

October 24-25, 2015
Zagreb, Croatia

EFLM
EUROPEAN FEDERATION
OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

15th EFLM Continuous Postgraduate Course in
Clinical Chemistry and Laboratory Medicine

VERIFICATION OF BLOOD COLLECTION SYSTEM

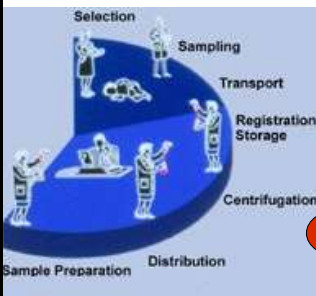
GIAN LUCA SALVAGNO , MD, PhD
University of Verona, Italy



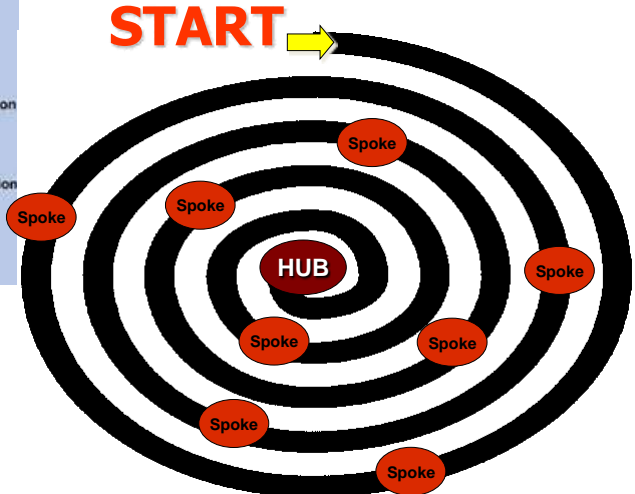

INTERNATIONAL JOURNAL OF LABORATORY HEMATOLOGY

Influence of temperature and time before centrifugation of specimens for routine coagulation testing

G. L. SALVAGNO*, G. LIPPI*, M. MONTAGNANA*, M. FRANCHINI†, G. POLI*, G. C. GUIDI*



START →



Clinical Chemistry 48:5
691–698 (2002)

Errors in Laboratory Medicine

PIERANGELO BONINI,^{1,2} MARIO PLEBANI,³ FERRUCCIO CERIOTTI,² and FRANCESCA RUBBOLI²

The improvement in analytical quality, documented through proficiency testing, should guarantee that the actual performances of clinical laboratories are suitable for improving a patient's health. Furthermore, increased attention to patients' needs is demonstrated by efforts to improve the quality of the entire service provided, e.g., reduction of the turn-around time (TAT). However, improvement of laboratory performance does not automatically indicate a reduction in the number of errors, both analytical and organizational.

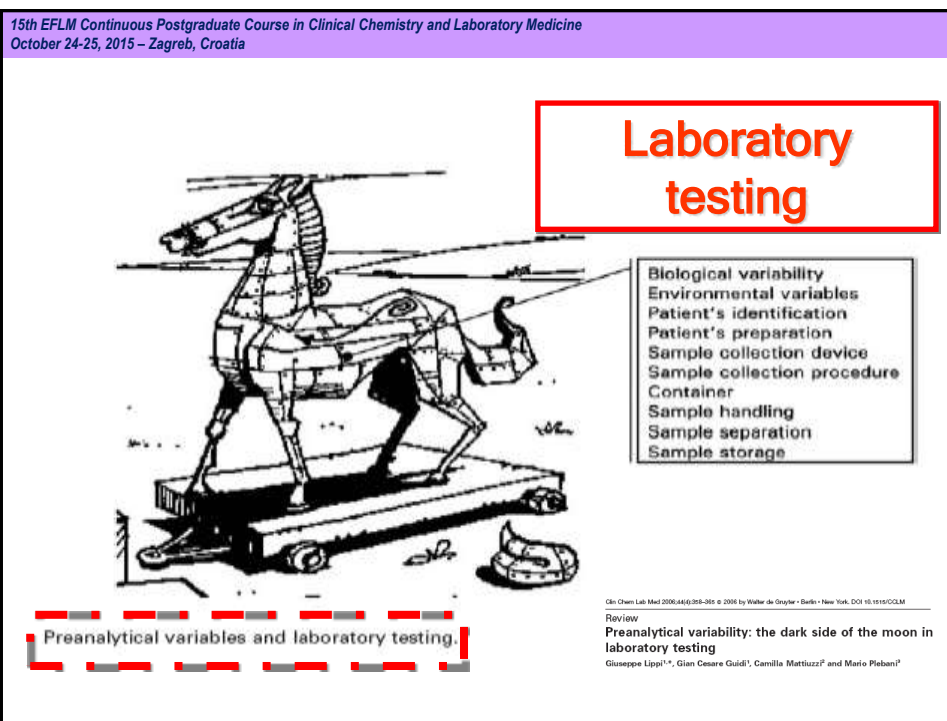
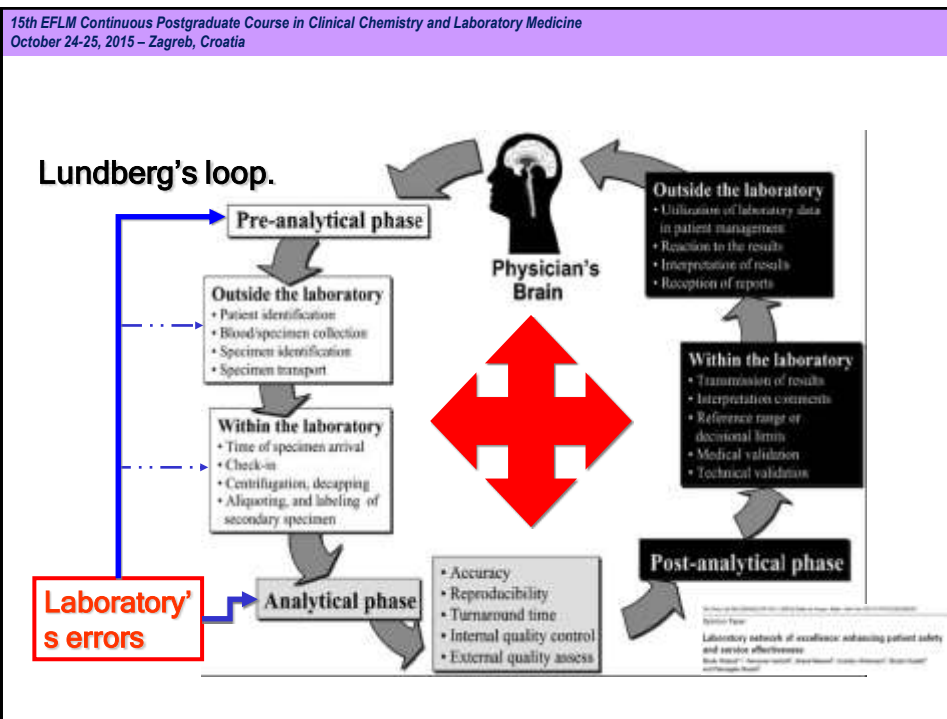
Clin Chem Lab Med 2005;43(3):319–325 © 2005 by Walter de Gruyter

Preanalytical variability in laboratory testing

Giuseppe Lippi*, Gian Luca Salvagno, Giorgio Brocco and Gian Cesare Guidi

Most recipients of laboratory testing ignore the possibility of other factors contributing to the test values, especially those that are abnormal. It is essential for everyone who either performs tests or uses their results for patient care to have a clear understanding of all the factors that can generate erroneous and misleading laboratory results.





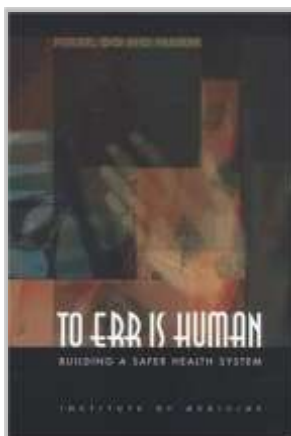
Clin Chem Lab Med 2006;44(4):358–365 © 2006 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2006.073

Review

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

Giuseppe Lippi^{1,*}, Gian Cesare Guidi¹, Camilla Mattiuzzi² and Mario Plebani³

Although there are several and heterogeneous characterizations for "laboratory error", a reasonable definition, recently acknowledged by the International Organization for Standardization, could be "any defect from ordering tests to reporting results and appropriately interpreting and reacting on these"



Errors and patient's outcome



When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors.³ The results of the New York Study suggest the number may be as high as 98,000.⁴ Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8th-leading cause of death.⁵ More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).⁶

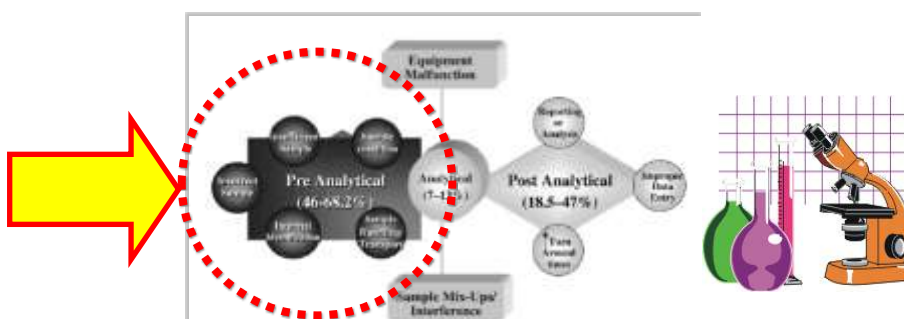
15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
October 24-25, 2015 – Zagreb, Croatia

Clin Chem Lab Med 2006;44(6):750–759 © 2006 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2006.123

Review

Errors in clinical laboratories or errors in laboratory medicine?

Mario Plebani*



15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
October 24-25, 2015 – Zagreb, Croatia

Editorial

Preanalytical phase – a continuous challenge for laboratory professionals

Ana-Maria Simundic¹, Giuseppe Lippi²

¹Editor-in-chief, *Biochimica Medica*, Zagreb, Croatia; EFLM (formerly EFCC) Working-group on Preanalytical Phase, chair

²Clinical Chemistry and Hematology Laboratory, Academic Hospital of Parma, Parma, Italy; Editorial Board member; EFLM (formerly EFCC) Working-group on Preanalytical Phase, member

*Corresponding author: am.simundic@gmail.com *Biochimica Medica* 2012;22(2):145–9

Blood Coagul Fibrinolysis 17:513–519 © 2006

Quality and reliability of routine coagulation testing: can we trust that sample?

Giuseppe Lippi^a, Massimo Franchini^b, Martina Montagnana^a, Gian Luca Salvagno^a, Giovanni Poli^a and Gian Cesare Guidi^a

Pre-analytical errors

There is consolidated evidence that lack of standardization and monitoring of several preanalytic variables, including procedures for patient identification, sample collection, handling, and processing before analysis, has an adverse influence on the reliability of test results, consuming valuable health care resources and compromising the patient's outcome.

Clinical Chemistry 48:5
691–698 (2002)

.....and in laboratory?

Errors in Laboratory Medicine

PIERANGELO BONINI,^{1,2*} MARIO PLEBANI,³ FERRUCCIO CERIOTTI,² and FRANCESCA RUBBOLI²

Review of the literature on laboratory errors.

	Sauer & Teal (28) ¹ Clinical chemistry 6 years	Goldfarb and Sam (7) ² Whole laboratory 6 years	Neigel et al. (38) ³ Urinary toxic 6 months	Phelan and Casper (8) ⁴ Non laboratory 3 months	Muller et al. (27) ⁵ Whole laboratory 3 years	McIntyre quality audit every error 12 years	Wentz 1 year	McIntyre quality audit every error 4.2 experiments 1 year
No. of tests	~907 000	ND	ND	304 000	6 78 000*	42 34	88 18	58 362
No. of patients	~210 000	ND	100 714	100	100	100	100	ND
No. of errors	220	120	100	136	4 336*	36	200	200
Pre-analytical phase	31.4%	9.3%	91.0%	100.0%	100%	4.4%	10%	93%
Analytical phase	31.4%	2.8%	10.2% overall (6.4% if radial flocculation not if POCT)	10.0%	1.9%	10%	12%	10%
Post-analytical phase	33.3%	3.6%	30%	100%	98%	12.3%	15%	10%
Identification errors linked to patient history	41 (3.4%) ND	77 (5.8%)	ND	5 (2.8%)	81	81	80	ND
None		4.3%		7.4%			10.4%	10.4%
Mist		2.3% (clinical)	1.0%	10.4% (clinical and POCT)		2.3%	20%	20%
Misdiagnosis		2.4% (potential damage)	1.3%	6.4% (potential damage)		5.6%	10.2%	10.2%
Subsets		8% (potential medical consequences)					6.4%	6.4%
Top errors		None						

Preanalytical: 56%
Analytical: 21%
Postanalytical: 18%
Multiple: 5%



Clinical Chemistry 48:5
691–698 (2002)

Errors in Laboratory Medicine

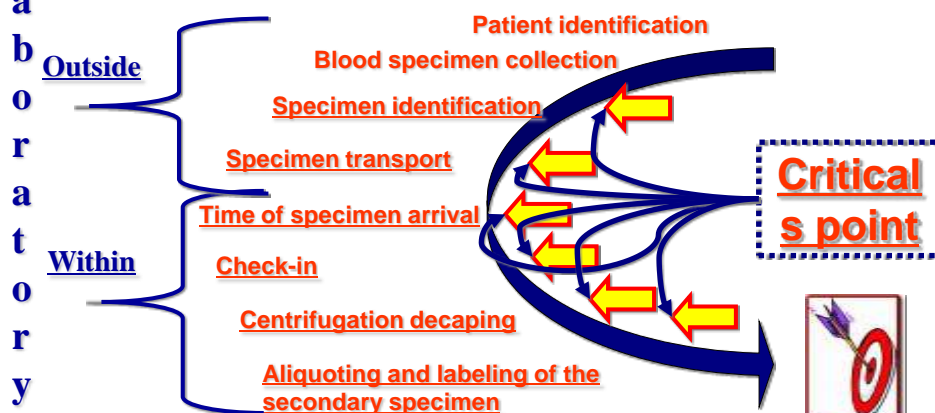
PIERANGELO BONINI,^{1,2*} MARIO PLEBANI,³ FERRUCCIO CERIOTTI,² and FRANCESCA RUBBOLI²

Types of preanalytical errors registered during the year 2000 at the Laboratory of San Raffaele Hospital.

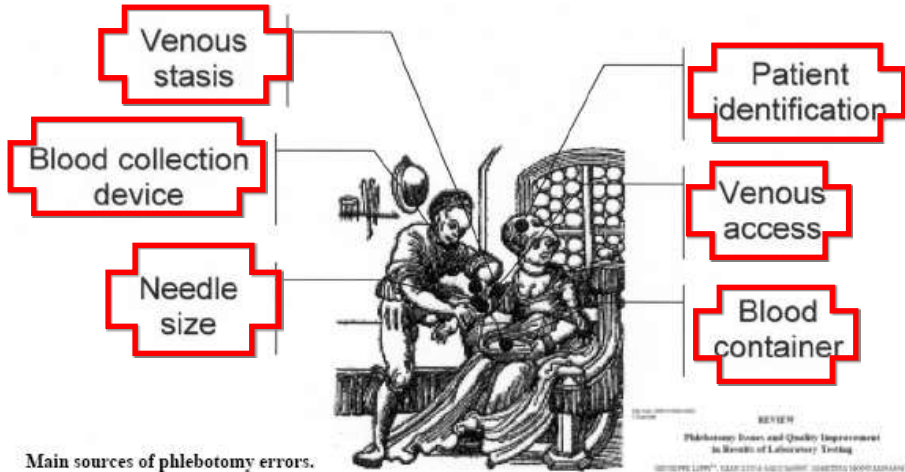
Type of error	No. of missing results	
	Inpatients	Outpatients
Hemolyzed sample	8494	256
Insufficient sample	3256	102
Incorrect sample	1824	289
Clotted sample	792	80
Incorrect identification	287	2
Lack of signature (blood group)	266	
Empty tube	238	8
Lack or wrong compilation of the accompanying module	120	
Sample not on ice	75	6
Tube broken in the centrifuge	57	36
Test not reserved	31	
Urine not acidified	24	
Open container	20	13
Module without signature	14	
Urine volume not indicated	5	
Total	15 503	792



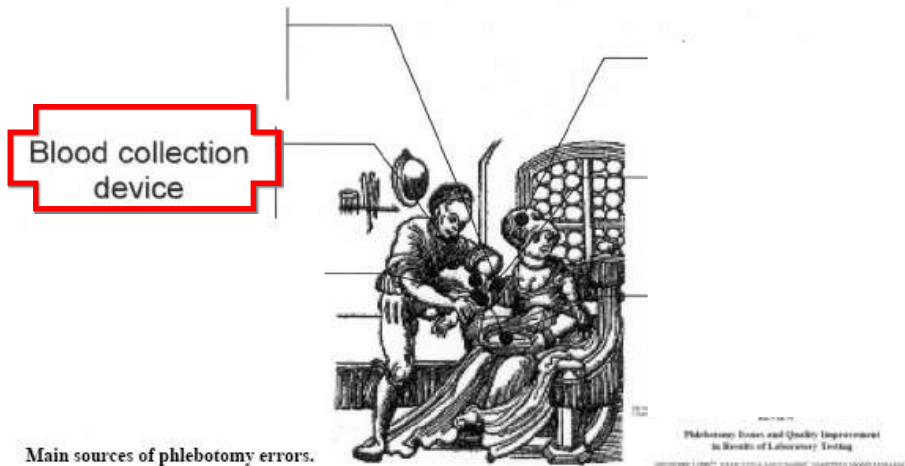
L a b o r a t o r y Pre-analytical phase: Where?



Phlebotomist?



Blood collection device



Preanalytical variability in laboratory testing: influence of the blood drawing technique

Giuseppe Lippi*, Gian Luca Salvagno, Giorgio Brocco and Gian Cesare Guidi



The 95% agreement interval in the set of differences was acceptable and was mostly within the current analytical quality specifications for desirable bias. The rate of hemolysis in plasma was not statistically different between the two collection techniques. Taken together, the results of the present investigation suggest that, when a proper technique is used and within certain limitations, the butterfly device may be a reliable alternative to the conventional straight needle to draw blood for laboratory testing.

Preanalytical variability in laboratory testing: influence of the blood drawing technique

Giuseppe Lippi*, Gian Luca Salvagno, Giorgio Brocco and Gian Cesare Guidi

Blood drawing technique

The results of the present investigation suggest that, when a proper technique is used and within certain limitations, the butterfly device may be a reliable alternative to the conventional straight needle to draw blood for laboratory testing.

No influence of a butterfly device on routine coagulation assays and D-dimer measurement

G. LIPPI, G. L. SALVAGNO, G. BROCCO, G. GUIDI

Service of Clinical Microbiology, Department of Clinical Pathology-Biochemistry, University Hospital of Ferrara, Ferrara, Italy



Therefore, we conclude that, when a proper technique is used and within certain limitations, the butterfly device may be a reliable alternative to the conventional straight needle for blood drawing for purposes of coagulation testing.

VENOUS STASIS

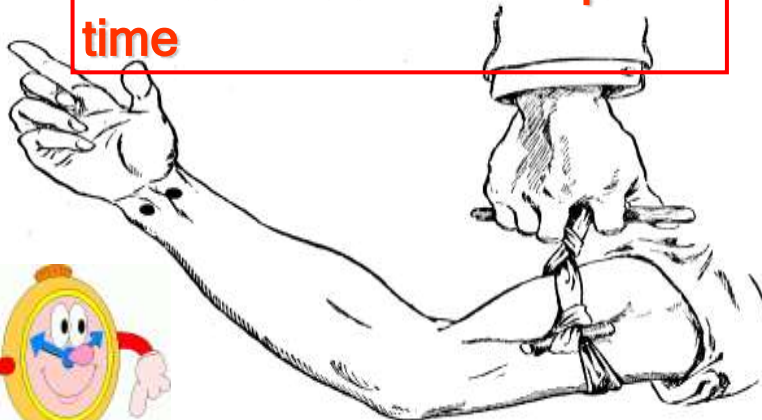
Venous
stasis

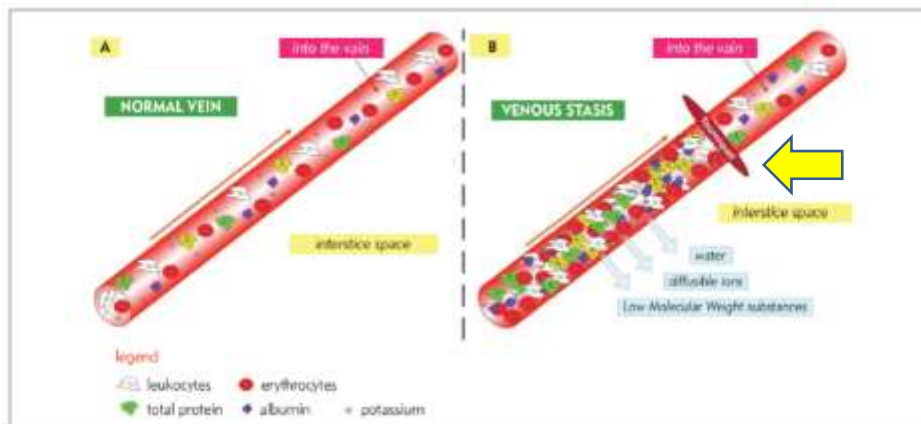


Main sources of phlebotomy errors.

Phlebotomy Errors and Quality Improvement
in Results of Laboratory Testing

Venous Stasis: Tourniquet time





J Med Biochem 33: 1-7, 2014

Review article
Problemi Klinički

LABORATORY DIAGNOSTICS AND QUALITY OF BLOOD COLLECTION
LABORATORIJSKA DIJAGNOSTIKA I KVALITET UZIMANJA UZORAKA KRVI

Gabriel Lima-Oliveira^{1,2,3,4}, Giuseppe Lippi⁵, Gian Luca Salvagno¹,
Gerald Pochetti⁶, Gian Cesare Guidi^{1,7}

J Med Biochem 33: 1-7, 2014

Review article
Problemi Klinički

LABORATORY DIAGNOSTICS AND QUALITY OF BLOOD COLLECTION
LABORATORIJSKA DIJAGNOSTIKA I KVALITET UZIMANJA UZORAKA KRVI

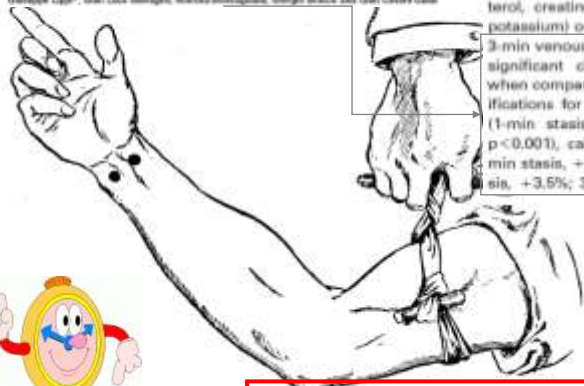
Gabriel Lima-Oliveira^{1,2,3,4}, Giuseppe Lippi⁵, Gian Luca Salvagno¹,
Gerald Pochetti⁶, Gian Cesare Guidi^{1,7}

Table III Impact of venous stasis by tourniquet application on routine laboratory tests (Z0–Z2).

Tests	Tourniquet application time				
	30 s	60 s	90 s	120 s	180 s
FIB	NS	NA	I	I	I
PT	NS	NA	NS	D	D
aPTT	NS	NA	NS	D	D
Glu	NS	I	I	I	D
TP	NS	I	I	I	I
ALB	NS	I	I	I	I
ALKP	NS	I	I	I	I
TG	NS	I	I	I	D
K	NS	I	I	I	I
Na	NS	NS	I	I	I
P	NS	NS	NS	NS	I
Ca	NS	I	I	I	I
Mg	NS	I	I	I	I
PLT	NS	I	I	I	I
RBC	NS	I	I	I	I
Hb	NS	I	I	I	I
Ht	NS	I	I	I	I
WBC	NS	I	I	I	I
NEU	NS	I	I	I	I
LYMP	NS	NS	I	I	I
MONO	NS	I	I	NS	NS
EOS	NS	I	I	NS	I
BASO	NS	NS	I	I	I

Influence of short-term venous stasis on clinical chemistry testing

Giuseppe Lippi*, Gian Luca Salvagno, Martina Montagnana, Giorgio Buzzo and Gian Cesare Guidi



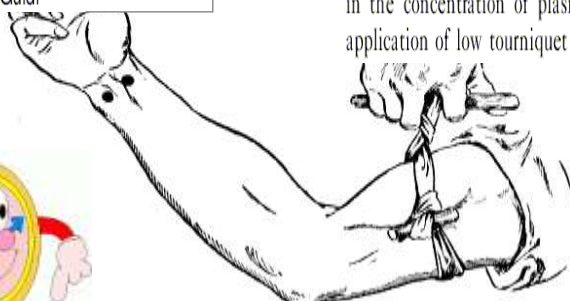
Statistically significant differences could be observed in seven (alanine aminotransferase, albumin, calcium, total cholesterol, creatine kinase, iron and potassium) and ten (alanine aminotransferase, albumin, calcium, chloride, total cholesterol, creatine kinase, creatinine, glucose, iron and potassium) out of the 12 analytes tested, after 1- and 3-min venous stasis, respectively. The most clinically significant changes from standard venepuncture, when compared to the current analytical quality specifications for desirable bias, occurred for potassium (1-min stasis, -2.8%; 3-min stasis, -4.8%, both $p < 0.001$), calcium (1-min stasis, +1.6%, $p < 0.05$; 3-min stasis, +3.6%, $p < 0.001$) and albumin (1-min stasis, +3.5%; 3-min stasis, +8.6%, both $p < 0.001$).

1) Tourniquet time: Clinical Chemistry

Blood Coagul Fibrinolysis 16:00-00 © 2005 Lippincott Williams & Wilkins.

Short-term venous stasis influences routine coagulation testing

Giuseppe Lippi, Gian Luca Salvagno, Martina Montagnana and Gian Cesare Guidi



Results of our investigation provide clear evidence that even a short-term tourniquet placing influences results of coagulation testing, thus confirming and complementing an earlier observation of a progressive increase in the concentration of plasma fibrinogen following application of low tourniquet pressure.

2) Tourniquet time: Coagulation testing

GLS

Published in final edited form as:

Clin Biochem. 2014 February ; 47(3): 150–157. doi:10.1016/j.clinbiochem.2013.11.003.

Blood collection tube-related alterations in analyte concentrations in quality control material and serum specimens

Raffick A.R. Bowen^{a,*}, Annie Sattayapiwat^a, Verena Gounden^b, and Alan T. Remaley^b

Review

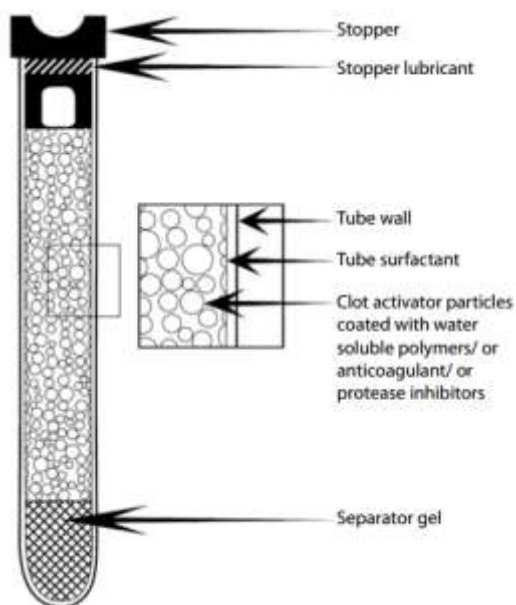
Interferences from blood collection tube components on clinical chemistry assays

Biochimica Medica 2014;24(1):31–44

Raffick A.R. Bowen^{a,1}, Alan T. Remaley²

¹Department of Pathology, Stanford University, Stanford, CA 94305, USA

²Department of Laboratory Medicine, National Institutes of Health, Bethesda, MD 20892, USA



Published in final edited form as:
Clin Biochem. 2014 February ; 47(3): 150–157. doi:10.1016/j.clinbiochem.2013.11.003.
Blood collection tube-related alterations in analyte concentrations in quality control material and serum specimens
Raffick A.R. Bowen^{a,*}, Annie Sattayapiwat^a, Verena Gounden^b, and Alan T. Remaley^b

Quality management of preanalytical phase: impact of lithium heparin vacuum tubes changes on clinical chemistry tests

Gabriel Lima-Oliveira · Gian Luca Salvagno · Giuseppe Lippi ·
Giorgio Brocco · Monica Voi · Martina Montagnana ·
Geraldo Picheth · Gian Cesare Guidi

Accred Qual Assur
DOI: 10.1007/s00769-013-0995-6

Tube	Brand	Volume (mL)	Lithium heparin (as reported)	Manufacturer
I	VACUETTE®	4.0	18 IU ^a	Greiner Bio-one GmbH, Kremsmünster, Austria
II	LABOR IMPORT®	5.0	Not supplied by the manufacturer	Guangzhou Improve Medical Instruments Co. Ltda, Zhejiang, China
III	S-Monovette®	4.9	~ 16 IU ^a	Sarstedt, Nümbrecht, Germany
IV	PST®	4.0	14–17 USP ^a	Becton, Dickinson and Company, Franklin Lakes, NJ, USA
V	PST II®	3.0	17 IU ^a	Becton, Dickinson and Company, Franklin Lakes, NJ, USA

Quality management of preanalytical phase: impact of lithium heparin vacuum tubes changes on clinical chemistry tests

Gabriel Lima-Oliveira · Gian Luca Salvagno · Giuseppe Lippi ·
Giorgio Brocco · Monica Voi · Martina Montagnana ·
Geraldo Picheth · Gian Cesare Guidi

Accred Qual Assur
DOI: 10.1007/s00769-013-0995-6

Table 2 Variability of results in routine clinical chemistry testing when applying five different brands of plasma vacuum tubes with lithium heparin and gel separator

Test component	Desirable bias (%)	Relative difference, % (p-value)										
		Tube I versus tube II	Tube I versus tube III	Tube I versus tube IV	Tube I versus tube V	Tube II versus tube III	Tube II versus tube IV	Tube II versus tube V	Tube III versus tube IV	Tube III versus tube V	Tube IV versus tube V	
Glucose ^a	1.8	1.8	-2.8 (0.007)	-3.8 (0.000)	-2.8 (0.013)	0.7 (0.229)	-1.1 (0.219)	0.0 (0.981)	3.1 (0.000)	1.1 (0.215)	4.1 (0.000)	3.1 (0.000)
Urea ^b	5.5	2.5	0.0 (0.264)	1.8 (0.026)	0.0 (0.263)	0.0 (0.493)	1.8 (0.010)	0.0 (1.000)	0.0 (0.993)	-1.9 (0.021)	-1.9 (0.021)	0.0 (0.270)
Creatinine ^b	4.0	2.5	0.0 (0.320)	0.0 (0.494)	-4.2 (0.000)	2.8 (0.132)	0.0 (0.322)	-4.2 (0.000)	2.8 (0.123)	-4.2 (0.260)	2.8 (0.016)	4.6 (0.000)
Alkaline phosphatase ^c	6.4	2.3	-0.9 (0.371)	-0.9 (0.385)	-1.7 (0.000)	-0.9 (0.395)	0.0 (0.978)	-0.9 (0.004)	0.0 (0.326)	-0.9 (0.139)	0.0 (0.635)	0.9 (0.007)
Aspartate ^c	3.8	0.0	0.0 (0.001)	2.8 (0.005)	0.8 (0.035)	0.8 (0.078)	-0.1 (0.000)	-7.0 (0.000)	-7.0 (0.000)	-0.8 (0.280)	-0.8 (0.379)	0.0 (0.014)
Aspartate:aminotransferase ^c	5.4	1.1	4.8 (0.000)	7.2 (0.000)	2.4 (0.094)	0.0 (0.520)	2.5 (0.007)	-2.5 (0.007)	-5.0 (0.000)	-5.1 (0.000)	-7.7 (0.000)	-2.8 (0.234)
Alanine aminotransferase ^c	11.4	1.2	-0.8 (0.004)	-13.8 (0.002)	-0.8 (0.001)	0.8 (0.001)	5.3 (0.014)	2.8 (0.213)	2.8 (0.317)	-2.8 (0.183)	-2.8 (0.190)	0.0 (0.927)
Lactate dehydrogenase ^c	8.3	0.0	8.7 (0.000)	10.7 (0.000)	-4.7 (0.001)	-4.9 (0.100)	6.6 (0.000)	-0.9 (0.017)	-0.2 (0.002)	-4.8 (0.000)	-17.2 (0.000)	-16.2 (0.000)
Total bilirubin ^d	0.4	2.1	8.1 (0.005)	0.1 (0.152)	0.3 (0.001)	0.1 (0.049)	-2.2 (0.307)	-2.3 (0.401)	-4.4 (0.004)	0.4 (0.924)	-2.2 (0.117)	-4.9 (0.024)
P ^e	2.2	2.8	1.7 (0.002)	0.0 (0.171)	0.0 (0.237)	0.0 (0.737)	-0.1 (0.338)	-0.1 (0.300)	-1.7 (0.000)	0.0 (1.000)	-0.1 (0.025)	-0.1 (0.025)
Ca ²⁺	0.8	0.6	1.3 (0.014)	0.0 (0.501)	1.3 (0.004)	0.0 (0.222)	-1.3 (0.004)	0.0 (0.121)	-1.3 (0.004)	0.0 (0.170)	0.0 (0.101)	-1.3 (0.004)
Mg ²⁺	1.8	1.0	0.0 (0.004)	0.0 (0.001)	0.0 (0.002)	0.0 (0.000)	0.0 (1.000)	0.0 (0.429)	-1.3 (0.016)	0.0 (0.429)	-1.3 (0.104)	-1.3 (0.102)
Fe ²⁺	0.8	2.5	-1.1 (0.004)	-0.8 (0.136)	-2.8 (0.000)	-1.7 (0.148)	0.0 (0.196)	-1.7 (0.007)	-0.8 (0.000)	-2.2 (0.267)	-1.1 (0.014)	1.1 (0.199)
K ⁺	1.8	1.2	3.7 (0.000)	1.2 (0.004)	2.8 (0.002)	-3.7 (0.000)	-2.8 (0.117)	-1.1 (0.010)	-3.7 (0.000)	1.2 (0.000)	-4.8 (0.000)	-4.3 (0.000)



Anticoagulants

Blood Coagulation and Fibrinolysis 2005, 00:00–00

Influence of two different buffered sodium citrate concentrations on coagulation testing

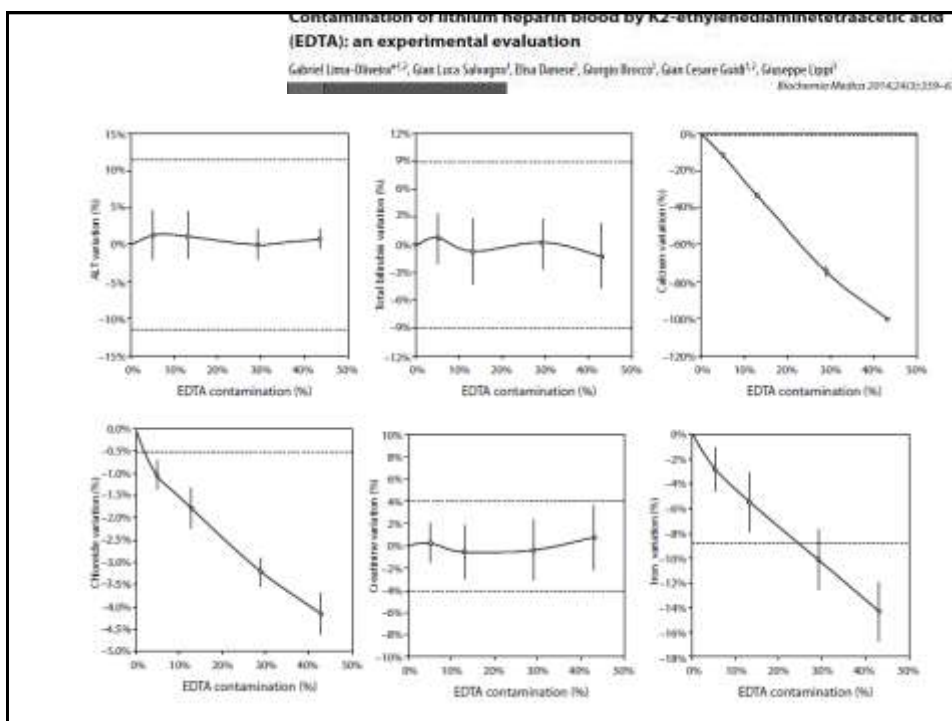
Giuseppe Lippi, Gian Luca Salvagno, Martina Montagnana and Gian Cesare Guidi

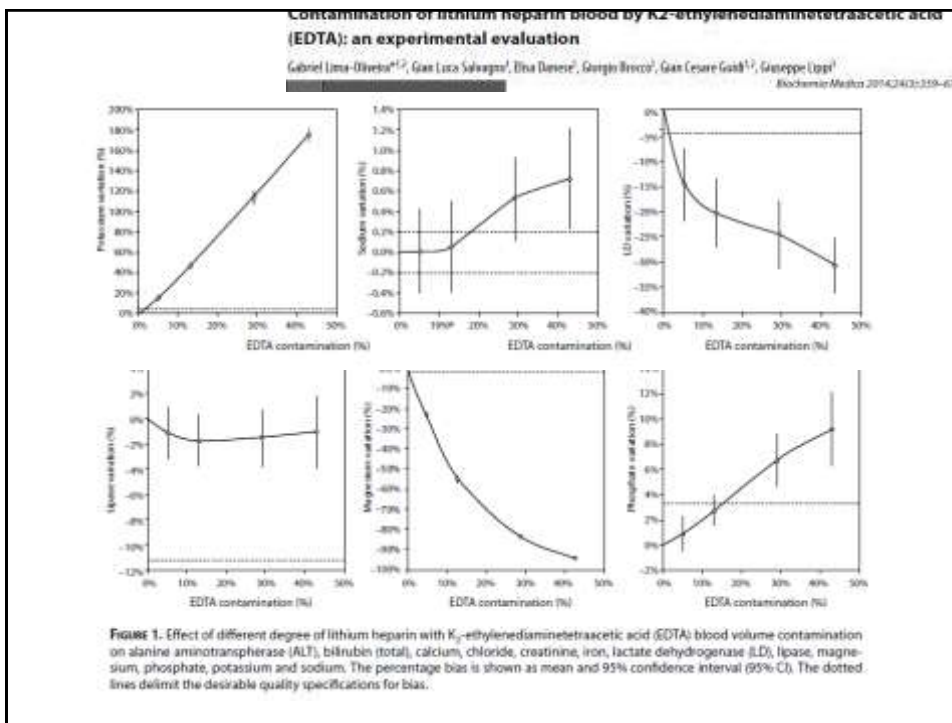


We demonstrated that either the final concentration of the anticoagulant in the collection tubes or the nature of the vials might influence significantly the measurement of PT, aPTT and fibrinogen, and might potentially generate misleading results in the diagnostic and therapeutic approach to patients with suspected coagulopathies.

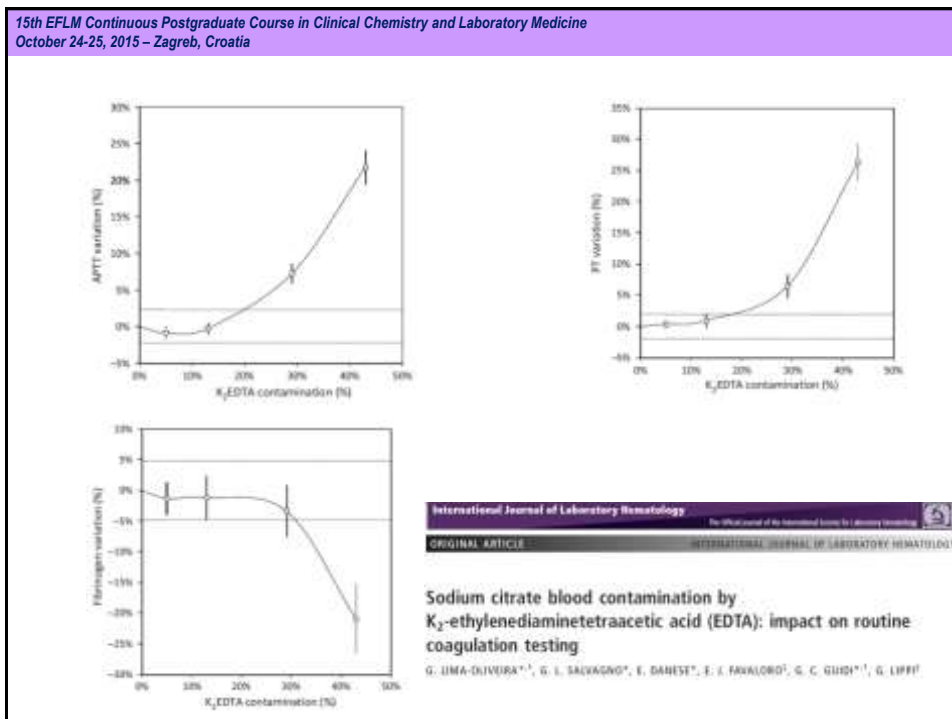


GLS





15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
October 24-25, 2015 – Zagreb, Croatia



15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
 October 24-25, 2015 – Zagreb, Croatia

VENOUS ACCESS

REVIEW
 Phlebotomy Errors and Quality Improvement
 in Results of Laboratory Testing
BRITISH JOURNAL OF CLINICAL PATHOLOGY, 2006; 59(6): 400-402

Main sources of phlebotomy errors.

GLS

15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
 October 24-25, 2015 – Zagreb, Croatia

(Arch Pathol Lab Med. 2006;130:181-184)

Interference of Blood Cell Lysis on Routine Coagulation Testing

Giuseppe Lippi, MD; Martina Montagnana, MD; Gian Luca Salvagno, MD; Gian Cesare Guidi, MD

The graphs show the following trends:

- Graph A (PT % Variation):** Shows a positive correlation between hemolysis and PT variation, starting near 0% and rising to approximately 25% at 9.1% hemolysis.
- Graph B (aPTT % Variation):** Shows a negative correlation, starting near 0% and decreasing to approximately -10% at 9.1% hemolysis.
- Graph C (Fibrinogen % Variation):** Shows a negative correlation, starting near 0% and decreasing to approximately -30% at 9.1% hemolysis.
- Graph D (D-Dimer % Variation):** Shows a positive correlation, starting near 0% and rising to approximately 25% at 9.1% hemolysis.

15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
October 24-25, 2015 – Zagreb, Croatia

Hemolysis: Clinical Chemistry

Clin Chem Lab Med 2006;44(5):511-516 © 2006 by Walter de Gruyter • Berlin • New York

Influence of hemolysis on routine clinical chemistry testing

Giuseppe Lippi*, Gian Luca Salvagno, Martina Montagnana, Giorgio Brocco and Gian Cesare Guidi

Clinically meaningful variations of AST, chloride, LDH, potassium and sodium were observed in specimens displaying mild or almost undetectable hemolysis by visual inspection (serum hemoglobin <0.6 g/L).

15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
October 24-25, 2015 – Zagreb, Croatia

(Arch Pathol Lab Med, 2006;130:181-184)

Interference of Blood Cell Lysis on Routine Coagulation Testing

Giuseppe Lippi, MD; Martina Montagnana, MD; Gian Luca Salvagno, MD; Gian Cesare Guidi, MD

Conclusion.—Our results confirm that, although slightly hemolyzed specimens might still be analyzable, a moderate blood cell lysis, as low as 0.9%, influences the reliability of routine coagulation testing. Because the interference in coagulation assays has a wide interindividual bias, we do not recommend lysis correction and we suggest that the most appropriate corrective measure should be free hemoglobin quantification and sample recollection.

Hemolysis: Coagulation testing

GLS

15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
October 24-25, 2015 – Zagreb, Croatia

**Hemolysis
:clinical
chemistry
testing**

Percentage RBC lysate on the total RBC mass.									
0	0.1	0.2	0.4	0.8	1.6	3.3	6.8	14.7	

**Visually
undetectable
hemolysis**

Clin Chem Lab Med 2006;44(2):211-216 © 2006 by Walter de Gruyter • Berlin • New York.
Influence of hemolysis on routine clinical chemistry testing
 Giuseppe Lipoti*, Gian Luca Salvagno, Martina Montagnana, Giorgio Brocco and Gian Cesare Guffè

GLS

15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
October 24-25, 2015 – Zagreb, Croatia

NEEDLE SIZE

Needle
size

Main sources of phlebotomy errors.

REVIEW

Phlebotomy Errors and Quality Improvement
in Results of Laboratory Testing

GIUSEPPE LIPOTI*, GIAN LUCA SALVAGNO†, MARTINA MONTAGNANA†, GIORGIO BROCCO† and GIAN CESARE GUFFÈ†

*LABORATORY MEDICINE,†LABORATORY MEDICINE, UNIVERSITÀ DEGLI STUDI DI TRIESTE, TRIESTE, ITALY

Blood Coagul Fibrinolysis 17:557–561 © 2006

Influence of the needle bore size on platelet count and routine coagulation testing

Giuseppe Lippi, Gian Luca Salvagno, Martina Montagnana, Giovanni Poli and Gian Cesare Guidi

Statistical analysis of free plasma hemoglobin, platelet count and coagulation testing for specimens collected into evacuated tubes, employing butterfly devices with 21, 23 or 25 G needles

	Desirable bias (%)	21 G needle		23 G needle		25 G needle	
		Mean ± SD	Mean ± SD	Passing-Bablok regression (r)	Mean ± SD	Passing-Bablok regression (r)	
Activated partial thromboplastin time (s)	± 2.3	31.3 ± 4.6	31.3 ± 4.7	$y = 1.05x - 1.69$ ($r = 0.992$)	30.9 ± 4.4	$y = 0.98x - 0.06$ ($r = 0.976$)	
Prothrombin time (s)	± 2.0	12.1 ± 0.8	12.1 ± 0.7	$y = 1.00x$ ($r = 0.975$)	12.1 ± 0.7	$y = 0.98x + 0.19$ ($r = 0.974$)	
Fibrinogen (mg/dl)	± 4.8	297 ± 52	300 ± 54	$y = 1.01x - 2.92$ ($r = 0.972$)	287 ± 53	$y = 0.98x + 5.72$ ($r = 0.972$)	
D-dimer (ng/ml)	Not available	178 ± 66	184 ± 73	$y = 1.05x - 5.07$ ($r = 0.985$)	186 ± 70*	$y = 1.02x + 1.91$ ($r = 0.989$)	
Platelet count (10^9 /ml)	± 5.9	254 ± 56	246 ± 54*	$y = 0.98 - 3.51$ ($r = 0.989$)	240 ± 54*	$y = 0.97x - 5.23$ ($r = 0.984$)	
Free hemoglobin (mmol/l)	± 1.8	0.09 ± 0.04	0.09 ± 0.05	$Y = 1.00x$ ($r = 0.991$)	0.09 ± 0.05	$y = 1.04x - 0.01$ ($r = 0.987$)	

Clin Chem Lab Med 2006;44(8):1009–1014 © 2006 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2006.172

Influence of the needle bore size used for collecting venous blood samples on routine clinical chemistry testing

Giuseppe Lippi*, Gian Luca Salvagno, Martina Montagnana, Giorgio Brocco and Gian Cesare Guidi

Recommendations for Collection of a Quality Specimen for Coagulation Testing

1. Patient preparation factors
 - a. Draw blood from patients fasting for at least 8 to 12 h.
 - b. Let the patient be in the sitting position for at least 10 to 15 min before venipuncture.
 - c. Patient to avoid physiologically stressing conditions and cigarette smoking before blood collection.
 - d. Acknowledge the use of anticoagulants or antiplatelet aggregant drugs.
 - e. Do not perform thrombophilia testing immediately after a thrombotic episode or while patients are on anticoagulant drugs.
 - f. Patients should not perform strenuous physical activity for at least 24 h before venipuncture.
2. Prevent misidentification errors
 - a. Use of at least two patient identifiers.
 - b. Blood tubes should be labeled before venipuncture, in the presence of the patient.
 - c. Do not process blood specimens whenever misidentification is suspected or confirmed.
3. Use of the correct technique
 - a. Appropriate education and training of phlebotomists should be established.
 - b. Collect blood preferably from median cubital and cephalic veins.
 - c. Deterge the site with 70% isopropyl alcohol and then accurately wipe off the alcohol with a dry cotton sponge.
 - d. Immediately stop the procedure and select another site when the first attempt is unsuccessful.
4. Use appropriate venous stasis
 - a. Place the tourniquet ~4 inches above the site of venipuncture.
 - b. The tourniquet should be tight enough to limit venous but not arterial circulation.
 - c. Do not prolong venous stasis after 1 min.
 - d. Use alternative means for visualizing the veins, e.g., transillumination devices.

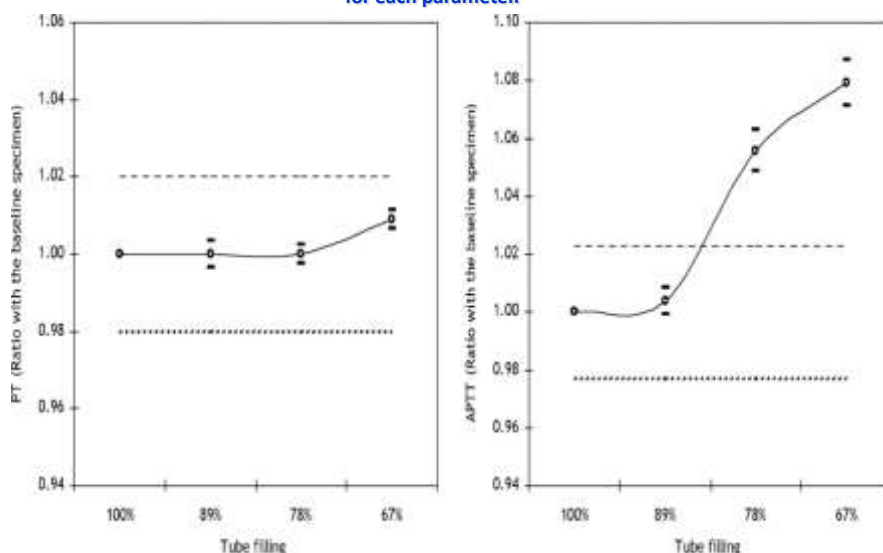
15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
October 24-25, 2015 – Zagreb, Croatia

Recommendations for Collection of a Quality Specimen for Coagulation Testing

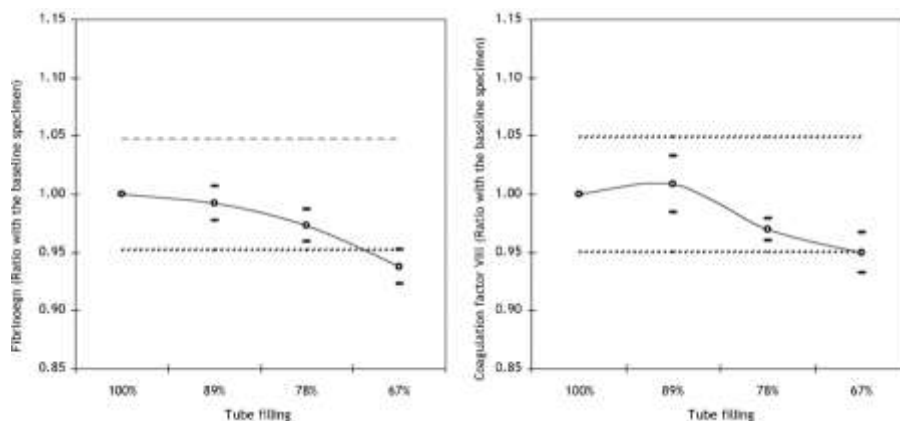
5. Use of appropriate devices and needles
 - a. Prefer straight needles rather than butterfly devices or syringes.
 - b. Prefer needles of intermediate size (i.e., from 19 to 21 gauge).
 - c. Collect the blood directly into primary vacuum tubes.
 - d. Use a discard tube when collecting blood through butterfly devices.
 - e. Always use safety devices.
6. Prevent collection of hemolyzed specimens and release of unreliable results
 - a. Follow the best practice for collecting blood.
 - b. Systematic inspection of all samples, preferably with hemolysis index.
 - c. Suppression of those tests more influenced by the presence of cell-free hemoglobin.
 - d. Recollection of another specimen.
7. Order of draw
 - a. Coagulation tubes (light blue top) should be collected after blood culture bottle or no additive tubes and before any other type of additive tube.
 - b. Collection of a discard tube is typically unnecessary (exceptions: butterfly devices, catheters, and PFA-100 testing).
8. Tube mixing
 - a. Gently invert—at least one to two times—the tube immediately after blood collection.
 - b. Avoid vigorous tube mixing.

Seminars in Thrombosis & Hemostasis Vol. 38 No. 4/2012

Influence of under-filling of 3.2% buffered sodium citrate blood tubes on results of activated partial thromboplastin time (APTT), prothrombin time (PT), fibrinogen, activated protein C resistance (APCR), and coagulation factor VIII. The dotted lines designate the desirable bias for each parameter.



Influence of under-filling of 3.2% buffered sodium citrate blood tubes on results of activated partial thromboplastin time (APTT), prothrombin time (PT), fibrinogen, activated protein C resistance (APCR), and coagulation factor VIII. The dotted lines designate the desirable bias for each parameter.



15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
October 24-25, 2015 – Zagreb, Croatia

National Patient Safety Goals

2007 Laboratory Services National Patient Safety Goals

- Goal 1 Improve the accuracy of patient identification.
- 1A Use at least two patient identifiers when providing care, treatment or services.
- 1B Prior to the start of any invasive procedure, conduct a final verification process, (such as a "time out,") to confirm the correct patient, procedure and site using active—not passive—communication techniques.



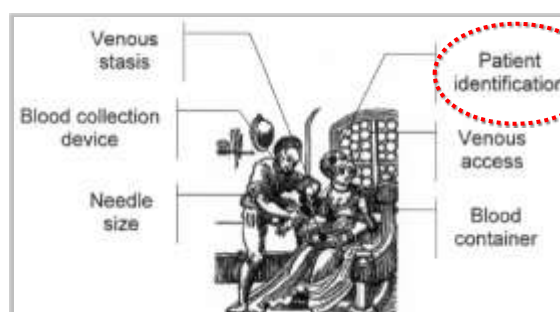
The **JCAHO** has recently given priority within the **2007 National Patient Safety Goals** to the improvement of the accuracy of patient identification and it applies to all JCAHO-accredited healthcare organizations and those seeking JCAHO accreditation. Failure to comply can result in a special Type I recommendation and jeopardize a facility's accreditation status.

GLS



The **International Organization for Standardization** 15189:2003 clause 5.4 “*Pre-examination procedures*” includes requirements for traceability of primary samples to an identified individual.

GLS



GLS

Review

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

Giuseppe Lippi^{1,*}, Gian Cesare Guidi¹, Camilla Mattiuzzi² and Mario Plebani³

The evidence that most laboratory testing errors occur for inpatients and are often outside the direct control of the laboratory staff suggests a solution that is apparently the most obvious, though not necessarily the simplest for reducing the complexity of the entire preanalytical phase. Some technologies have improved in a linear fashion or incrementally over time, whereas others have truly led to a paradigm shift. Beyond the rapid spread of point-of-care devices, there are emerging scenarios in biochemical testing that may soon revolutionize the current diagnostic approach in vitro. Progress has been made in improving process robustness, and in manufacturing rugged and miniaturized electroanalytical devices.

GLS

Laboratory quality improvement by implementation of phlebotomy guidelines

Errors and quality of laboratory testing

Giuseppe Lippi, MD, Professor; Camilla Mattiuzzi, MD and Gian Cesare Guidi, MD, Professor

Although restrictive specimen-acceptance policies and intolerance criteria often are revealed as convenient defenses, proactive efforts to intervene further upstream will definitely grant major benefits, especially in the long term.

In this perspective, recommendations and knowledge dissemination, training, and certification of phlebotomists should be welcomed, even outside the United States, as they represent essential steps that laboratory professionals should assiduously promote.



GLS

What's next?

Vol. 25 No. 9

Collection, Transport, Preparation, and
Storage of Specimens for Molecular
Methods; Approved Guideline

Vol. 23 No. 35

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

Vol. 23 No. 21

Blood Collection on Filter Paper for
Newborn Screening Programs; Approved
Standard—Fifth Edition

GP34-A  **CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®** December 2010

Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline

GP34-A  **CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®** December 2010

Validation and Verification of Tubes for
Venous and Capillary Blood Specimen
Collection; Approved Guideline

3.1	A Note on Terminology	1
3.2	Definitions	2
3.3	Abbreviations and Acronyms	4
4	<u>Impact of Blood Collection Tubes on Test (Examination) Performance</u>	4
4.1	Tube Wall	5
4.2	Closures	5
4.3	Closure Lubricant	6
4.4	Surfactants	6
4.5	Clot Activators	6
4.6	Anticoagulants	7
4.7	Separator Gel	8
4.8	Trace Metals	8
5	<u>Validation and Verification of Venous Blood Collection Tubes</u>	9
5.1	Preanalytical (Preexamination) Considerations	9
5.2	Determining the Need for Validation and Verification	9
5.3	Clinical Evaluation—Planning, Designing, and Conducting the Clinical Evaluation	10
5.4	Data Analysis	14
5.5	Clinical Acceptance Criteria	15

“Which is the best choice?”

Opinion Paper

Giuseppe Lippi*, Kathleen Becan-McBride, Darina Behúlová, Raffick A. Bowen, Stephen Church, Joris Delanghe, Kjell Grankvist, Steve Kitchen, Mads Nybo, Matthias Nauck, Nora Nikolac, Vladimir Palicka, Mario Plebani, Sverre Sandberg and Ana-Maria Simundic

Preanalytical quality improvement: in quality we trust

Opinion Paper

Ana-Maria Simundic*, Michael P. Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Ferruccio Ceriotti, Elvar Theodorsson and Mauro Panteghini on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM)

Colour coding for blood collection tube closures – a call for harmonisation

Take a home message

VERIFICATION OF BLOOD COLLECTION SYSTEM

- The Clinical Laboratory Standards Institute (CLSI) has issued several standards related to blood sampling and sample transportation and handling
- Some blood collection tube components such as various additives, clot activators, anticoagulants, surfactants, lubricants, stoppers and separator gels may interact with blood and therefore cause variable biases of the results of different laboratory tests.
- The verification process is essential in accredited medical laboratories, but seldom it is regarded as an issue in the pre-analytical management.