Clinical Biochemistry xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

Clinical Biochemistry

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

Post-analytical stability of 23 common chemistry and immunochemistry analytes in incurred samples

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ARTICLE INFO

Keywords:
Post-analytical stability
Clinical chemistry tests
Immunochemistry
Blood platelets
Dimension Vista

ABSTRACT

Background: Storage of blood samples after centrifugation, decapping and initial sampling allows ordering of additional blood tests. The pre-analytic stability of biochemistry and immunochemistry analytes has been studied in detail, but little is known about the post-analytical stability in incurred samples.

Methods: We examined the stability of 23 routine analytes on the Dimension Vista® (Siemens Healthineers, Denmark): 42–60 routine samples in lithium-heparin gel tubes (Vacutainer, BD, USA) were centrifuged at 3000 × *g* for 10 min. Immediately after centrifugation, initial concentration of analytes were measured in duplicate (t = 0). The tubes were stored decapped at room temperature and re-analyzed after 2, 4, 6, 8 and 10 h in singletons. The concentration from reanalysis were normalized to initial concentration (t = 0). Internal acceptance criteria for bias and total error were used to determine stability of each analyte. Additionally, evaporation from the decapped blood collection tubes and the residual platelet count in the plasma after centrifugation were quantified.

Results and conclusion: We report a post-analytical stability of most routine analytes of ≥ 8 h and do therefore – with few exceptions – suggest a standard 8 hour-time limit for reordering and reanalysis of analytes in incurred samples.

1. Introduction

Laboratory test results are crucial for daily clinical care and it is our most important task to secure the reliability of these results [1,2]. At hospital laboratories, blood samples are often stored for a given time after analysis. This allows rapid and easy delivery of additional analytes requested by the clinicians, spare repeated phlebotomies, and reduce test result turnaround time (TAT).

Analytical stability of whole blood samples is commonly defined as "*the capacity of sample material to retain the initial value of the quantity measured within specific limits and under specified conditions*" [3,4]. As well as pre-analytical stability, post-analytical stability is influenced by time and storage temperature. In contrast to the often automated and precisely timestamped pre-analytical sample handling (e.g. pneumatic tube transfer, automated decapping and analysis) post-analytical sample handling is still often manual and less documented. As an example, incurred samples at our laboratory, are manually removed from the conveyor belt (Flexlab automation, Inpeco SA, Italy) to a refrigerator. How long time the tubes are on the conveyer belt and at the instrument output module may vary and not be recorded.

Although it is common practice at hospital laboratories to store samples for potential later analysis, little is known about the reliability and stability of analytes in samples decapped, incurred, and stored at room temperature [3]. Due to this the lack of knowledge, at our laboratory we refer to known pre-analytical stability in capped plasma samples, and use this as guidance and time limit for adding tests to already incurred samples [5]. A number of studies on stability of analytes in whole blood samples and in plasma/serum separated from the blood cells have been published [6–10]. Most of these studies are on capped sample tubes contrasting the daily practice of storing decapped tubes. A recent small Danish study of post-analytical stability of analytes in decapped plasma samples indicate that the stability is decreased compared to storage in capped tubes [11]. It is highly relevant to examine the stability of decapped samples, at room temperature since this is these are the conditions faced at many automated hospital

Abbreviations: ALT, alanine aminotransferase; ALB, albumin; AMYL, amylase; TBIL, bilirubin; CA, calcium; CHOL, cholesterol; B12, cobalamin; CRP, C-reactive protein; CREA, creatinine; FERR, ferritin; FOL, folate; GGT, gamma-glutamyltransferase; HAPT, haptoglobin; HDL, HDL cholesterol; FE, iron; LD, lactate dehydrogenase; K, potassium; NA, sodium; TSH, thyroid-stimulating hormone; FT4, free thyroxin; TRF, transferrin; TRG, triglyceride; FT3, free triiodothyronine; SEM, standard error of mean; TE, total error; TAT, turnaround time

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http://dx.doi.org/10.1016/j.clinbiochem.2017.08.003
Received 7 April 2017; Received in revised form 20 July 2017; Accepted 8 August 2017

Table 1
Analytes, abbreviations, quality control materials used to quantify the methods and the method uses.

Analyte	Abbreviation	Internal QC	External QC	Method
Alanine aminotransferase	ALT	MUL	A	Photometry
Albumin	ALB	MUL	A	Photometry
Amylase	AMYL	MUL	A	Photometry
Bilirubin	TBIL	MUL	A	Photometry
Calcium	CA	MUL	A	Photometry
Cholesterol	CHOL	MUL	A	Photometry
Cobalamin	B12	IA	B	Chemiluminescence immunoassay
C-reactive protein	CRP	IM	C	Nephelometry
Creatinine	CREA	MUL	A	Photometry (enzymatic)
Ferritin	FERR	IA	B	Chemiluminescence immunoassay
Folate	FOL	IA	B	Chemiluminescence immunoassay
Gamma-glutamyltransferase	GGT	MUL	A	Photometry
Haptoglobin	HAPT	IM	A	Nephelometry
HDL cholesterol	HDL	MUL	A	Photometry
Iron	FE	MUL	A	Photometry
Lactate dehydrogenase	LD	MUL	A	Photometry
Potassium	K	MUL	A	Potentiometry (indirect)
Sodium	NA	MUL	A	Potentiometry (indirect)
Thyroid stimulating hormone (TSH)	TSH	MUL	B	Chemiluminescence immunoassay
Thyroxine, free (fT4)	FT4	MUL	B	Chemiluminescence immunoassay
Transferrin	TRF	IM	A	Nephelometry
Triglyceride	TRG	MUL	A	Photometry
Triiodothyronine, free (fT3)	FT3	MUL	B	Chemiluminescence immunoassay

External QC (DEKS: Danish Institute for External Quality Assurance for Laboratories in Health Care. http://www.deks.dk).
A: Labquality serums B and C, General clinical chemistry, DEKS.
B: Labquality, Basale Hormoner og immunkemi, DEKS.
C: Almen klinisk biokemi, C-reaktivt protein, DEKS.
Internal QC.
MUL: Liquid Assayed Multiqual, levels 1 and 3, Bio-Rad, Denmark.
IM: Liquichek Immunology Control, levels 1 and 3, Bio-Rad, Denmark.
IA: Liquichek Immunoassay Plus Control levels 1 and 3, Bio-Rad, Denmark.

laboratories. In order to establish guidelines for reanalysis of decapped samples stored at room temperature we investigated the stability of 23 of the most common requested chemistry and immunochemistry analytes on Dimension Vista® (Siemens Healthineers, Denmark).

2. Materials and methods

The study was conducted at the Department of Clinical Biochemistry, Nykøbing F Hospital (Nykøbing F, Denmark). Blood samples were drawn from in-hospital patients. Participants were recruited on one of three days: 60 patients on day one, 48 patients on the second and on the third day (total n = 156). Blood was drawn in 3.0 mL lithium heparin gel tubes (Vacutainer, BD Biosciences, Denmark) by trained laboratory personnel or a trained biomedical laboratory scientist student. Within an hour, blood samples were centrifuged at 3000 *g* for 10 min to obtain platelet free plasma.

A maximum of eight analytes were analyzed on each sample to minimize the amount of plasma needed from each patient. Each analyte was analyzed on 32–60 samples (Table 1). Shortly after centrifugation, the initial value of each analyte, was assigned in duplicates (t = 0). The mean was recorded as baseline value. Tubes were decapped and stored at room temperature (20–25 °C) and reanalysis was performed in singletons 2, 4, 6, 8 and 10 h after decapping (Fig. 1). This strategy was chosen to mimic every day conditions at our laboratory. Between analyses, the tubes were stored upright in a rack under the previously described conditions.

2.1. Analytes and analyses

Plasma was analyzed on one of two Dimension Vista® instruments, both routinely calibrated and quality assured, with certified internal and external quality control material. Assays in the Dimensions Vista® are photometric, nephelometric, indirect potentiometric and chemiluminescence immunoassays. Analytes, and internal and external quality control programs are listed in Table 1.

2.2. Evaporation from the samples

To assess whether evaporation could explain changes in analyte concentration in decapped tubes, we measured the loss of water (plasma) during storage. Five batches of 3.0 mL lithium heparin gel tubes, ten in each batch (50 samples in total) were centrifuged for 10 min at 3000 × *g* and decapped. Tubes was immediately weighed on a calibrated weight (Mettler-Toledo XP205DR, Mettler-Toledo, Denmark). Weighting was repeated after 2, 4, 6, 8 and 10 h of storage at room temperature. We estimated evaporation, based the on the assumption that any decrease in weight could be contributed to loss of water (plasma) from the samples. In a properly filled Vacutainer

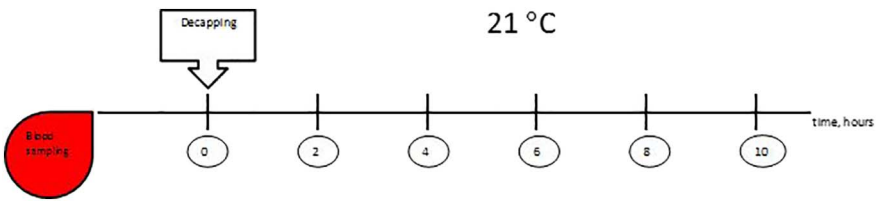

Fig. 1. Sample handling.