GASOMETRIA: L'IMPORTANZA DELLA CORRETTA PREANALITICA

Dott. Luca Germagnoli
Unilabs Ticino

ISO 22870 deleted

NO added requirements compared to ISO 22870

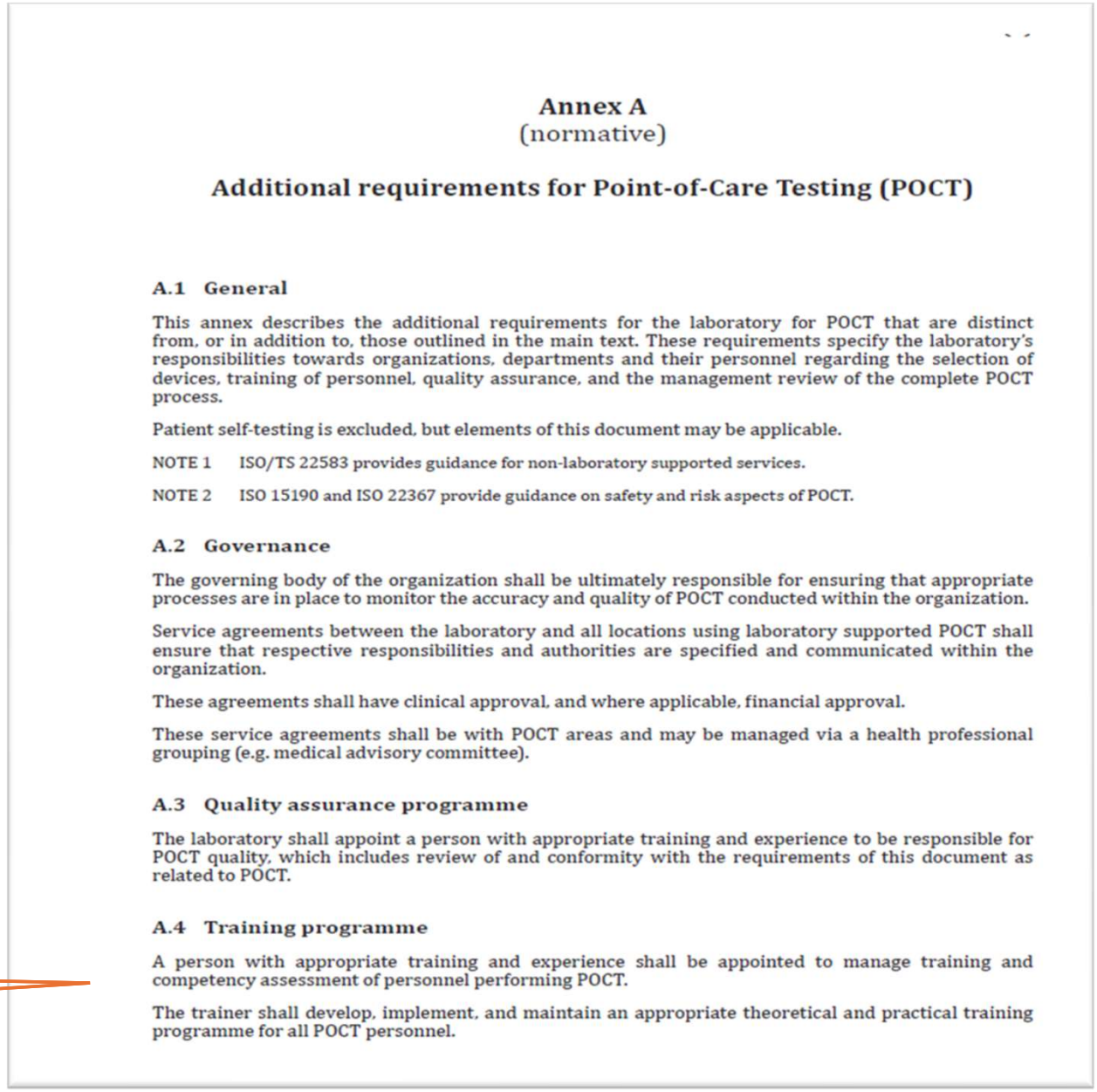
POCT requirements in

- 6.2.1
- 6.3.1
- 6.6.1
- 6.7.2
- 7.3.1
- 7.3.7.3 (EQC)
- 7.4.1.7
- 8.9.2

POCT provider must fulfill all relevant requirements of ISO 15189 AND POCT Ones

3.22: POCT – examination performed near or at the site of a patient

ISO 22583: guidance for supervisor
And operators of POCT equipment



Annex A
(normative)

Additional requirements for Point-of-Care Testing (POCT)

A.1 General

This annex describes the additional requirements for the laboratory for POCT that are distinct from, or in addition to, those outlined in the main text. These requirements specify the laboratory's responsibilities towards organizations, departments and their personnel regarding the selection of devices, training of personnel, quality assurance, and the management review of the complete POCT process.

Patient self-testing is excluded, but elements of this document may be applicable.

NOTE 1 ISO/TS 22583 provides guidance for non-laboratory supported services.

NOTE 2 ISO 15190 and ISO 22367 provide guidance on safety and risk aspects of POCT.

A.2 Governance

The governing body of the organization shall be ultimately responsible for ensuring that appropriate processes are in place to monitor the accuracy and quality of POCT conducted within the organization.

Service agreements between the laboratory and all locations using laboratory supported POCT shall ensure that respective responsibilities and authorities are specified and communicated within the organization.

These agreements shall have clinical approval, and where applicable, financial approval.

These service agreements shall be with POCT areas and may be managed via a health professional grouping (e.g. medical advisory committee).

A.3 Quality assurance programme

The laboratory shall appoint a person with appropriate training and experience to be responsible for POCT quality, which includes review of and conformity with the requirements of this document as related to POCT.

A.4 Training programme

A person with appropriate training and experience shall be appointed to manage training and competency assessment of personnel performing POCT.

The trainer shall develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel.

• POCT:

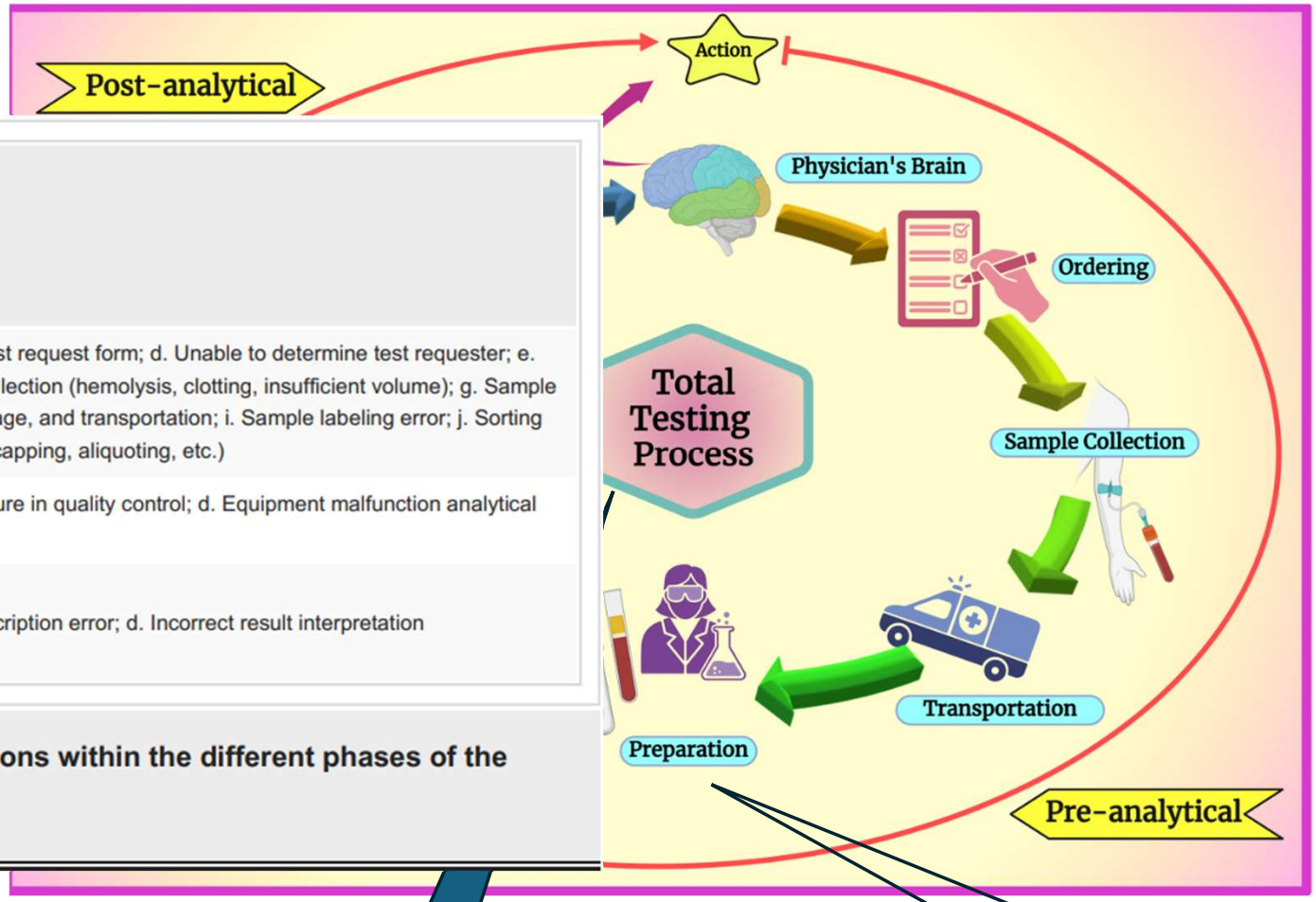
I RISULTATI DETERMINANO RAPIDAMENTE MODIFICHE NEL MANAGEMENT CLINICO DEI PAZIENTI

SE SI VERIFICA UN ERRORE, ABBIAMO POCO E MENO TEMPO A DISPOSIZIONE PER PORVI RIMEDIO

- **POCT:**

The phase of the testing process	Source of error
Pre-analytical [1,2,10,11]	a. Inappropriate test request; b.Order entry errors; c. Misplaced test request form; d. Unable to determine test requester; e. Patient misidentification; f. Inappropriate tube Improper sample collection (hemolysis, clotting, insufficient volume); g. Sample collected from the infusion site; h. Improper sample handling, storage, and transportation; i. Sample labeling error; j. Sorting and routing errors; k.Sample processing errors (centrifugation, decapping, aliquoting, etc.)
Analytical [2,11]	a. Sample loss; b. Sample mix-up/ interference; c. Undetected failure in quality control; d. Equipment malfunction analytical errors
Post-analytical [11]	a. Test result loss; b. Erroneous validation of test results; c. Transcription error; d. Incorrect result interpretation

TABLE 1: Source of laboratory errors and their distributions within the different phases of the testing processes.



68%/14%/18%

MINUTI

ASSICURAZIONE DELLA QUALITA' DEL RISULTATO

Cite this article as: Nordin N, Ab Rahim S, Wan Omar W, et al. (March 30, 2024) Preanalytical Errors in Clinical Laboratory Testing at a Glance: Source and Control Measures. Cureus 16(3): e57243. doi:10.7759/cureus.57243

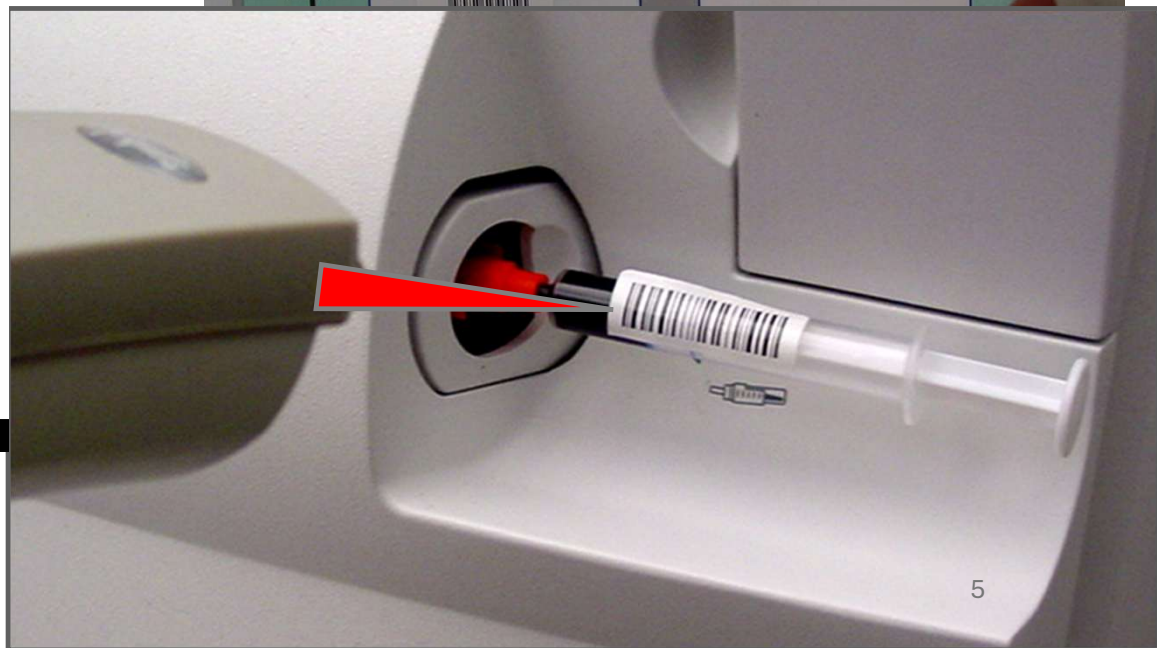
IDENTIFICA SEMPRE IL PAZIENTE

IDENTIFICA SEMPRE IL CAMPIONE (ETICHETTA/ID UNIVOCO)

FAI SEMPRE LEGGERE IL BARCODE DELLA SIRINGA/CAMPIONE AL LETTORE BG

IDENTIFICATI SEMPRE:

- OBBLIGO DI INSERIMENTO DI ID OPERATORE
- ACCESSO E TRACCIABILITA' A BG SOLO PER OPERATORI ABILITATI

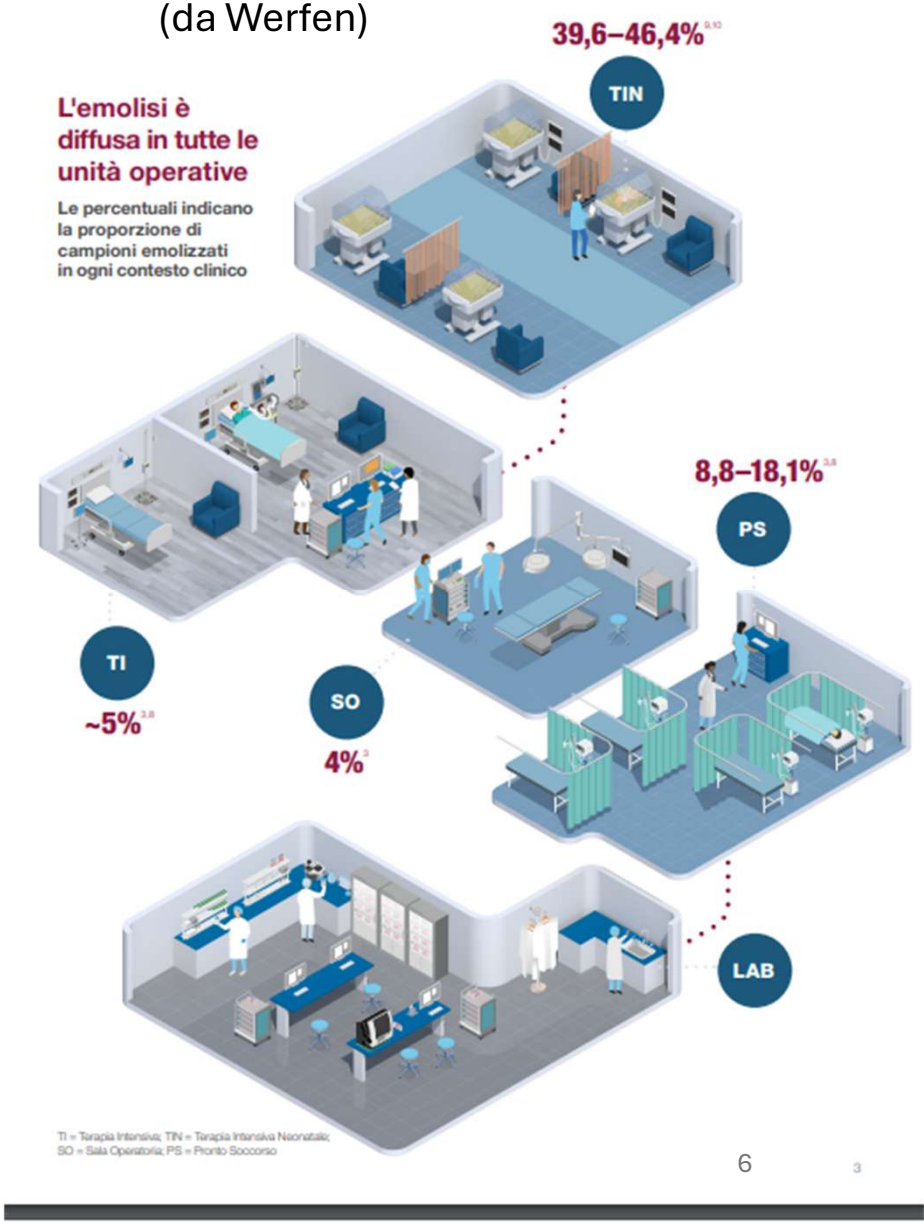


INTERFERENZE: EMOLISI

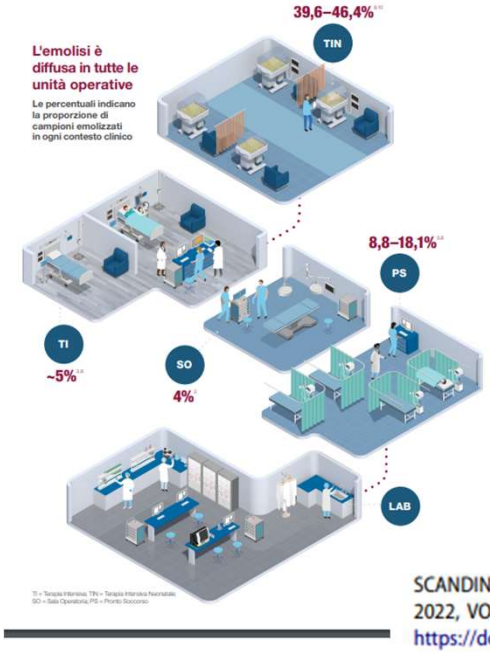
- FREQUENTE, problema per tutte le unità operative
- Tende ad essere più frequente in alcuni reparti (ICU, NICU, PS)
- Più spesso con origine multifattoriale

  - Scelta errata del dispositivo di prelievo
  - Mancata gestione dell'antisettico cutaneo
  - Laccio > 2 minuti
  - Miscelazione troppo vigorosa della provetta/siringa, shaking
  - (Scorretto utilizzo della siringa)
  - Volumi scarsi (<1mL)
  - Condizioni legate al paziente
    - Disordini metabolici
    - Condizioni di emolisi in vivo (intravascolare, che deve essere riconosciuta)
    - Poliglobulie, Piastrinosi, Leucocitosi
  - Condizioni di trasporto

(da Werfen)



EMOLISI



- Cobas b123 POC
- Cobas 8000

SCANDINAVIAN JOURNAL OF CLINICAL AND LABORATORY INVESTIGATION
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https://doi.org/10.1080/00365513.2022.2034037

Table 1. Hemolysis rates in 100 whole blood samples from each of ED and ICU, in 32709 serum samples from ED and in 4342 serum samples from ICU.[a]

	ED		ICU	
	No. of samples (%)		No. of samples (%)	
	Whole blood	Serum	Whole blood	Serum
No hemolysis	7 (7%)	25840 (79%)	81 (81%)	3562 (82%)
Slight hemolysis	80 (80%)	4717 (14.4%)	15 (15%)	751 (17.3%)
Hemolysis	6 (6%)	700 (2.14%)	3 (3%)	24 (0.55%)
Severe hemolysis	7 (7%)	1302 (3.98%)	1 (1%)	5 (0.12%)
Gross hemolysis	0 (0%)	150 (0.46%)	0 (0%)	0 (0%)

[a] See text for definitions of the severity categories of hemolysis.

Table 1. Serum indices of plasma in all routine blood gas samples referred to the central laboratory over a one-week period.

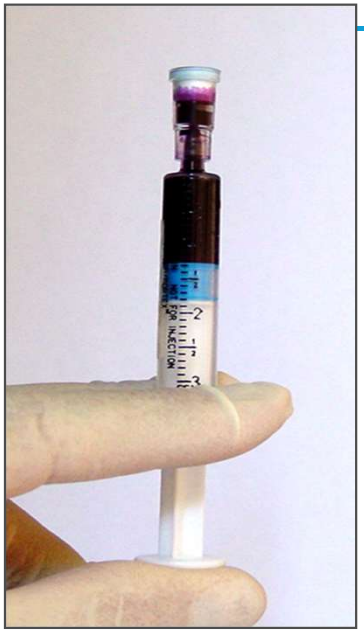
		Serum indices					
		Hemolysis index, *n* (%)		Lipaemic index, *n* (%)		Icterus index, *n* (%)	
Clinical ward	Sample (*n*)	<60	≥60	<30	≥30	<2	≥2
Ambulatory	69	68 (99)	1 (1)	67 (97)	2 (3)	61 (88)	8 (12)
Surgery	59	57 (98)	2 (2)	52 (88)	7 (12)[a]	53 (90)	6 (10)
Dialysis	107	105 (98)	2 (2)	102 (95)	5 (5)	102 (95)	5 (5)[a]
Medicine	286	281 (98)	5 (2)	264 (92)	22 (8)[a]	247 (86)	39 (14)[a]
Oncology	99	97 (98)	2 (2)	86 (87)	13 (13)[a]	90 (91)	9 (9)
Pediatrics	46	43 (91)	3 (6)[a]	45 (98)	1 (2)	43 (93)	3 (7)
Emergency department	288	248 (86)	40 (14)[a]	263 (91)	25 (9)[a]	268 (93)	20 (7)

[a]Significant difference between samples collected in the ambulatory versus those collected in the clinical ward units ($p < .01$). See *Materials and Methods* for details.

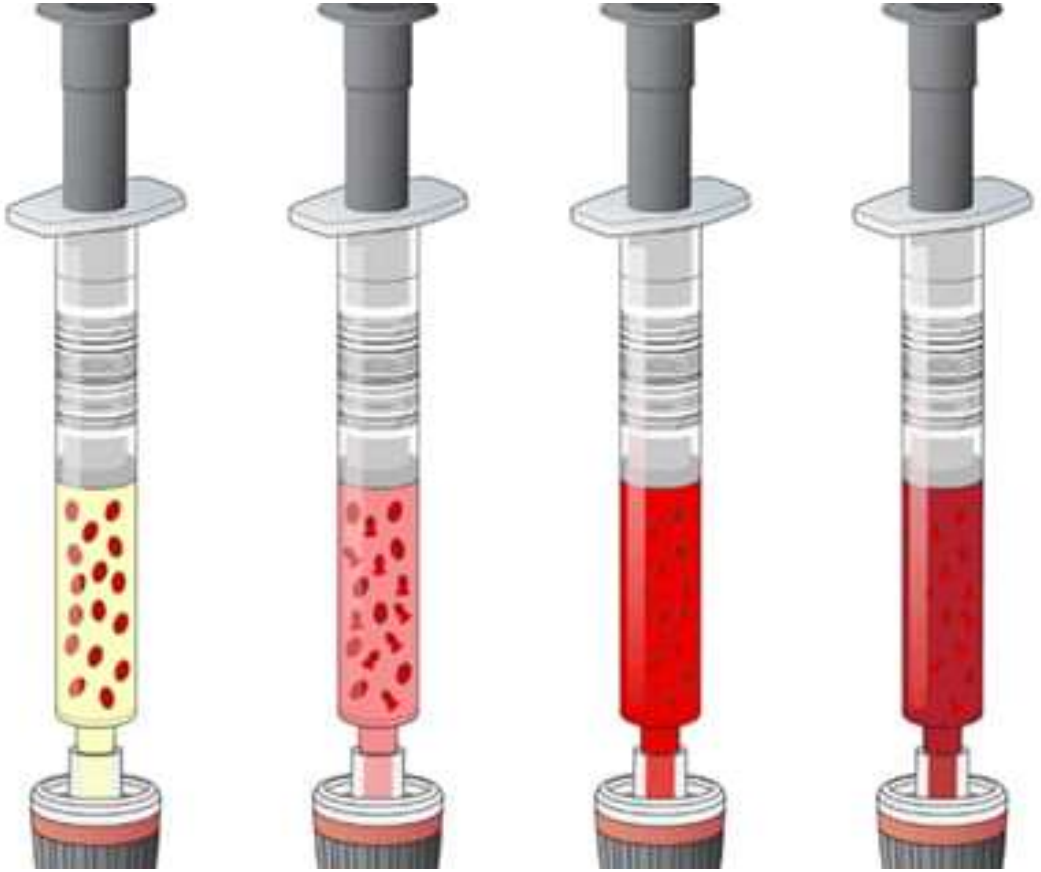
- RapidPoint 500
- Cobas C6000

EMOLISI

K+



S.I.



L'EMOLISI E' INVISIBILE

EMOLISI

S.I.?

NO CENTRIFUGAZIONE

NO SERUM INDEX (HI, II E LI)

EMOLISI NON RILEVABILE

L'EMOLISI E' INVISIBILE

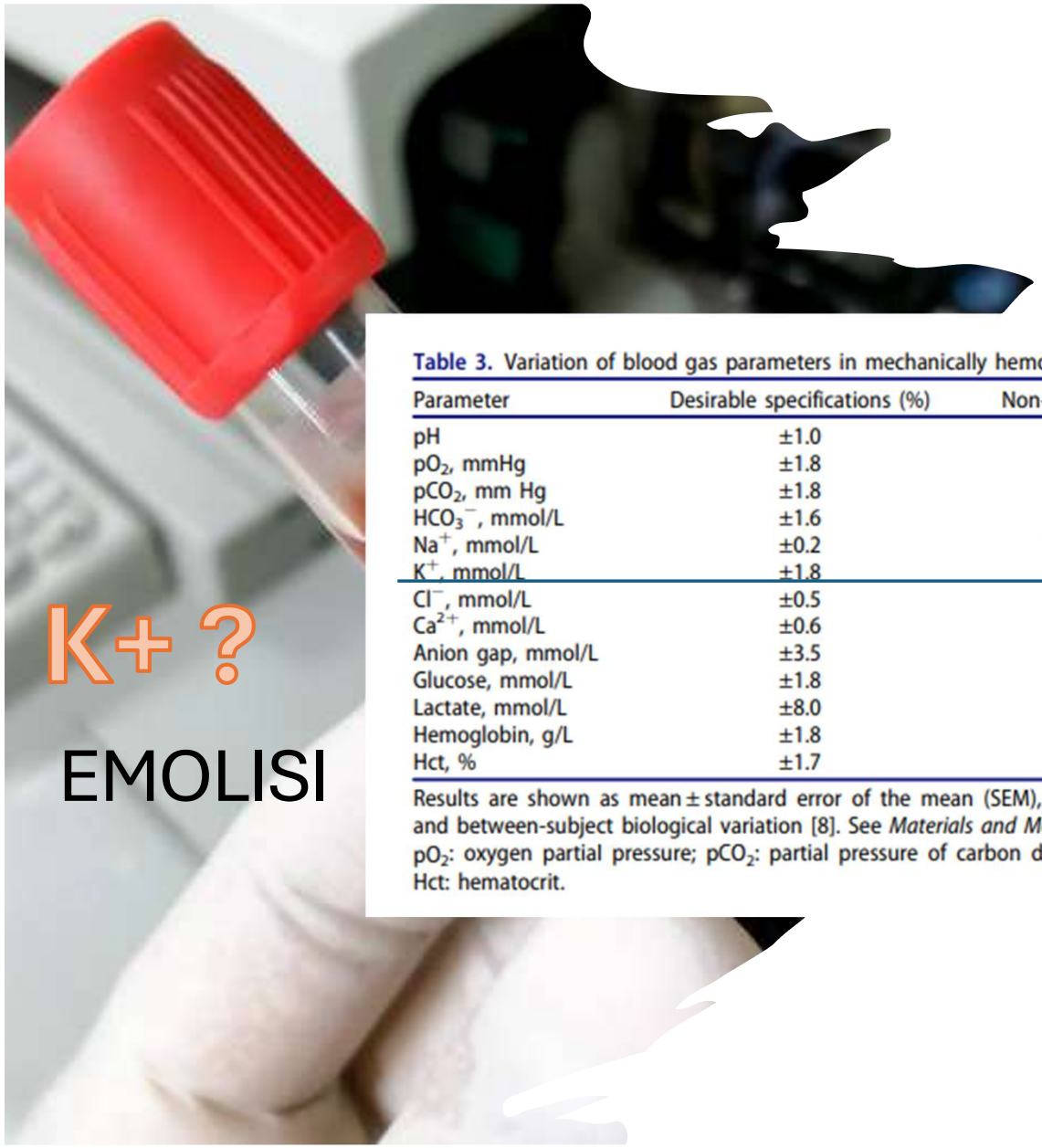
L'EMOLISI E' INVISIBILE

- RISCHIO/DANNO
  - AUMENTO CONCENTRAZIONE PER IL RILASCIO DI MISURANDI INTRACELLULARI NEL COMPARTIMENTO EXTRACELLULARE
  - RIDUZIONE CONCENTRAZIONE PER EFFETTO DELLA DILUIZIONE
  - (INTERFERENZE SU METODI DI DOSAGGIO)

- ↑ K^+, LDH, AST, Mg^{++}
- ↓ GLU, Cl^-, Na^+, Ca^{++}

K+ ?

EMOLISI



L'EMOLISI E' INVISIBILE

- RISCHIO/DANNO

K+ ?

EMOLISI

Table 3. Variation of blood gas parameters in mechanically hemolyzed specimens.

Parameter	Desirable specifications (%)	Non-hemolyzed blood	Hemolyzed blood	*p* Value	Bias
pH	±1.0	7.29 ± 0.01	7.33 ± 0.01	<.01	0.2 % (0.0 % to 1.2 %)
pO_2, mmHg	±1.8	49.2 ± 4.7	55.3 ± 4.7	<.01	12.4 % (−9.7 % to 80.9 %)
pCO_2, mm Hg	±1.8	52.6 ± 1.4	45.1 ± 1.4	<.01	−14.3 % (−26.7 % to −5.3 %)
HCO_3^-, mmol/L	±1.6	24.6 ± 0.5	23.2 ± 0.5	<.01	−3.2 % (−11.7 % to −2.2 %)
Na^+, mmol/L	±0.2	139.6 ± 0.8	137.4 ± 0.6	<.01	−1.6 % (−17.2 % to 6.2 %)
K^+, mmol/L	±1.8	4.4 ± 0.1	5.2 ± 0.8	<.01	18.2 % (−0.5 % to 117 %)
Cl^-, mmol/L	±0.5	99.7 ± 0.6	99.9 ± 0.6	.08	0.2 % (−1.8 % to 2.1 %)
Ca^{2+}, mmol/L	±0.6	1.3 ± 0.02	1.2 ± 0.02	<.01	−7.7 % (−13.7 % to −0.4 %)
Anion gap, mmol/L	±3.5	18.9 ± 0.4	19.6 ± 0.4	<.01	3.7 % (−14.2 % to 22.3 %)
Glucose, mmol/L	±1.8	5.9 ± 0.3	5.8 ± 0.3	<.01	−0.6 % (−16.3 % to 3.3 %)
Lactate, mmol/L	±8.0	3.95 ± 0.31	4.31 ± 0.31	<.01	−1.5 % (−2.8 % to 66.7 %)
Hemoglobin, g/L	±1.8	10.4 ± 0.4	10.4 ± 0.5	.68	15.6 % (−19.5 % to 37.1 %)
Hct, %	±1.7	33.2 ± 1.2	33.6 ± 1.3	.06	13.5 % (−22.3 % to 65.7 %)

Results are shown as mean ± standard error of the mean (SEM), and compared with the available desirable specifications for bias obtained from data within- and between-subject biological variation [8]. See *Materials and Methods* for details.

pO_2: oxygen partial pressure; pCO_2: partial pressure of carbon dioxide; HCO_3^-: bicarbonate; Na^+: sodium; K^+: potassium; Cl^-: chloride; Ca^{2+}: ionized calcium; Hct: hematocrit.

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https://doi.org/10.1080/00365513.2022.2034037

EMOLISI

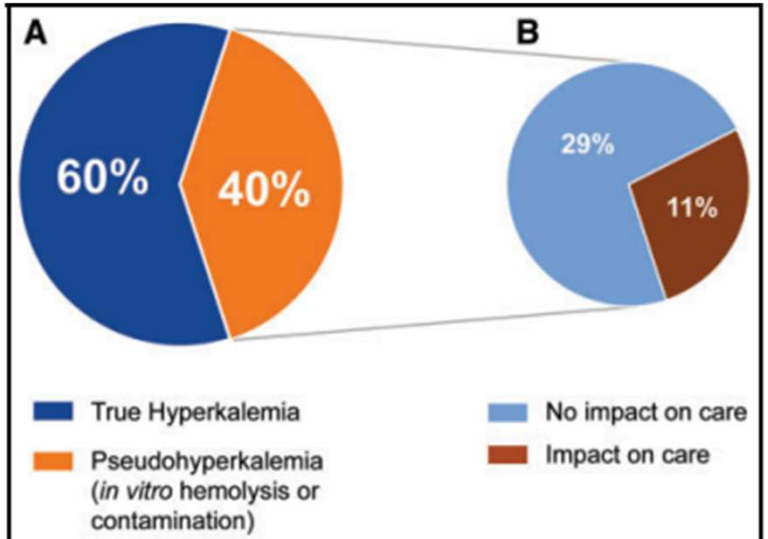
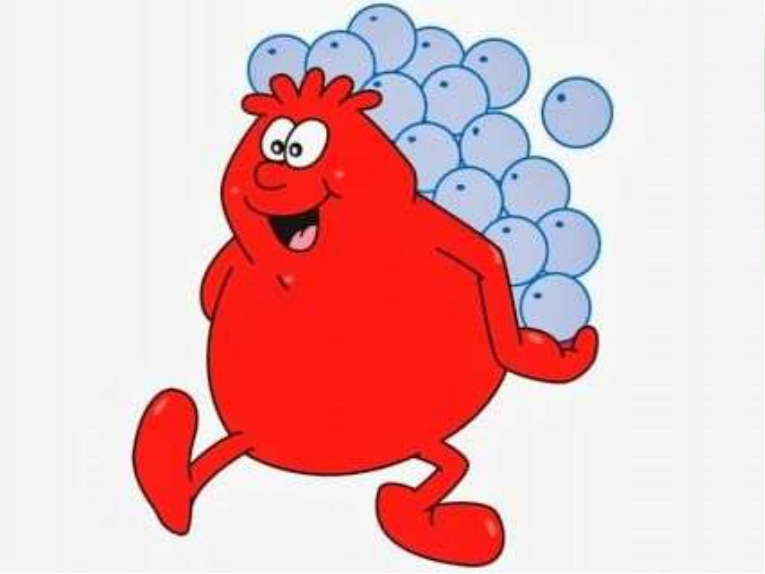


Fig. 3. Percentage of samples hemolyzed and subsequent impact on care in patients with increased POC potassium. (A) The 100 unique patient admissions with increased POC potassium are displayed as the percentage of samples with either true hyperkalemia or pseudohyperkalemia (39% in vitro hemolysis; 1% contamination). (B) The 40% with pseudohyperkalemia were classified as experiencing either no impact on care or impact on care, with corresponding percentages out of the 100 representative patient admissions.

Table 1. Distribution of altered outcomes in patient management or care across patients with pseudohyperkalemia.

Altered outcome in patient management or care	Patients with pseudohyperkalemia *n* = 40
Unnecessary follow-up tests	6 (15.0%)
Delay in treatment	3 (7.5%)
Inappropriate intervention	2 (5.0%)
No change	29 (72.5%)

Patients with altered care were subdivided into 3 groups: unnecessary follow-up tests, which included repeat blood testing or other tests, delay in treatment due to pseudohyperkalemia, or inappropriate medical intervention. Patients with no change are those who did not experience altered care that was specifically due to pseudohyperkalemia. Data are shown as *n* (%).



GESTIONE INAPPROPRIATA DEL PAZIENTE
SODDISFAZIONE DEL PAZIENTE
PERSONALE SANITARIO
AUMENTO DEI COSTI

DOI: 10.1373/clinchem.2003.027227

classification.

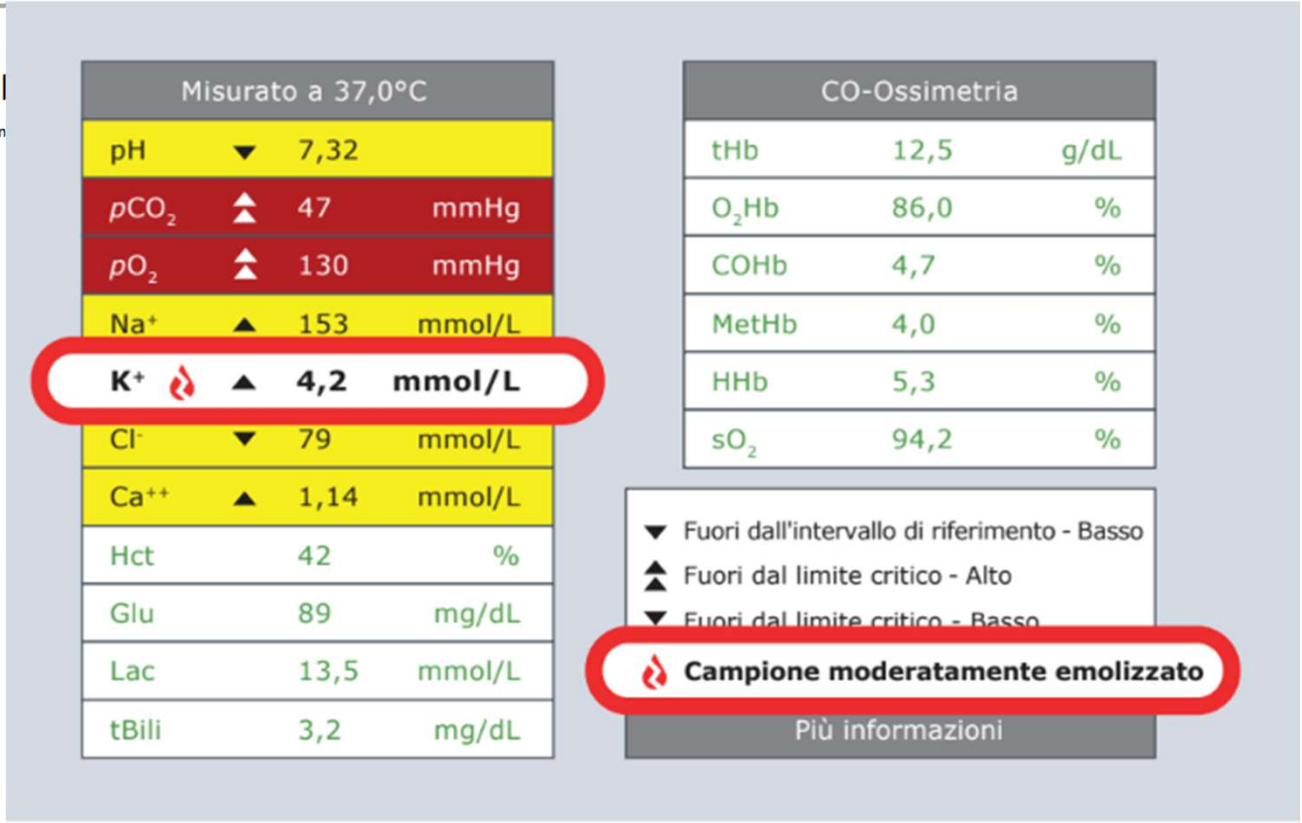
Clinical Chemistry 70:12
1485–1493 (2024)

Novel In-Line Hemolysis Detection on a Blood Gas Analyzer and Impact on Whole Blood Potassium Resul

Shankar Balasubramanian [a,*] Emily J. McDowell,[a] Erving T. Laryea,[b] Gert Blankenstein,[a] Prasad V.A. Pam
Anne M. Winkler,[a] and James H. Nichols [b,*]

EMOLISI

- Rilevazione emolisi mediante misurazione spettrofotometrica del sangue intero
- Cella di flusso acustofluidica integrata nel percorso del campione per la determinazione degli analiti e la rilevazione dell'emolisi: in una porzione del campione il plasma viene separato localmente all'interno del modulo emolisi
- Rilevatore ottico e sorgente luminosa per illuminare la cella a flusso e determinare l'assorbanza alle differenti lunghezze d'onda
- Misurazione spettrofotometrica di Hb nel plasma e determinazione del grado di emolisi
- Concentrazione K con flag di allarme ed indicazione qualitativa del grado di emolisi



Il messaggio appare sulla schermata dei risultati

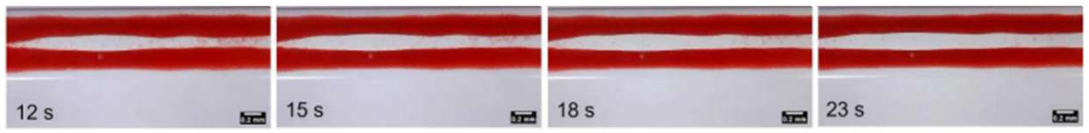


Fig. 2. Representative images showing the timeline of blood separation in the GEM 7000 hemolysis module.

EMOLISI

Com'è possibile rilevare l'emolisi nel sangue intero?

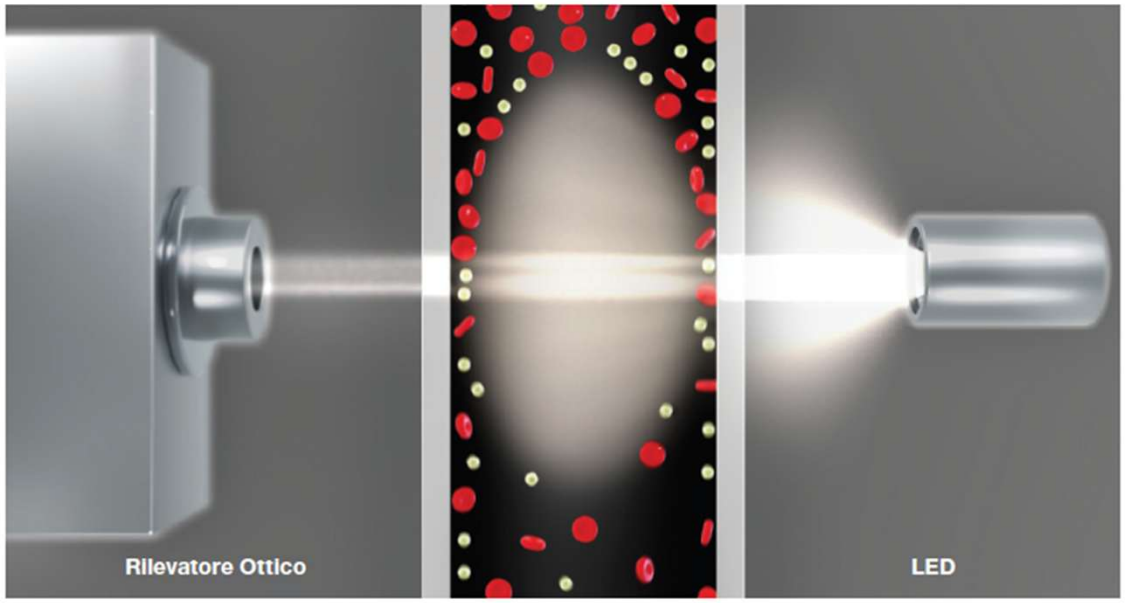
GEM Premier 7000 con iQM3® utilizza una tecnologia brevettata, simile a quella utilizzata dagli analizzatori di laboratorio, per rilevare l'emolisi, basata su una misurazione spettrofotometrica del sangue intero:

Cella di flusso acustofluidica integrata nel percorso fluidico del campione per la misurazione simultanea di tutti gli analiti e la rilevazione dell'emolisi.

- Su una piccola porzione del campione il plasma viene separato localmente all'interno del modulo di emolisi, senza necessità di volume aggiuntivo

Rilevatore ottico e sorgente luminosa a LED per illuminare la cella ottica di flusso e determinare l'assorbanza a ciascuna lunghezza d'onda.

- Utilizzando la misurazione spettrofotometrica dell'emoglobina libera nel plasma, viene determinato il livello di emolisi nel campione



Tecnologia brevettata: all'interno del modulo di rilevazione dell'emolisi

 Errori causati dal metabolismo

 Conservazione del prelievo e TRASPORTO

ESEGUIRE L'ANALISI ENTRO 5 - 10 MINUTI DAL PRELIEVO

IL METABOLISMO DELLE CELLULE PROSEGUE

LE CONSEGUENZE DELL'ANALISI RITARDATA

pO2	↓	viene utilizzato
pCO2	↑	viene prodotta
pH	↓	varia a causa della produzione di pCO_2 e della glicolisi
Ca++	↑	le variazione di pH influenzano il legame tra Ca^{++} e proteine
Glu	↓	viene metabolizzato (inibito a bassa temperatura)
Lat	↑	causato dalla glicolisi (maggiore a bassa temperatura)

TRASPORTO del CAMPIONE

SCANDINAVIAN JOURNAL OF CLINICAL AND LABORATORY INVESTIGATION
2022, VOL. 82, NO. 2, 138–142
https://doi.org/10.1080/00365513.2022.2034037

Table 2. Serum indices of plasma in the blood gas samples received in the central laboratory and separated following four different criteria: time of arrival, storage during transport, transportation mode, and blood volume.

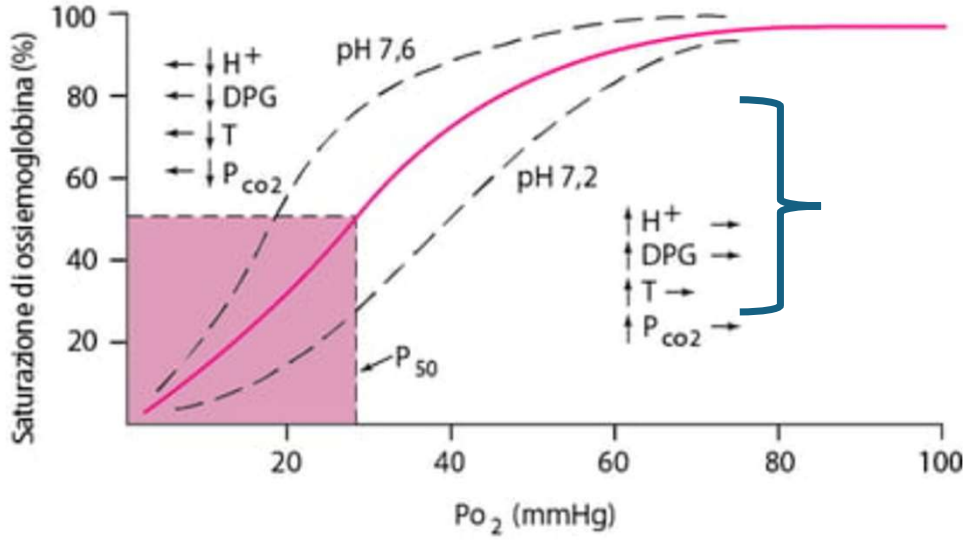
	Serum indices					
	Hemolysis index, *n* (%)		Lipemic index, *n* (%)		Icterus index, *n* (%)	
	<60	≥60	<30	≥30	<2	≥2
Time of arrival						
8 a.m.–8 p.m.	776 (94)	46 (6)	748 (91)	74 (9)	718 (87)	104 (13)
8 p.m.–8 a.m.	123 (93)	9 (7)	105 (80)	27 (20)[a]	111 (84)	21 (16)
Storage during transport						
with ice (4°–8°)	765 (95)	38 (5)	345 (80)	82 (20)[a]	345 (77)	100 (23)[a]
without ice (RT)	134 (89)	17 (11)[a]	508 (96)	19 (4)	484 (95)	25 (5)
Transportation						
pneumatic tube system	191 (90)	21 (10)[a]	183 (86)	29 (14)	181 (85)	31 (15)
hand courier	708 (95)	34 (5)	670 (90)	72 (10)	648 (87)	94 (13)
Blood volume						
>0.5 mL and <1 mL	87 (89)	11 (11)[a]	92 (94)	6 (6)	88 (90)	10 (10)
>1 mL and <2 mL	628 (94)	40 (6)	596 (89)	72 (11)	583 (87)	85 (13)
>2 mL	184 (98)	4 (2)	165 (88)	23 (12)[a]	158 (84)	30 (16)[a]

[a]Significant difference between samples of the same group ($p < .01$). See *Materials and Methods* for details.

CLSI C46-A2, ritirata, 2009

Curva di dissociazione dell'ossiemoglobina

La saturazione arteriosa di ossiemoglobina è messa in relazione con la PO2. PO2 al 50% di saturazione (P50) è normalmente 27 mmHg.
La curva di dissociazione è spostata verso destra dall'aumento della concentrazione di idrogenioni (H^+), dall'aumento del contenuto di 2,3-difosfoglicerato nei globuli rossi, dall'aumento della temperatura e dall'aumento della PCO2.
Ridotti livelli di H^+, difosfoglicerato, temperatura e PCO2 spostano la curva a sinistra.
L'emoglobina caratterizzata da uno spostamento a destra della curva ha una ridotta affinità per l'ossigeno e quella caratterizzata da uno spostamento a sinistra ha un'aumentata affinità per l'ossigeno.



K^+ values to be measured.

STABILITA' del CAMPIONE

(trasporto)

- PROCEDURA (CLSI C46-A2, RITIRATA, 2009)

- ESEGUI LA MISURA IMMEDIATAMENTE A TEMPERATURA AMBIENTE E COMUNQUE NON OLTRE I 30 MINUTI

- SE RITARDI NELL'ESECUZIONE (>30'): SIRINGA (IN VETRO) IN GHIACCIO (SHOULD BE)

- SIRINGHE DI PLASTICA SONO PERMEABILI AI GAS

- ↓ TEMPERATURA →↑ PERMEABILITA' AI GAS

PLASTICA/VETRO? GHIACCIO?

Clin Chem Lab Med 2023; 61(10): 1750–1759 DE GRUYTER

Gerald S. Zavorsky* and Xander M.R. van Wijk

The stability of blood gases and CO-oximetry under slushed ice and room temperature conditions

- Nei laboratori si utilizzano in genere siringhe in plastica
- Le siringhe in plastica sono permeabili ai gas, ma non sono costose, non sono fragili e sono disposable
- Non esiste un reale consenso per modalità di trasporto eper stabilità
- I principali documenti di consenso suggeriscono l'utilizzo di plastica entro 30 minuti e se > 30 minuti, conservazione in ghiaccio
- Alcuni analiti non sono stabili in ghiaccio: K e pO2 e, in caso di combinazioni di analiti, trasporto e conservazione dovrebbero seguire l'analita piu' fragile

Gli Autori formalizzano una “survival analysis” che dimostra:

- Il 5% dei campioni si dimostrano instabili a RT dopo 40’ e dopo 20’ se in ghiaccio, per pO2 15-150 mmHg
- Il bias medio di pO2 per tempi > 85 minuti dimostra differenze medie significative tra RT e ghiaccio, piu’ evidenti se pO2 iniziale > 60 mmHg
- Differente comportamento per O2Hb considerandio l’intero range analitico (2-98.8%)

il bias medio, considerando O2Hb >90% e <90% separatamente, dimostra differenze medie significative (dal punto di vista statistico)

COLL

PLASTICA/VETRO? GHIACCIO?

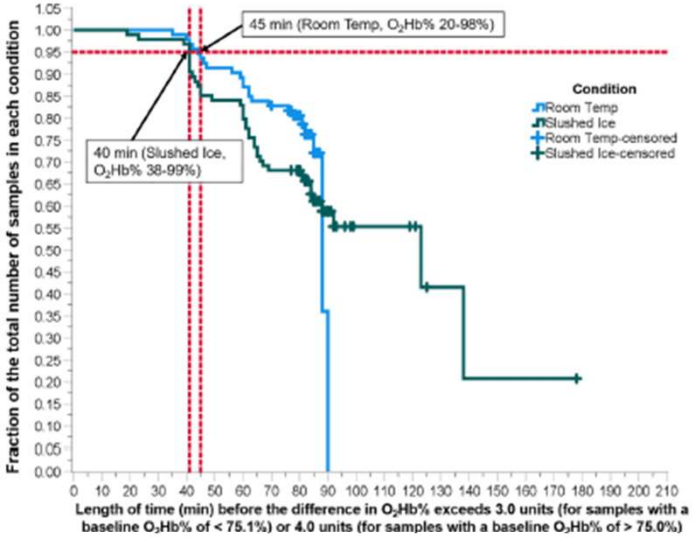


Figure 3: The time before the change in oxyhemoglobin percentage (O_2Hb%) exceeds the threshold of acceptability for stability. When samples are stored at room temperature, about 5% exceed the acceptable threshold after 45 min. When samples are stored on ice in a plastic syringe (no air bubbles), about 5% of the examples exceed this threshold by 40 min. The comparison between conditions was not statistically significant [Log Rank (Mantel–Cox)=Chi-square=1.8, df=1, p=0.18]. There were 94 samples stored on ice [mean 83.6 (SD) (17.1 range 37.9–98.8%] and another 93 samples stored at room temperature [mean 80.2 (SD

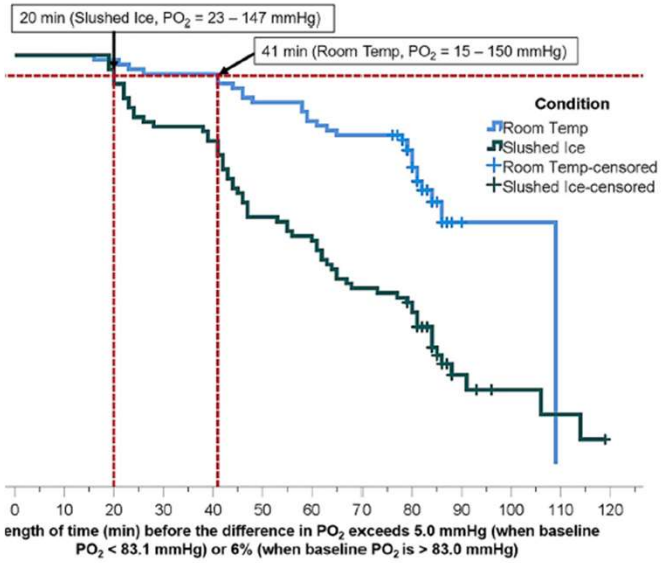


Figure 1: The time before the change in pO_2 exceeds the threshold of acceptability for stability. When samples are stored at room temperature in a plastic syringe (no air bubbles), about 5% exceed the acceptable threshold after 41 min. Comparison between survival curves was statistically significant [Log Rank (Mantel–Cox)=Chi-square=25.5, df=1, p<0.001]. There were 86 samples stored on ice (range 23–147 mmHg) and another 87 samples stored at room temperature (range=15–150 mmHg).

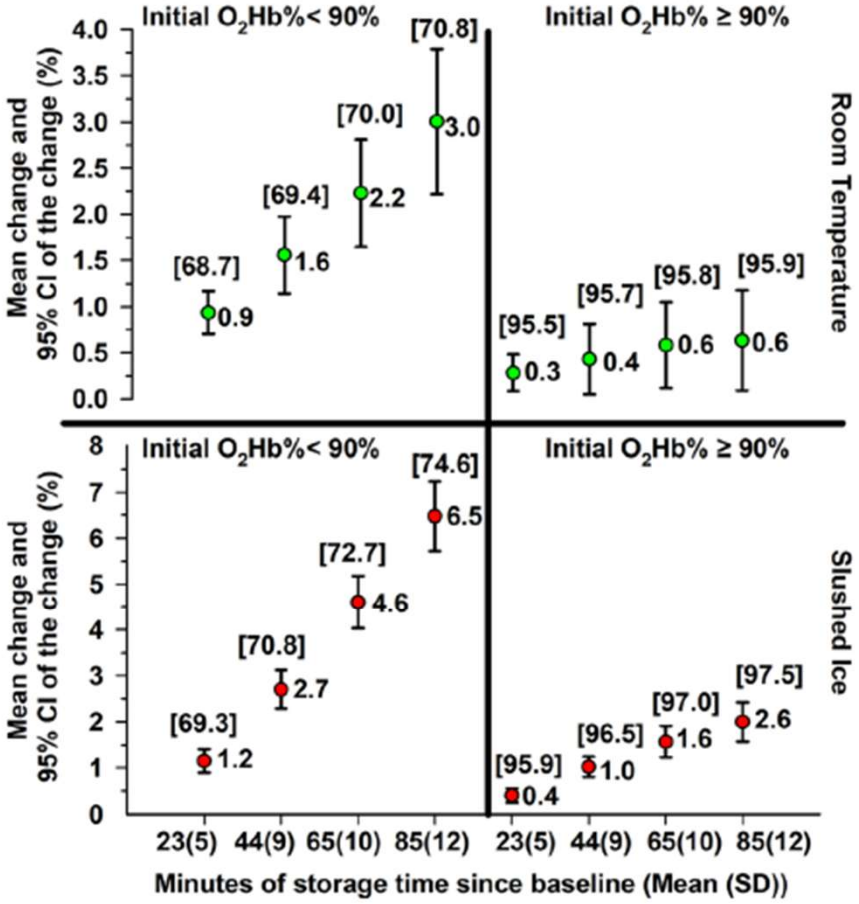


Figure 4: The mean change in O_2Hb% (and 95% CI of the mean change) compared to baseline at each time point, including the initial measurement under different conditions (room temperature vs. slushed ice) and varying initial oxyhemoglobin percentages (<90% or ≥90%). The numbers within the brackets represent the mean O_2Hb% at that time point. The numbers to the right of the green and red-filled circles represent the mean change value.

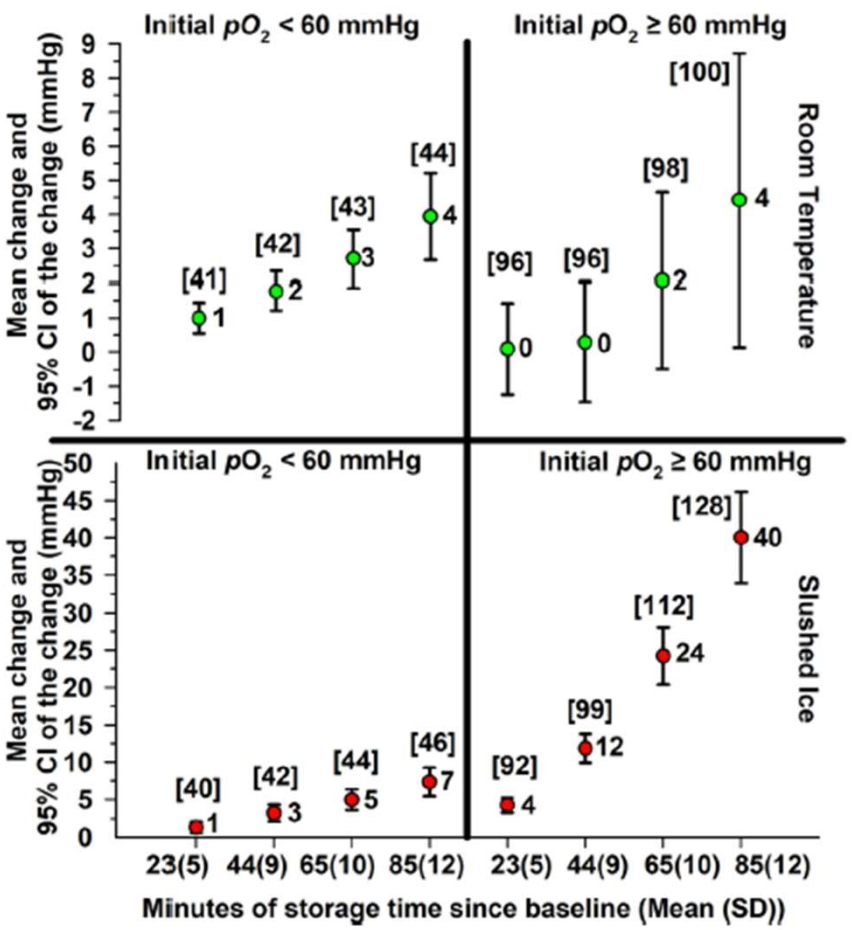


Figure 2: The mean change in pO_2 (and 95% CI of the mean change) compared to baseline at each time point under different conditions (room temperature vs. slushed ice) and varying initial oxygen partial pressures (<60 mmHg or ≥60 mmHg). The numbers within the brackets represent the mean pO_2 at that time point. The numbers to the right of the green and red-filled circles represent the mean change value.

Protocollo operativo deve essere validato localmente

Campioni raccolti 2019-2020

No pO2> 150 mmHg

99 campioni a RT
93 campioni in ghiaccio

ne recommended allowable storage time (min) for analytes grouped in various combinations.

alytes analyzed and eported in combinations	Room temperature	Slushed ice
Blood-gases only pO_2 (15–150 mmHg) pCO_2 (16–72 mmHg) pH (6.73–7.52)	40 min [storage time limited by the pO_2]	20 min [storage time limited by the pO_2]
Blood-gases only pO_2 (<60 mmHg) pCO_2 (16–72 mmHg) pH (6.73–7.52)	60 min [all analytes had similar storages times, separately]	40 min [storage time limited by the pO_2]
Blood-gases only pO_2 (≥60 mmHg) pCO_2 (16–72 mmHg) pH (6.73–7.52)	25 min [storage time limited by the pO_2]	20 min [storage time limited by the pO_2]
CO-oximetry panel only Total Hb (5.4–19.3 g/dL) O_2Hb% (20.0–98.8%) COHb (90.1–5.4%) MetHb (0.2–4.6%)	45 min [storage time limited by the O_2Hb%]	40 min
Metabolite panel only Lactate (0.6–13.5 mmol/L) Glucose (2–17 mmol/L)	40 min [storage time limited by lactate]	~180 min
Electrolyte panel only K^+ (2.2–11.7 mmol/L) Ca^{2+} (0.73–1.50 mmol/L) Cl^- (77–130 mmol/L) Na^+ (97–167 mmol/L)	120 min	~70 min [storage time limited by potassium concentration]
Blood gas panel and CO-oximetry panel together, with or without the metabolite panel (pO_2<150 mmHg)	40 min [storage time limited by the pO_2 and lactate]	20 min [storage time limited by the pO_2]
Blood gas panel and CO-oximetry panel together (pO_2<60 mmHg)	45 min [storage time limited by the O_2Hb%]	40 min [storage time limited by the pO_2]
Blood gas panel and CO-oximetry panel together, including the metabolite panel (pO_2<60 mmHg)	40 min [storage time limited by lactate]	40 min [storage time limited by the pO_2]
Blood gas panel and CO-oximetry panel, together with or without the metabolite panel (pO_2≥60 mmHg)	25 min [storage time limited by the pO_2]	20 min [storage time limited by the pO_2]
pH values in pleural fluid (pH 7.00–7.61)	60 min	135 min

In conclusion, this study provides a novel method to determine appropriate storage times of blood in plastic syringes using survival analysis. Another strength of this study was the large sample size (~200 human blood specimens measured over five different time points under room temperature and slushed ice conditions). We show that 95% of all whole blood specimens obtained from humans remain stable at room temperature when the complete CO-oximetry panel or the combination of the CO-oximetry panel and pO_2, pCO_2, and pH are assessed together within 45 min of the draw time, but only when the baseline pO_2<60 mmHg. If the baseline pO_2 is ≥60 mmHg, 95% of the samples remain stable within 25 min of the draw time. When baseline pO_2≥60 mmHg, the reduction in stability time can be due to the decreased buffering capacity of hemoglobin since hemoglobin is more saturated at higher oxygen pressures, reducing its buffering capacity. When assessing multiple analytes together, ice usually worsens stability and shortens the storage time before 5% of the samples become unstable. Nevertheless, if a laboratory wishes to have one practical, simple recommendation on blood gas stability, which includes most analytes obtained from a blood-gas analyzer, 30 min of storage time at room temperature can be recommended. However, a storage time of up to 40 min is acceptable under room temperature conditions, depending on the lab's total allowable error and stability criteria used.

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The stability of blood gases and CO-oximetry under slushed ice and room temperature conditions

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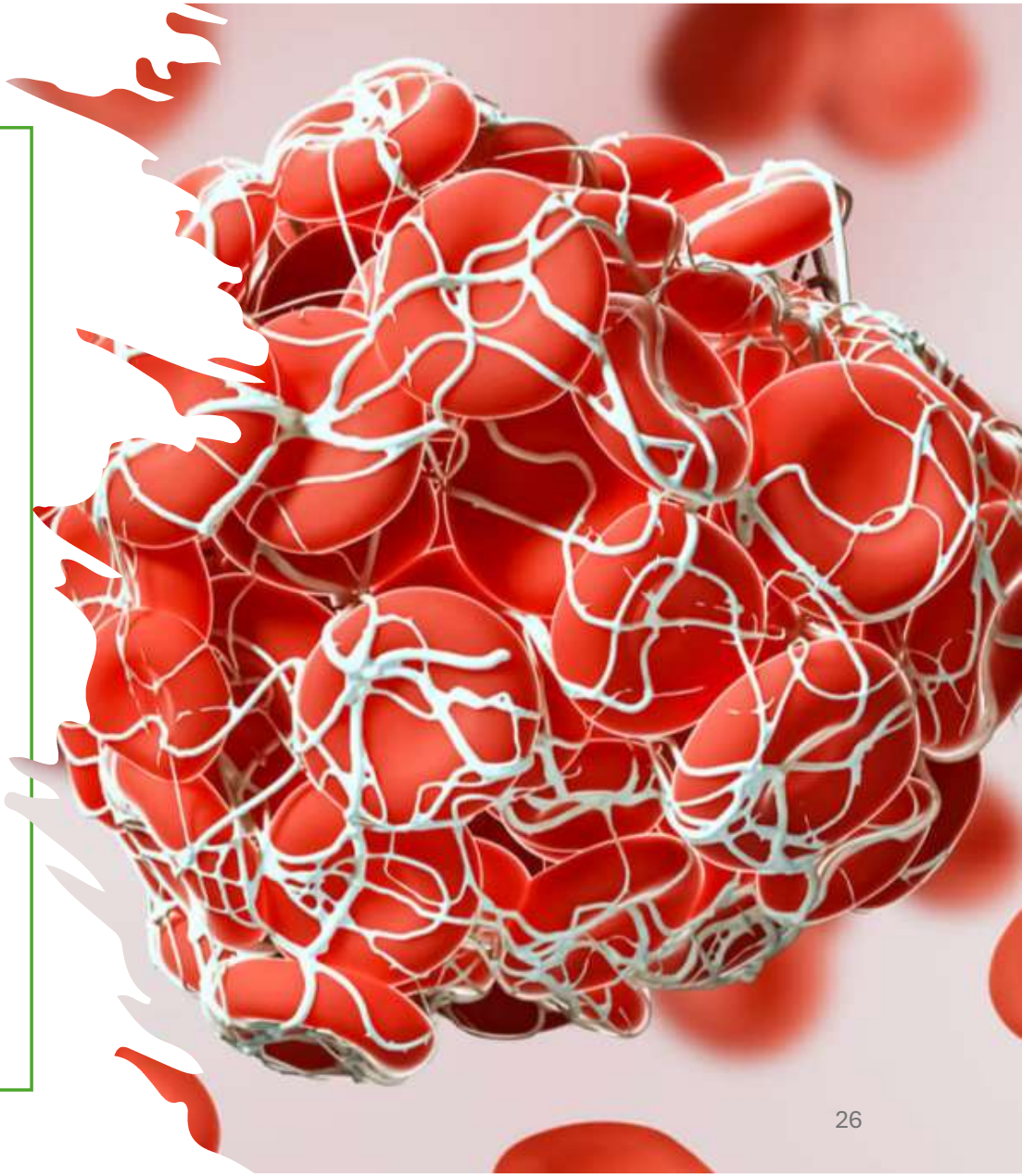
Keywords: arterial; arterial carbon dioxide pressure; arterial oxygen pressure; kinetics; measurable change; oxyhemoglobin saturation; storage temperature; survival; time-course; venous

- **COAGULI**
  - INTERFERENZA NEI DOSAGGI
  - CAMPIONE DISOMOGENEO
  - ATTENZIONE AI CAMPIONI SCARSI (<1 mL)
  - MISCELAZIONE DEL CAMPIONE
  - VERIFICARE VISUALMENTE IL CAMPIONE
  - BLOCCO STRUMENTALE, SPESSO È LA CAUSA PIU' FREQUENTE DI INTERVENTO ASSISTENZA TECNICA
  - CIRCA 1% DEI CAMPIONI PER BG

- **BOLLE DI ARIA**
  - RARA
  - INTERFERENZE SU DOSAGGI CON ↑ pO2
  - IN PARTE TEMPO DIPENDENTE, MAGGIORE EFFETTO DOPO 15 MINUTI
  - MAGGIORE EFFETTO SE BASSA TEMPERATURE
  - RIPETERE IL PRELIEVO SE PRESENTE EFFETTO "SCHIUMA"



- **DISOMOGENEITA’**
  - PER RITARDO NELL’ANALISI DEL CAMPIONE CON SEPARAZIONE NELLE DIFFERENTI FASI
  - DETERMINA ↑↓ HB E HCT
  - MISCELA DOLCEMENTE IL CAMPIONE SUBITO DOPO IL PRELIEVO PER FACILITARE IL MIXING DELL’ANTICOAGULANTE
  - MISCELA NUOVAMENTE IMMEDIATAMENTE PRIMA DELL’ANALISI
  - IDEALMENTE MIXER AUTOMATICO

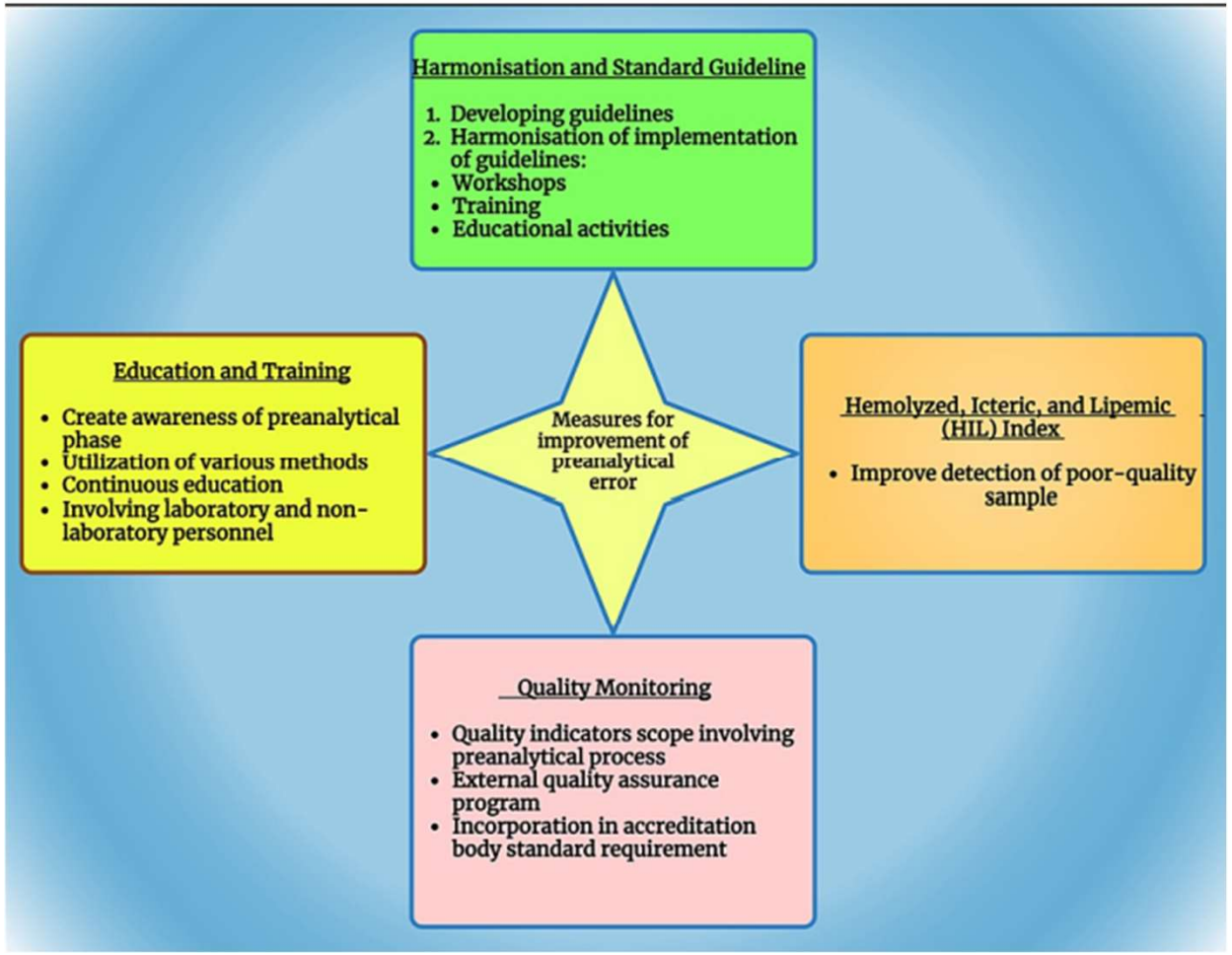
- **DILUIZIONE**

  - Interferenza su dosaggio
    - ↑↓ elettroliti
    - ↓ pH, pO2, pCO2, HB e HCT

  - Considera il volume morto delle vie infusive
  - Rimuovi un adeguato volume di sangue (circa 2 volte il volume morto)

  - Se possibile, accesso controlaterale

- CRITICITA' DELLA FASE PREANALITICA
- 70% DEGLI ERRORI SONO IN FASE PREANALITICA
- IMPORTANZA DEL FATTORE UMANO
- FORMAZIONE DEL PERSONALE DI REPARTO DA PARTE DELLO SPECIALISTA DI MEDICINA DI LABORATORIO
- NON DEGLI SPECIALISTI DI PRODOTTO



7.3.4 Evaluation of measurement uncertainty (MU): Statistically possible, but clinically useful??
7.3.5 biological reference values
7.3.7 Ensuring the validity of examination results:

- 7.3.7.2 ICQ
  - Materiali di terza parte (SHOULD), ma effetto matrice, materiali non stabili, quali operatori ???
  - Variazione Lot to lot
  - Simili ai campioni dei pazienti ??
- 7.3.7.3 EQA

ICQ automatico, monitoraggio da parte del laboratorio, analisi retrospettiva e puntuale giornaliera → obbligatorio, qualab, APS
EQA → quale operatore?
obbligatorio, qualab, APS

Annex A
(normative)

Unilabs

Additional requirements for Point-of-Care Testing (POCT)

A.1 General

This annex describes the additional requirements for the laboratory for POCT that are distinct from, or in addition to, those outlined in the main text. These requirements specify the laboratory's responsibilities towards organizations, departments and their personnel regarding the selection of devices, training of personnel, quality assurance, and the management review of the complete POCT process.

Patient self-testing is excluded, but elements of this document may be applicable.

NOTE 1 ISO/TS 22583 provides guidance for non-laboratory supported services.

NOTE 2 ISO 15190 and ISO 22367 provide guidance on safety and risk aspects of POCT.

A.2 Governance

The governing body of the organization shall be ultimately responsible for ensuring that appropriate processes are in place to monitor the accuracy and quality of POCT conducted within the organization.

Service agreements between the laboratory and all locations using laboratory supported POCT shall ensure that respective responsibilities and authorities are specified and communicated within the organization.

These agreements shall have clinical approval, and where applicable, financial approval.

These service agreements shall be with POCT areas and may be managed via a health professional grouping (e.g. medical advisory committee).

A.3 Quality assurance programme

The laboratory shall appoint a person with appropriate training and experience to be responsible for POCT quality, which includes review of and conformity with the requirements of this document as related to POCT.

A.4 Training programme

A person with appropriate training and experience shall be appointed to manage training and competency assessment of personnel performing POCT.

The trainer shall develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel.

La teoria è quando si sa tutto e niente funziona.
La pratica è quando tutto funziona e nessuno sa il perché.
Noi abbiamo messo insieme la teoria e la pratica: non c'è niente che funzioni...
e nessuno sa il perché!

Albert Eninstein

GRAZIE PER L'ATTENZIONE