Stability of the Gel Barrier in VACUETTE® Plasma Gel Tubes during Transport

Background:

Greiner Bio-One, Austria has sold plastic evacuated tubes (VACUETTE®) for venous blood collection since 1986.

VACUETTE® gel tubes contain an inert gel material with a specific gravity intermediate to plasma and cells. During centrifugation, the gel material forms an impermeable barrier between these two blood components.

Study Objective:

The aim of this study was to show the stability of the inert gel material barrier in VACUETTE® heparin tubes during transport.

Especially in thinly populated areas physicians are forced to send blood samples by courier to the nearest laboratory. This can take up to two days during which the samples are shaken repeatedly.

Questions arose if the gel material Greiner Bio-One uses forms a barrier between plasma and the cells, that withstands the physical stress of dispatch by post.

The parameters analysed in this study are chosen because they are known to be influenced by the presence of blood cells (erythrocytes, granulocytes, or thrombocytes). The tubes should be centrifuged within two hours after blood collection to avoid extended contact between plasma and cells.

Study design:

For this study, the following tube type containing an inert gel material has been evaluated:

VACUETTE® LH Lithium Heparin Sep.

In an external laboratory venous blood was collected from 9 patients using the VACUETTE® Standard Tube Holder and VACUETTE® 21G Multi-Sample Needle. Four tubes were randomly collected from each patient.

Directly after venipuncture, the tubes were carefully inverted 5-10 times according to the instructions given by the tube manufacturer. The samples were then centrifuged at 2200g for 15 minutes in a swing-out bucket centrifuge.

Immediately after centrifugation 0h-values of the below mentioned parameters were obtained. One of the four samples was kept at 4°C for 24 hours as a reference tube. With the other three tubes the transport was simulated by the methods described in Table 1 "Overview samples".

Using a pneumatic dispatch system represents the greatest possible stress on the gel barrier. Handling during dispatching by post (samples are possibly shaken repeatedly) will not be as strenuous as sending the tubes by a pneumatic dispatch system.

Sample	Description	Transport method
A	VACUETTE® LH Lithium Heparin Sep.	none (reference tube)
B		additional manual inversion of the centrifuged tube (5 times)
C		using a pneumatic dispatch system
D		additional treatment of the centrifuged tube with a laboratory mixer (Rotamix RM-1) for 1 minute

Table 1:Overview samples

The analysis of the following parameters was performed again 24 hours after sampling on the Vitros 950 System from Ortho Diagnostics with the accompanying reagents in an external laboratory from all four tubes:

- LDH Lactate Dehydrogenase
- P_i Phosphate (inorganic)
- K Potassium

Results in detail can be found in the Annex.

Conclusion:

In all four tubes, representing for different transportation methods, an increase for all three parameters is apparent. The following values are detected:

- for LDH an increase between 7 and 12 U/l
- for phosphate an increase between 0,02 and 0,03 mmol/l
- for potassium an increase between 0,1 and 0,2 mmol/l

As slight increases are found in all four tubes – treated or not – dispatch services do not influence the gel barrier's stability. The increases in activity or concentration are judged as normal and known and are not of clinical significance.

In addition to these results, a slight increase in the sensitive values for LDH, phosphate, and potassium over 24 hours of storage is also known[1,2,3]. Neither is this alteration clinically significant, nor do dispatch services (pneumatic dispatch system, dispatch by post) influence the function of the gel barrier.

References:

(1) Guder W.G., Narayanan S., Wisser H., Zawta B., Samples: From the Patient to the Laboratory. Wiley-VCH, 3rd edition (2003)

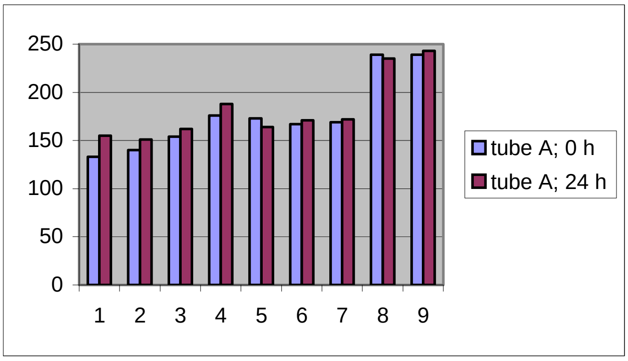
(2) Thomas L., Labor und Diagnose. TH-Books, 5. Auflage (1998)

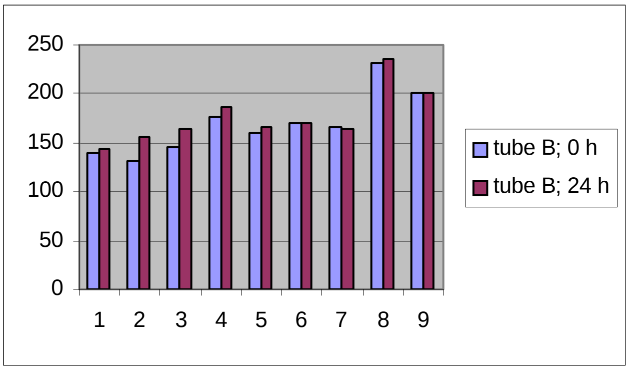
(3) Tietz N.W., Clinical Guide to Laboratory Tests. W.B. Saunders Company, third edition (1995)

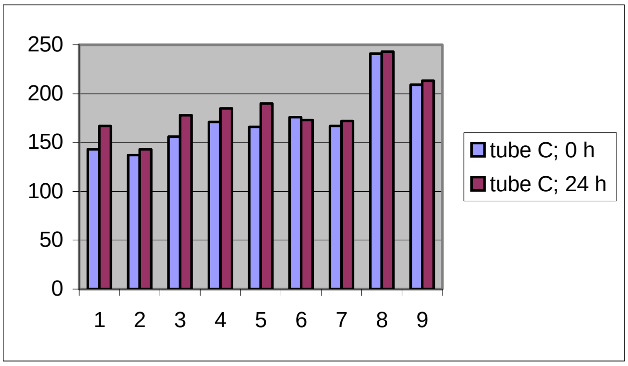
<u>Annex / Results in detail:</u>

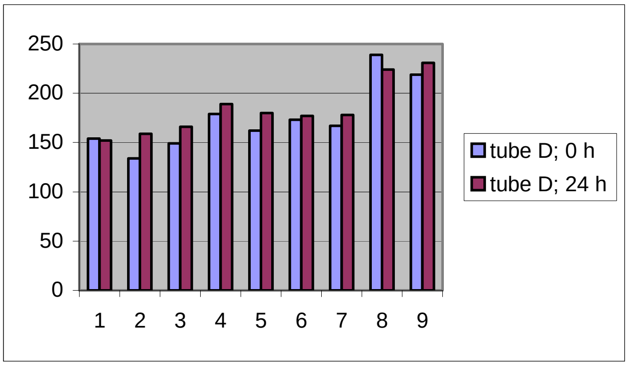
Lactate dehydrogenase [U/l]
normal range: < 248 U/l

Donor	Tube A		Tube B		Tube C		Tube D	
	0 h	24 h	0 h	24 h	0 h	24 h	0 h	24 h
1	133	155	139	144	143	167	154	152
2	140	151	132	156	137	143	134	159
3	154	162	146	163	156	178	149	166
4	176	188	177	187	171	185	179	189
5	173	164	160	167	166	190	162	180
6	167	171	170	171	176	173	173	177
7	169	172	167	163	167	172	167	178
8	239	235	231	235	241	243	239	224
9	239	243	200	200	209	213	219	231





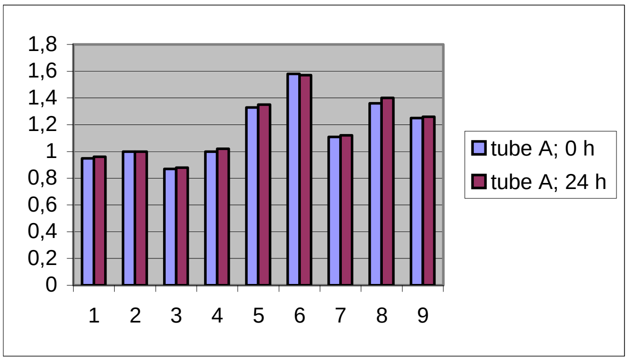


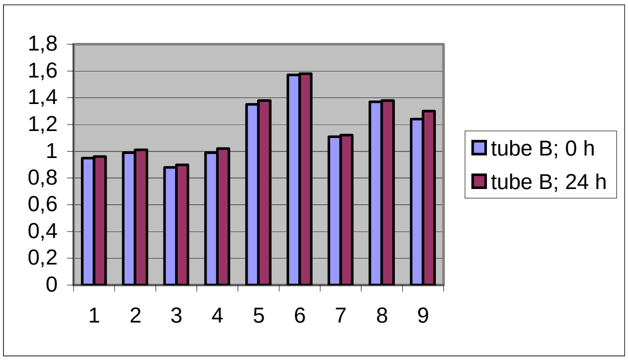


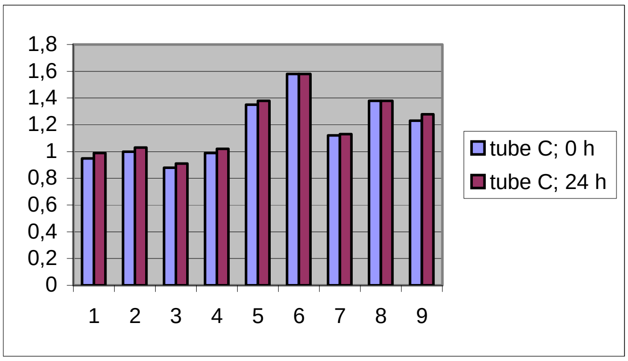
x-axis: Lactate dehydrogenase in [U/l]
y-axis: Donor No.

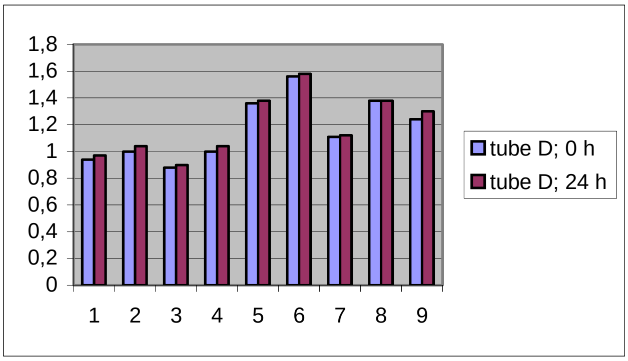
Phosphate (inorganic) [mmol/l]
normal range: 0,87 - 1,45 mmol/l

Patient	Tube A		Tube B		Tube C		Tube D	
	0 h	24 h	0 h	24 h	0 h	24 h	0 h	24 h
1	0,95	0,96	0,95	0,96	0,95	0,99	0,94	0,97
2	1,00	1,00	0,99	1,01	1,00	1,03	1,00	1,04
3	0,87	0,88	0,88	0,90	0,88	0,91	0,88	0,90
4	1,00	1,02	0,99	1,02	0,99	1,02	1,00	1,04
5	1,33	1,35	1,35	1,38	1,35	1,38	1,36	1,38
6	1,58	1,57	1,57	1,58	1,58	1,58	1,56	1,58
7	1,11	1,12	1,11	1,12	1,12	1,13	1,11	1,12
8	1,36	1,40	1,37	1,38	1,38	1,38	1,38	1,38
9	1,25	1,26	1,24	1,30	1,23	1,28	1,24	1,30





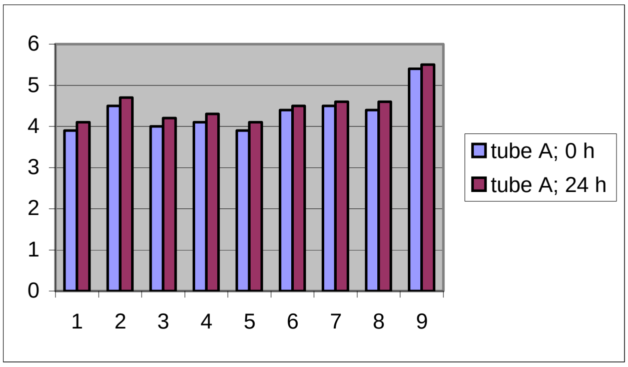


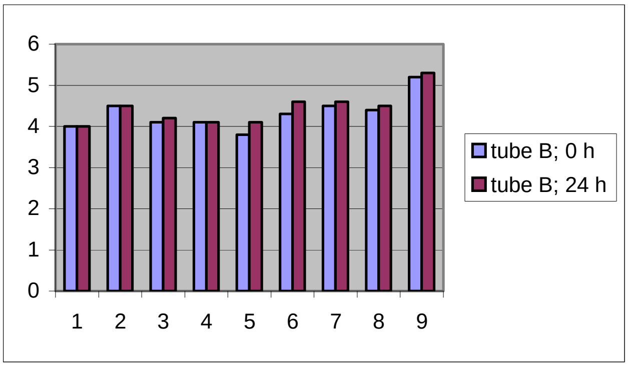


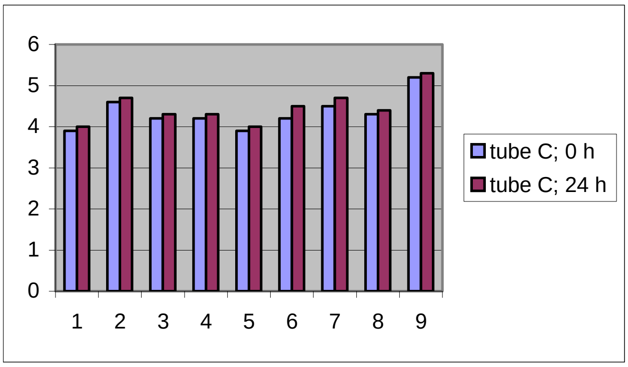
x-axis: Phosphate (inorganic) in [mmol/l]
y-axis: Donor No.

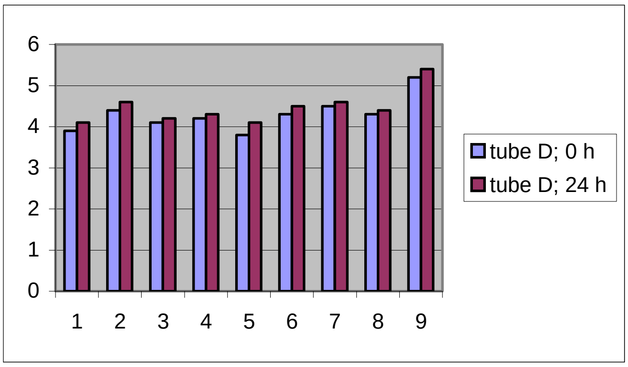
Potassium [mmol/l]
normal range: 3,4 – 4,5 mmol/l

Donor	Tube A		Tube B		Tube C		Tube D	
	0 h	24 h	0 h	24 h	0 h	24 h	0 h	24 h
1	3,9	4,1	4,0	4,0	3,9	4,0	3,9	4,1
2	4,5	4,7	4,5	4,5	4,6	4,7	4,4	4,6
3	4,0	4,2	4,1	4,2	4,2	4,3	4,1	4,2
4	4,1	4,3	4,1	4,1	4,2	4,3	4,2	4,3
5	3,9	4,1	3,8	4,1	3,9	4,0	3,8	4,1
6	4,4	4,5	4,3	4,6	4,2	4,5	4,3	4,5
7	4,5	4,6	4,5	4,6	4,5	4,7	4,5	4,6
8	4,4	4,6	4,4	4,5	4,3	4,4	4,3	4,4
9	5,4	5,5	5,2	5,3	5,2	5,3	5,2	5,4









x-axis: Potassium in [mmol/l]
y-axis: Donor No.