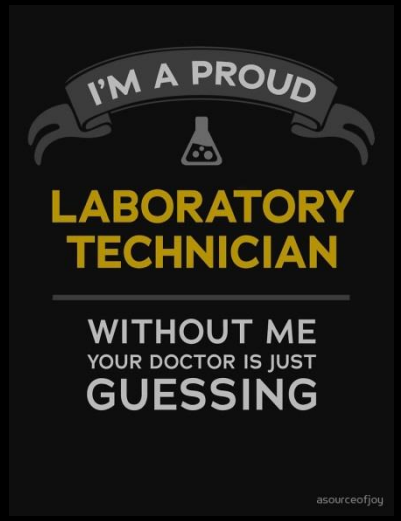
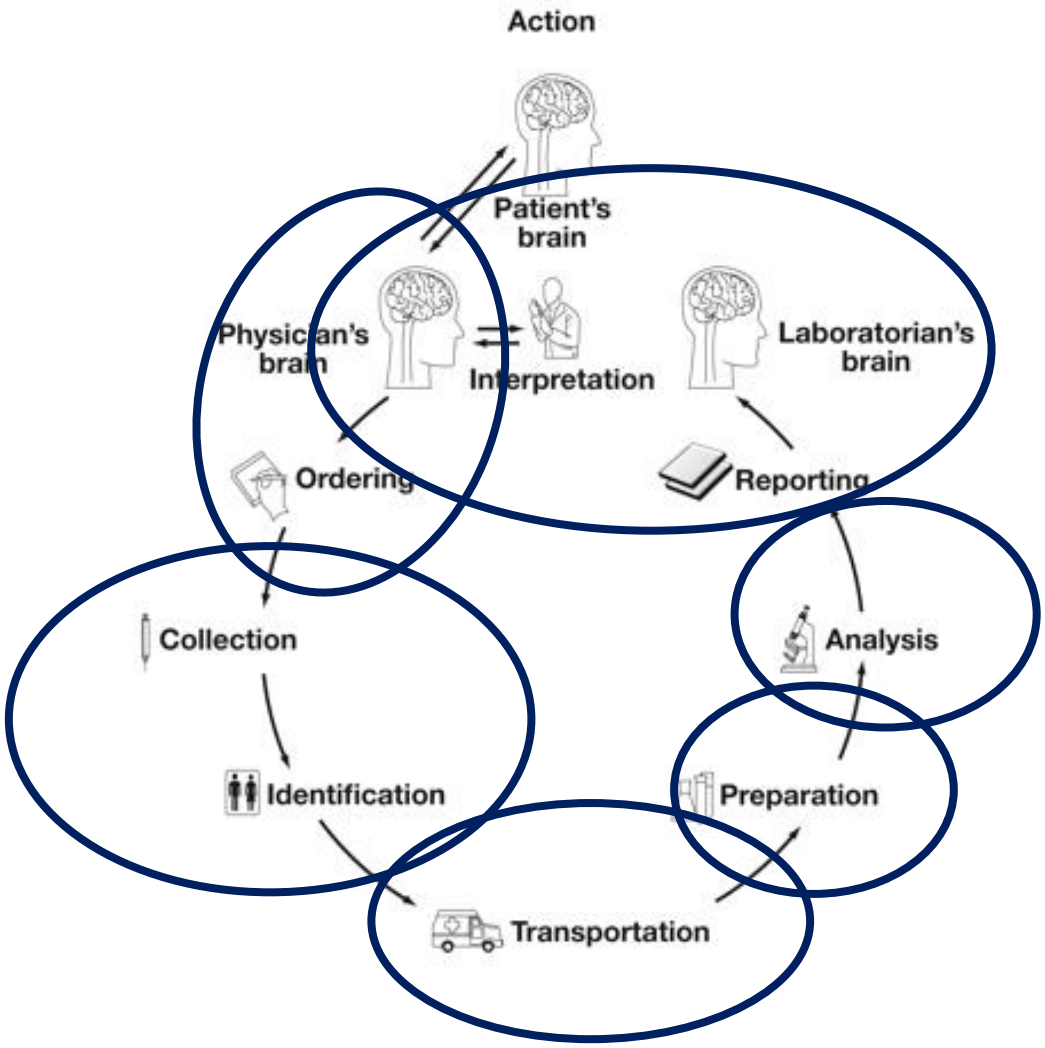
Preanalytical challenges in laboratory automation?

Mads Nybo
Dept. of Clinical Biochemistry
and Pharmacology
Odense University Hospital

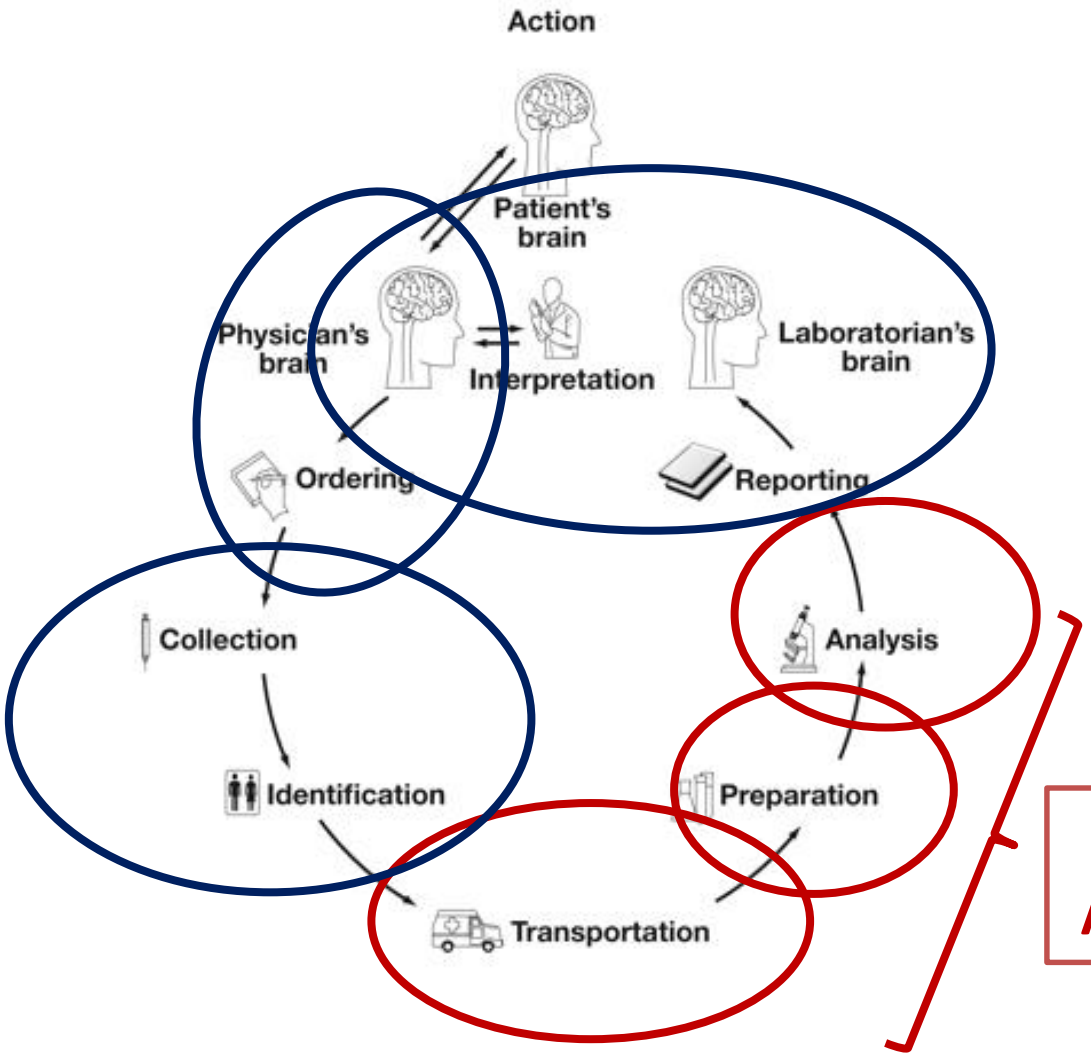


Brain-to-brain loop



Plebani et al. Am J Clin Pathol 2011;136:829-833.

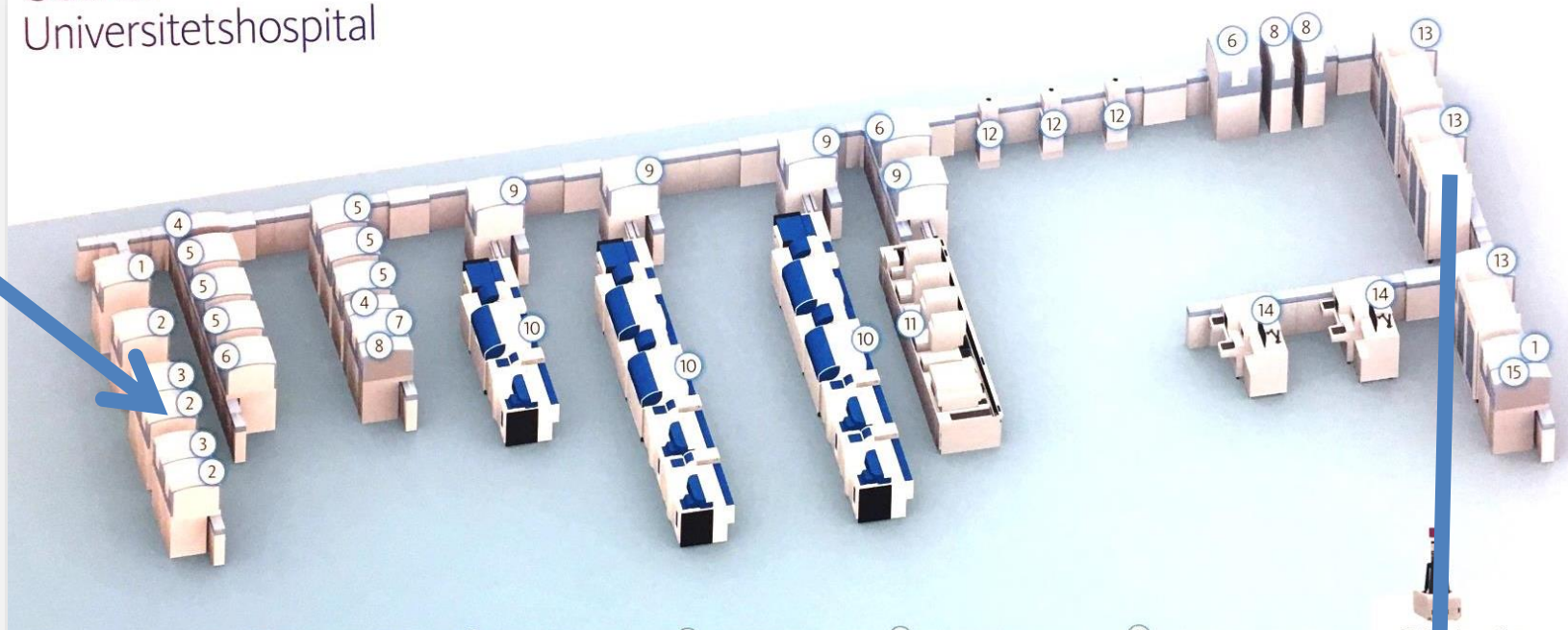
Brain-to-brain loop



Plebani et al. Am J Clin Pathol 2011;136:829-833.

Preanalytical challenges in an automated lab?

Odense Universitetshospital



1 GLP systems Input/Output Module

- Acts as an input area or sorting area.
- Processes up to 1,000 tubes per hour.
- Has a loading capacity of 500 tubes via four drawers (125 tubes per drawer: five FlexRacks with 25 positions).
- Allows an individual configuration of the four drawers as input or output and offers independent access.
- Can be equipped with customised RackPorts for IVD rack sorting.

2 GLP systems Tube Assessment Module

- Introduces samples to the GLP systems Track as the central loading point.
- Processes up to 1,000 tubes per hour.
- Is equipped with weight identification and a camera unit for cap colour assessment.
- Has a loading capacity of 375 tubes via three drawers (125 tubes per drawer: five FlexRacks with 25 positions).
- Allows an individual configuration of the three drawers as input or output and offers independent access.

3 GLP systems Tempus Module

- Offers integration of the Tempus600 transport systems into the GLP systems Track.
- Unique concept that allows maintaining a 'single piece flow' from blood drawing to processing on the track.
- Can connect up to 6 Tempus lines per module.

4 GLP systems Decapper Module

- Removes the caps from tubes on the GLP systems Track prior to their arrival at connected analysers.
- Two decapping stations provide each individual Decapper Module with a throughput of up to 1,200 tubes per hour.

5 GLP systems Centrifuge Module

- Is flexible and fully configurable with an integrated temperature control.
- Has a throughput of up to 480 samples per hour.
- Offers rapid bucket loading by combining a double bucket system and internal balance weights.
- Offers automated balancing in combination with a Tube Assessment Module.
- Allows the continuous loading of buckets while the centrifuge operates.
- Initiates the centrifuge by a prompt that can be configured to the laboratory's demands.

6 GLP systems Buffer Module

- Optimizes re-analysis capacities by allowing faster access for reflex, rerun and repeat testing.
- Streamlines the workflow as a room temperature storage solution.
- Automatically reloads tubes onto the track by random access if further testing is required during the set storage interval.
- Has a total capacity of 750 tubes and can process up to 1,000 tubes per hour.

7 GLP systems Aliquotter Module

- Provides automated sample aliquotting into secondary tubes for analyses on connected analysers or stand-alone analysers.
- The module can produce up to 300 aliquots per hour, with volumes ranging from 50 µL to 2,000 µL.
- The automated barcode labelling of secondary tubes is possible and fully configurable to meet the laboratories' requirements.

8 GLP systems Recapper Module

- Recaps open sample tubes with a GLP archive cap or a secondary screw cap.
- Two recapping stations provide each individual Recapper Module with a throughput of up to 1,200 tubes per hour (with GLP archive caps).

9 GLP systems Rackbuilder Module

- Interfaces rack processing instruments to the GLP systems Track.
- Offers pre-sorting capability to improve the internal processing on the IVD instruments.
- Features dynamic rack loading control.
- Bi-directionally processes up to 800 samples per hour.

10 Roche cobas® 8000

- Contains the core unit, ISE, C702, E602 and sample buffer modules.
- Specimen integrity check via serum indices, clot and liquid level detection.
- E602: Heterogeneous immunochemistry testing with almost 100 assays for anaemia, bone, tumour markers, hormones, cardiac and infectious diseases.
- C702: More than 120 assays and applications on the clinical chemistry platform including substrates, enzymes, proteins, DATs and TDMs.
- Clot, liquid level and air bubbles detection.
- Carry-over-free disposable tips.

11 Sysmex XN-9000

State-of-the-art fully integrated EDTA tube automation line. Facilitates the elimination of manual EDTA sample handling through advanced automatic reflex testing, including:

- Automatic reflex testing of samples for reticulocyte analysis.
- Automatic reflex testing of extended white cell and/or platelet analysis using the specialist 'WPC' and/or 'PLT-F' channels.
- Nucleated red blood cell analysis on every sample as part of the basic differential, making it unnecessary as a reflex test.
- Automatic reflex testing of samples requiring a blood smear with the SP-10 slide maker/stainer.

12 Tosoh G8

- Automated HbA_{1c} testing.
- HbA_{1c} system connected to GLP systems with cap piercing functionality.
- HPLC technology.

13 GLP systems Single Archive Module

- Compact medium-term refrigerated tube storage solution. Consists of loading and storage module.
- Full storage capacity of nearly 10,000 tubes and capable of archiving up to 800 tubes per hour.
- Archiving, storage, retrieval and disposal are fully automated with definable protocols for tube disposal.
- Retrieval time – back to the track – for reflex testing is minimised by intelligent tray handling.
- Temperature storage range: 4–16°C.

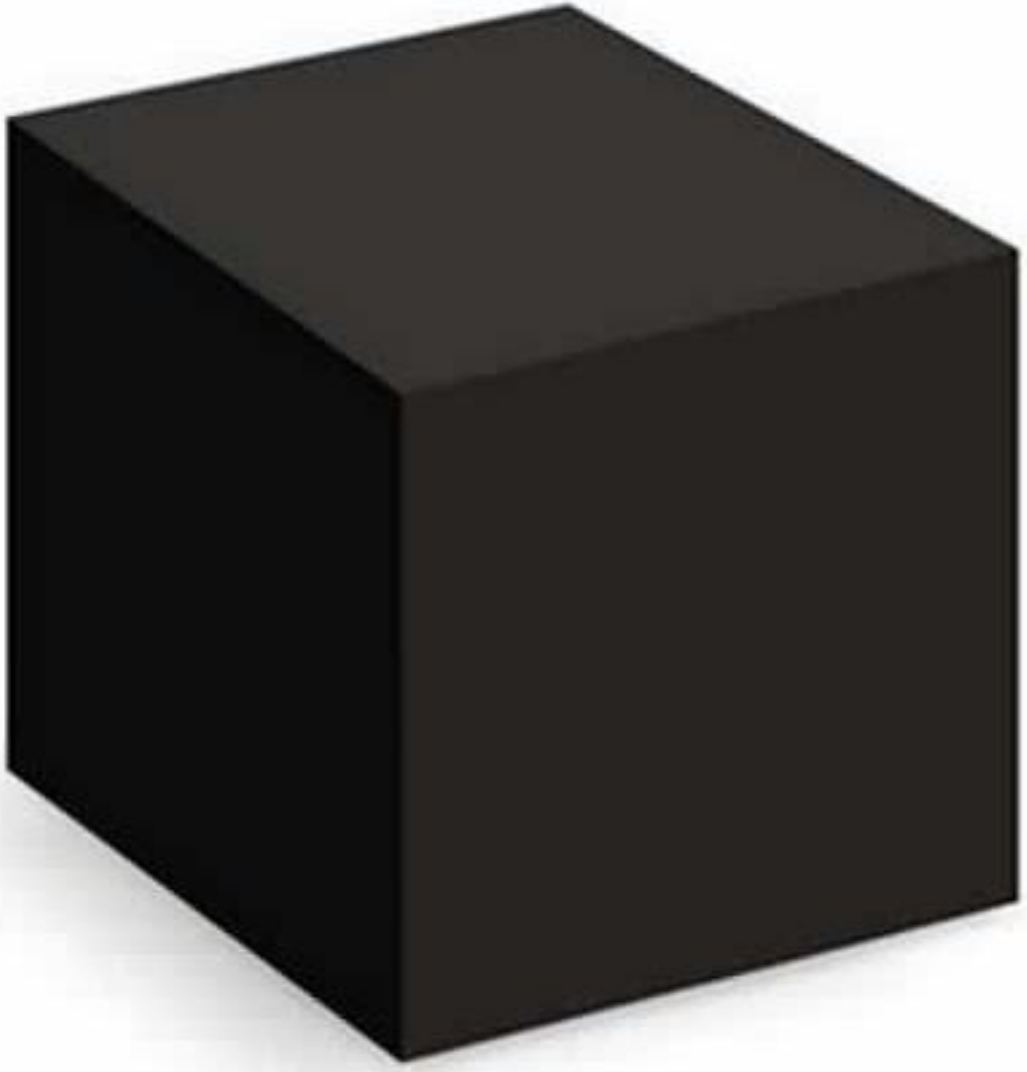
14 Sysmex CS-5100

- Fully automated haemostasis analyser.
- Exceptionally high throughput of up to 400 tests per hour.
- Pre-analytical sample integrity check for primary sample volume and interfering substances.
- Powerful multi-wavelength techn
  60 parameters.
- Efficient workflow, rapid turnarou
  simultaneous random access.

GLP systems Car (Tub Carrier)

- Tran the samples individually on the G stems Track.
- Powe by a lithium polymer battery, it can l at a top speed of 250 mm/s.
- Has eed, state of charge and position remo controlled using NFC technology.
- Indic its status via a visible LED with an intui ght code.

Preanalytical challenges in an automated lab?



27/08/1998 | 01/02/2001 | Vis alle

Analyse	Enhed	2001-02-01	2001-02-01	2000-08-07
		Lab	Lab	Lab
Hæmatologi				
Erytrocytvol. Middel [MCV];Erc(B)	fl	90	91	79
Trombocytter;B	10E9/l	160	161	120
Væske- og elektrolytbalance				
Kreatinin (Jaffé);P	µmol/l	72	85	65
Syre/base- og oxygenstatus				
Hæmoglobin;B	mmol/l	10.0	10.1	9.5
Organmarkører				
Alaninтransaminase [ALAT];P	U/l	31	34	70
Basisk fosfatase;P	U/l	120	140	320
Metabolisme				
Kolesterol;P	mmol/l	6.0	6.6	5.2
Endokrinologi				
Triiodthyronin [T3];P		2.1	2.2	3.1
Thyroxin [T4];P		2.0	2.2	0.9
Thyrotropin [TSH];P	arb.enh.	2.5	2.6	4.2
Immunologi og inflammation				
C-reaktivt protein [CRP];P	mg/l	5	4	6
Sedimentationsreaktion;B	mm	10	11	7
Cerebrospinal- led- og pleuravæske, ascites m.m.				
Leukocytter;B	10E9/l	7.1	7.2	6.4
Andre undersøgelser				
Elektrokardiografi [EKG12];Pt				Tekst
CMV PCR;P				KOMM

Preanalytical challenges in an automated lab?

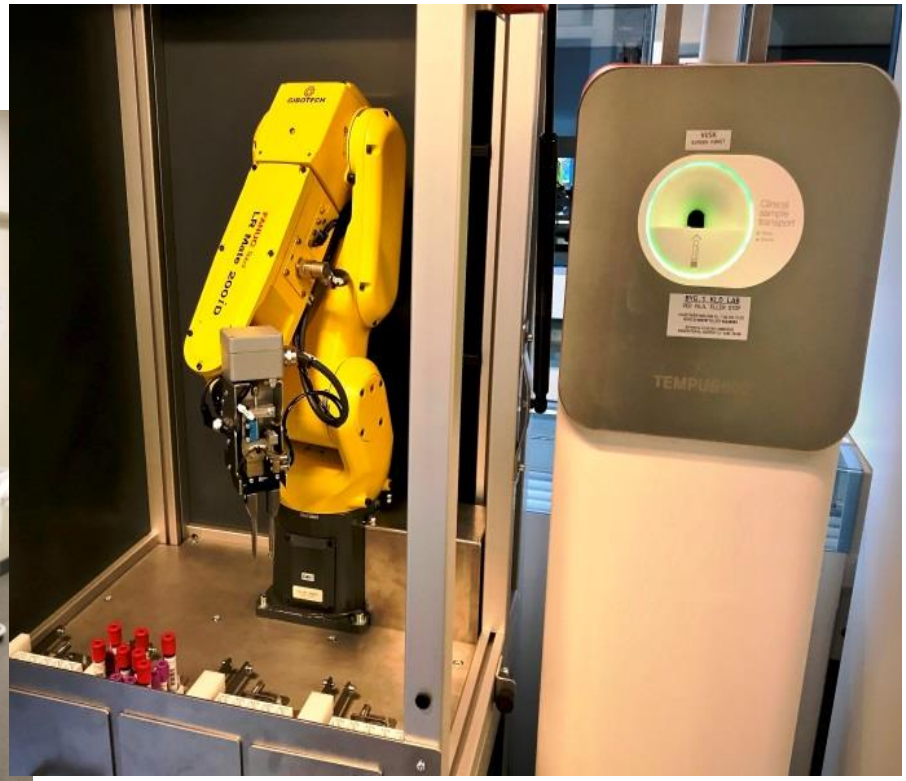
- Sample transportation
- Sample reception
- On-track stability
- Volume detection
- HIL indices
- IT

Sample transportation

- External samples (GP’s, other hospitals)

Sample transportation

Sample transportation



Sample transportation

Do we have everything under control?

Table 2. Basic data of participants

How many samples are received by PTS in percentage of in-house samples?		
Less than 10 %	6	14
From 10-25 %	8	19
25-50 %	14	33
From 50-75 %	3	7
More than 75 %	11	26
Has your system been validated?		
Yes	31	69
No	14	31
How did you validate your system?		
Hemolysis indices	23	32
Potassium concentration	19	26
Visible hemolysis	6	8
Sample rejection	4	6
G-logger	3	4
Other, please specify	17	24

Sample transportation

CONCLUSIONS: Owing to their high degree of heterogeneity, the retrieved studies were unable to supply evidence for the safety of using PTSs for blood sample transportation. In consequence, laboratories need to measure and document the actual acceleration forces in their existing PTS, instituting quality target thresholds for these measurements such as acceleration vector sums. Computer modeling might be applied to the evaluation of future PTS installations. With the increasing use of PTS, a har-

Sample transportation

Sample transportation

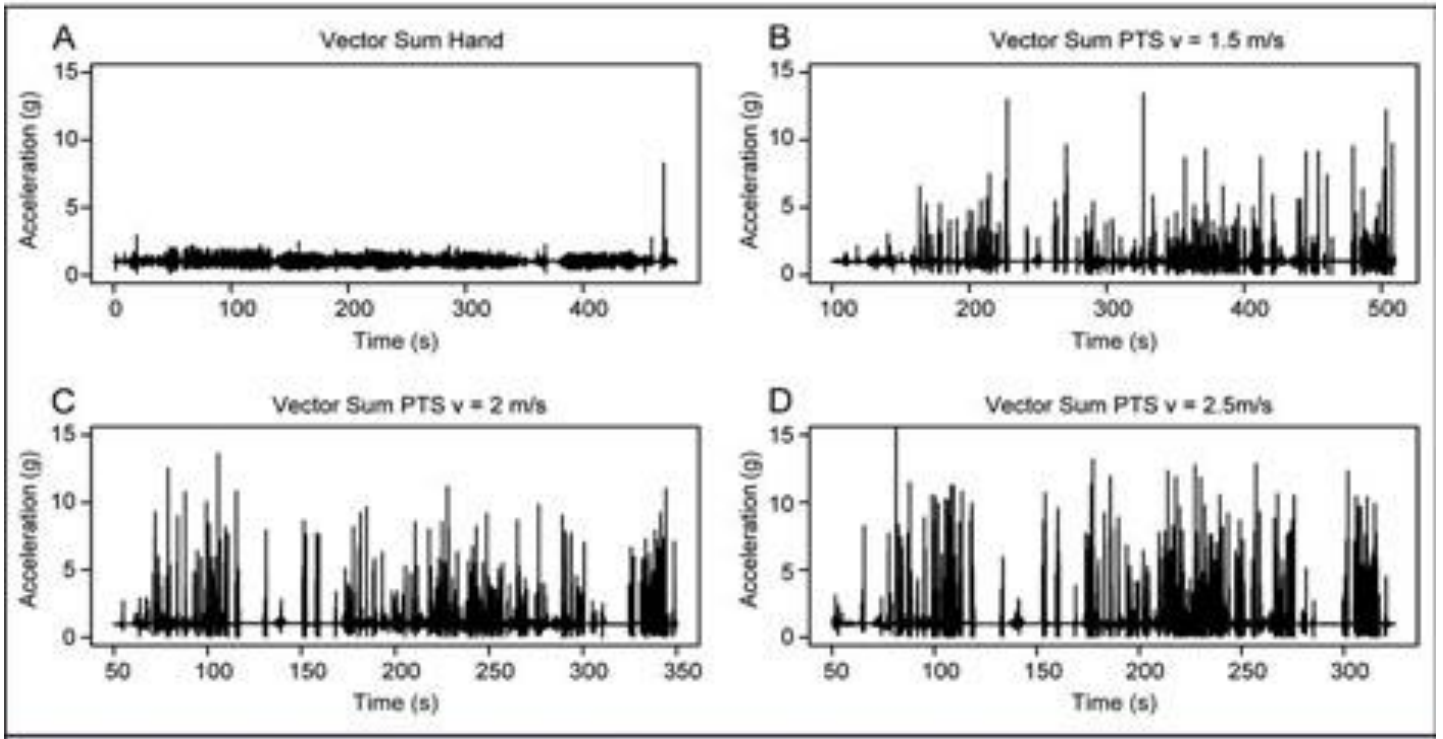


Fig. 2. Acceleration profiles after calculation of the vector sum for the *x*, *y*, and *z* axes.

The profiles were recorded with data loggers that were sent together with blood samples to the laboratory. The number of peaks observed in the profiles and their amplitudes increased with transportation speed. (A), Acceleration profile of hand transport, which served as control. (B–D), Acceleration profiles of transports by PTS with different speed settings, 100%, 80%, and 62%; v, velocity.

Streichert et al. Determination of hemolysis thresholds by the use of data loggers in pneumatic tube systems. Clin Chem 2011;57:1390-7.

Sample transportation

- Y
- tior
- mar
- ge
- E
- c

Papers in Press. Published February 28, 2018 as doi:10.1373/clinchem.2018.301408
The latest version is at http://clinchem.aacnjnls.org/cgi/doi/10.1373/clinchem.2018.301408

Clinical Chemistry 65:5
000–000 (2019)

Parameters for Validating a Hospital Pneumatic Tube System

Christopher W. Farnsworth,[1] Daniel M. Webber,[1] James A. Krakeler,[1] Melissa M. Budelier,[1] Nancy L. Bartlett,[2] and Ann M. Gronowski[1]*

BACKGROUND: Pneumatic tube systems (PTSs) provide rapid transport of patient blood samples, but physical stress of PTS transport can damage blood cells and alter test results. Despite this knowledge, there is limited information on how to validate a hospital PTS.

METHODS: We compared 2 accelerometers and evaluated multiple PTS routes. Variabilities in PTS forces over the same routes were assessed. Response curves that demonstrate the relationship between the number and magnitude of accelerations on plasma lactate dehydrogenase (LD), hemolysis index, and potassium in PTS-transported blood from volunteers were generated. Extrapolations from these relationships were used to predict PTS routes that may be prone to false laboratory results. Historical data and prospective patient studies were compared with predicted effects.

RESULTS: The maximum recorded g-force was 10*g* for the smartphone and 22*g* for the data logger. There was considerable day-to-day variation in the magnitude of accelerations (CV, 4%–39%) within a single route. The linear relationship between LD and accelerations within the PTS revealed 2 PTS routes predicted to increase LD by ≥20%. The predicted increase in LD was similar to that observed in patient results when using that PTS route.

CONCLUSIONS: Hospital PTSs can be validated by documenting the relationship between the concentrations of analytes in plasma, such as LD, with PTS forces recorded by 3-axis accelerometers. Implementation of this method for PTS validation is relatively inexpensive, simple, and robust.

Hospital pneumatic tube systems (PTSs)[3] provide rapid and efficient transport of samples (*1*). However, the physical stress induced by a PTS on blood can induce cellular lysis (*2–4*). As a result, multiple laboratory results are susceptible to error. Several studies have demonstrated that lactate dehydrogenase (LD), potassium (K+), and hemolysis index (HI) are prone to increases owing to PTS transport (*5–7*), with LD being the most sensitive to acceleration (*3, 4, 6, 8, 9*). Despite the known impact of PTS transport on cellular lysis, there is no consensus on how to best evaluate a PTS for its effects on clinical test results (*10*).

Previous studies have evaluated PTSs by correlating number and magnitude of accelerations, measured by various 3-axis accelerometers with changes in laboratory results (*2, 4, 11*). False increases in LD, K+, and HI have been associated with prolonged time in the PTS, excessive number of accelerations with g-forces >3*g* (*4*), and excessive cumulative accelerations measured by area under the curve (AUC) of the acceleration distribution (*2*). Although these studies have been successful in demonstrating the impact of acceleration changes within the PTS on patient samples, many questions remain with regard to how to best "validate" a PTS to ensure accurate reporting of clinical tests. For example, yet undefined variables include the type of device that should be used to measure the number and magnitude of shock forces, parameters that best correlate with clinically significant changes in test results, day-to-day variability in PTS forces, and appropriate individuals to use for validation studies.

A recent review of this subject called for all laboratories to perform a validation of their PTS (*10*). Given the lack of guidance on how to best undertake a validation, we set out to define the parameters for evaluating a hospital PTS.

Materials and Methods

MEDICAL CENTER AND PTS

The Barnes-Jewish Hospital/Washington University (BJH/WU) PTS is primarily a Swisslog system, although a few

[1] Department of Pathology and Immunology, Division of Laboratory and Genomic Medicine, Washington University, St. Louis, MO; [2] Department of Medicine, Siteman Cancer Center, Washington University, St. Louis, MO.
* Address correspondence to this author at: Washington University School of Medicine, 425 S. Euclid Ave., Campus Box 8118, St. Louis, MO 63110. Fax 314-362-1461; e-mail gronowskiw@wustl.edu.

An abstract of this study has been submitted to the AACC for presentation at the 2019 annual meeting.

Received December 31, 2018; accepted February 4, 2019.
Previously published online at DOI: 10.1373/clinchem.2018.301408

[3] Nonstandard abbreviations: PTS, pneumatic tube system; LD, lactate dehydrogenase; K+, potassium; HI, hemolysis index; AUC, area under the curve; BJH/WU, Barnes-Jewish Hospital/Washington University; IQR, interquartile range.

DE GRUYTER

Mini Review

Diagnosis 2019; 6(1): 39–43

Mads Nybo*, Janne Cadamuro, Michael P. Cornes, Rubén Gómez Rioja and Kjell Grankvist

Sample transportation – an overview

https://doi.org/10.1515/dx-2018-0051
Received July 13, 2018; accepted November 22, 2018; previously published online December 18, 2018

Abstract: Transportation of blood samples is a major part of the preanalytical pathway and can be crucial in delaying laboratory results to the clinicians. A variety of aspects however makes sample transportation a complex, challenging and often overlooked task that needs thorough planning and dedicated resources. The purpose of this review is to outline the options available for this task and to emphasize the preanalytical aspects that need consideration in this process, e.g. performance specifications for sample transportation as stated in ISO standards 15189 and 20658, quality control of automated transportation systems, monitoring of sample integrity parameters and temperature surveillance in general and for external samplers in particular. All these are tasks that the laboratory must assure on a daily basis in terms of continuous quality control, and simultaneously the laboratory must remain alert to alterations in clinical demands (sample frequency, turn-around-times) and new regulations within this area (e.g. the recent General Data Protection Regulation from the EU).

Keywords: preanalytical; sample transportation.

*Corresponding author: Mads Nybo, MD, PhD, Department of Clinical Biochemistry and Pharmacology, Odense University Hospital, Sdr. Boulevard 29, Odense 5000, Denmark, Phone: +45 2055 3952, E-mail: mads.nybo@rsyd.dk
Janne Cadamuro: Department of Laboratory Medicine, Paracelsus Medical University, Salzburg, Austria, E-mail: janne.cadamuro@salk.at
Michael P. Cornes: Department of Clinical Chemistry, Worcestershire Acute Hospitals NHS Trust, Worcester, UK, E-mail: michael.cornes@nhs.net
Rubén Gómez Rioja: Laboratorio Clínico Hospital La Paz, Madrid, Spain, E-mail: rgrioja@salud.madrid.org, https://orcid.org/0000-0002-3429-0427
Kjell Grankvist: Department of Medical Biosciences, Clinical Chemistry, Umeå University, Umeå, Sweden, E-mail: kjell.grankvist@medbio.umu.se

Background

Transportation of blood samples is a major part of the preanalytical pathway and can be crucial in delaying laboratory results to the clinicians [1]. Due to increasing demands from the clinicians, it is important to have the primary venous specimen collection tubes transported to the laboratory as fast as possible to be able to measure analytes within the established stability time [2–7] to maintain fast turnaround times and ensure sample integrity [8, 9]. Furthermore, the transportation process itself must be firmly controlled to assure that the analyses requested are not affected by temperature, agitation, or other physical or biological influences [10]. Finally, transportation logistics must be well arranged to satisfy sample flow from hospital wards as well as, e.g. general practitioners (GPs), while at the same time matching sample reception with the workflow at the laboratory in terms of numbers of samples, peak arrival during daytime, etc. Any delay from blood collection to centrifugation and analysis or any deviation from standard transportation conditions could potentially alter laboratory results and subsequently have a negative impact on patient safety [11]. Of note, the impact of transportation time and conditions on test results is highly dependent on the analytes requested, time to centrifugation as well as on the analytical method applied. Multiple sample stability studies are available for separated as well as whole blood samples, though not necessarily for every analyte [2–7].

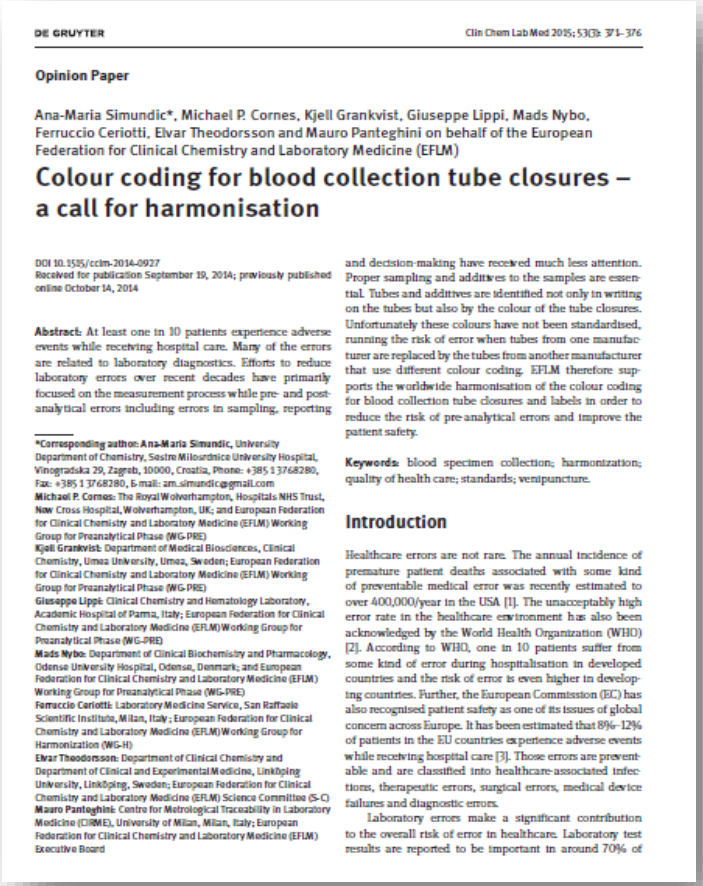
All these aspects make sample transportation a complex, challenging and often overlooked task that needs thorough planning and resources taking into account a profound understanding of which preanalytical factors that could alternate the test results. This information has to be cascaded amongst all parties involved in the transportation process (e.g. clinicians, nurses, phlebotomists, carriers, etc.). The purpose of this review is to outline the options available for this task and to emphasize the preanalytical aspects that need consideration in this process.

Regulations

A wide number of regulations and legislations has to be obeyed when biological materials are transported. In

Sample reception

- Automated sample reception
  - Bulk sorters/direct on track
  - Racks from internal sampling
  - Racks from GPs
- Arrival registration
- Cap colour recognition
- Sorting



DE GRUYTER

Clin Chem Lab Med 2015; 53(3): 371–376

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

DOI 10.1515/cclm-2014-0927
Received for publication September 19, 2014; previously published online October 14, 2014

Abstract: At least one in 10 patients experience adverse events while receiving hospital care. Many of the errors are related to laboratory diagnostics. Efforts to reduce laboratory errors over recent decades have primarily focused on the measurement process while pre- and post-analytical errors including errors in sampling, reporting and decision-making have received much less attention. Proper sampling and additives to the samples are essential. Tubes and additives are identified not only in writing on the tubes but also by the colour of the tube closures. Unfortunately these colours have not been standardised, running the risk of error when tubes from one manufacturer are replaced by the tubes from another manufacturer that use different colour coding. EFLM therefore supports the worldwide harmonisation of the colour coding for blood collection tube closures and labels in order to reduce the risk of pre-analytical errors and improve the patient safety.

Keywords: blood specimen collection; harmonization; quality of health care; standards; venipuncture.

***Corresponding author:** **Ana-Maria Simundic**, University Department of Chemistry, Sestre Milosrdnice University Hospital, Vinogradska 29, Zagreb, 10000, Croatia, Phone: +385 1 3768280, Fax: +385 1 3768280, E-mail: am.simundic@gmail.com
Michael P. Cornes: The Royal Wolverhampton, Hospitals NHS Trust, New Cross Hospital, Wolverhampton, UK; and European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Preanalytical Phase (WG-PRE)
Kjell Grankvist: Department of Medical Biosciences, Clinical Chemistry, Umea University, Umea, Sweden; European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Preanalytical Phase (WG-PRE)
Giuseppe Lippi: Clinical Chemistry and Hematology Laboratory, Academic Hospital of Parma, Italy; European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Preanalytical Phase (WG-PRE)
Mads Nybo: Department of Clinical Biochemistry and Pharmacology, Odense University Hospital, Odense, Denmark; and European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Preanalytical Phase (WG-PRE)
Ferruccio Ceriotti: Laboratory Medicine Service, San Raffaele Scientific Institute, Milan, Italy; European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Harmonization (WG-H)
Elvar Theodorsson: Department of Clinical Chemistry and Department of Clinical and Experimental Medicine, Linköping University, Linköping, Sweden; European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Science Committee (S-C)
Mauro Panteghini: Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Milan, Italy; European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Executive Board

Introduction

Healthcare errors are not rare. The annual incidence of premature patient deaths associated with some kind of preventable medical error was recently estimated to over 400,000/year in the USA [1]. The unacceptably high error rate in the healthcare environment has also been acknowledged by the World Health Organization (WHO) [2]. According to WHO, one in 10 patients suffer from some kind of error during hospitalisation in developed countries and the risk of error is even higher in developing countries. Further, the European Commission (EC) has also recognised patient safety as one of its issues of global concern across Europe. It has been estimated that 8%–12% of patients in the EU countries experience adverse events while receiving hospital care [3]. Those errors are preventable and are classified into healthcare-associated infections, therapeutic errors, surgical errors, medical device failures and diagnostic errors.

Laboratory errors make a significant contribution to the overall risk of error in healthcare. Laboratory test results are reported to be important in around 70% of

Sample reception

Benefits

- Well-described, uniform procedures
- Less *hands-on*
- Expedit sample registration
- Faster TATs

Pitfalls

- Overview?
- The sorting algorithm?
- How do we gather experience?
- And initiate optimizations?

Sample reception

ERROR stic_ March 2019

Start da Mar-2019

Days	01	02	03	04	05	06	07	08	09	10	11	12	13	14
ERROR_ALIQUOT	0	16	87	97	66	67	6	4	72	68	72	99	38	4
ERROR_BARCODE	32	50	218	191	112	130	23	23	198	170	134	191	159	30
ERROR_GENERAL	4	8	219	186	289	154	18	10	377	339	234	317	34	5
ERROR_LOOPING	13	11	137	111	51	48	11	15	202	130	76	94	68	28
ERROR_SENSOR	5	5	56	36	40	33	11	7	18	24	42	29	34	5
ERROR_TAC	33	26	115	93	70	83	11	12	86	96	82	73	76	11
TAM_3 ERROR ORDER	24	66	176	143	119	147	11	55	174	138	158	164	144	29
Error total	**111**	**182**	**1008**	**857**	**747**	**662**	**91**	**126**	**1127**	**965**	**798**	**967**	**553**	**112**
Input total	**1718**	**1708**	**9478**	**8304**	**8049**	**7764**	**1604**	**1488**	**9280**	**9047**	**8468**	**8591**	**7350**	**1411**
Error %	**6,5**	**10,7**	**10,6**	**10,3**	**9,3**	**8,5**	**5,7**	**8,5**	**12,1**	**10,7**	**9,4**	**11,3**	**7,5**	**7,9**

Sample reception

Clin Chem Lab Med 2017; 55(10): 1478–1488 DE GRUYTER

Table 5: Example of performances specifications for some QIs of the key processes.

Quality indicator	Code	Performance specifications		
		High	Medium	Low
Pre-anaytical phase				
Misidentification errors	Pre-MisR	<0.002	0.002–0.13	>0.13
	Pre-MisS	0	0–0.056	>0.056
	Pre-Iden	0	0–0.23	>0.23
Incorrect sample type	Pre-WroTy	0	0–0.03	>0.03
	Pre-WroCo	<0.003	0.003–0.03	>0.03
Incorrect fill level	Pre-InsV	<0.014	0.014–0.092	>0.092
	Pre-SaAnt	<0.07	0.07–0.57	>0.57
Unsuitable samples for transportation and	Pre-NotSt	0	0–0.01	>0.01
storage problems	Pre-ExcTim	0	0–0.13	>0.13
Clotted samples	Pre-Clot	<0.11	0.11–0.43	>0.43
Intra-anaytical phase				
Unacceptable performances in EQA-PT schemes	Intra-Unac	<2.4	2.4–3.8	>3.8
Post-anaytical phase				
Inappropriate turnaround times	Post-PotTAT	<55	55–70	>70
Incorrect laboratory reports	Post-IncRep	0	0–0.03	>0.03

Sample reception

You may need

- Stability control (sampling → reception)
- Overview – daily/weekly/monthly?
- Quality indicators!
- Continuous optimization of sorting algorithms
- What about STAT samples? Pediatric samples?

On-track stability?

On-track stability?

- Has the stability actually been tested?
- Stability after decapping? (ammonium, CO_2)
- Evaporation, especially for pediatric samples?
- What ***is*** the track time actually? Any queues?

On-track stability?

You may need

- Validation of the stability of fragile samples
- And analytes!
- Time statistics is necessary – also considering *worst case scenario*
- Place equipments correct (e.g. for Ca++)

Volume detection

Benefits

- A precise, standardized evaluation
- Security (primarily for coagulation testing)

Pitfalls

- Rejection of too many marginal samples?
- Time?
- Calibration?

Volume detection

You may need

Magnette *et al. Thrombosis Journal* (2016) 14:49
DOI 10.1186/s12959-016-0123-z

Thrombosis Journal

REVIEW Open Access

Pre-analytical issues in the haemostasis laboratory: guidance for the clinical laboratories

A. Magnette[1], M. Chatelain[1], B. Chatelain[1], H. Ten Cate[2] and F. Mullier[1*]

HIL indices

Benefits

- Standardized
- Reproducible
- Can be defined individually for each analysis
- Documentation available, e.g. for QI

Pitfalls

- Evidence-based?
- Extra analyses (= time)
- Are the HIL analyses in control?

HIL indices

LETTER TO THE EDITOR

Hemolysis-Icterus-Lipemia Index Analysis: A National Survey on the Validation and Use on Automated Equipment

TO THE EDITOR:

According to the accreditation standard ISO 15189:2012 (*1*), laboratory analyses must be validated before being implemented into daily use to assure the performance of the analysis in terms of precision, bias, CV, analysis range, etc. However,

cal error (*3*), and the proportion of hemolyzed samples received at the laboratory has been reported as high as 3.3% of all routine blood samples (*4*). It is therefore important to study the magnitude of the challenge an unvalidated H index analysis poses.

To elucidate this, we investigated the use and the validation procedure of an automated HIL index analysis at Danish departments of clinical biochemistry. A questionnaire was sent to all Danish departments of clinical biochemistry (n = 17). The questionnaire was answered by a medical director or a technical

ment only used it for chemistry analyses. Four departments also used the HIL index analysis for their coagulation analyses. Seven departments performed the HIL index analysis before performing the requested analyses, whereas 7 did not. One department performed the HIL index analysis and the requested analysis simultaneously (2 did not answer this question). Four departments had validated the HIL index analysis and performed internal QC, while 5 participated in an external QC program. Only 1 department blocked analysis

Gils et al., JALM 2017

HIL indices

Table 1. The questionnaire.

	Yes	No	Missing answer
Are the HIL analyses performed on chemistry/immunochemistry instruments?	17	0	0
Are the HIL analyses performed on coagulation instruments?	4	12	1
Are the HIL analyses validated?	4	13	0
Do you use internal QC for the HIL analyses?	4	12	0
Do you participate in an external QC program for the HIL analyses?	5	12	0
Are the HIL analyses calibrated?	3	13	0
Is the HIL index always performed *before* the requested analysis?	8	7	2
Is the requested analysis blocked if the HIL index exceeds the recommended threshold, or is it only the answer that is withheld?	1: The requested analysis is blocked 16: Only the answer is withheld	0	0
Is the result of the HIL index reported together with the requested analysis?	0	17	0

Gils et al., JALM 2017

HIL indices

You may need

Contents lists available at ScienceDirect

Clinica Chimica Acta

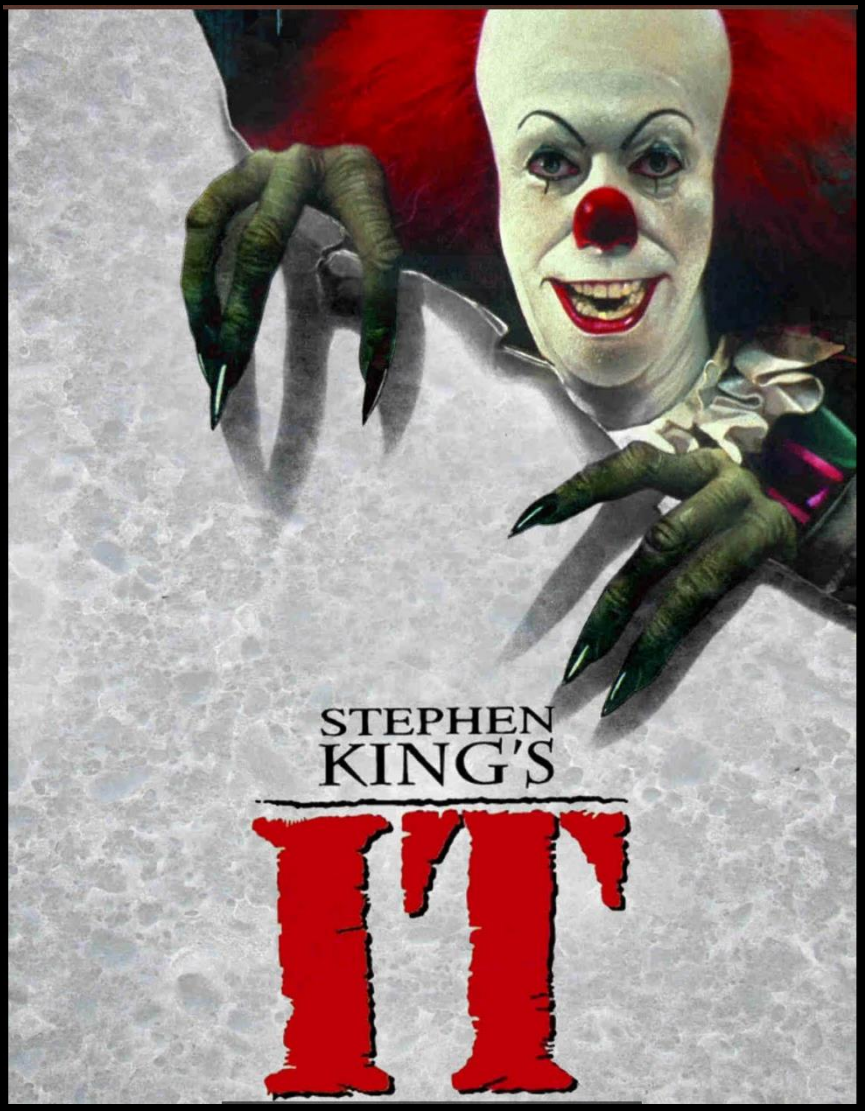
journal homepage: www.elsevier.com/locate/cca

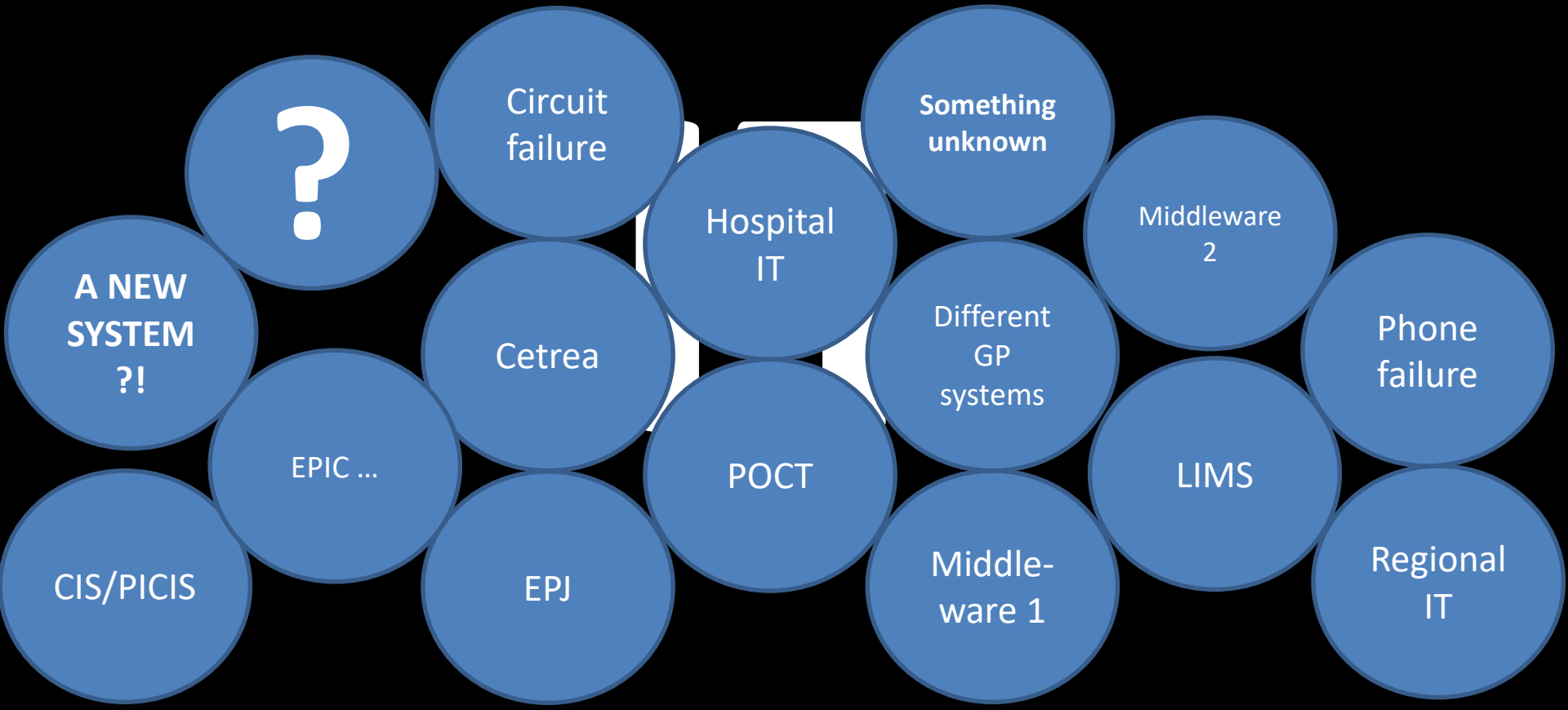
Discussion

Call for more transparency in manufacturers declarations on serum indices: On behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

Alexander von Meyer[a,*], Janne Cadamuro[b], Giuseppe Lippi[c], Ana-Maria Simundic[d]

[a] Institute for Laboratory Medicine, Kliniken Nordoberpfalz AG and Klinikum St. Marien, Weiden and Amberg, Germany
[b] Department of Laboratory Medicine, Paracelsus Medical University, Salzburg, Austria
[c] Section of Clinical Biochemistry, University Hospital of Verona, Verona, Italy
[d] Department of Medical Laboratory Diagnostics, University Hospital Sveti Duh, Zagreb, Croatia


STEPHEN
KING'S
IT


?
Circuit failure
Something unknown
Hospital IT
Middleware 2
A NEW SYSTEM ?!
Cetrea
Different GP systems
Phone failure
EPIC …
POCT
LIMS
CIS/PICIS
EPJ
Middle-ware 1
Regional IT

IT

Challenges?

- IT QC when:
  - New equipment is added
  - New analyses are established
  - Applications are added or updated
  - After service/PM
- Routine cooperation between manufacturers of middleware, LIMS and EPJ systems, along with local/regional IT and your own specialist
- Should test reports be tested regularly at the ”receiving end”?

IT

You may need

- Clear, well-known SOP's
- IT experts at the lab (!)
- Improved systems from the companies – what happened to plug'n play?
- IT bots that can solve the problems themselves?

In summary

- **Automation *do* improve lab efficiency!**
- **But it is *not* fully automated!**
- **There are still many issues to monitor to ensure quality of the entire process – especially preanalytically!**

As a minimum you must be aware of

In summary

- **PTS** QC prior to use *and* continuously
- **Reception** Statistics and continuous reevaluation of sorting algorithms
- **Volume** QC and reevaluation of accept limit
- **HIL** Validation and continuous QC
- **Storage** Reevaluate algorithms
- **IT** Yes, QC is indeed needed!
- **And** **Use Quality Indicators**
- **Remember** **Keep your eyes on the sample!**

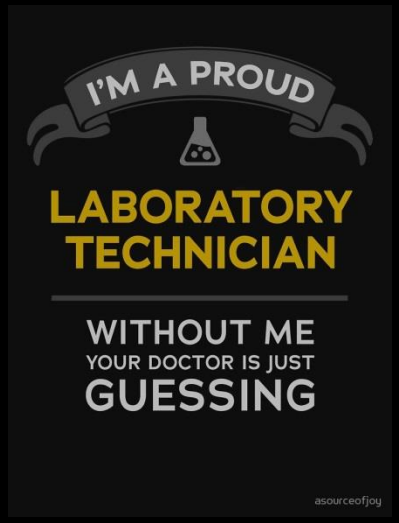
SO

Are **there any preanalytical challenges in an automated lab?**

INDEED!

But they can be solved with knowledge, awareness and *good old-fashioned QC*

ENJOY


I'M A PROUD
LABORATORY TECHNICIAN
WITHOUT ME
YOUR DOCTOR IS JUST
GUESSING
asourceofjoy