-A3
Vol. 18 No. 20

Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition

Volume 24 Number 38

Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third Edition

H18-A3
ISBN 1-56238-555-0
ISSN 0273-3099

Roger R. Calam, Ph.D., DABCC
J. David Bessman, M.D.
Dennis J. Ernst, M.T.(ASCP)
Susan S. Smith
Diane I. Szamosi, M.A., M.T.(ASCP), SH
David J. Warunek, Ph.D., M.B.A.
Joan D. Wiseman, M.T.(ASCP), CT

CLINICAL AND LABORATORY STANDARDS INSTITUTE
(Formerly NCCLS)
Providing NCCLS standards and guidelines, ISO/TC 212 standards, and ISO/TC 76 standards

H3-A5
Vol. 23 No. 32
Replaces H3-A4
Vol. 18 No. 7

Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition

WORLD HEALTH ORGANIZATION

USE OF ANTICOAGULANTS IN DIAGNOSTIC LABORATORY INVESTIGATIONS

Stability of blood, plasma and serum samples

The WHO document "Use of Anticoagulants in Diagnostic Laboratory Investigations" (WHO/DIL/LAB/99.1 Rev. 1) received a surprising resonance and experts around the world provided many additional observations. This information has been included in the 2nd revision of the document. The document provides an extensive summary of observations on the effects of anticoagulants in blood, plasma and serum. Information on the effects of haemolysis, hyperbilirubinaemia and hyperlipoproteinaemia on measurement procedures has been added.

www.who.int/library/ WHO
www.clsi.org/

KOMUNIKACIJA

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Quality and Regulations
Education & Training
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Communications

RSS / Atom

EUROMEDLAB MILANO 2013 19-23 MAY

EFLM · Science

WG: Preanalytical Phase

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Pinar Eker (Turkey)
João Tiago Guimarães (PT)
Mercedes Ibarz (Spain)
Edmée van Dongen-Lases (NL)

Corporate members:
Stephen Church (GB)
Christa Seipelt (DE)

European Federation
of Clinical Chemistry and Laboratory Medicine

WG: Preanalytical Phase

Members

WG-Preanalytical Phase
Terms of reference

- To **promote the importance** of the of the preanalytical phase of laboratory medicine.
- To design **questionnaires** and conduct **surveys** to assess the current practices related to some pre-analytical variables.
- To define the **best practices** and provide **recommendations** for some critical activities in the preanalytical phase.
- Organize **symposia**, workshops, webinars or training courses on preanalytical phase issues.

Prvi sastanak WG-PRE, Zagreb, april 2012.

Submitted 6.17.11 | Revision Received 7.20.11 | Accepted 7.25.11

A Review of Medical Errors in Laboratory Diagnostics and Where We Are Today

Julie A. Hammerling, MSH, MS, MLS(ASCP)CM
(Division of Health Sciences, Florida Gulf Coast University, Fort Myers, FL)

DOI: 10.1309/LMGEF8WJR1IHGAUY

Giuseppe Lippi[a,*], Giuseppe Banfi, Stephen Church[a], Michael Cornes[a], Gabriella De Carli, Kjell Grankvist[a], Gunn B. Kristensen[a], Mercedes Ibarz[a], Mauro Panteghini, Mario Plebani, Mads Nybo[a], Stuart Smellie, Martina Zaninotto and Ana-Maria Simundic[a] on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine Working Group for Preanalytical Phase

Preanalytical quality improvement. In pursuit of harmony, on behalf of European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working group for Preanalytical Phase (WG-PRE)

Clin Chem Lab Med 2015; 53(3): 357–370

VENEPUNKCIJA

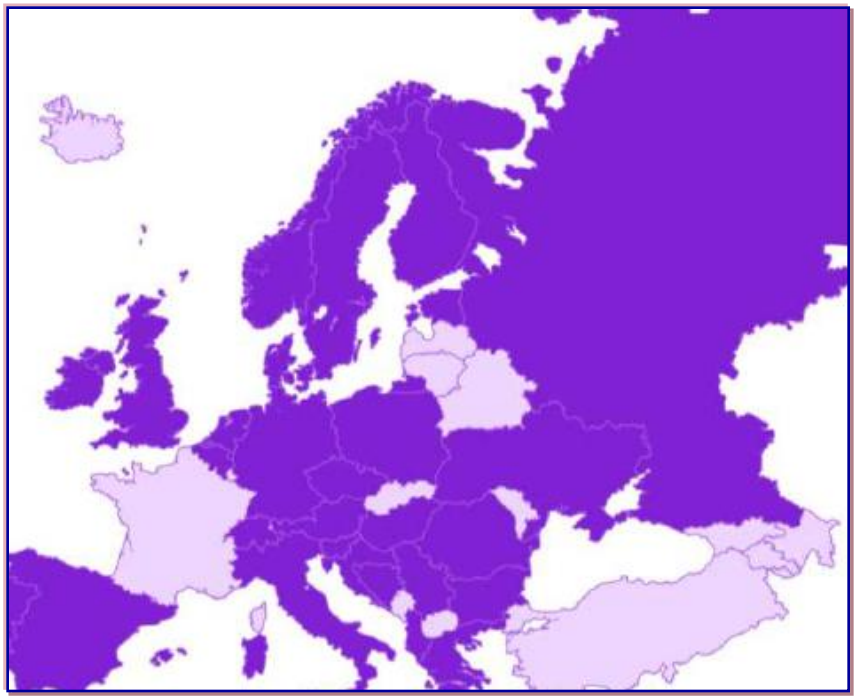
- **KO OBAVLJA VENEPUNKCIJU ???**
- **EDUKACIJA**

EFLM WG-PRE
I projekat

DE GRUYTER DOI 10.1515/cclm-2013-0283 — Clin Chem Lab Med 2013; 51(8): 1585–1593

Ana-Maria Simundic*, Michael Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Svjetlana Kovalevskaya, Ludek Sprongl, Zorica Sumarac and Stephen Church

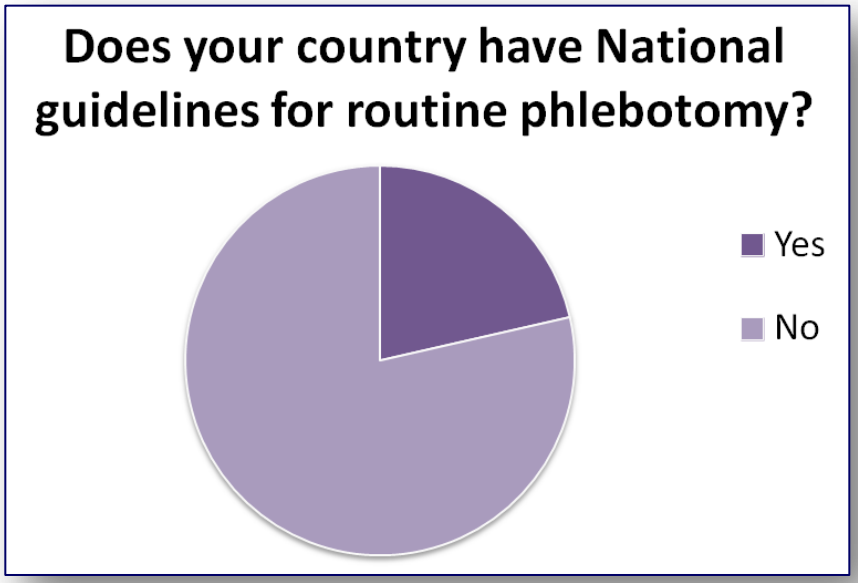
Survey of national guidelines, education and training on phlebotomy in 28 European countries: an original report by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PA)

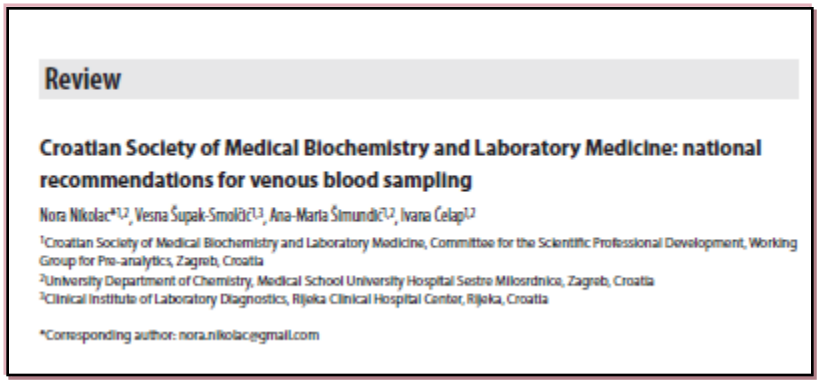


- April-Avgust 2012
- 28/39 (72%) zemalja članica EFLM učestvovalo
- Upinik-20 pitanja

Cilj ?

- ✓ Kako se uzorkovanje krvi sprovodi u zemljama EFLM?
- ✓ Ko obavlja uzorkovanje krvi ?
- ✓ Nivo obrazovanja i edukacije osoba koje uzorkuju krv?
- ✓ Da li postoje nacionalne smernice za uzorkovanje krvi i kakva je njihova usklađenost?




Review

Croatian Society of Medical Biochemistry and Laboratory Medicine: national recommendations for venous blood sampling

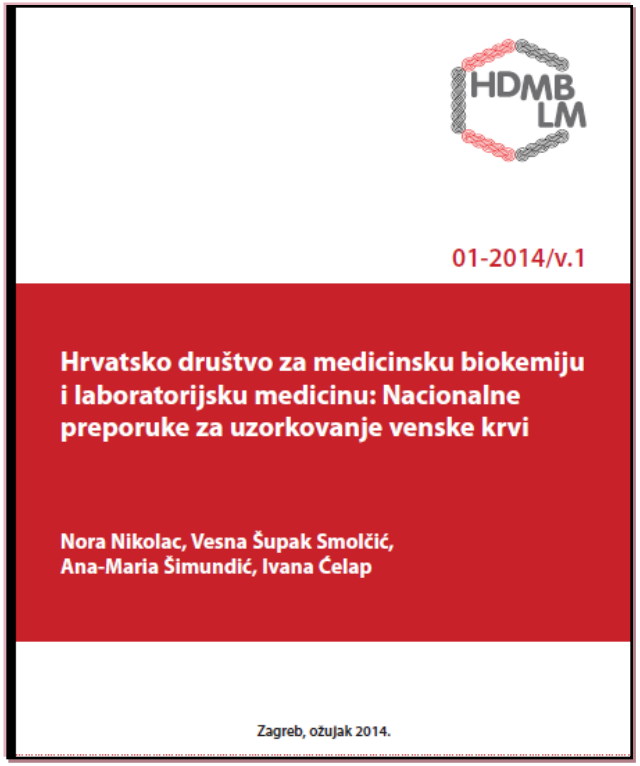
Nora Nikolac*[1,2], Vesna Šupak-Smolčić[1,3], Ana-Maria Šimundić[1,2], Ivana Čelap[1,2]

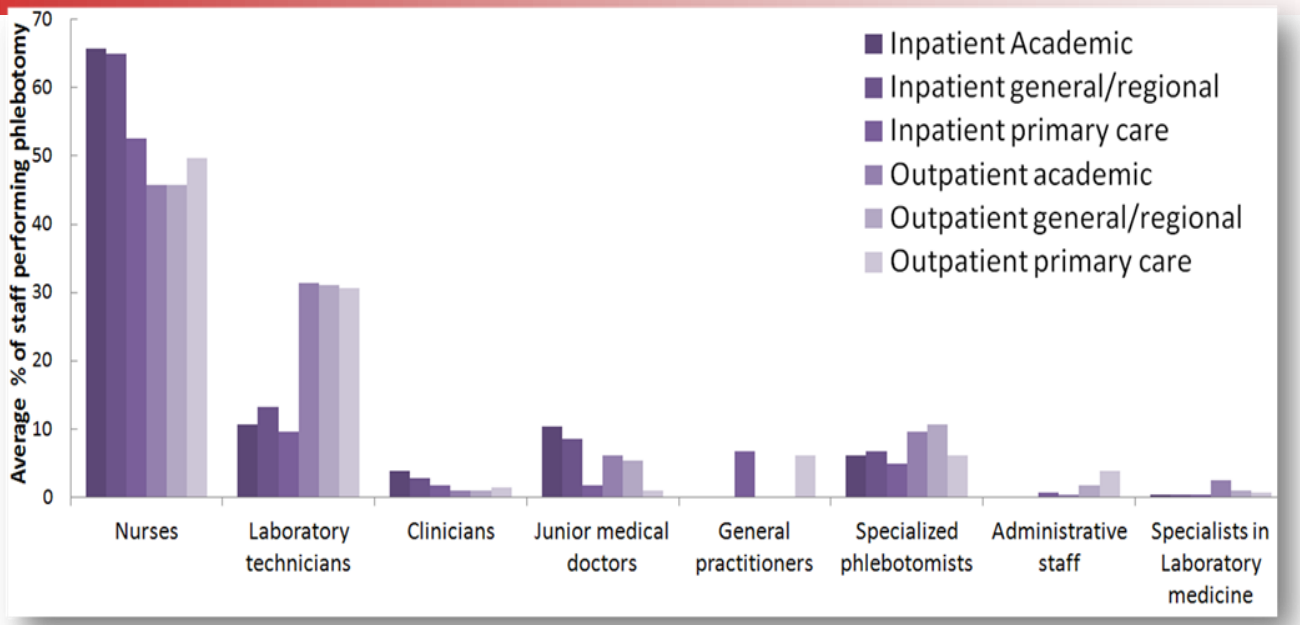
[1]Croatian Society of Medical Biochemistry and Laboratory Medicine, Committee for the Scientific Professional Development, Working Group for Pre-analytics, Zagreb, Croatia
[2]University Department of Chemistry, Medical School University Hospital Sestre Milosrdnice, Zagreb, Croatia
[3]Clinical Institute of Laboratory Diagnostics, Rijeka Clinical Hospital Center, Rijeka, Croatia

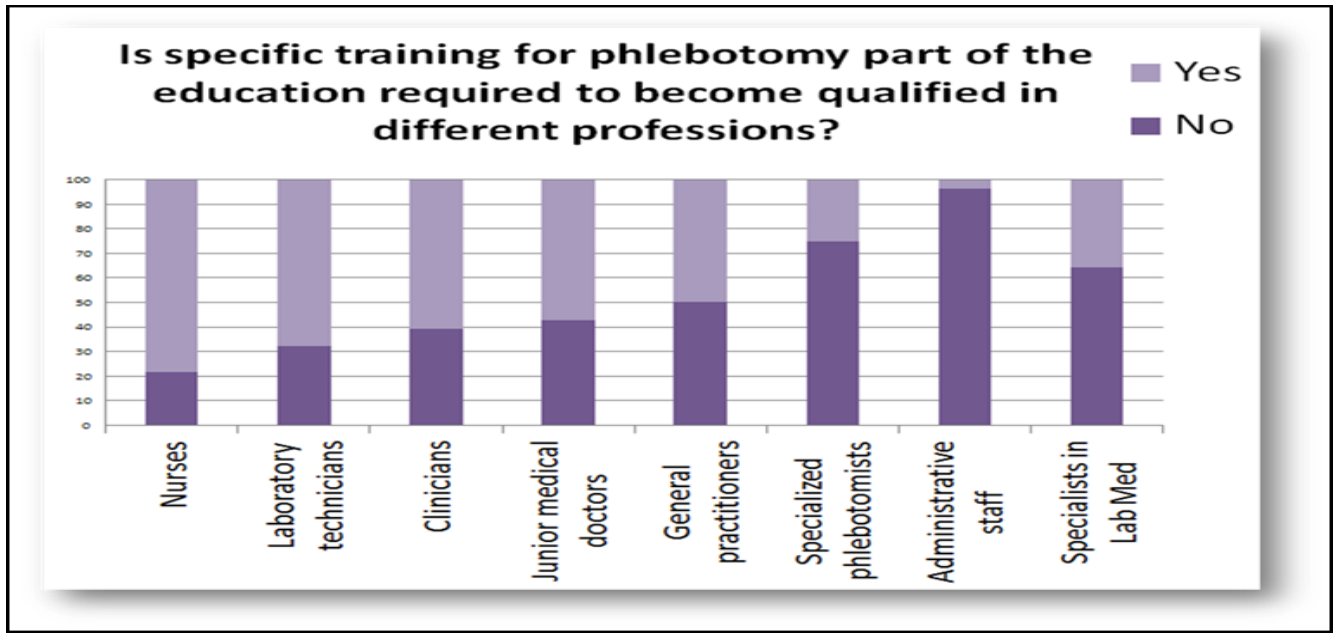
*Corresponding author: nora.nikolac@gmail.com

- **7/28 zemalja (25%) ima nacionalne smernice:**

  Irska, UK, Španija, Slovenija, Švedska, Italija i Hrvatska
- **24% koristi CLSI H3-A6**
- **75% vrlo zainteresovano za EFLM smernice**




Average % of staff performing phlebotomy
70
60
50
40
30
20
10
0
Inpatient Academic
Inpatient general/regional
Inpatient primary care
Outpatient academic
Outpatient general/regional
Outpatient primary care
Nurses
Laboratory technicians
Clinicians
Junior medical doctors
General practitioners
Specialized phlebotomists
Administrative staff
Specialists in Laboratory medicine


Is specific training for phlebotomy part of the education required to become qualified in different professions?
Yes
No
Nurses
Laboratory technicians
Clinicians
Junior medical doctors
General practitioners
Specialized phlebotomists
Administrative staff
Specialists in Lab Med

DE GRUYTER DOI 10.1515/cclm-2013-0283 — Clin Chem Lab Med 2013; 51(8): 1585–1593

Ana-Maria Simundic*, Michael Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Svjetlana Kovalevskaya, Ludek Sprongl, Zorica Sumarac and Stephen Church

Survey of national guidelines, education and training on phlebotomy in 28 European countries: an original report by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PA)

Conclusions and recommendations

Based on the results of this survey we conclude the following: 1) There is a need to assess the quality of current practices, compliance to the CLSI H3-A6 guidelines and to identify some most critical steps which occur during phlebotomy, in different healthcare settings, across Europe; 2) Existing CLSI H3-A6 phlebotomy guidelines should be adapted and used locally in all European countries which do not have their own guidelines; 3) National EFLM societies need to be engaged in basic training program development and continuous education of healthcare phlebotomy staff (implementing the certification of competence).

- **Veliki stepen heterogenosti**
- **Veliki broj zemalja nema nacionalne smernice**
- **Uzorkovanje krvi obavlja medicinski i nemedicinski kadar**
- **Različiti nivo obrazovanja, obuke**
- **Nedovoljno edukacije**
- **Potreba za standardizacijom i harmonizacijom**

EFLM WG-PRE
II projekat

DE GRUYTER

Clin Chem Lab Med 2014; aop

Ana-Maria Simundic*, Stephen Church, Michael P. Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Nora Nikolac, Edmee van Dongen-Lases, Pinar Eker, Svjetlana Kovalevskaya, Gunn B.B. Kristensen, Ludek Sprongl and Zorica Sumarac

Compliance of blood sampling procedures with the CLSI H3-A6 guidelines: An observational study by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PRE)

Ciljevi

- Ispitivanje nivoa usklađenosti procedura uzorkovanja krvi sa CLSI H3-A6
- Identifikacija najkritičnijih postupaka koji zahtevaju hitnu izmenu i unapređenje

Question 1																	
Did the collector assemble all necessary supplies prior to collection?	Yes	X		No			Yes	X		No			Yes	X		No		
Question 2																	
Does the collector have an identified request form?	Yes	X		No			Yes	X		No			Yes	X		No		
Question 3																	
Did the collector check the expiry dates of devices in use?	Yes			No	X		Yes			No	X		Yes			No	X	
Question 4																	
Did the collector identify the patient according to CLSI or local guidelines	Yes	X		No			Yes	X		No			Yes	X		No		
Question 5																	
Did the collector appropriately sanitize hands?	Yes			No	X		Yes			No	X		Yes			No	X	
Question 6																	
Has the collector verified that the patient is properly prepared for phlebotomy?	Yes			No	X		Yes			No	X		Yes			No	X	
Question 7																	
Was the chair used for venipunture specific to the task?	Yes	X	No		N/A		Yes	X	No		N/A		Yes	X	No		N/A	
Question 8																	
If lying, did the collector ensure the arm was appropriately positioned?	Yes			No			Yes			No			Yes			No		
Question 9																	
Did the collector place the tourniquet 4 finger widths (10cm) above the venipuncture site?	Yes	X		No			Yes	X		No			Yes	X		No		
Question 10																	
Did the collector select a suitable venipuncture site according to standard pract	Yes	X		No			Yes	X		No			Yes	X		No		
Question 11																	
Did the collector put on a new, fresh clean pair of gloves?	Yes			No	X		Yes			No	X		Yes			No	X	
Question 12																	
Did the collector clean the venipuncture site?	Yes	X		No			Yes	X		No			Yes	X		No		
Question 13																	
Did the collector leave the venipuncture site to dry (30secs)?	Yes	X		No			Yes	X		No			Yes	X		No		
Question 14																	
Did the collector leave the venipuncture site untouched post cleaning?	Yes			No	X		Yes			No	X		Yes	X		No		
Question 15																	
Did the collector ensure a fist was released when blood flow commenced?	Yes			No	X		Yes	X		No			Yes	X		No		
Question 16																	
Did the collector release the tourniquet when blood flow commenced?	Yes	X		No			Yes	X		No			Yes	X		No		
Question 17																	
Was the collector using a closed system for venipuncture?	Yes	X		No			Yes	X		No			Yes	X		No		
Question 18																	
Did the collector follow the correct order of draw according to the guidelines?	Yes	X		No			Yes	X		No			Yes	X		No		
Question 19																	
Were any of the sample tubes clearly under or over filled?	Yes			No	X		Yes			No	X		Yes			No	X	
Question 20																	
Were all sample tubes immediately and appropriately mixed according to manufacturers specifications?	Yes	X		No			Yes	X		No			Yes	X		No		
Question 21																	

Table 4 Risk occurrence chart for various phlebotomy steps.

Occurrence probability	Severity of harm				
	None	Limited	Moderate	Severe	Life threatening
	S1	S2	S3	S4	S5
Frequent O6					
Probable O5		Q7, Q11, Q24	Q3		
Occasional O4		Q5, Q13, Q28, Q29	Q6, Q14, Q15, Q16, Q19, Q20, Q23		Q25, Q26
Remote O3		Q8, Q9, Q21	Q12	Q2	Q4
Improbable O2	Q1	Q27, Q18	Q17	Q22	
Rare O1					

Q3: Did the collector check the expiry dates of devices in use?

Procedure identifikacije i obeležavanja!!

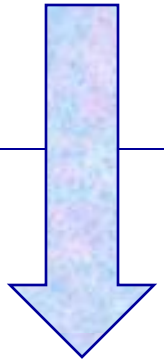
Q25: When were the sample tubes labeled?

Q26: Were the tubes labeled in the presence of the patient?

Q4: Did the collector identify the patient according to CLSI or local guidelines

Zaključci:

- Nivo usklađenosti procedure uzorkovanja venske krvi sa CLSI H3-A6 u 12 zemalja EFLM je veoma nizak.
- Postupci koji zahtevaju hitno unapređenje su: identifikacija pacijenata i obeležavanje uzoraka (*tube labelling*) tokom procedure uzorkovanja krvi.
- Neophodna revizija CLSI H3-A6

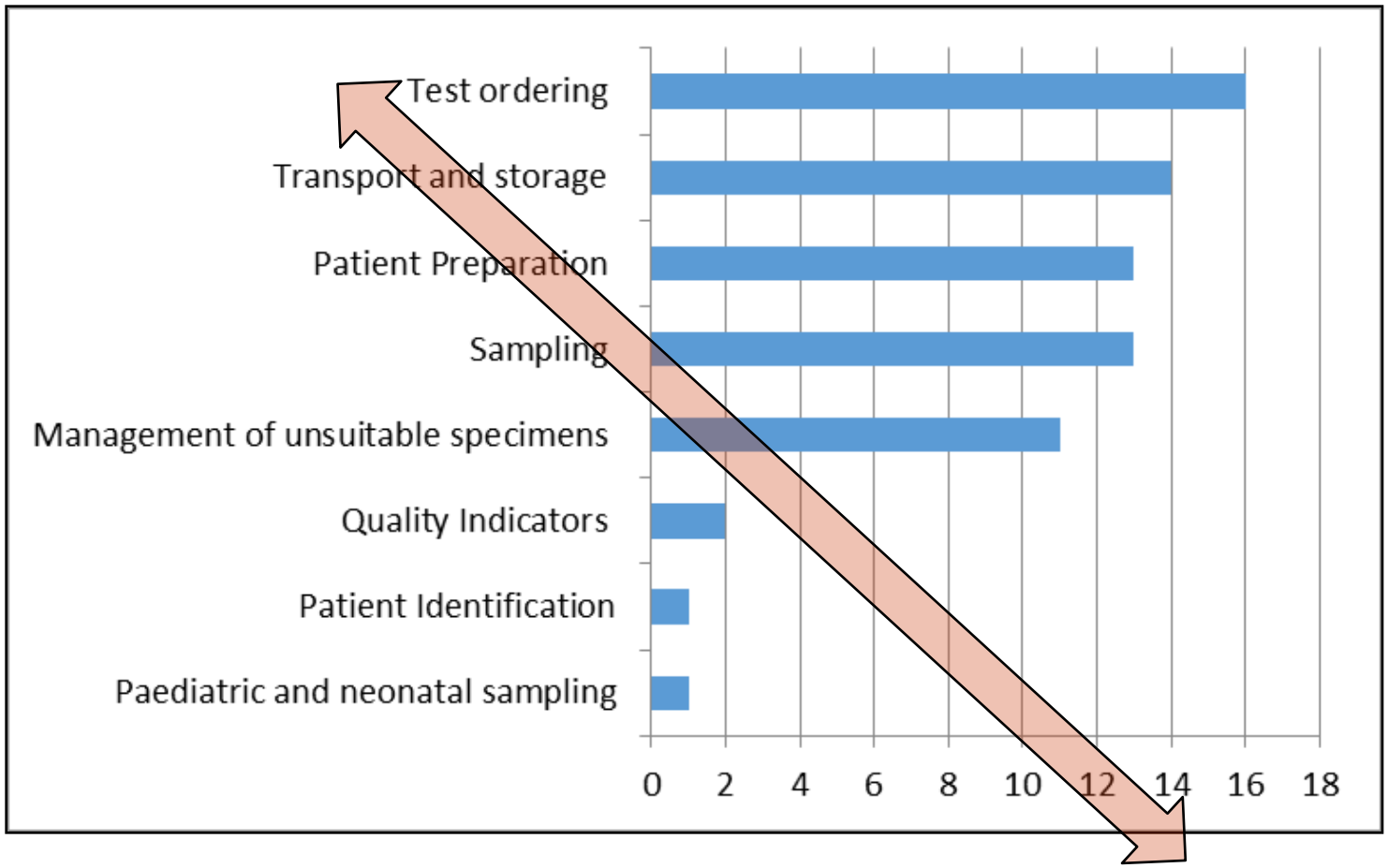


EFLM WG-PRE
III projekat

The role of EFLM in standardization and harmonization of the preanalytical phase in Europe

Cornes M , Simundic AM et al. The role of EFLM in standardization and harmonization of the preanalytical phase in Europe. *Manuscript under preparation.*

EFLM WG-PRE



Ključni pre-analitički postupci koji zahtevaju hitnu harmonizaciju

Nacionalna društva

Budući projekti EFLM WG-PRE u oblasti pre-analitičke faze

EUROMEDLAB PARIS 2015
21-25 JUNE
REVOLUTION IN LABORATORY MEDICINE

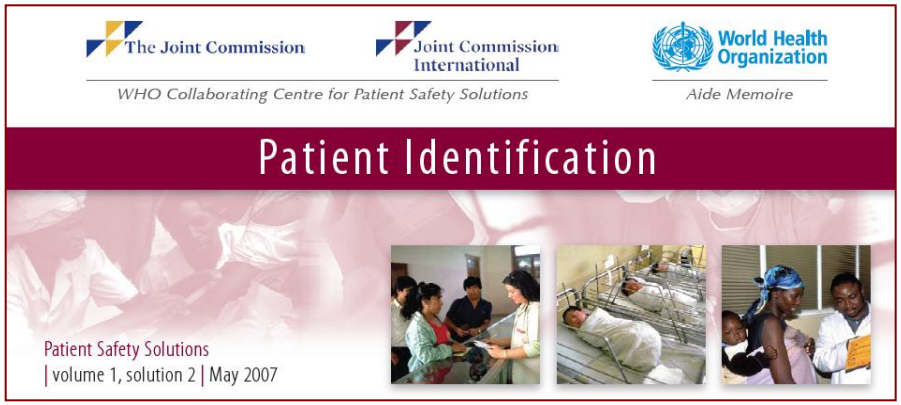
1. UZORKOVANJE KRVI

EFLM WG-PRE

- Započeta izrada (konsenzus) smernica za proceduru venepunkcije
- Rezultati rada: *AM Simundic et al. Compilance of blood sampling procedures with the CLSI H3-A6 guidelines. CCLM 2014.*
- CLSI H3-A6, WHO, preporuke nacionalnih društava
- Re-evaluacija postupaka zasnovana na dokazima
- Opservacione studije
- Uključivanje industrije-proizvođača sistema za venepunkciju
- Uključivanje udruženja sestara i laboratorijskih tehničara iz zemalja EFLM
- Sastanak EFLM WG-PRE-Zagreb, novembar 2015

2. Identifikacija pacijenata

- ✓**CLSI H3-A6: ime i prezime, adresa, ID i/ili datum rodjenja (svesni)**
- ✓**Politika ustanove: odstupanja, pacijenti bez svesti, hitni pacijenti**
- ✓**Različita zakonska regulativa u zemljama Evrope (usklađivanje)**
- ✓**Rezultati EFLM WG-PRE II projekta (*Compilance of blood sampling procedures with the CLSI H3-A6*): kritični postupci: identifikacija pacijenata i obeležavanja**
- ✓**EFLM WG-PRE: konsenzus smernice-procedura venepunkcije (*patient identification, specimen labeling*)**
- ✓ **Neophodna harmonizacija**



EFLM WG-PRE

Opinion Paper: Edmée C. van Dongen-Lases, Michael P. Cornes, Kjell Grankvist, Mercedes Ibarz, Gunn B.B. Kristensen, Giuseppe Lippi, Mads Nybo and Ana-Maria Simundic. **Patient identification and tube labelling – a call for harmonisation by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PRE).** Clin Chem Lab Med.

3. Priprema pacijenata

Clinica Chimica Acta 432 (2014) 33–37

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Standardization of collection requirements for fasting samples For the Working Group on Preanalytical Phase (WG-PA) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

A.M. Simundic [a,b,*], M. Cornes [b,c], K. Grankvist [b,d], G. Lippi [b,e], M. Nybo [b,f]

Clinical Chemistry

Table 1. Evaluation of articles published in relevant journals in 2002.

Journal	Articles with a group of fasting patients,[a] n	Well-defined fasting, n (%)	Insufficient definition, n (%)	No definition, n (%)
Clinical Chemistry	20	1 (5)	5 (25)	14 (70)
Clinical Chemistry and Laboratory Medicine	24	0 (0)	6 (25)	18 (75)
Scandinavian Journal of Clinical and Laboratory Investigation	18	3 (17)	4 (22)	11 (61)
Diabetes	94	7 (7)	36 (38)	51 (54)

[a] If the term "fasting patient" was used in the Materials and Methods, Results, or Discussion, the publication was considered as using fasting patients.

Hrvatsko društvo za medicinsku biokemiju 2015

Original papers

Are patients well informed about the fasting requirements for laboratory blood testing?

Sanja Kackov[1*], Ana-Maria Simundic[2], Ani Gatti-Drnic[3]

[1]Medical biochemistry laboratory, Policlinic Bonifarm, Zagreb, Croatia
[2]University Department of Chemistry, Medical School University Hospital Sestre Milosrdnice, Zagreb, Croatia
[3]Medical biochemistry laboratory, Public Health Centre Zagreb-Centar, Zagreb, Croatia

Biochemia Medica 2013;23(3):326–31

Institution: ☐ Interviewed by: ☐ Questionnaire №: ☐

Date: ☐

Patient age (years):

☐ ≤ 25 ☐ 26 - 45 ☐ 46 – 65 ☐ ≥ 65

Gender:

☐ male ☐ female

1) Are you taking regularly any of the following products? If yes, please state for how long?

Products	≤ 7 days	8-30 days	≥ 30 days	No
1. Acetylsalicylic acid (Aspirin) (not ordered by physician)				
2. Aloe vera (Aloe Barbadensis Miller)				
3. Cranberry (tea, capsules)				
4. Red yeast rice				
5. Ginkgo Biloba				
6. Minerals (Ca, Mg, Zn, Se, Fe, etc.)				
7. Noni juice				
8. Omega-3 fatty acids				
9. Propolis				
10. Caraway oil (Carum carvi)				
11. Silymarin (Silybum marianum)				
12. Vitamins (A, B, C, D, E, etc.)				
13. Green coffee bean extract				
14. Weight loss supplements				
15. other (please specify):*				

** other: apple cider vinegar (capsules), guarana (Paullinia cupana), royal jelly, papaya enzyme (chewable tablets) echinacea, Green magma (Hordeum vulgare) beta-glucan, hyaluronic acid, garlic capsules, evening primrose oil (Oenothera biennis), neem (Azadirachta indica) etc.*

2) Does your physician know that you take these products?

☐ yes ☐ no ☐ not applicable

3) Is it important to inform your physician that you are taking* some of the listed products?
(*patients who are not taking any of the listed products should simply give their opinion about the statement)

☐ yes ☐ no

4) Is it important to inform the laboratory staff that you are taking* some of the listed products?
(*patients who are not taking any of the listed products should simply give their opinion about the statement)

☐ yes ☐ no

5) What do you think, could the below listed factors affect the laboratory tests results?

Factor	yes	no	I don't know
Intense physical activity on the day before the blood sampling**			
Alcohol consumption on the day before the blood sampling			
Consumption of coffee on the day before the blood sampling			
Consumption of grapefruit on the day before the blood sampling			
Consumption of broccoli 3 days before the blood sampling			
Consumption of any of the products from the Table 1.			

*** cycling, tennis, running*

PREPORUKE EFLM WG-PRE

1.Neophodna revizija CLSI H3-A6 –pripema pacijenata

- uzorkovanje krvi 07-09h
- gladovanje 12h, dozvoljeno uzimanje vode
- alkohol izbegavati 24h
- pred vađenje krvi ne konzumirati kafu, čaj i cigarete

2. IFCC, EFLM-harmonizacija preporuka

3. Na nacionalnom nivou laboratorije treba da implementiraju standardizovane procedure uzorkovanja krvi i pripreme pacijenata.

4. Kriterijumi za prihvatanje uzoraka na osnovu pripreme pacijenata.

5. Laboratorijsko osoblje odgovorno za informisanost doktora i pacijenata.

4. Izbor testova

The three rules of laboratory test utilization:

1. "If you ask a stupid question, you get a stupid answer"
2. "Laboratory testing is for sick people"
3. "Too many good tests are the same as one bad test"

Review

The laboratory test utilization management toolbox

Geoffrey Baird

Biochemia Medica 2014;24(2):223–34

Inappropriate test
Unnecessary test
Appropriate test

Nepotrebni laboratorijski testovi:

4,5%-95% - van Walraven C, JAMA, 1998.
23-67% - Lippi G, Semin Thromb Hemost 2014.

Missed or delayed diagnoses and failure to order appropriate diagnostic or laboratory tests

Clinical Setting	Incidence (%)	Position in the rank	References
Ambulatory	55	1°	Gandhi TK et al, Ann Int Med 2006
Emergency Depts	58	1°	Kachalia A et al, Ann Emerg Med 2007
Internal Medicine	18	2°	Graber ML et al, Arch Int Med 2005
General and Medical Subspecialty Divisions	44	1°	Schiff GD et al, Arch Int Med 2009
Pediatrics	35	5°	Singh H et al, Pediatrics 2010

DIAGNOSTIC ERRORS IN TEST ORDERING and INTERPRETATION

Setting	Primary care	Internal medicine	ED
Failure to order an appropriate diagnostic test	55%	28%	58%
Incorrect interpretation	37%	38%	37%

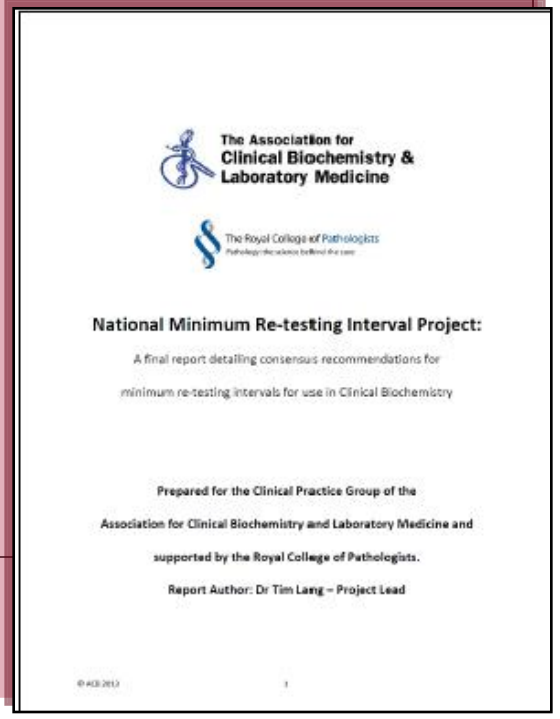
Gandhi TK et al. Ann Int Med 2006
Kachalia A. et al. Ann Emerg Med 2007
Graber ML et al. Arch Int Med 2005

- ✓ **Troškovi-** za pojedinačne testove mali, ukupni uticaj višestrukog neprikladnog korišćenja testova je značajan.
- ✓ **Stres kod pacijenta** - neptreban test koji je dao lažno pozitivne rezultate (tumorski markeri)

Razlozi koji dovode do prekomernog korišćenja testova

- napredak tehnologije i višestrukog testiranje istog uzorka
- ubrzanje obrtnog vremena servisa
- novi testovi - mnogo mogućnosti za izbor
- neznanje o dg. značaju, specifićnosti i osetljivosti
- nesigurnost
- upute često ispunjavaju sestre
- navika i radoznalost...

- **Standardizovati mehanizme koji omogućavaju pravilan odabir testova**
- **Obrazovanje kadrova**
- **Revizija dokumenata**
- **Izrada smernica sa ciljem smanjenja korišćenja testova** (klinički vodiči, reflex testovi, određivanje intervala za ponavljanje testova)
- **Redizajniranje uputa** (izbacivanje zastarelih testova, pravljenje panela, klinički algoritmi, cene testova)
- **Modeli finansiranja**


The Association for Clinical Biochemistry & Laboratory Medicine

The Royal College of Pathologists

National Minimum Re-testing Interval Project:

A final report detailing consensus recommendations for minimum re-testing intervals for use in Clinical Biochemistry

Prepared for the Clinical Practice Group of the Association for Clinical Biochemistry and Laboratory Medicine and supported by the Royal College of Pathologists.

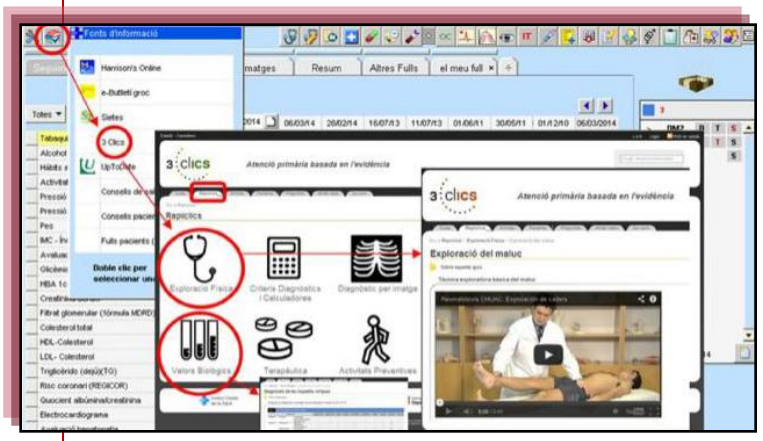
Report Author: Dr Tim Lang – Project Lead

QOF - UK Quality and Outcomes Framework

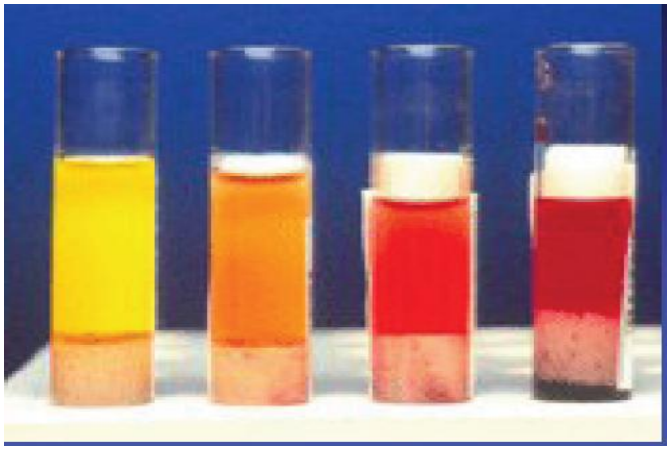
Unos zahteva preko kompjutera
(Computerized Physician Order Entry, CPOE)

Prednosti:

- ❑**Efektivnost**
- ❑**Lični odabir testova od strane lekara**
- ❑**Prethodni rezultati pacijenta**
- ❑**Ograničavanje ponavljanja zahteva**
- ❑**Usklađenost sa smernicama, kliničkim algoritmima**
- ❑**Podrška softvera**
- ❑**On-line komunikacija sa laboratorijom**
- ❑**Cena testova**
- ❑**Broj analiza po pacijentu**
- ❑**Linkovi za baze podataka**



5. UPRAVLJANJE INTERFERENCIJAMA



Review

The Haemolytic, Icteric and Lipemic Sample Recommendations Regarding their Recognition and Prevention of Clinically Relevant Interferences

Recommendations of the Working Group on Preanalytical Variables of the German Society for Clinical Chemistry and the German Society for Laboratory Medicine

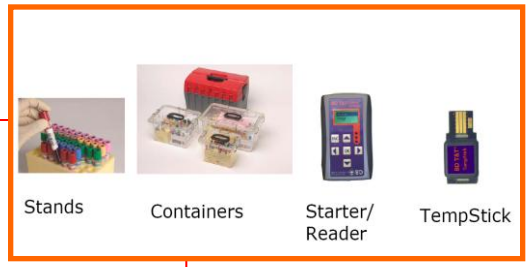
W.G. Guder, Munich (chairman), *F. da Fonseca-Wollheim,* Berlin, *W. Heil,* Wuppertal, *Y. M. Schmitt,* Darmstadt, *G. Töpfer,* Görlitz, *H. Wisser,* Mannheim, *B. Zawta,* Mannheim

Clin Chem Lab Med. 2009;47(8):934-9.
Multicenter evaluation of the hemolysis index in automated clinical chemistry systems.
Lippi G, Luca Salvagno G, Blanckaert N, Giavarina D, Green S, Kitchen S.

Clin Chem Lab Med. 2008 46 (6):764-72.
Haemolysis: an overview of the leading cause of unsuitable specimens in clinical laboratories.
Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Pleba

Clin Chem Lab Med. 2009;47(8):899-902.
Haemolysis index: quality indicator or criterion for sample rejection?
Plebani M, Lippi G.

6. Transport i stabilnost uzoraka

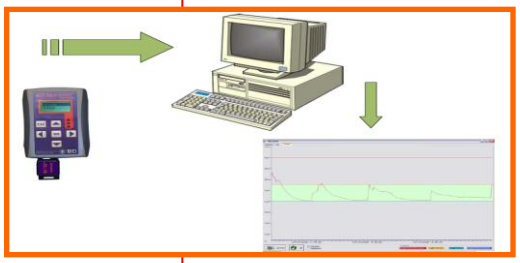


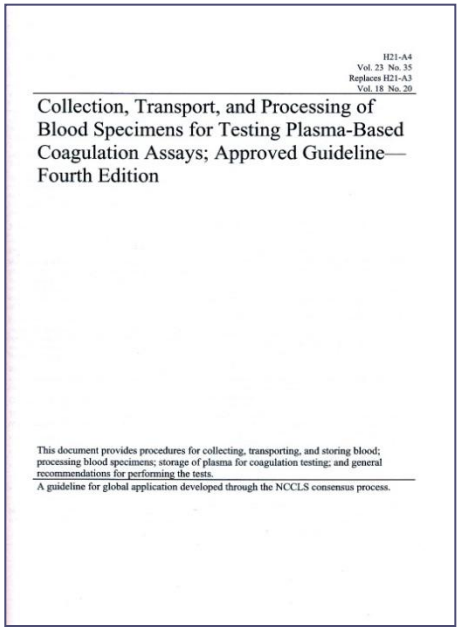
- Transport i rukovanje unutar laboratorije
- Transport uzoraka do centralne (*core*) laboratorije
- Poznavanje stabilnosti analita
- Praćenje uslova transporta (vreme, temperatura)

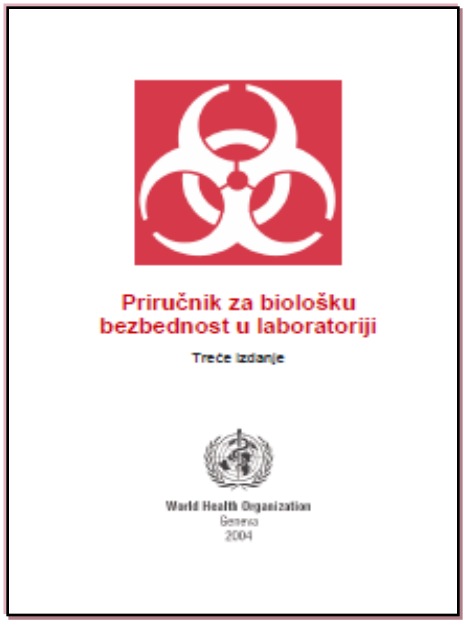
Zahtevi ISO 15189:2012

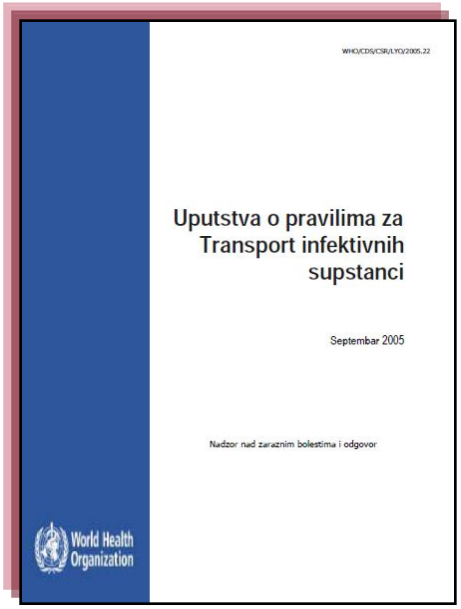
Verifikacija:

1. Vremenskog perioda između uzorkovanja i analiziranja
2. Temperature i vremena čuvanja uzoraka od uzorkovanja do analiziranja
3. Uslova pakovanja i pozicioniranja u transportne kutije/torbe prilikom transporta
4. Identifikacija i evidencija odbacivanja uzoraka









Clinical and Laboratory Standards Institute. Procedures for handling and processing of blood specimens for common laboratory tests. H18-A4; approved guideline – 4th ed. CLSI: Wayne, PA, 2010.

Guder WG, Ehret W, da Fonseca-Wollheim F, Heil W, Müller Plathe O, Töpfer G, et al. 1. Auflage Deutsche Gesellschaft für Clinische Chemie und Deutsche Gesellschaft für Laboratoriumsmedizin, 1999. Heidelberg: Becton Dickinson GmbH; [Die Qualität diagnostischer Proben]

Quality of Diagnostic Samples

Recommendations of the Working Group on Preanalytical Quality of the German Society for Clinical Chemistry and Laboratory Medicine

BD — Helping all people live healthy lives

W.G.Guder, F. da Fonseca-Wollheim, W. Heil

or whole blood?

- Choi
- The
- Stab
- The

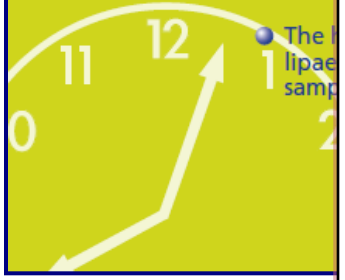


Table: Samples and Stability of Analytes

Analytes	Samples: Serum	Heparin-ized Plasma	EDTA Plasma	Citrated Plasma	Whole blood: Hep	Whole blood: EDTA	Whole blood: Citrat	Biological half-life	Stability: Stability in blood at room temperature	Stability in serum/plasma: -20 °C	Stability in serum/plasma: 4-8 °C	Stability in serum/plasma: 20-25 °C	Stabiliser	Remarks/ Comments	References
Calcitonin	+	+	⊖					min-h	4 h stabilised*	1 y	1 d	4 h	*Aprotinin 400 KIU/mL		100, 263
Calcium – total – ionised (free)	+ –	+ (+)	~≥ ~≥	~≥ ~≥	+ ⊖*			h min	2 d∨ 16 min∧ 1 d *	8 m	3 w 2 h	7 d 3 d	*Use calcium-titrated heparin (24)	pH-dependent! **Stable in gel tubes for 25 h & 72 h after centrifugation in closed tube (123).	106, 271, 289 24, 29, 123
Campylobacter jejuni/coli antibodies	+														
Candida albicans – antibodies – antigen detection	+ +													Blood culture bottle	
Carbamazepine	+	+α,β,γ	+β,γ	(+)α,β, β,γ, Ω				10-26 h	2 d	1 m	7 d	5 d		10% higher results in plasma (α), unstable in gel separator tubes, but stable in SSTn tubes (30)	30, 36, 65
Carbohydrate deficient transferrin (CDT)	+	+	+	(+)				5-10 d	3 d	3 m	2 w	1 d		Method-dependent	224
Carcino-embryonic antigen (CEA)	+	+	+α,γ,β,γ, μ	+γ				2-4 d	7 d	6 m	7 d	2 d		EDTA reduces by 13%-α	96,179,217 237, 248, 269, 269
Cardiolipin antibody	+									1 m	2-3 d	1d			43
Catecholamines (epinephrine, norepinephrine)	–	⊖	(+)	–				3-5 min	1 h if not stabilised	1 m 6 m stabilised	2 d	1 d	Glutathione 1.2 g/L + EDTA (26)	EDTA plasma to be separated within 15 min and frozen at -20°C .	26, 99
Ceruloplasmin	+	+	+, ~γγ					4 d		1 y	2 w	8 d			264, 268, 271
Chlamydia antibodies (C. trachomatis, C. pneumoniae)	+		(+)								7 d	5 d		DNA-PCR possible after 3-4 d of room temperature.	173
Chloramphenicol	+	+β	+	(+)				2-5 h							274
Chloride	+	+	–	–	+			1 h	1 d∨	y	4 w	7 d			29, 106
Cholesterol	+	+	+, ~α,γ,β, Ω	(+)					2-7 d∧	3 m	7 d	7 d			11, 27, 44 63, 106
Cholesterol, HDL	+	+	+β,λ,γ,δ, ~α	–					2 d∧	3 m	7 d	2 d		3% lower cholesterol observed in EDTA plasma due to osmotic dilution effect	11, 44, 63
Cholesterol, LDL	+	–,+β,γ,λ	+β, ~γ,λ	–					1 d∨	3 m	7 d	1 d			11, 44, 63
Cholinesterase, including dibucain number	+	+	+, ~γ,Ω					10 d*	7 d∨	1 y	7 d				
Ciclosporin	–	–	–	–			⊕	10-27 h	13 d	3 m*	3 w				
									4 h	1 y	5 h				

SPECIMEN COLLECTION

Coagulation Testing

http://www.utmb.edu/lsg/speccol/speccolcoag.htm

CONDITIONS of TRANSPORT and STORAGE

Coagulation tests are enzymatic procedures and, as such, are subject to stringent time-frame and storage guidelines. Reaction temperatures and the pH of specimens must be controlled at all times. **For best results, most sources recommend that specimens for Coagulation testing be delivered to the laboratory for testing within 1/2 hour of collection.** Considering the logistics and problems associated with transporting specimens, this recommendation is rarely achieved. More realistic time-frame guidelines have been established and must be adhered to. Receipt in lab beyond the stated guidelines will result in REJECTION of the specimen. The allowable time interval between collection of the specimen and testing of the sample will depend on the transport temperature and the storage of the specimen. Specimens for coagulation testing should be processed/stored as follows:

Most specimens for routine Coagulation testing can be transported either as whole blood or centrifuged (plasma) form. If plasma is sent, proper centrifugation protocol must be followed.

Specimens for routine Coagulation testing should be transported either at room temperature* (18-24°C) or refrigerated (2-4°C). *Specimens for **Prothrombin Time** testing (PT) should be **transported at room temperature**. They should NOT be refrigerated.

- PT assays must be performed within 24 hours of collection.
- APTT assays must be performed within 4 hours of collection.
- ALL other COAGULATION tests must be performed within 4 hours of collection.
- When samples cannot be assayed within the required time frame, the plasma must be separated from the red cells and frozen within one hour of collection.

Snap freezing **platelet-free plasma** (-70°C) is acceptable ***ONLY*** if performed by trained technical personnel. There are inherent problems associated with proper freezing/ thawing techniques that can result in inaccurate test results. If properly frozen (-70°C) and aliquotted (capped plastic cryo-tubes), plasma is viable for Coagulation testing for 6 months or at -20°C for 2 weeks.

7. Uzorkovanje kapilarne krvi; Uzorkovanje krvi kod dece i novorođenčadi

CLSI document H4-A6. Procedures and Devices for collection of Diagnostic Capillary Blood specimens; approved guideline, 6th ed. 2008.

WHO guidelines on drawing blood: best practices in phlebotomy (WHO, 2010).

Original papers

Nationwide survey of policies and practices related to capillary blood sampling in medical laboratories in Croatia

Jasna Lenicek Krleza

Children's Hospital Zagreb, Department of Laboratory Diagnostics, Zagreb, Croatia

- ✓ Ograničena primena
- ✓ Teškoće u izvođenju, mešanju; pravilan izbor lanceta-prst-peta/starost bebe
- ✓ Posebna pažnja na mesto punkcije u zavisnosti od starosi (peta, prst)!
- ✓ Mali volumen uzorka
- ✓ Problem detekcije hemolize i lipemije
- ✓ Neophodne preporuke zasnovane na dokazima

8. Upravljanje neprihvatljivim uzorcima

- **Neprihvatljivi uzorci:**
  - ◊ Pogršna identifikacija (pacijent, uzorak, uput)
  - ◊ Hemolizirani, lipemični uzorci
  - ◊ Koagulisani uzorci
  - ◊ Nepravilno izvađeni uzorci (pogrešna epruveta)
  - ◊ Neodgovarajući odnos krv-antikoagulans
  - ◊ Nedovoljno uzorka
  - ◊ Nepravilno transportovani i/ili čuvani uzorci
- **Nedostatak preporuka**
  - ◊ Prate se preporuke proizvođača za hemolizu, lipemiju, ikterus
- **Uvođenje EQA za pre-analitiku**
- **EFLM WG-PRE Pilot EQA za pre-analitiku u saradnji sa EQALM**

9. Indikatori kvaliteta

- **Objektivno merilo** kojim se procenjuju kritični zdravstveni segmenti: sigurnost pacijenata, efektivnost, nepristrasnost, pravovremenost, efikasnost.
- Usklađeni sa zahtevima **ISO 15189** i nacionalnim standardima; primenljivost na TTP.
- Praćenje kvaliteta TTP, identifikacija potencijalnih rizika, identifikacija postupaka koji zahtevaju dalja ispitivanja i unapređenja.
- **Karakteristike**: značajnost, primenljivost, izvodljivost, pravovremenost, naučna osnova, usmerenost ka pacijentu.

EFLM
EUROPEAN FEDERATION
OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

www.preanalytical-phase.org

... dalje aktivnosti EFLM WG-PRE

- Standardizacija i harmonizacija pre-analitičkih postupaka.
- Saradnja sa ostalim EFLM WGs: WG for Harmonization of the Total Testing Process (WG-H), WG-Postanalytical Phase, WG Guidelines, WG-Accreditation and ISO/CEN standards.
- Saradnja sa nacionalnim društvima EFLM.
- Uključivanje svih laboratorijskih profesionalaca, proizvođača opreme i tela koja izdaju standarde kako bi se definisali univerzalno primenljivi standardi za pre-analitičku fazu i implementirali na globalnom nivou.
- Dalja promocija značaja pre-analitičke faze kroz organizaciju skupova i edukaciju svih učesnika zdravstvenog sistema u Evropi i širom sveta...

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European Conference on Preanalytical Phase

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HVALA NA PAŽNJI