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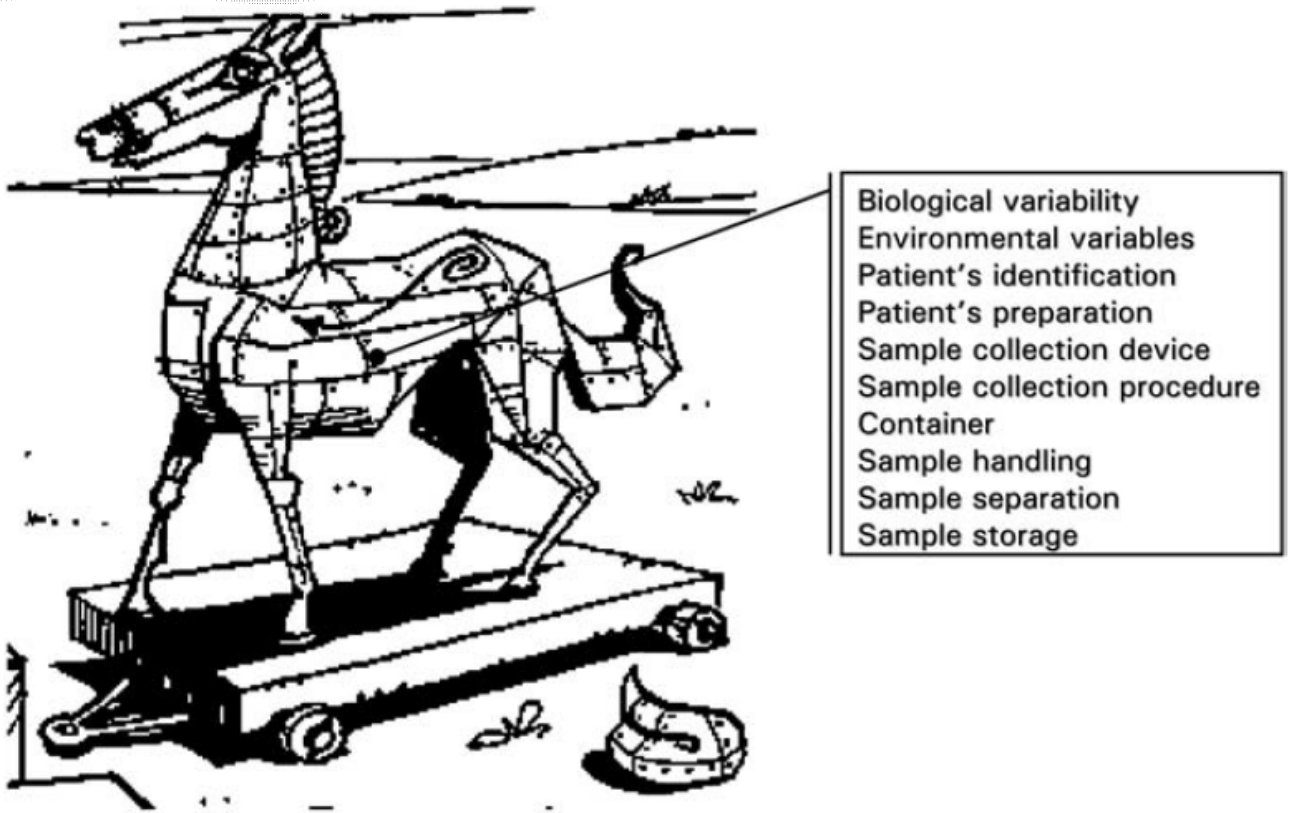
Preanalytical variability: the dark side of the moon in laboratory testing

Giuseppe Lippi

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

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

Giuseppe Lippi

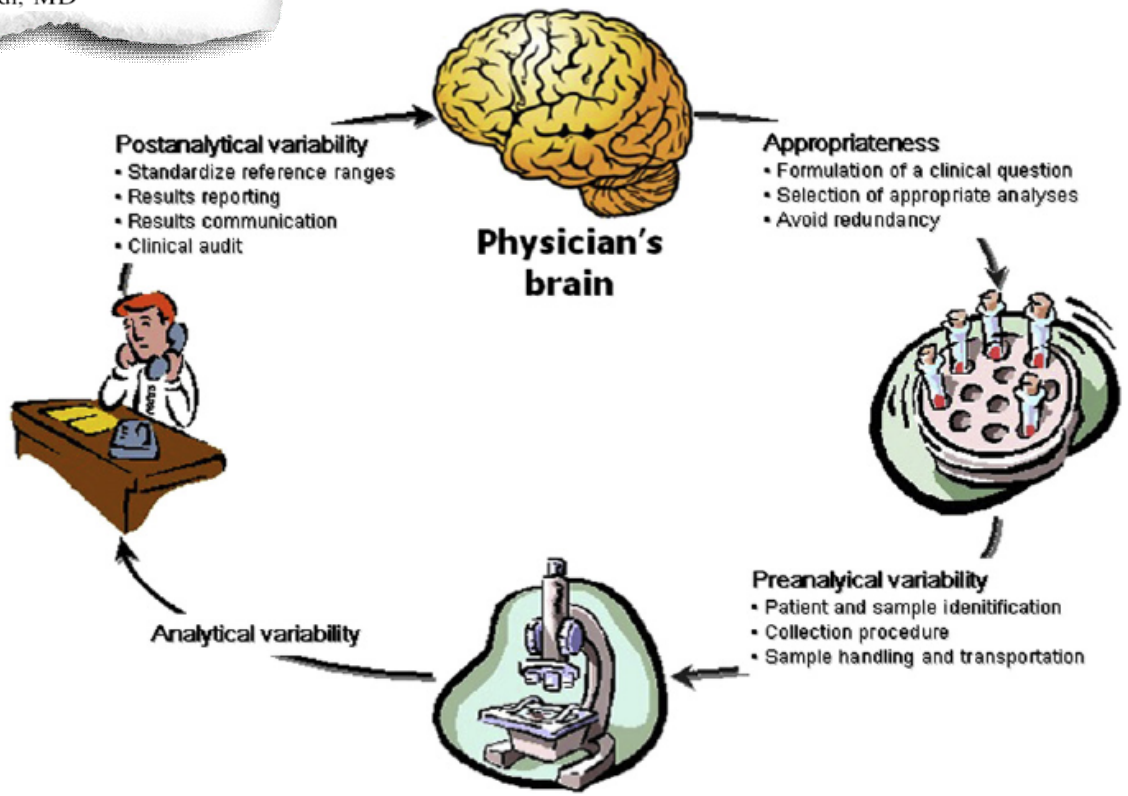


Preanalytical variables and laboratory testing.

Clin Lab Med 28 (2008) 285–294

Quality Improvement in Laboratory Medicine: Extra-Analytical Issues

Giuseppe Lippi, MD[a,*], Roberto Fostini, MD[b], Gian Cesare Guidi, MD[a]



Development of laboratory errors throughout the total testing process.

DE GRUYTER DOI 10.1515/cclm-2012-0597 — Clin Chem Lab Med 2013; 51(1): 229–241

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

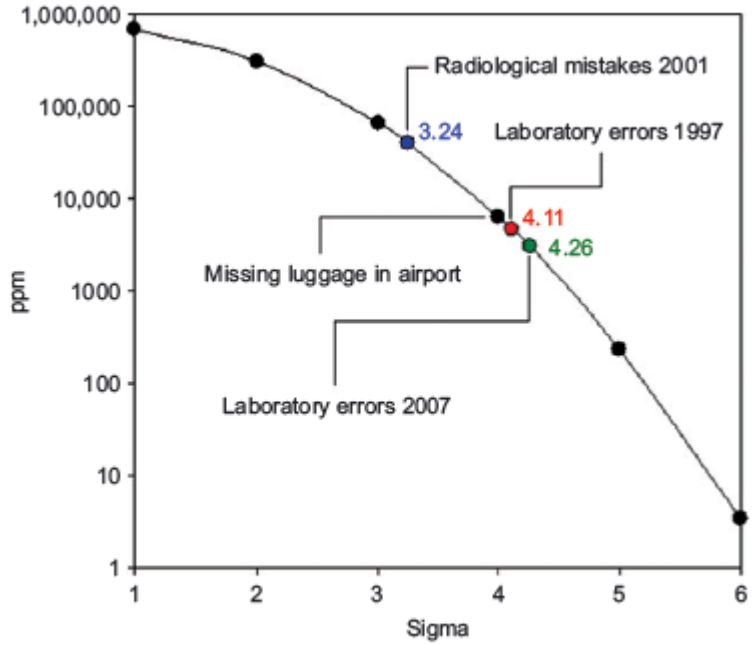


Figure 1 Six sigma metrics of laboratory errors.

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Exploring the iceberg of errors in laboratory medicine

Mario Plebani *

Department of Laboratory Medicine, University Hospital of Padova, Italy

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Post-analytic phase

ABSTRACT

The last few decades have seen a significant decrease in the rates of analytical errors in clinical laboratories, and currently available evidence demonstrates that the pre- and post-analytical steps of the total testing process (TTP) are more error-prone than the analytical phase. In particular, most errors are identified in pre- pre-analytic and post-post analytic steps outside the walls of the laboratory, and beyond its control. However, in a patient-centered approach to the delivery of health care services, there is the need to investigate any possible defect in the total testing process that may have a negative impact on the patient. In fact, in the interests of patients, any direct or indirect negative consequence related to a laboratory test must be considered, irrespective of which step is involved and whether the error is caused by a laboratory professional (eg., calibration or testing error) or by a non-laboratory operator (e.g., inappropriate test request, error in patient identification and/or blood collection). Data on diagnostic errors in primary care and in the emergency department setting demonstrate that inappropriate test requesting and incorrect interpretation account for a large percentage of total errors whatever the discipline involved, be it radiology, pathology or laboratory medicine. Patient misidentification and problems in communicating results, which affect the delivery of all diagnostic services, are widely recognized as the main goals for quality improvement. Therefore, some common problems affect diagnostic errors, although specific faults characterising errors in laboratory medicine should lead to preventive and corrective actions if evidence-based quality indicators are developed, implemented and monitored. The lesson we have learned is that each practice must examine its own total testing process to discover its weaknesses and identify appropriate remedies.

1. Introduction

Quality measurement in healthcare is shifting from a focus on quality assurance to transparency and accountability for patient care outcomes. Every step in the process of patient care carries a risk of harm and while the dictum "first, do no harm" is a cornerstone in medicine, only relatively recently has unsafe patient care been recognized as a worldwide problem and a significant source of morbidity and mortality [1].

The US Institute of Medicine (IOM) report, *To Err is Human: building a safer health system*, as well as the UK report *An organization with a memory* [3] galvanized a dramatic increase in concern about adverse events and patient safety at an international level [2]. Subsequent IOM reports, *Crossing the quality chasm* [4] and *Patient Safety: achieving a new standard for care* [5] stressed the concept of patient-centred care and the fact that complex systems (health care) are characterised by specialisation and interdependency.

Most available data on errors in health care focus on medication-related errors (particularly in hospitals) and related adverse events. However, in recent years large-scale surveys have demonstrated that patients and physicians perceive that diagnostic errors are a common occurrence and a cause of concern [6]. Throughout the last decade, diagnostic errors have led to the most prevalent type of malpractice claim in the US [7,8]. However, on considering the frequency and impact of diagnostic errors, one is struck by the widespread lack of awareness of this type of medical error. The diagnostic process, which consists of numerous clinical steps, stretches across multiple providers, and error that can harm patients are the fruit of the alignment of multiple breakdowns which, in turn, stem from a confluence of contributory factors [9].

In the past, clinical laboratories may have lacked information about how such system-wide issues were affecting them and the quality of services delivered. Numerous efforts have been made in recent decades to implement quality indicators for laboratory tests, which focus on either analytical performance or the achievement of a specific efficiency target, such as valuable turnaround time and contained costs [10]. However, a systematic framework for laboratory quality measurement is either unavailable or still in embryo and, therefore, little information is available on how to demonstrate whether services provided by laboratories, and the use of these services, is safe, timely, efficient, effective, equitable, and patient-centered. As stated by Nancy C. Elder et al., "the testing process begins and ends with the patient" [11]. A multidisciplinary framework which takes into account the total

* Dipartimento di Medicina di Laboratorio, Azienda Ospedaliera Università di Padova, Via Giustiniani 2, 35128 Padova, Italy. Tel.: +39 049 8212392; fax: +39 049 8212463.
E-mail address: mario.plebani@unipd.it.

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doi:10.1016/j.cca.2009.03.022

Frequency of errors (%) in the main phases of the total testing process.

Year	Author(s)	Pre	Intra analytic	Post	Reference
•1991	Ross et al.	45.5	7.3	47.2	17
•1997	Plebani et al.	68.2	13.3	18.5	18
•2003	Astion et al.	71.0	18.0	11.0	26
•2007	Carraro et al.	61.9	15.0	23.1	19

The clinical perspective...

Clinical Chemistry 53:7
1338–1342 (2007)

Errors in a Stat Laboratory: Types and Frequencies 10 Years Later

Paolo Carraro and Mario Plebani*

Table 4. Laboratory errors and patients' outcomes.

	No.	%
Total errors	160	
No effect	121	75.6
Inappropriate intensive care unit admission	1	0.6
Inappropriate transfusion	2	1.3
Further inappropriate investigation	9	5.6
Laboratory tests repetition	27	16.9

The economic perspective...

Prevalence and cost of hemolyzed samples in a large urban emergency department

G. Lippi*, P. Bonelli*, G. Cervellin†

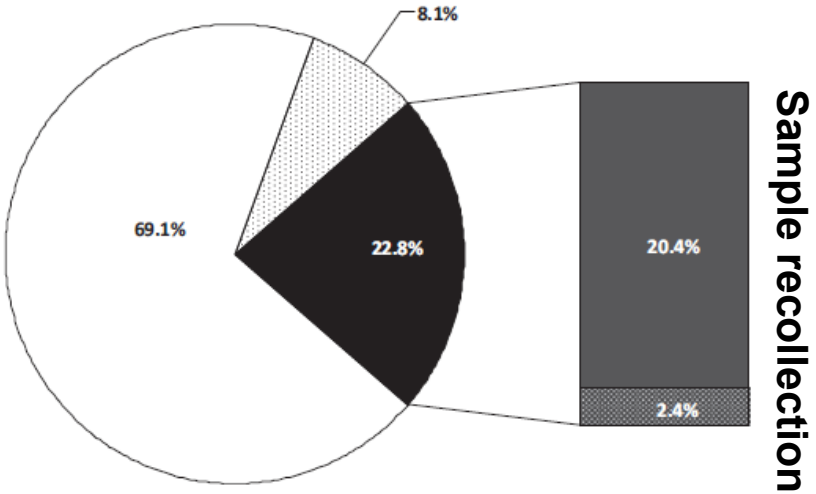


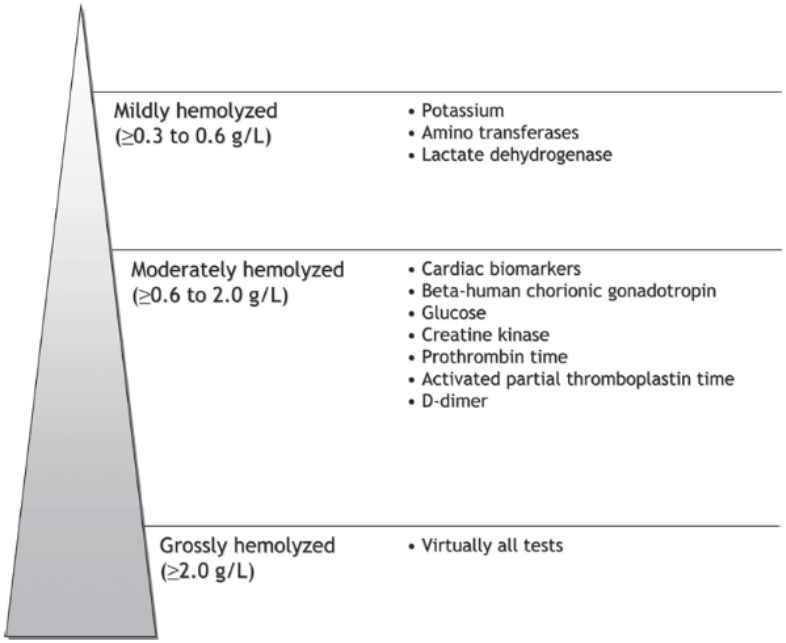
Figure 1. Estimated cost of diagnostic samples collection in a large urban emergency department. □,non hemolyzed samples (material); ⊠,non hemolyzed samples (personnel); ■,recollection of hemolyzed samples (material); ⊞, recollection of hemolyzed samples (personnel).

The organizational perspective...

Critical Reviews in Clinical Laboratory Sciences, 2011; 48(3): 143–153

Hemolyzed specimens: a major challenge for emergency departments and clinical laboratories

Giuseppe Lippi[1], Mario Plebani[2], Salvatore Di Somma[3], and Gianfranco Cervellin[4]



Clin Chem Lab Med 2011;49(x):xxx–xxx © 2011 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2011.600

Preanalytical quality improvement: from dream to reality

Giuseppe Lippi[1,*], Jeffrey J. Chance[2], Stephen Church[3], Paola Dazzi[3], Rossana Fontana[3], Davide Giavarina[4], Kjell Grankvist[5], Wim Huisman[6], Timo Kouri[7], Vladimir Palicka[8], Mario Plebani[9], Vincenzo Puro[10], Gian Luca Salvagno[11], Sverre Sandberg[12], Ken Sikaris[13], Ian Watson[14], Ana K. Stankovic[2] and Ana-Maria Simundic[15]

Major sources of pre-analytical variability

1. **Patient preparation**
   - Biological variability
   - Environmental conditions (e.g., climate, pollution)
   - Postural changes
2. **Sample collection**
   - Patient identification and sample labeling
   - Type of disposal for collecting blood (e.g., straight needle, butterfly, cannula)
   - Caliber (gauge) of the needle
   - Tourniquet time
   - Container (e.g., primary tube)
   - Order of draw
   - Phlebotomy procedure
   - Contamination from ….
   - Tube/s mixing
3. **Sample transportation**
   - Length and environmental conditions
   - Pneumatic tube systems
4. **Sample preparation for analysis**
   - Length, speed and temperature of centrifugation
   - Preparing aliquots
5. **Sample storage**
   - Length
   - Temperature
   - Freezing & thawing

Clin Chem Lab Med 2007;45(6):720–727 © 2007 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2007.167

Risk management in the preanalytical phase of laboratory testing

Giuseppe Lippi* and Gian Cesare Guidi

Table 1 Absolute and relative prevalence of preanalytical problems according to the literature.

Problem	Bonini et al. (9)	Dale et al. (17)	Romero et al. (18)	Plebani et al. (19)	Lippi et al. (21)
Absolute prevalence, %	0.35	NA	NA	0.2	0.75
Inpatients	0.60	NA	2.3	2.8	0.82
Outpatients	0.04	0.3	NA	0.06	0.37
Relative prevalence, %					
1° Hemolysis (total)	54	NA	NA	39	69
Inpatients	55	NA	50	40	68
Outpatients	32	18	NA	30	75
4° Clotting (total)	5	NA	NA	9	12
Inpatients	5	NA	15	7	13
Outpatients	10	13	NA	17	11
2° Insufficient volume (total)	21	NA	NA	15	9
Inpatients	21	NA	NA	16	10
Outpatients	13	16	NA	8	1
3° Inappropriate container (total)	13	NA	NA	10	5
Inpatients	12	NA	11	9	5
Outpatients	35	NA	NA	16	8
5° Misidentification (total)	2	NA	NA	1	2
Inpatients	2	NA	NA	1	2
Outpatients	0.2	6	NA	0.1	6

NA, not available.

Clin Chem Lab Med 2009;47(2):xxx–xxx © 2009 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2009.045

Review

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

Giuseppe Lippi[1,*], Norbert Blanckaert[2,4], Pierangelo Bonini[2,3,5], Sol Green[2,6], Steve Kitchen[2,7], Vladimir Palicka[2,8], Anne J. Vassault[2,9], Camilla Mattiuzzi[10] and Mario Plebani[2,11]

[1] Clinical Chemistry Laboratory, University of Verona, Verona, Italy
[2] EPSC – European Preanalytical Scientific Committee (www.specimencare.com)
[3] International Federation of Clinical Chemistry Working Group on Patient's Safety
[4] Laboratory Medicine, University Hospital Leuven, Leuven, Belgium
[5] Clinical Biochemistry, School of Medicine, University Vita-Salute San Raffaele, Milano, Italy
[6] BD Diagnostics – Preanalytical Systems, New Jersey, USA
[7] Sheffield Haemophilia and Thrombosis Center, Royal Hallamshire Hospital, Sheffield, UK
[8] Institute of Clinical Biochemistry and Diagnostics, Charles University, Medical Faculty and University Hospital, Hradec Kralove, Czech Republic
[9] Laboratoire de Biochimie B, Hôpital Necker Enfants Malades, APHP, Paris, France
[10] Direzione Medica, Azienda Ospedaliera di Verona, Verona, Italy
[11] Department of Laboratory Medicine, University of Padova, Padova, Italy

Abstract

Laboratory diagnostics, a pivotal part of clinical decision making, is no safer than other areas of healthcare, with most errors occurring in the manually intensive preanalytical process. Patient misidentification errors are potentially associated with the worst clinical outcome due to the potential for misdiagnosis and inappropriate therapy. While it is misleadingly assumed that identification errors occur at a low frequency in clinical laboratories, misidentification of general laboratory specimens is around 1% and can produce serious harm to patients, when not promptly detected. This article focuses on this challenging issue, providing an overview on the prevalence and leading causes of identification errors, analyzing the potential adverse consequences, and providing tentative guidelines for detection and prevention based on direct-positive identification, the use of information technology for data entry, automated systems for patient identification and specimen labeling, two or more identifiers during sample collection and delta check technology to identify significant variance of results from historical values. Once misidentification is detected, rejection and recollection is the most suitable approach to manage the specimen.
Clin Chem Lab Med 2009;47

Keywords: errors; laboratory medicine; misidentification; patient identification; patient safety.

Introduction

Recent evidence attests that healthcare is no safer place than it has traditionally been assumed to be. Today, an estimated 98,000 Americans die each year as a result of medical error, and a nearly equal number succumbs to infections they acquire in hospitals (1). While those numbers have been revised by estimating the patient prognosis and probability that death could have been prevented by optimal care (2), the more closely we examine patient care, the more errors we find. These error rates mirror a disappointing situation worldwide which is objectionable at the beginning of the new millennium. In fact, despite many efforts and recommendations to improve patient safety, we still lack concrete evidence that safety and quality of healthcare have reached their pinnacle. The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as "...any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer" (3). By definition, medical errors can occur at any stage in professional practice, including prescribing, order communication, product labeling, packaging, compounding, dispensing, distribution, and administration. Although there is a common perception that most medical errors arise from inappropriate or delayed clinical management, mistakes associated with diagnosis, either delayed or missed, may still occur with frequency. In the renowned publication of the IOM report on medical errors (To Err is Human) (1), the term "medication errors" is cited 70 times, while "diagnostic errors" appears only twice. This is interesting, since diagnostic errors comprised 17% of

*Corresponding author: Prof. Giuseppe Lippi, MD, Sezione di Chimica e Microscopia Clinica, Dipartimento di Scienze Morfologico-Biomediche, Università degli Studi di Verona, Ospedale Policlinico G.B. Rossi, Piazzale Scuro, 10, 37 134 Verona, Italy
Phone: +39-045-8124308, Fax: +39-045-8201889,
E-mail: ulppi@tin.it, giuseppe.lippi@univr.it
Received July 16, 2008; accepted November 25, 2009

Misidentification:

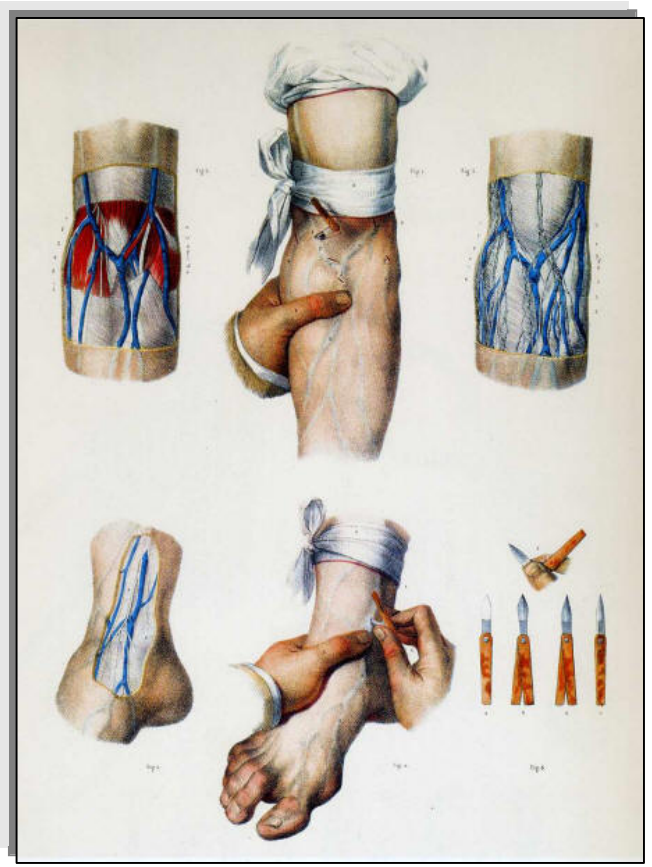
Relatively rare, but the worst!

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.

Semin Thromb Hemost

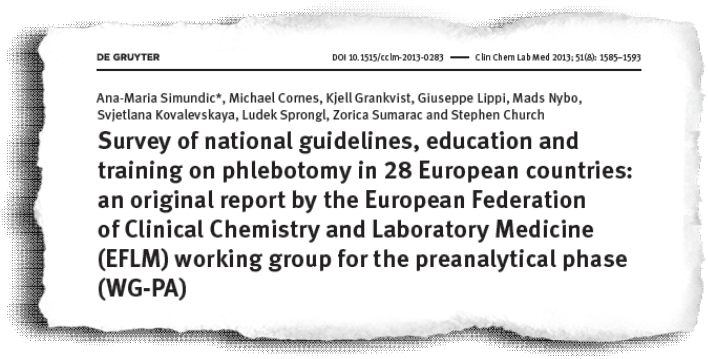
Quality Standards for Sample Collection in Coagulation Testing

Giuseppe Lippi, M.D.[1] Gian Luca Salvagno, M.D.[2] Martina Montagnana, M.D.[2]
Gabriel Lima-Oliveira, M.D.[2] Gian Cesare Guidi, M.D.[2]
Emmanuel J. Favaloro, Ph.D., M.A.I.M.S., F.F.Sc. (RCPA)[3]



Blood drawing:

The leading source of “our” problems!


DE GRUYTER DOI 10.1515/cclm-2013-0283 — Clin Chem Lab Med 2013; 51(6): 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)

The EFLM WG-PA has designed and disseminated a specific questionnaire aimed at establishing the state-of-the-art of phlebotomy practices across Europe.

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

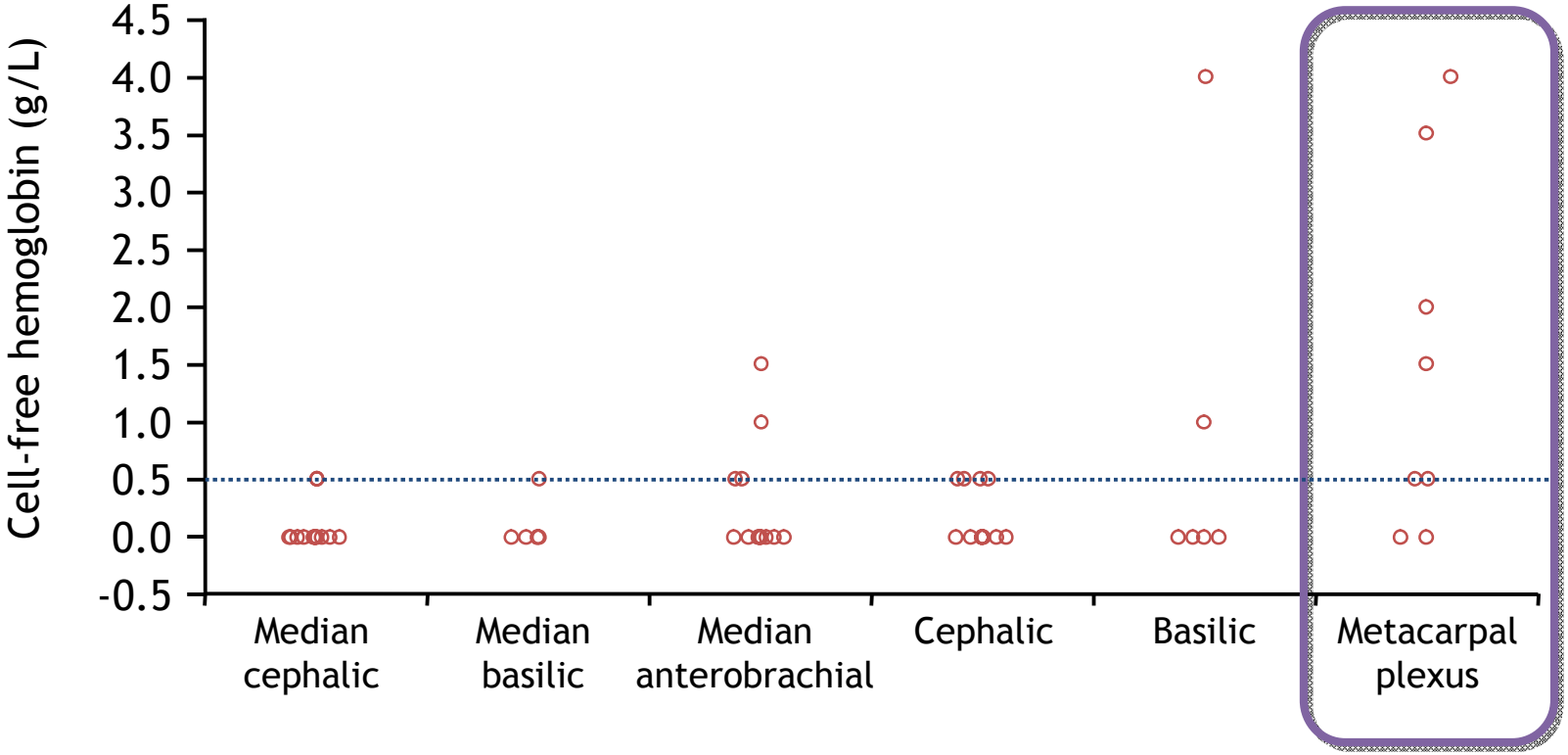
2) Existing CLSI H3-A6 phlebotomy guidelines should be adapted and used locally in all European countries which do not have their own guidelines;

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).

Clinical Biochemistry 46 (2013) 561–564

Prevention of hemolysis in blood samples collected from intravenous catheters

Giuseppe Lippi [a,*], Paola Avanzini [a], Gianfranco Cervellin [b]



Clin Chem Lab Med 2005;43(6):669–675 © 2005 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2005.148

Influence of short-term venous stasis on clinical chemistry testing

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

Istituto di Chimica e Microscopia Clinica, Dipartimento di Scienze Morfologico-Biomediche, Università degli Studi di Verona, Verona, Italy

Clin. Lab. Haem. 2006, **28**, 332–337

doi: 10.1111/j.1365-2257.2006.00818.x

Venous stasis and routine hematologic testing

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

*Sezione di Chimica e Microscopia Clinica, Dipartimento di Scienze Morfologico-Biomediche, Università degli Studi di Verona, Verona, Italy

†Servizio di Immunematologia e Trasfusione, Azienda Ospedaliera di Verona, Verona, Italy

Blood Coagulation and Fibrinolysis 2005, 16:453–458

Short-term venous stasis influences routine coagulation testing

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

USE OF TOURNIQUET:

(a) The tourniquet should be applied to the area approximately 10 cm above the intended site of venipuncture.

(b) It should be tight enough to restrict venous flow but not tight enough to obstruct arterial circulation. The pulse should be palpable below the level of the tourniquet.

(c) The tourniquet should not be left in situ for >1 min (when more time is required to find a suitable vein or the venipuncture protracts, the tourniquet may be released and reapplied).

(d) When vein is selected, tourniquet is released, skin cleansed and allowed to dry, then tourniquet re-tightened to proceed with venipuncture.

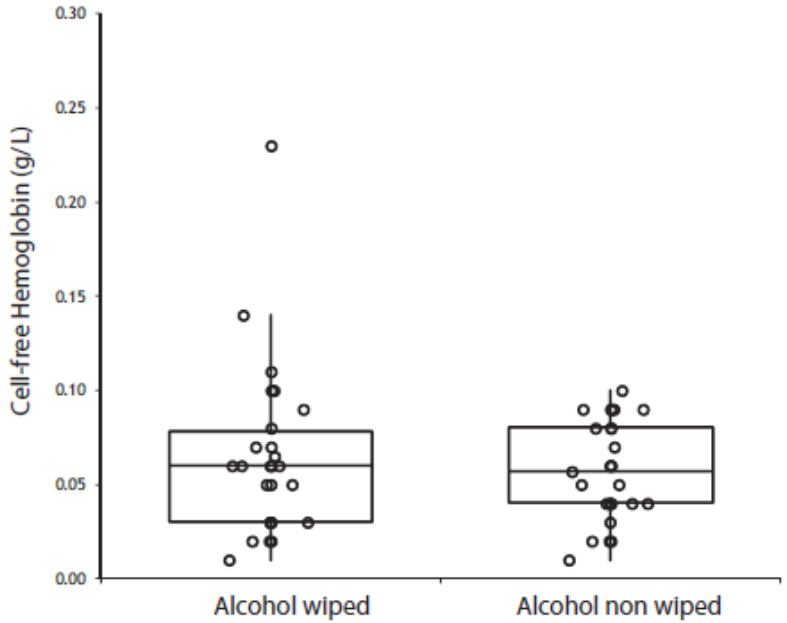
(e) Once blood flow starts (or needle is safely in vein), tourniquet is released. Should flow diminish or cease before sufficient blood is obtained, the tourniquet may be reapplied lightly.

(f) Tourniquet should not cause pain or discomfort to patient.

Biochemia Medica 2013;23(2):201–5

Avoidance to wipe alcohol before venipuncture is not a source of spurious hemolysis

Gian Luca Salvagno[1], Elisa Danese[1], Gabriel Lima-Oliveira[1,2], Gian Cesare Guidi[1], Giuseppe Lippi*[3]



DE GRUYTER DOI 10.1515/cclm-2013-0412 — Clin Chem Lab Med 2013; aop

Gianluca Salvagno, Gabriel Lima-Oliveira, Giorgio Brocco, Elisa Danese, Gian Cesare Guidi and Giuseppe Lippi*

The order of draw: myth or science?

Table 1 Results (median and IQR) and bias (mean and 95% confidence interval) of potassium, sodium, calcium, magnesium, and phosphorus measured in serum tubes collected before or after either a K_2-EDTA or sodium citrate tube.

	Before	After	Bias
K_2-EDTA tube			
Potassium, mmol/L	4.40 (4.17 to 4.62)	4.45 (4.24 to 4.68), p=0.064	0.04 (-0.01 to 0.08), p=0.127
Sodium, mmol/L	143 (142 to 144)	143 (142 to 144), p=0.091	0.2 (-0.1 to 0.4), p=0.182
Calcium, mmol/L	2.41 (2.35 to 2.46)	2.41 (2.36 to 2.46), p=0.095	0.00 (0.00 to 0.01), p=0.190
Magnesium, mmol/L	0.85 (0.81 to 0.89)	0.84 (0.81 to 0.87), p=0.127	-0.01 (-0.02 to 0.01), p=0.253
Phosphorus, mmol/L	1.06 (0.97 to 1.16)	1.06 (0.97 to 1.16), p=0.070	0.00 (0.00 to 0.01), p=0.141
Sodium citrate tube			
Potassium, mmol/L	4.50 (4.27 to 4.87)	4.54 (4.34 to 4.95), p=0.058	0.04 (0.00 to 0.08), p=0.056
Sodium, mmol/L	144 (142 to 145)	144 (142 to 145), p=0.170	0.1 (-0.1 to 0.4), p=0.341
Calcium, mmol/L	2.38 (2.32 to 2.44)	2.38 (2.33 to 2.45), p=0.054	0.01 (0.00 to 0.02), p=0.108
Magnesium, mmol/L	0.85 (0.80 to 0.88)	0.84 (0.80 to 0.88), p=0.231	0.00 (-0.01 to 0.01), p=0.462
Phosphorus, mmol/L	1.05 (0.94 to 1.18)	1.04 (0.94 to 1.20), p=0.063	0.00 (0.00 to 0.01), p=0.126

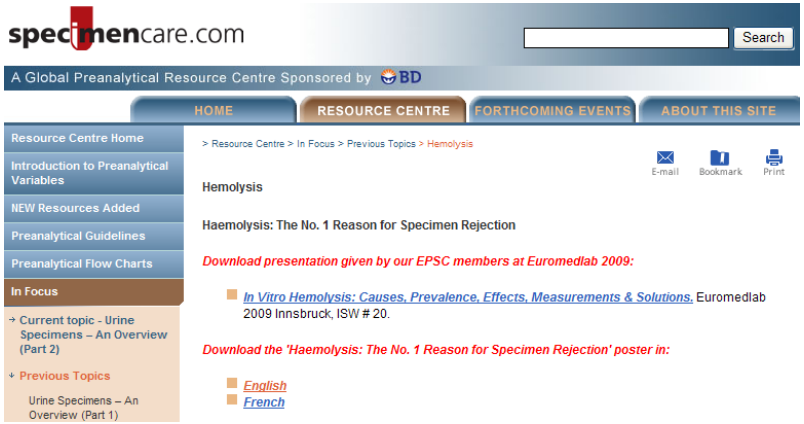
In vitro HEMOLYSIS

Clin Chem Lab Med 2008;46(6):764–772 © 2008 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2008.170

Review

Haemolysis: an overview of the leading cause of unsuitable specimens in clinical laboratories

Giuseppe Lippi[1,9,10,*], Norbert Blanckaert[2,9], Pierangelo Bonini[3,9,10], Sol Green[4,9], Steve Kitchen[5,9], Vladimir Palicka[6,9], Anne J. Vassault[7,9] and Mario Plebani[8,10]



Biochemia Medica 2010;20(2):154–9

Special issue: Quality in laboratory diagnostics: from theory to practice

Hemolysis detection and management of hemolyzed specimens

Ana-Maria Simundic[1*], Elizabeta Topic[2], Nora Nikolac[1], Giuseppe Lippi[3]

[1]University Department of Chemistry, Sestre Milosrdnice University Hospital, Zagreb, Croatia
[2]Croatian Society of Medical Biochemists, Zagreb, Croatia
[3]Laboratory of Clinical Chemistry and Hematology, Department of Pathology and Laboratory Medicine, University Hospital, Parma, Italy

Clin Chem Lab Med 2009;47(8):934–939 © 2009 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2009.218

Multicenter evaluation of the hemolysis index in automated clinical chemistry systems

Giuseppe Lippi[1,9,10,*], Gian Luca Salvagno[1], Norbert Blanckaert[2,9], Davide Giavarina[3], Sol Green[4,9], Steve Kitchen[5,9], Vladimir Palicka[6,9], Anne J. Vassault[7,9] and Mario Plebani[8–10]

Clin Chem Lab Med 2009;47(8):899–902 © 2009 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2009.229

Editorial

Hemolysis index: quality indicator or criterion for sample rejection?

Mario Plebani[1,3,*] and Giuseppe Lippi[2,3]

Biochemia Medica 2010;20(2):154–9

Hemolysis detection and management of hemolyzed specimens

Ana-Maria Simundic[1*], Elizabeta Topic[2], Nora Nikolac[1], Giuseppe Lippi[3]

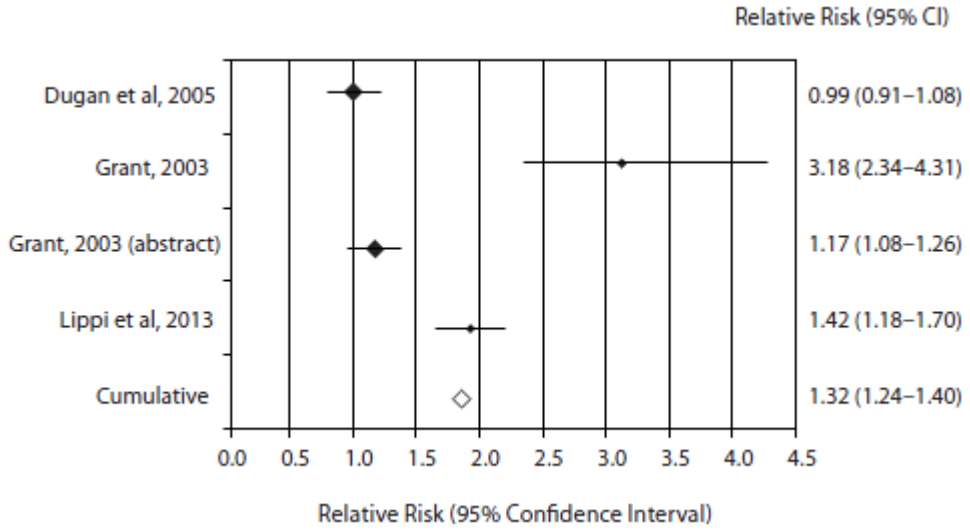
Hemolytic specimens are frequent occurrence in laboratory medicine.

- The prevalence is as high as 3.3% of all routine samples.
- They account for 40-70% of all unsuitable specimens.
- The are the first cause of unsuitable specimens, nearly five times higher than the second.
- In vitro hemolysis remains the leading cause of unsuitable specimens for both outpatient and inpatient samples, for routine and stat specimens.
- Several tests that are unreliable on hemolyzed specimens must be suppressed.

Biochemia Medica 2013;23(2):193–200

Critical review and meta-analysis of spurious hemolysis in blood samples collected from intravenous catheters

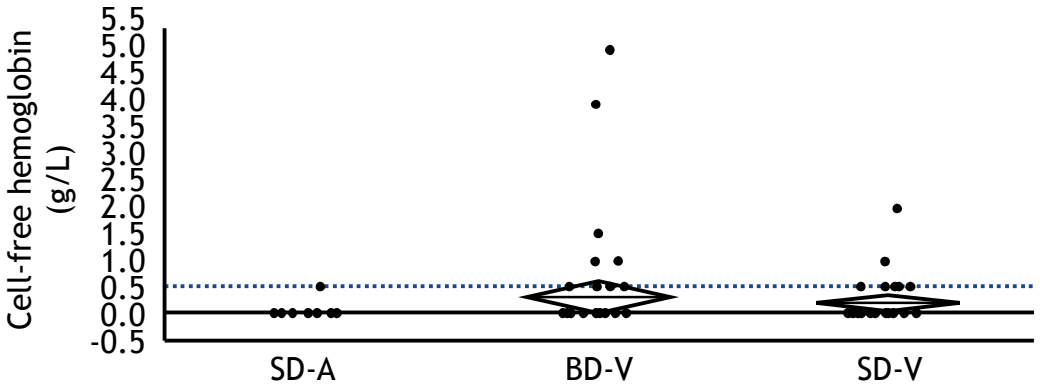
Giuseppe Lippi*[1], Gianfranco Cervellin[2], Camilla Mattiuzzi[3]



Biochemia Medica 2013;23(1):64–9

Evaluation of sample hemolysis in blood collected by S-Monovette® using vacuum or aspiration mode

Giuseppe Lippi*[1], Paola Avanzini[1], Roberta Musa[1], Franca Sandei[1], Rosalia Aloe[1], Gianfranco Cervellin[2]



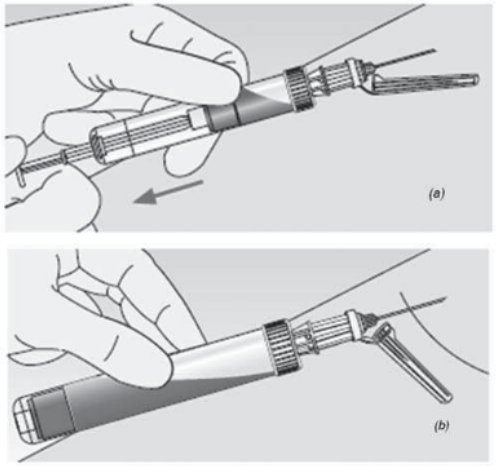


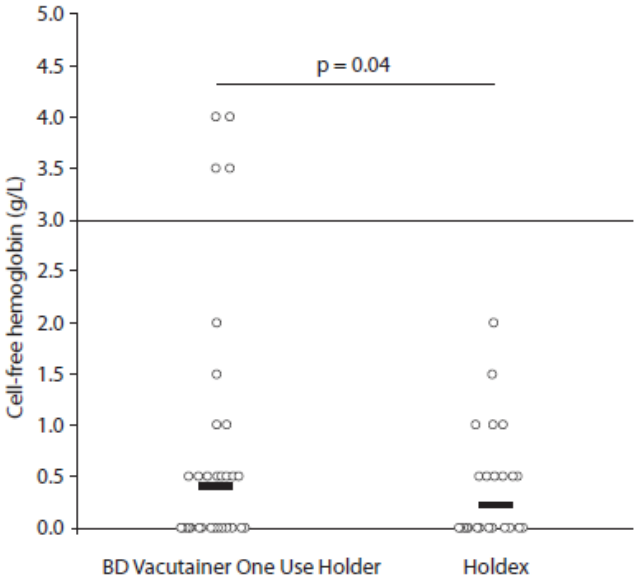
Figure 1. Blood collection with s-Monovette in aspiration (a) and vacuum (b) mode.

	Desirable specifications	Within-run imprecision	SD-A	BD-V	Bias from SD-A	p vs. SD-A	SD-V	Bias from SD-A	p vs. SD-A	p vs. BD-V
n			52	52			52			
LDH (U/L)	±4.3%	0.6%	432 (344-521)	495 (398-593)	14.6%	0.01	463 (370-555)	7.0%	0.01	0.05
Potassium (mmol/L)	±1.8%	0.6%	4.04 (3.90-4.18)	4.15 (3.96-4.34)	2.7%	0.04	4.11 (3.96-4.26)	1.7%	0.01	0.22
Cell-free hemoglobin Value (g/L)			0 (0-0)	0.3 (0.1-0.6)		0.01	0.2 (0.1-0.3)		<0.01	0.10
Frequency ≥0.5 g/L			1 (2%)	15 (29%)		<0.01	16 (31%)		<0.01	0.70

Biochemia Medica 2013;23(3):303–7

Reduction of gross hemolysis in catheter-drawn blood using Greiner Holdex® tube holder

Giuseppe Lippi*[1], Paola Avanzini[1], Rosalia Aloe[1], Gianfranco Cervellin[2]



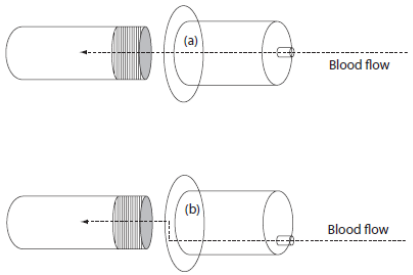


Table 1. Concentration of potassium and cell-free haemoglobin and lactate dehydrogenase (LD) activity in serum samples drawn from intravenous line using a conventional tube holder (BD Vacutainer One Use Holder) and Holdex.

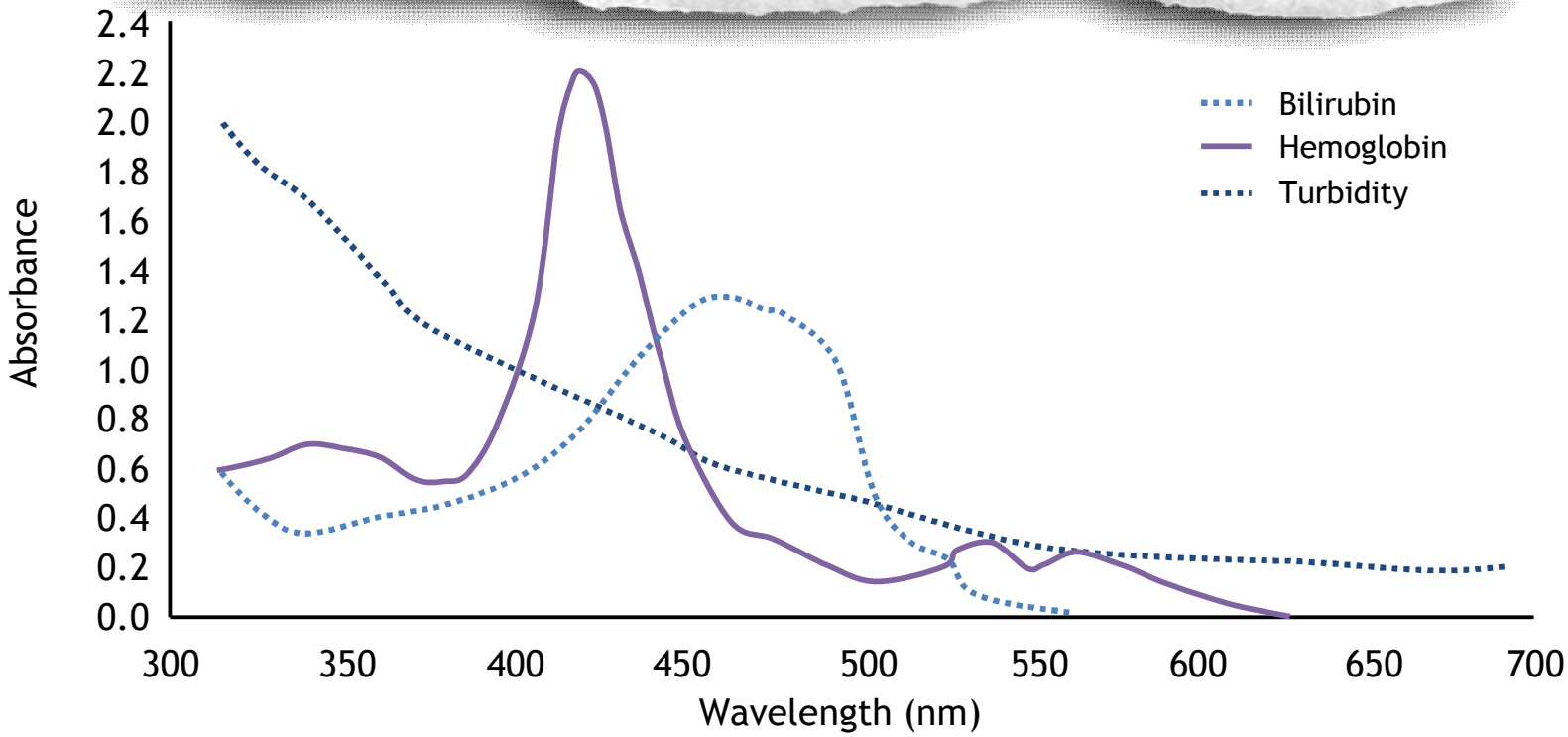
	BD Vacutainer One Use Holder	Holdex	P
Potassium (mmol/L)	4.25 (4.10-4.40)	4.16 (4.05-4.26)	0.031
LD (U/L)	498 (423-573)	459 (397-521)	0.039
Cell-free haemoglobin (g/L)	0.42 (0.17-0.67)	0.22 (0.11-0.32)	0.042
Cell-free haemoglobin > 0.5 g/L (rate)	17/60 (0.28)	17/60 (0.28)	1.000
Cell-free haemoglobin > 3 g/L (rate)	4 (0.07)	0 (0.00)	0.042

Data are presented as mean and 95% confidence intervals.

Semin Thromb Hemost 2013;39:258–266.

Interference in Coagulation Testing: Focus on Spurious Hemolysis, Icterus, and Lipemia

Giuseppe Lippi, MD [1] Mario Plebani, MD [2] Emmanuel J. Favaloro, PhD, FFSc (RCPA) [3]

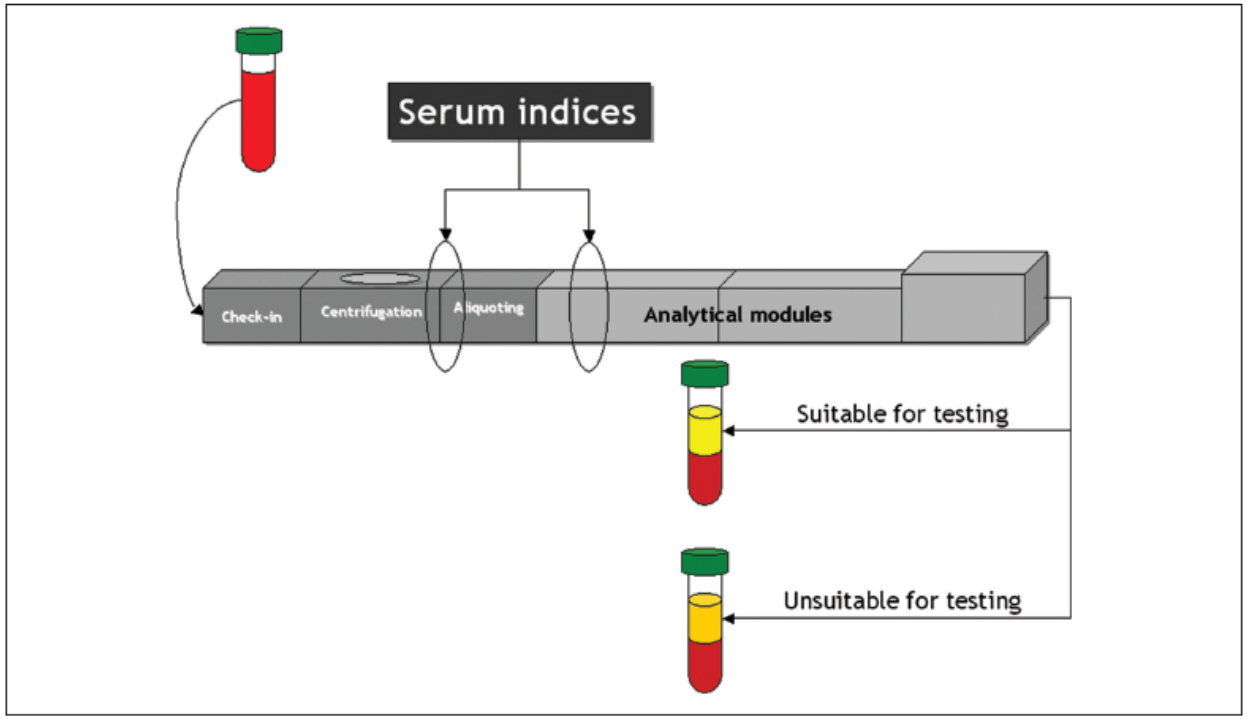


Journal of Laboratory Automation
XX(X) 1–5

DOI: 10.1177/2211068212450014
http://jala.sagepub.com
SAGE

Continuous-Flow Automation and Hemolysis Index: A Crucial Combination

Giuseppe Lippi[1] and Mario Plebani[2]



Article

Technical Evaluation of the Novel Preanalytical Module on Instrumentation Laboratory ACL TOP: Advancing Automation in Hemostasis Testing

Giuseppe Lippi[1], Luigi Ippolito[1], and Emmanuel J. Favaloro[2]

Journal of Laboratory Automation
XX(X) 1–9

DOI: 10.1177/2211068213491747
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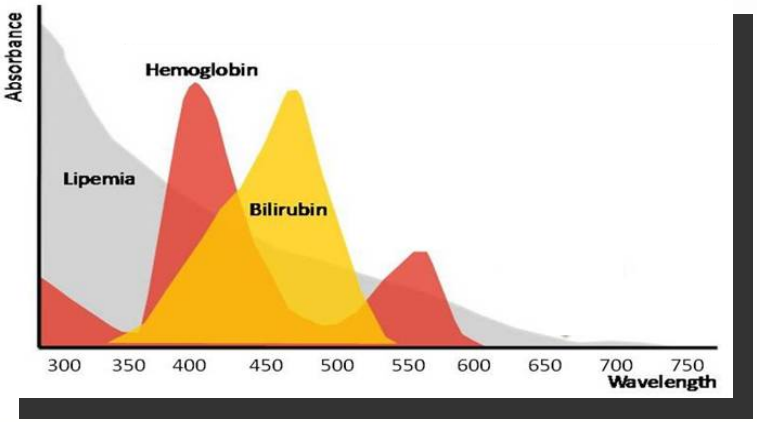
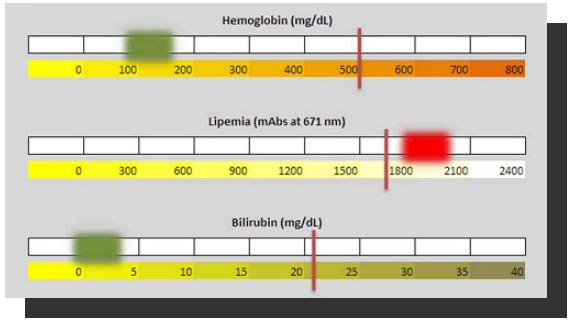
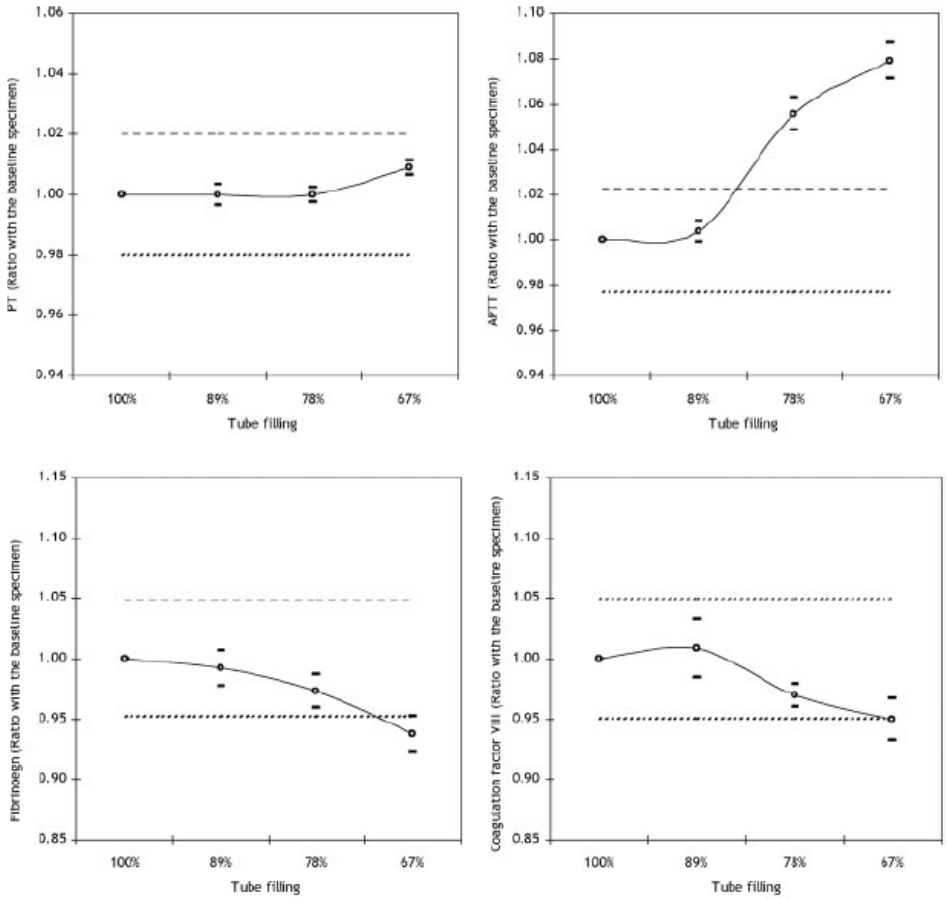


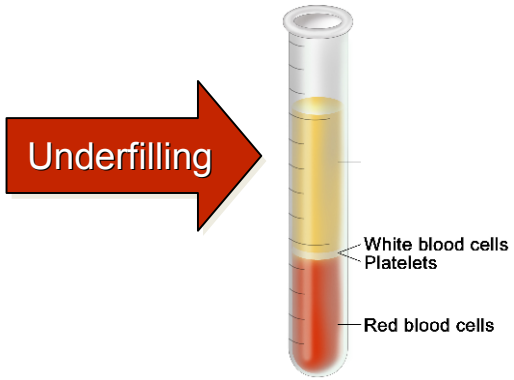




Semin Thromb Hemost

Quality Standards for Sample Collection in Coagulation Testing

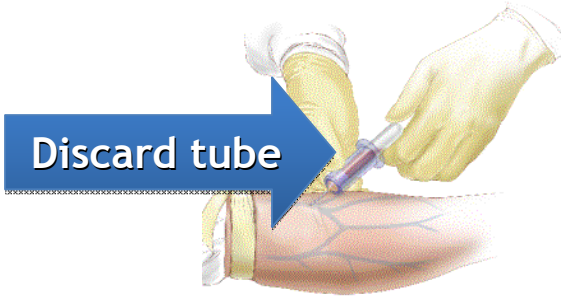
Giuseppe Lippi, M.D.[1] Gian Luca Salvagno, M.D.[2] Martina Montagnana, M.D.[2]
Gabriel Lima-Oliveira, M.D.[2] Gian Cesare Guidi, M.D.[2]
Emmanuel J. Favaloro, Ph.D., M.A.I.M.S., F.F.Sc. (RCPA)[3]



Am J Clin Pathol 2010;134:849-853

Discard Tubes Are Sometimes Necessary When Drawing Samples for Hemostasis

Emmanuel J. Favaloro, PhD Giuseppe Lippi, MD



We continue to support the current CLSI recommendations and assert that **a discard tube is unnecessary** when collecting samples for haemostasis tests, excepting for select circumstances.

This would include when using ***catheters*** or ***butterfly devices***, because the air space in the tube of this collection system may cause under-filling of the first-drawn tube, as well as perhaps when collecting for testing of ***platelet function*** such as by the PFA-100.

Do not mix blood from different tubes!

- EDTA irreversibly sequestrate calcium, which is essential for clotting tests
- In serum, clotting has already been triggered

British Journal of Biomedical Science 2013 70 (4)

Blood sample contamination by glucose-containing solutions: effects and identification

G. LIPPI*, P. AVANZINI*, F. SANDEI*, R. ALOE* and G. CERVELLIN†

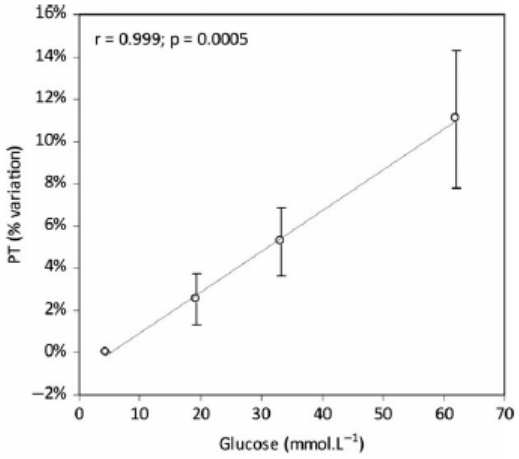
Table 1. Concentration (mean ± standard error of the mean) of plasma glucose, potassium, sodium, chloride, lactate dehydrogenase (LDH) and cholesterol in aliquots of heparinised blood contaminated with different amounts of 5% glucose solution.

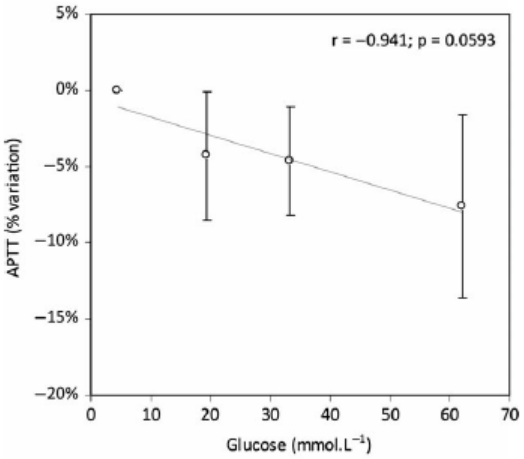
Heparinised blood	5% glucose solution	Contamination	Glucose (mmol/L)	Sodium (mmol/L)	Potassium (mmol/L)	Chloride (mmol/L)	LDH (U/L)	Cholesterol (mmol/L)
1 mL	0 mL	0%	5.3±0.1	143±0.7	4.04±0.08	108±0.4	290±13	4.7±0.5
1 mL	0.05 mL	5%	20.2±0.3	134±1.1	3.78±0.09	101±0.6	275±14	4.4±0.5
1 mL	0.10 mL	9%	34.4±0.5	127±0.9	3.59±0.08	96±0.5	256±14	4.1±0.5
1 mL	0.15 mL	13%	45.4±1.6	120±0.8	3.38±0.07	91±0.6	242±14	3.9±0.4
1 mL	0.20 mL	17%	57.1±1.4	115±1.1	3.25±0.08	87±0.4	230±11	3.7±0.4
1 mL	0.25 mL	20%	66.0±1.6	109±0.8	3.10±0.07	83±0.4	215±10	3.6±0.4
1 mL	0.30 mL	23%	77.3±1.3	103±1.1	2.97±0.07	79±0.5	204±8	3.4±0.4
0	1.00 mL	100%	278.1	–	–	–	–	–

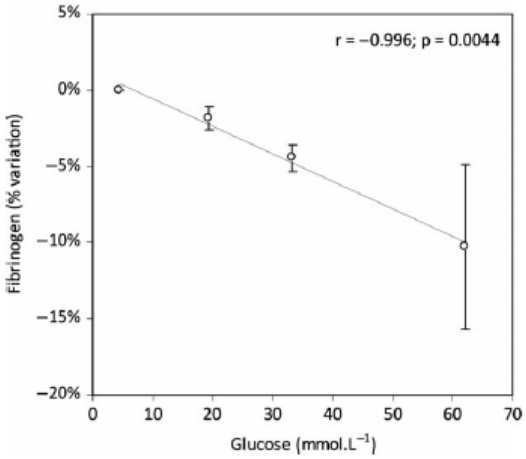
Anaesthesia 2014 doi:10.1111/anae.12990

The effect of hyperglycaemia on haemostasis testing – a volunteer study

G. Lippi,[1] R. Buonocore,[2] R. Musa,[3] L. Ippolito,[3] A. Picanza[2] and E. J. Favaloro[4]



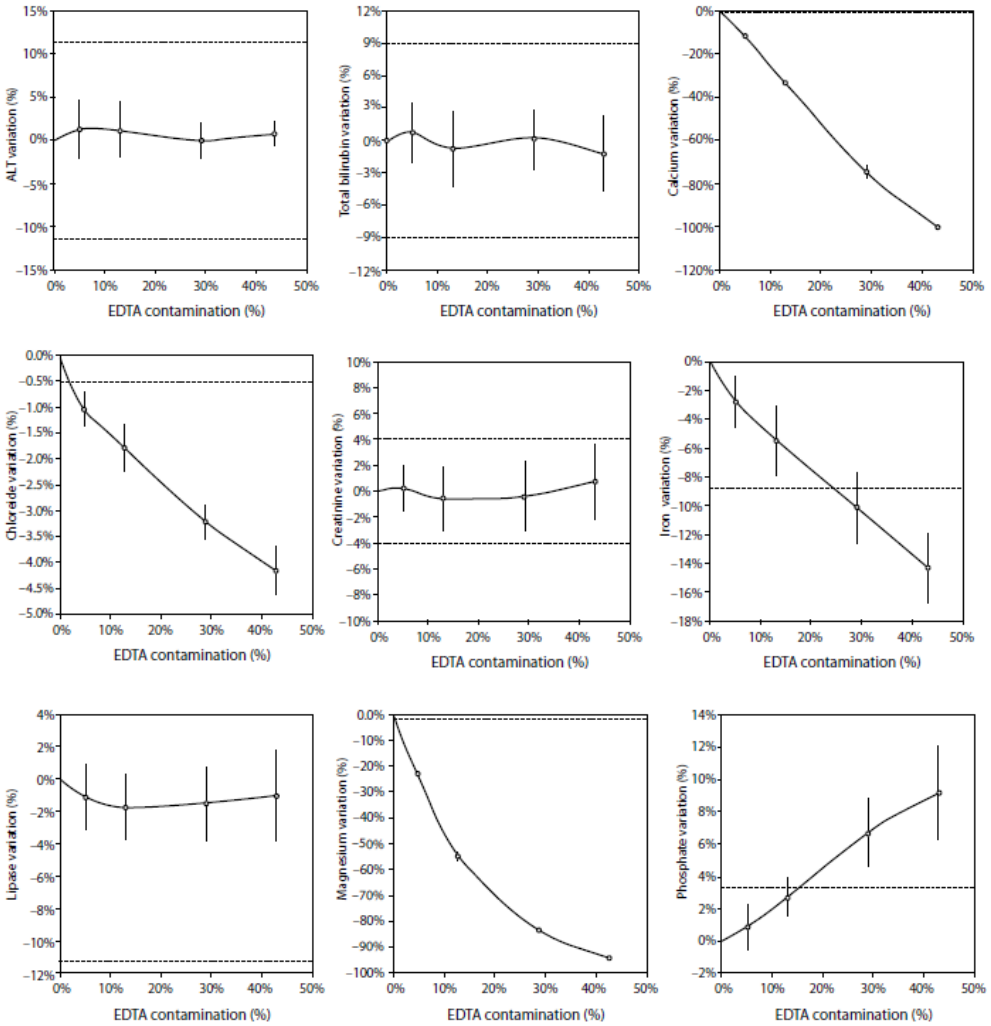




Biochemia Medica 2014;24(3):359–67

Contamination of lithium heparin blood by K2-ethylenediaminetetraacetic acid (EDTA): an experimental evaluation

Gabriel Lima-Oliveira*[1,2], Gian Luca Salvagno[1], Elisa Danese[1], Giorgio Brocco[1], Gian Cesare Guidi[1,2], Giuseppe Lippi[3]



Biochemia Medica 2010;20(1):5–8

Kontrola kvalitete u laboratorijskoj dijagnostici iz nove perspektive

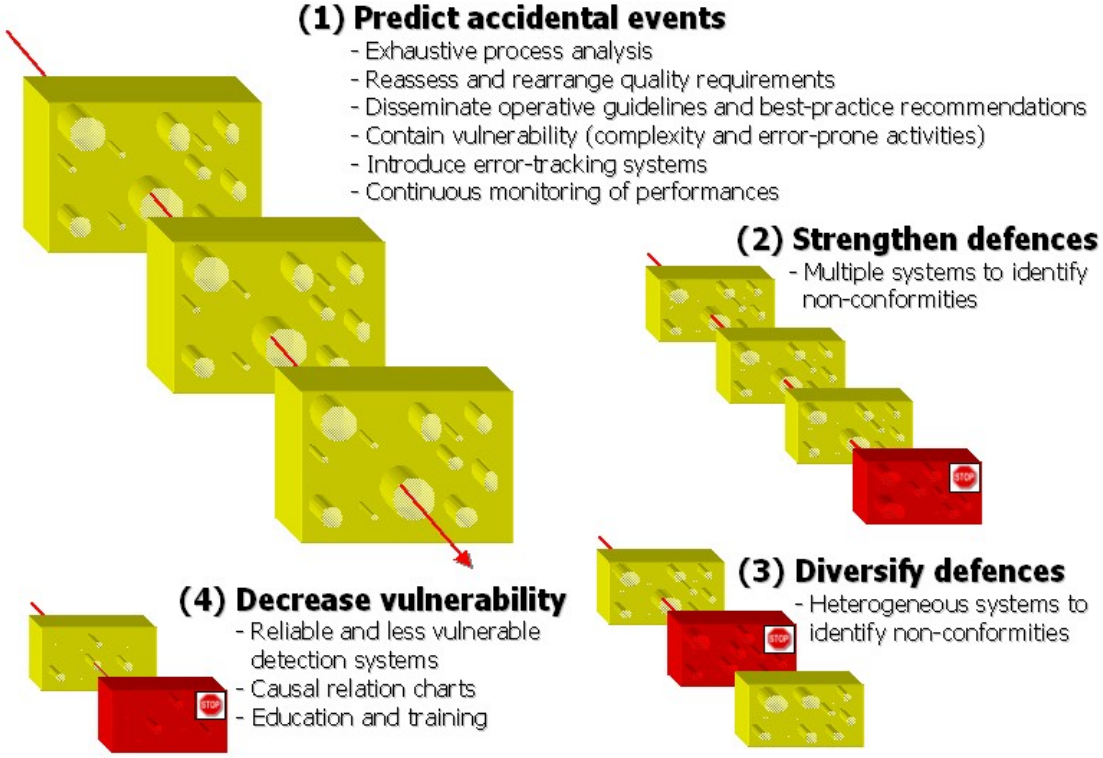
Total quality in laboratory diagnostics. It's time to think outside the box

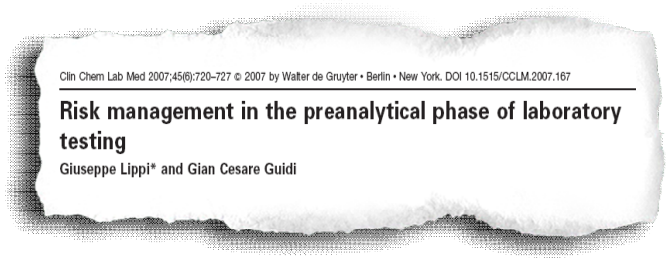
Giuseppe Lippi[1*], Ana-Maria Simundic[2]

Clin Chem Lab Med 2007;45(6):720–727 © 2007 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2007.167

Risk management in the preanalytical phase of laboratory testing

Giuseppe Lippi* and Gian Cesare Guidi




Clin Chem Lab Med 2007;45(6):720–727 © 2007 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2007.167

Risk management in the preanalytical phase of laboratory testing

Giuseppe Lippi* and Gian Cesare Guidi

Development of a multifaceted risk management strategy to enhance quality in the total testing process

1. Systematic analysis of **workflows and bottlenecks** in the system:
   - Elimination or redesign of **flawed/mishandled** procedures
   - Identification of **solutions** to suit local circumstances.
2. Do **not blame** individuals.
3. Continues **process monitoring** through development and implementation of suitable "***error tracking systems***".
4. Continuous **education** through *reliable recommendations*, *improved communication*, *interpretive rounds* within and outside the laboratory.
5. Definition and implementation of representative **quality indicators** and **outcome measures**.

biochimica clinica, 2013, vol. **37**, n. 4

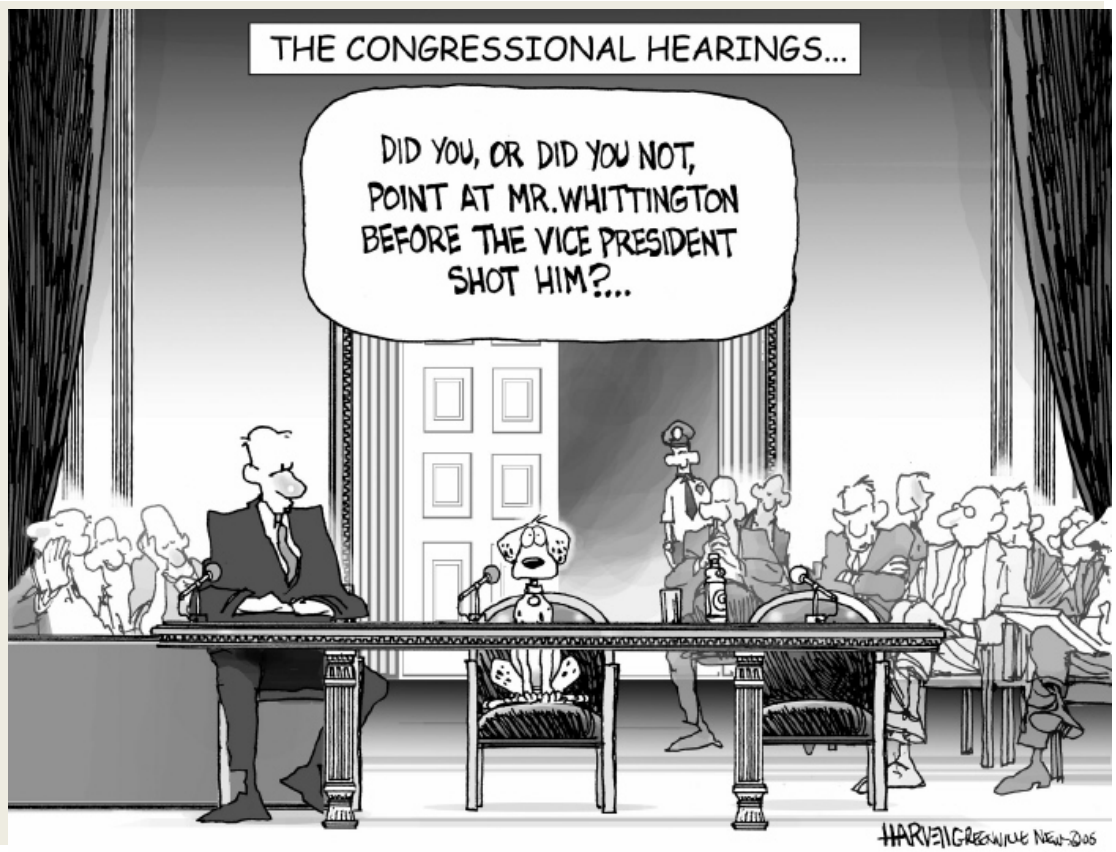
DOCUMENTI SIBioC **SIBioC DOCUMENTS**

Proposal of a checklist for venous blood collection.

Giuseppe Lippi[1], Camilla Mattiuzzi[2], Giuseppe Banfi[3], Mauro Buttarello[4], Marco Caputo[5], Massimo Daves[6], Alberto Dolci[7], Valentino Miconi[8], Bruno Milanesi[9], Martina Montagnana[10], Margherita Morandini[11], Elisa Piva[12], Gian Luca Salvagno[10], Teresa Troiano[13], Gianfranco Cervellin[14], Davide Giavarina[15] a nome del Gruppo di Studio Intersocietario SIBioC-Società Italiana di Medicina di Laboratorio (SIMeL) Variabilità extra-analitica

N.	Item
1	Use individual protection devices (IPD)
2	Patient is seated or supine for 5 min
3	Verify patient identity
4	Verify correspondence of patient identity on tube labels
5	Label blood tubes before venipuncture
6	Prepare the material for venipuncture
7	Prepare the material for venipuncture
8	Place the tourniquet for less than 2 min
9	Avoid repeated attempts in difficult venipunctures
10	Follow the order of draw
11	Fill the tubes properly
12	Mix gently blood tubes
13	Safe disposal of material

Do we always know for sure who is guilty???



Whenever an error occurs, BLAME your SYSTEM, and not your STAFF!

Clin Chem Lab Med 2007;45(6):728–736 © 2007 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2007.174

Recommendations for detection and management of unsuitable samples in clinical laboratories

Giuseppe Lippi[1,*], Giuseppe Banfi[2], Mauro Buttarello[3], Ferruccio Ceriotti[4], Massimo Daves[5], Alberto Dolci[6], Marco Caputo[7], Davide Giavarina[8], Martina Montagnana[1], Valentino Miconi[9], Bruno Milanesi[10], Andrea Mosca[11], Margherita Morandini[12] and Gian Luca Salvagno[1] for the Italian Intersociety SIBioC-SIMeL-CISMEL Study Group on Extra-analytical Variability

Tentative database for the registration of unsuitable specimens.

Operator ID[1)]	Date and time[2)]	Sample ID[3)]	Type of problem[4)]	Solution to the problem[5)]	Receiver ID[6)]
G.L.	01/03/2007; 10:30	45200899 ED	C-CLOT	REQ-SPEC	Mr. Paolo Rossi
A.B.	01/03/2007; 10:42	53200612 INT MED	C-CONT	SI-DEP	Dr. Giovanni Rossi

[1)]Insert the identification of the operator who identified the unsuitable specimen. [2)]Insert the date and time of identification of the unsuitable specimen. [3)]Insert the code for the unsuitable specimen and the referring department. [4)]Insert the type of problem encountered in the specimen according to a standardized format: a) hemolytic specimen, C-HEM; b) clotted specimen, C-CLOT; c) contaminated specimen, C-CONT; d) insufficient specimen, C-INS; e) inadequate container, C-INA; f) missing or wrong identification, C-NC. [5)]Insert the procedure used to manage the problem according to a standardized format: a) cited department, SI-DEP; b) second specimen requested (for inpatients), REQ-SPEC; c) recalled patient (for outpatients), REQ-PAT; d) specific comment included in the laboratory report, INS-COM. [6)]Insert the identification of the person to whom the problem and solution were reported.

Izvorni stručni članak **Original professional article**

Razvoj programa za bilježenje prijeanalitičkih pogrešaka

Development of a preanalytical errors recording software

Giuseppe Lippi*, Patrizia Bonelli, Rossana Rossi, Mirco Batdi, Rosalia Aloe, Alberta Caleffi, Enrichetta Bonilauri
U.O. di Diagnostica Ematochimica, Dipartimento di Patologia e Medicina di Laboratorio, Azienda Ospedaliero-Universitaria di Parma, Parma, Italy

*Corresponding author: glippi@ao.pr.it, ulippi@tin.it, giuseppe.lippi@univr.it

Sažetak

Uvod: Iako je doprinos laboratorijskoj dijagnostici od integralne važnosti u procesu donošenja kliničkih odluka, kvaliteta rada i sigurnost tijekom dijagnostičkih analiza od ključnog su značaja za unapređenje zdravstvene zaštite koja je na visokom stupnju što se kvalitete i sigurnosti tiče. Unatoč izvanrednom napretku u kvaliteti cjelokupnog procesa laboratorijske analize, prijeanalitička varijabilnost predstavlja vodeći izvor pogrešaka i nesigurnosti. Uvođenje sistematične politike bilježenja prijeanalitičkih pogrešaka uvelike bi poboljšala definiranje ključnih aktivnosti tog procesa, planiranje i praćenje učinkovitih radnji s ciljem poboljšanja cjelokupnog procesa. U ovom članku želimo dati opis kompjuterskog programa razvijenog za bilježenje prijeanalitičkih pogrešaka u našem laboratoriju.

Materijali i metode: Naš smo program razvili na temelju Microsoftovog programa Access. Glavna polja uključena u program obuhvaćala su brojač za progresivno brojanje uzoraka, datum primitka uzorka, identifikacijski broj uzorka, ime bolesnika, tip pretrage, odjel s kojeg je bolesnik upućen, matriks uzorka, tip nesukladnosti, radnja koja je poduzeta kako bi se riješio problem, drugo polje za moguće radnje koje su dodatno poduzete, identifikacijski broj operatera. Baza podataka nalazi se na središnjem računalu unutar našeg laboratorijskog informatičkog sistema, tako da se do nje može doći s bilo kojeg računala u laboratoriju, što omogućuje kontinuirani i standardizirani unos podataka.

Rezultati i rasprava: Uvođenje kompjuterskog programa za sistematično bilježenje prijeanalitičkih pogrešaka donosi velika poboljšanja, kao što su harmonizacija protokola za bilježenje incidenata, jednostavnost digitalnog bilježenja, eliminaciju rukom pisanih izvješća, uključivanje mjera učinkovitosti ključnih segmenata laboratorijskog rada, jednostavna prilagodba korisniku (laboratoriju), korištenje tablica s podacima za opsežne statističke analize, poboljšano pretraživanje i obrada podataka kao i poboljšana izrada statističkih izvješća.

Ključne riječi: pogreške; ispitivanje laboratorija; kompjuterski program; informatika; izvananalitička faza

Pristigło: 24. studenog 2009.
Prihvaćeno: 27. prosinca 2009.

Abstract

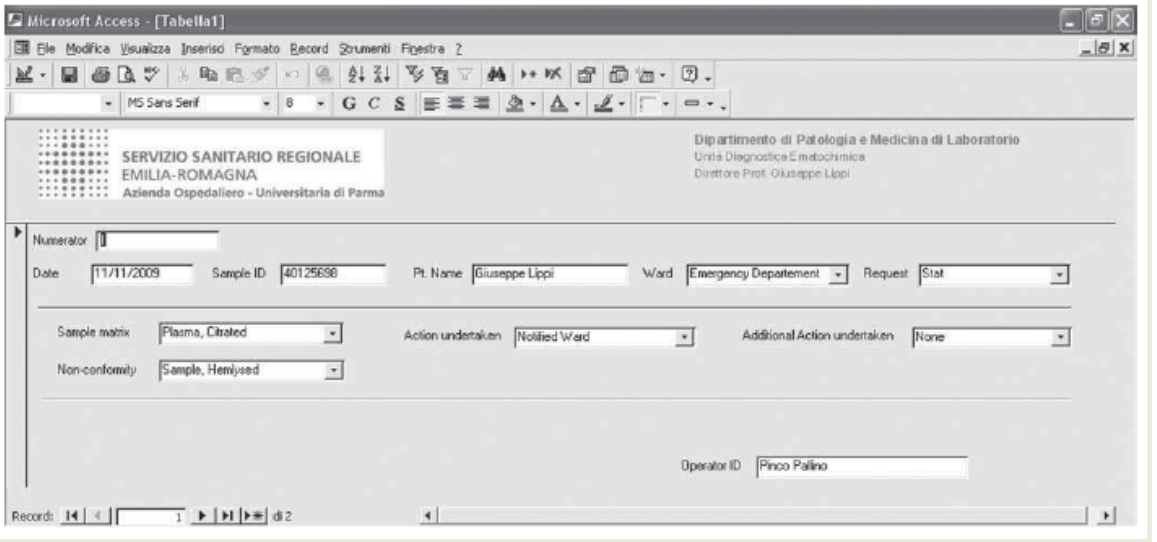
Background: Although the contribution of laboratory diagnostics is integral to the clinical decision making, quality and safety in diagnostic testing are essential to furthering the goal of high-quality and safe healthcare. Despite remarkable advances in the quality of the total testing process, the preanalytical variability is the leading source of errors and uncertainty. As such, the implementation of a systematic policy for recording preanalytical errors would grant major benefits for identifying critical activities of this process, planning and monitoring effective actions for improvement. The aim of this article is to describe the software developed for the recording of preanalytical errors in our laboratory.

Materials and methods: We have developed error recording software based on Microsoft Access. The main fields included in the software comprehend a numerator for progressive enumeration of the samples, the date of receipt of the specimen, the Sample ID, the patient's name, the type of request, the referring ward, sample matrix, the type of non-conformity, the action undertaken to solve the problem, a second field for possible additional actions undertaken, and the operator ID. The database is stored on a common repository in our laboratory information system, so that it can be accessed by any computer in the laboratory, allowing continuous and standardized input of the data.

Results and discussion: The implementation of a software for systematical recording of preanalytical errors grants major benefits, including harmonization of incident reporting practices, simplicity of digital recording, elimination of handwritten reports, inclusion of validated measures of laboratory performance, handily customization, exportation on worksheets for comprehensive statistical analyses, improved data searching and processing, as well as production of improved statistical reports.

Keywords: errors; laboratory testing; computer program; informatics; extra-analytical phase

Received: November 24, 2009
Accepted: December 27, 2009



Scandinavian Journal of Clinical & Laboratory Investigation
2009, 1–4, iFirst article

The importance of incident reporting in laboratory diagnostics

GIUSEPPE LIPPI[1,3] & MARIO PLEBANI[2,3]

INCIDENT REPORTING

NZ J Med Lab Science 2015

Pre-analytical variability and quality of diagnostic testing. Looking at the moon and gazing beyond the finger

Giuseppe Lippi[1], Camilla Mattiuzzi[2] and Emmanuel J Favaloro[3]
[1]Academic Hospital of Parma, Italy; [2]General Hospital of Trento, Italy;
[3]Westmead Hospital, Australia