Comparison of various VACUETTE® Glucose Tubes to the Vacutainer® Glucose Tube for lactate testing

Background:

Greiner Bio-One offers various blood collection tubes for determination of lactate concentration.

These tubes are available with different additives and are suitable for the analysis of glucose concentration within 48h [1,2]:

- VACUETTE® FX Sodium Fluoride/Potassium Oxalate
- VACUETTE® FE Sodium Fluoride/K$_3$EDTA

The additive compositions meet the requirements provided in ISO 6710 [3].

Study Objective:

A clinical study including 20 male and female subjects aged 18-64 was carried out to compare the performance of various VACUETTE® standard glucose tubes to a VACUTAINER® glucose tube in order to demonstrate the stability of lactate concentration in aliquoted plasma samples.

Study design:

The following tube types were used in this study:

Sample ID	Description	Tube dimension	Prod. No.	Volume
A	VACUTAINER® Fluoride/Oxalate	13/75	368920	2 ml
B	VACUETTE® FX Sodium Fluoride/Potassium Oxalate	13/75	454061	2 ml
C	VACUETTE® FE Sodium Fluoride/K$_3$EDTA	13/75	454085	2 ml

The study has been approved by Ethics Commission. Informed consent was given by all participants.

All donors rested for at least 5 minutes in the phlebotomy chair before starting the blood collection. Blood was drawn from 20 donors ages 18-64 into one tube of each type using an SBC-Set (#450085), a tourniquet (#840050) and a discard tube. All tubes were gently inverted 8x after collection to mix the blood with the additive and stored on ice immediately after collection and until centrifugation. All samples A were immediately centrifuged at 1300g for 10 min at 20°C and all samples B and C were centrifuged at 1800g for 10 min at 20°C in a swing bucket centrifuge (Hettich Rotanta 460R) so that cell separation was done within 15 min of blood collection according to assay instructions. After centrifugation, the plasma was transferred into a secondary tube for measurements at initial time point as well as for replicate analysis after storage.

Analysis of lactate concentration was done at the following time points:

- Initial (t_0), 8h ±1 (t_8) and 24h ±1 (t_{24})

All tubes were stored at room temperature between the time points for analysis.

Lactate concentration was measured immediately after centrifugation for the initial time point and at all subsequent replicate analyses using an AU680 instrument from Beckman Coulter (serial no. 2012101804). Analysis was performed with the instrument's accompanying reagents.

Statistical analysis was done by STATISTICA 13.2 and clinical assessment was performed on the basis of the acceptance criteria given for lactate (11% [4]; 0.2 mmol/l = 1.8 mg/dl [5]).

Results:

Comparison of sample A (BD Vacutainer®) to B1 – C1 (GBO VACUETTE®) measured at t_{0h} (initial analysis) using plasma.

Higher deviations in lactate concentrations were found comparing Vacutainer® Fluoride/Oxalate tubes to VACUETTE® FX Sodium Fluoride/Potassium Oxalate tubes and VACUETTE® FE Sodium Fluoride/K$_3$EDTA tubes at initial time point when analyzed from plasma transferred into a secondary tube after storage on ice and centrifugation within 15 min.

The table below shows the mean values for lactate concentration measured at the initial timepoint using plasma aliquots.

Sample	Lactate concentration (initial plasma) mean values ± SD in mg/dl
	Initial plasma
A	10.33±3.73
B	10.70±3.61*
C	10.63±3.73*

*higher deviation than recommended by RiliBaek [4] when compared to sample A

However, there are various guidelines for acceptance criteria available in literature. The acceptance criteria for lactate defined by WSLH [5] do not result in higher than allowable deviations than recommended.

Stability of lactate concentration in all tested glucose tubes analyzed from stored plasma after transfer into a secondary tube:

Higher deviations in lactate concentration than those recommended by RiliBaek[4] were found when comparing Vacutainer® Fluoride/Oxalate tubes to VACUETTE® FX NaF/KOx tubes at time point t_8 relative to the initial time point t_0 when measured from plasma transferred into a secondary tube after storage on ice and centrifugation within 15 min.

The table below shows the mean values for lactate concentration analyzed at the initial timepoint from plasma aliquots and the replicate values from analyses after storage in a secondary tube at room temperature.

Sample	Lactate concentration mean values ± SD in mg/dl		
	Initial plasma aliquot	Plasma after 8h in a secondary tube	Plasma after 24h in a secondary tube
A	10.33±3.73	10.65±3.56*	10.50±3.59
B	10.70±3.61	10.95±3.62*	10.75±3.52
C	10.63±3.73	10.70±3.88	10.70±3.88

*higher deviation than recommended by RiliBaek [4] when compared to initial value

However, there were not any higher than recommended deviations according to the acceptance criteria defined by WSLH [5].

Conclusion

On basis of the WSLH acceptance criteria, equivalent performance was demonstrated for VACUETTE® standard glucose tubes (Samples B–C) in comparison to Vacutainer® Fluoride/Oxalate tubes (Sample A) for the initial analysis of lactate concentration at t_{0h}.

All VACUETTE® Glucose tubes tested are suitable to stabilize lactate in aliquoted plasma for a time period of 24 hours when stored at room temperature.

References:

[1] Greiner Bio-One. Evacuated Blood Collection System 980200_Rev.19. Instructions for Use. Kremsmünster, Austria. 2017.
[2] Greiner Bio-One. Product Information G01_E-Rev02
[3] ISO 6710:1995(E), Single-use containers for venous blood specimen collection. International Standard. 1995
[4] RILIBAEK: Guideline of the German Medical Association for Quality Assurance.
[5] WSLH Wisconsin State Laboratory of Hygiene.

Annex:

Lactate
Normal Range: 4,5 - 19,8 mg/dl
GBO/RCV: 11.00%/4.99%

Normal range: 4,5 - 19,8 mg/dl
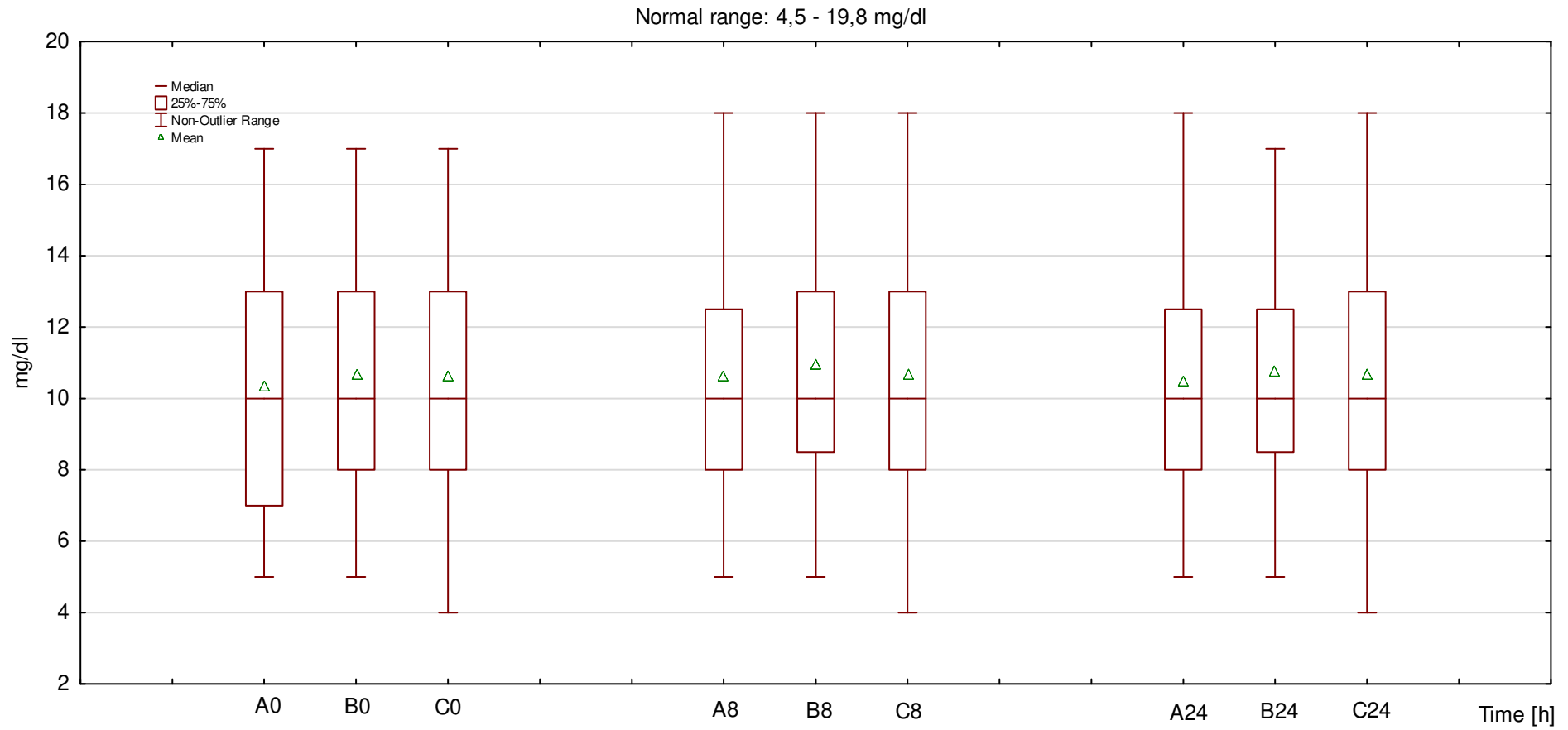
Correlation: Lactate [mg/dl] A0h/B0h

Correlation: r = ,99274
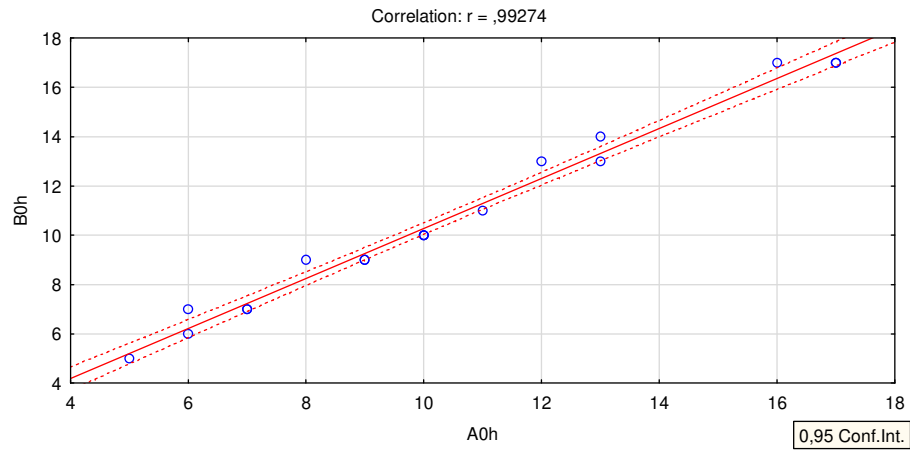
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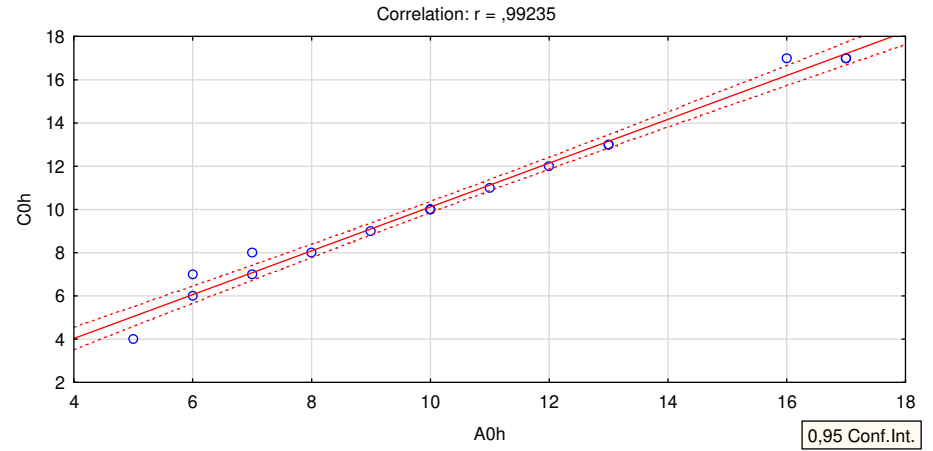
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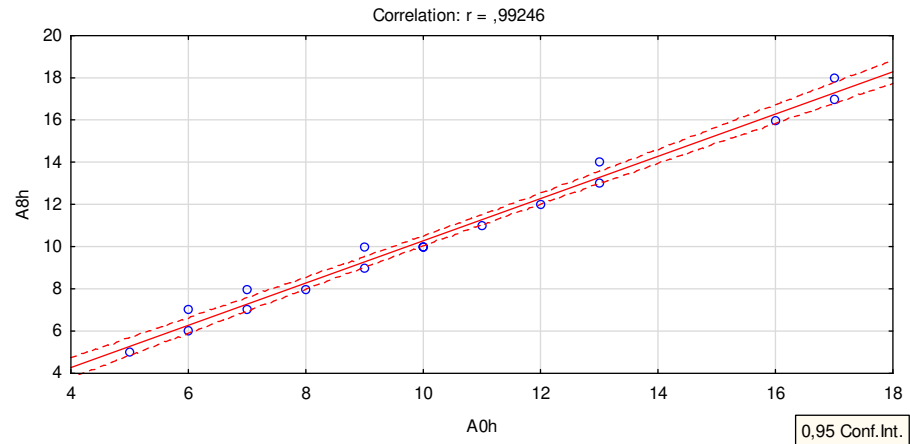
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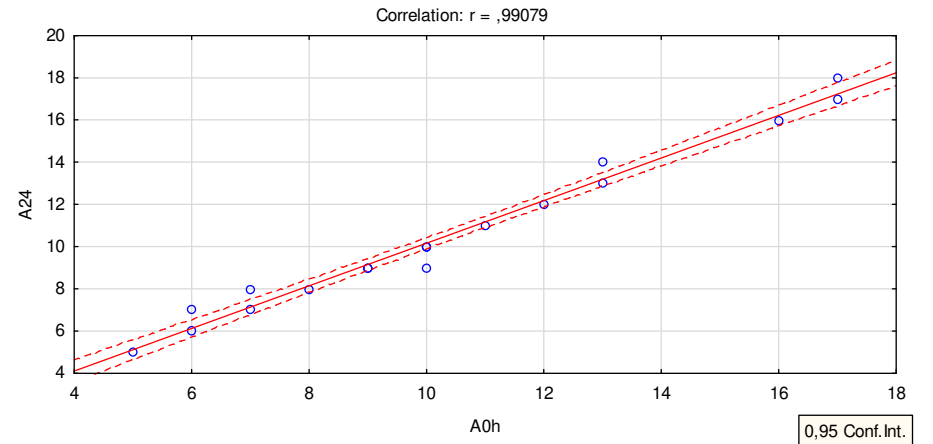
Correlation: Lactate [mg/dl] B0h/B8h

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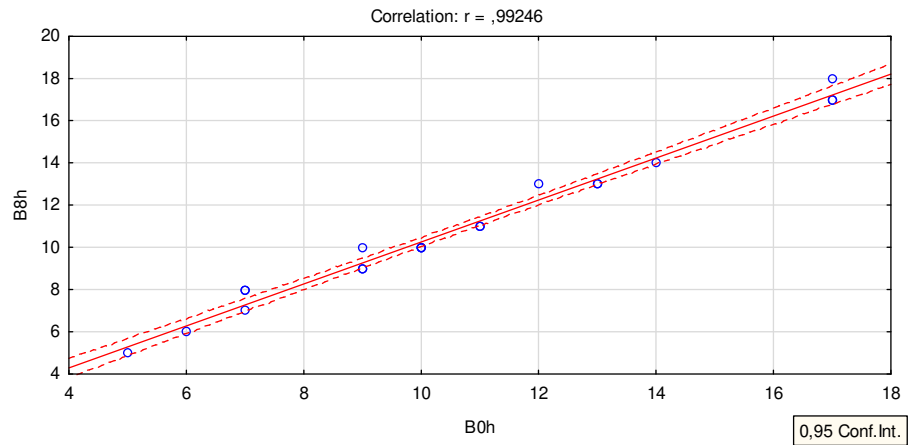
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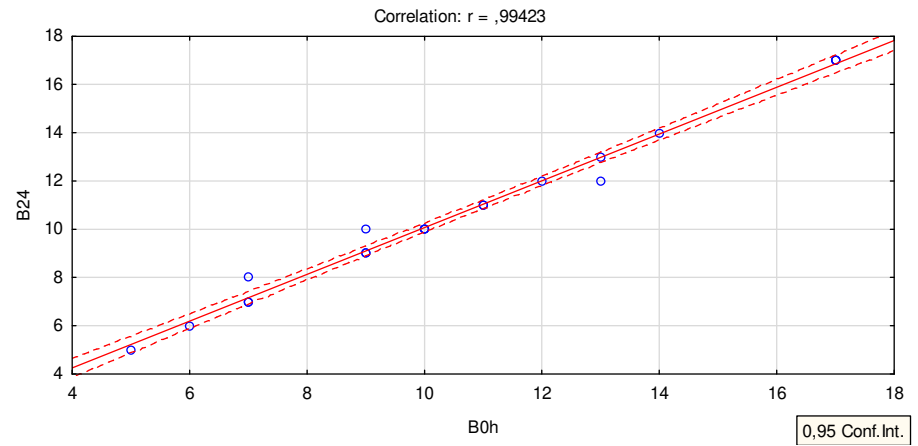
Correlation: Lactate [mg/dl] C0h/C8h

Correlation: r = ,99714

Correlation: Lactate [mg/dl] C0h/C24
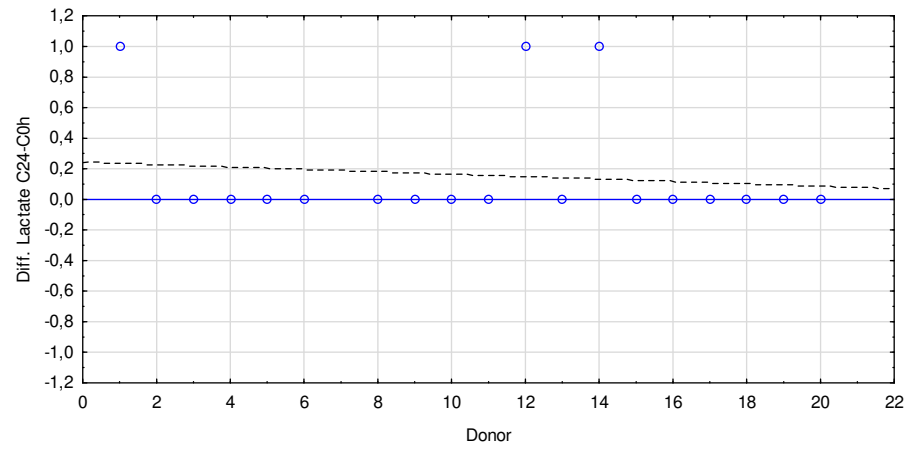
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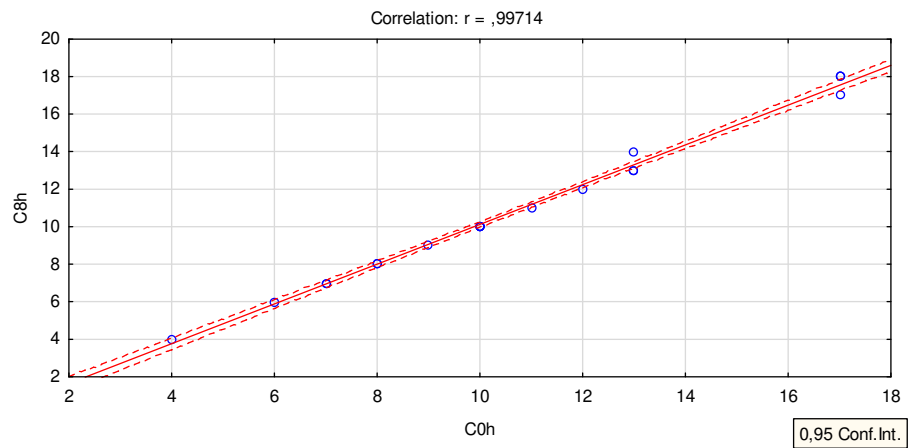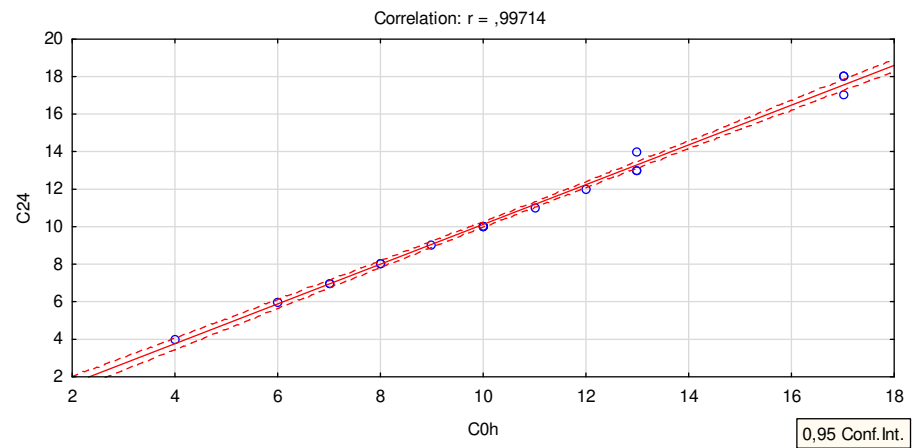
Difference Plot: Lactate [mg/dl] A0h/B0h
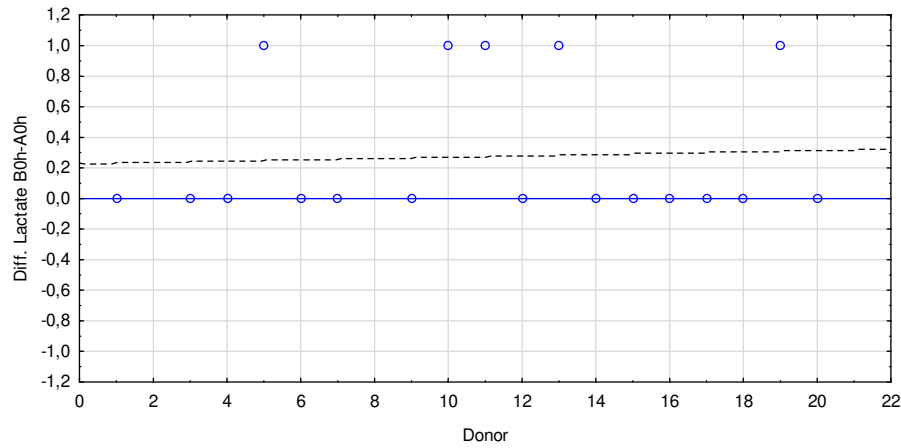
Difference Plot: Lactate [mg/dl] A0h/C0h
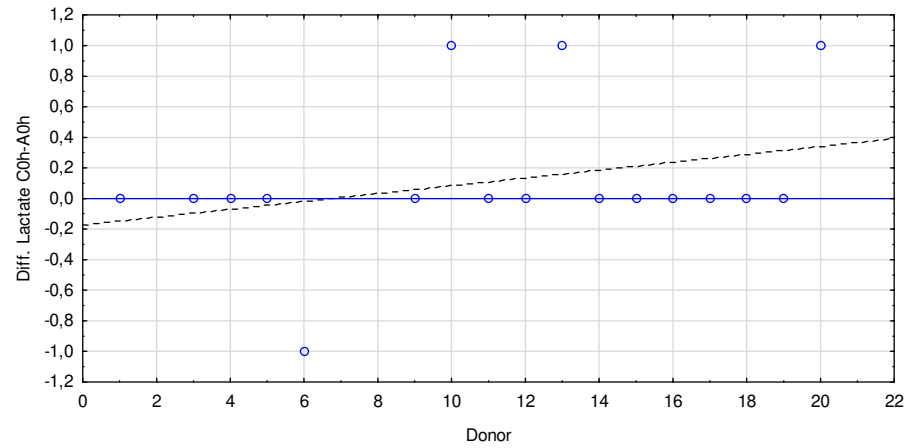
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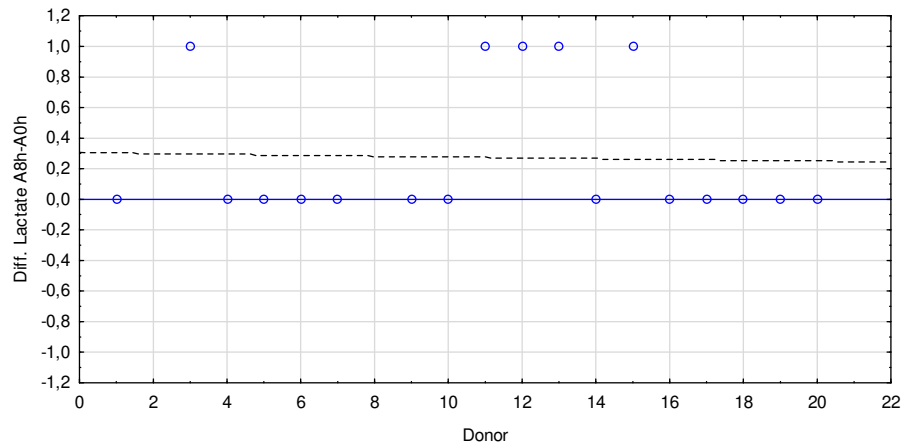
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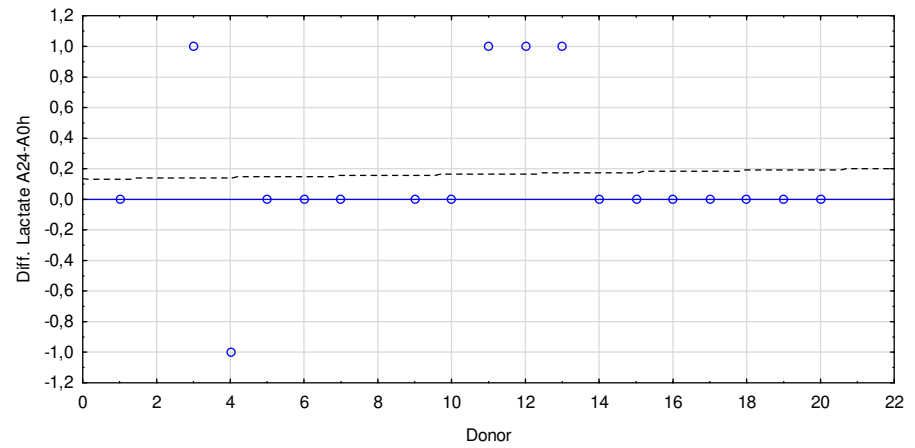
Difference Plot: Lactate [mg/dl] B0h/B8h
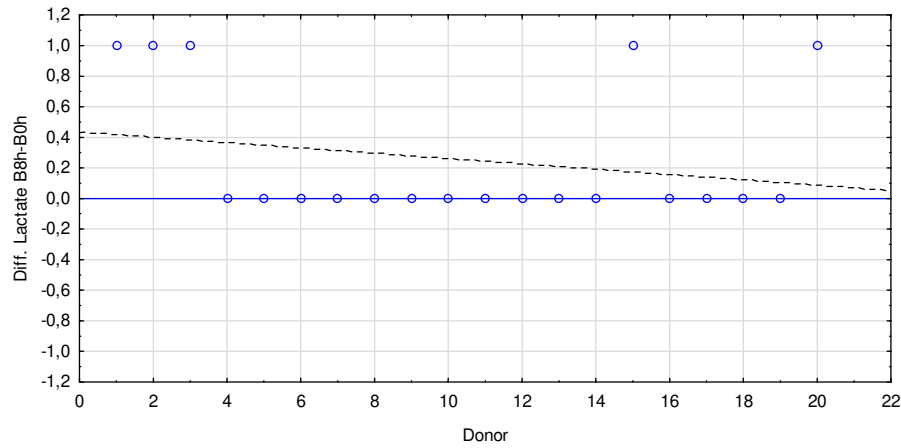
Difference Plot: Lactate [mg/dl] B0h/B24
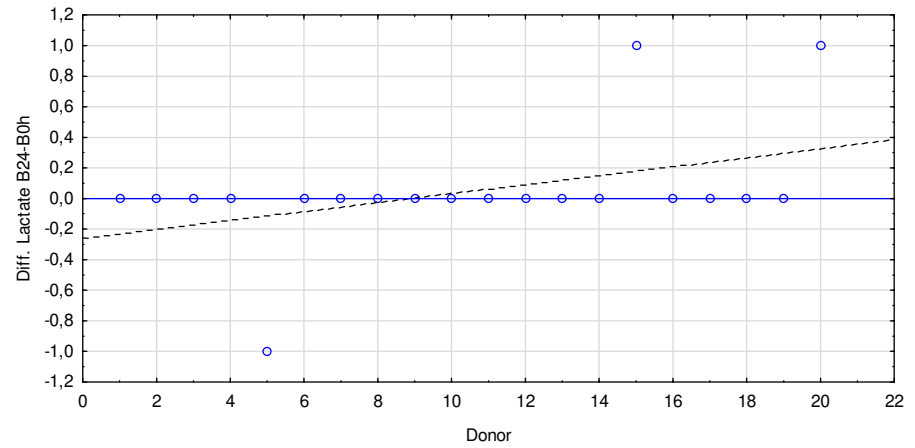
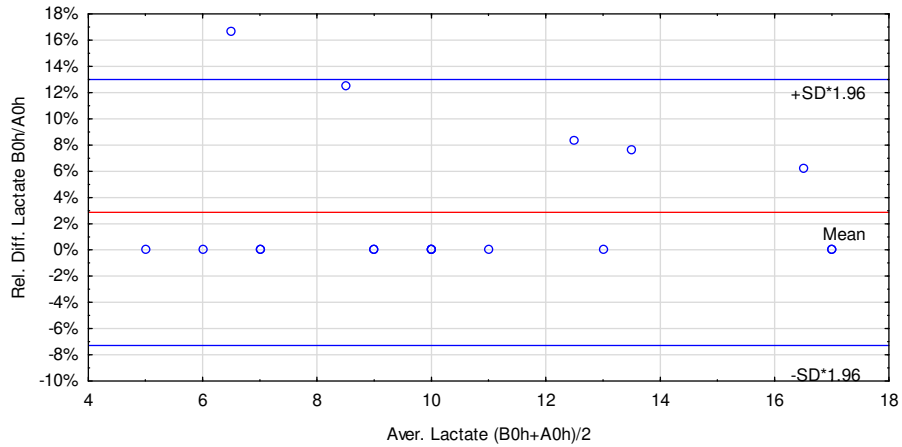## Difference Plot: Lactate [mg/dl] C0h/C8h
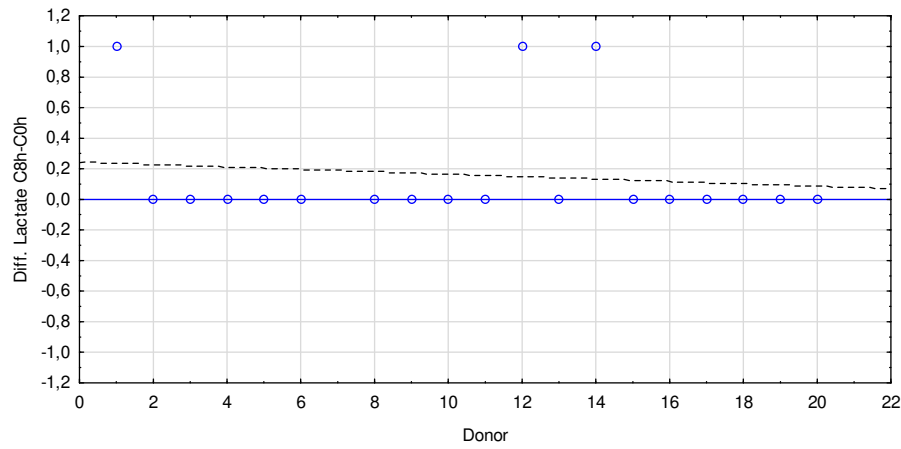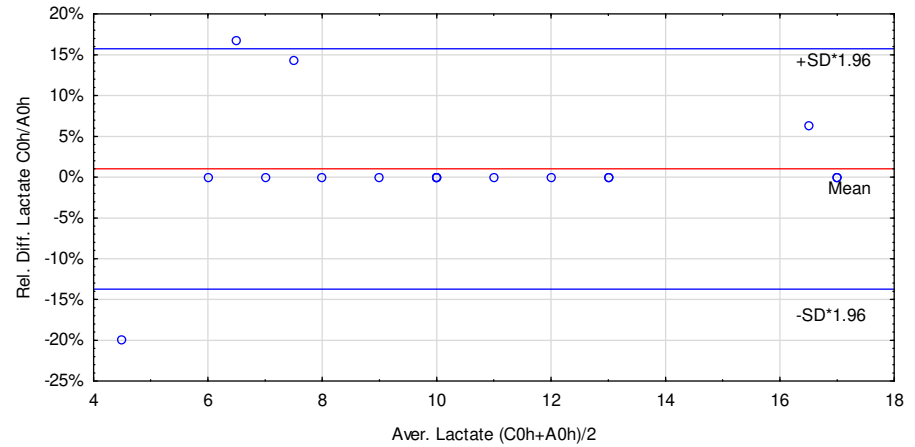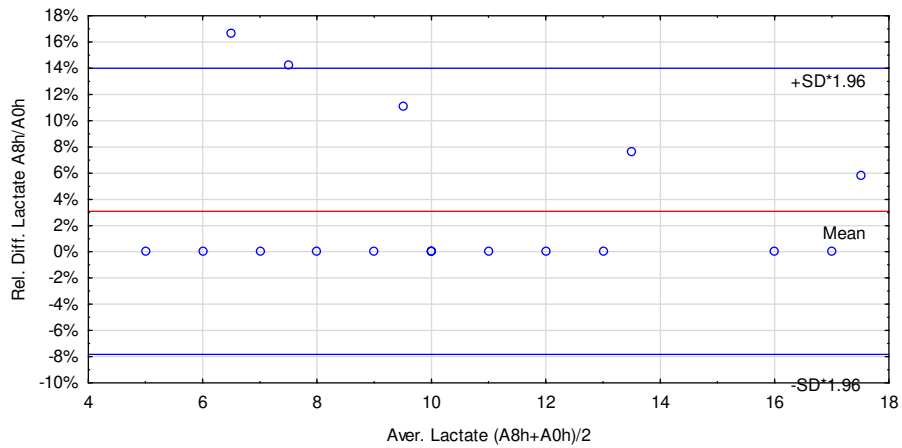

Difference Plot: Lactate [mg/dl] C0h/C24

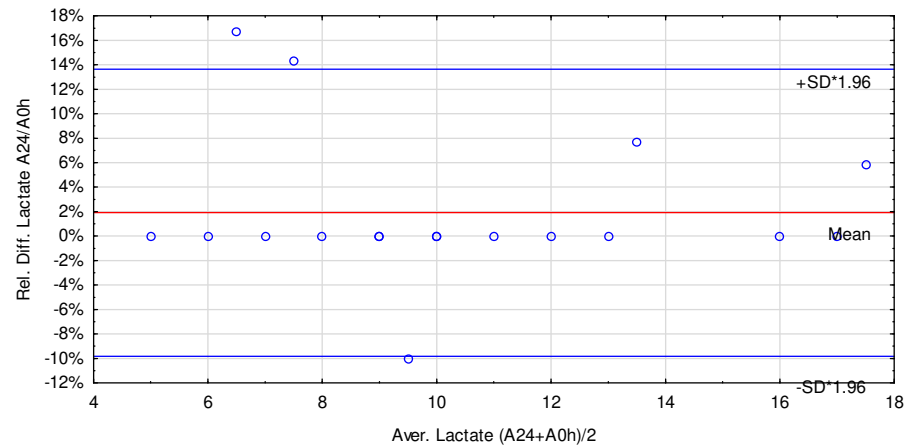Bland Altman: Lactate [mg/dl] A0h/B0h

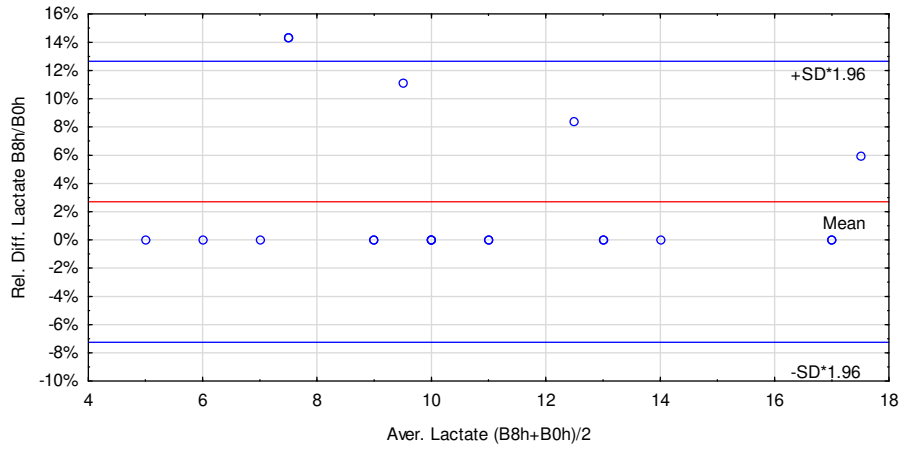Bland Altman: Lactate [mg/dl] A0h/C0h
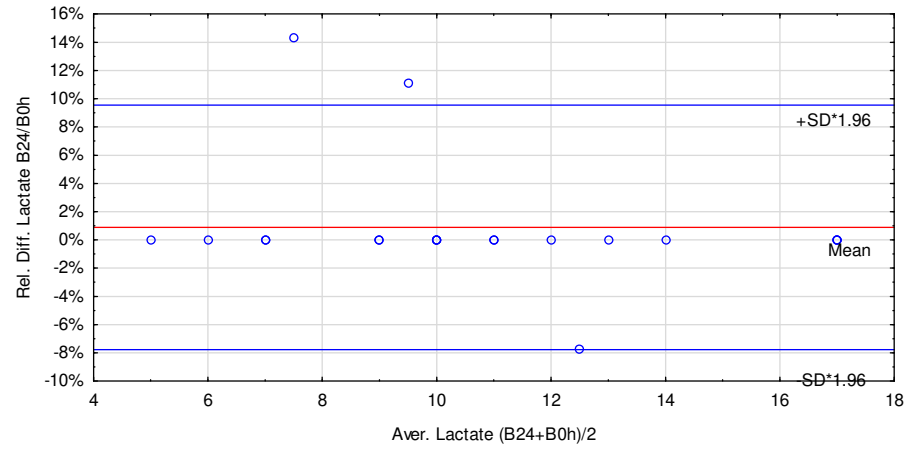
Bland Altman: Lactate [mg/dl] A0h/A8h

Bland Altman: Lactate [mg/dl] A0h/A24

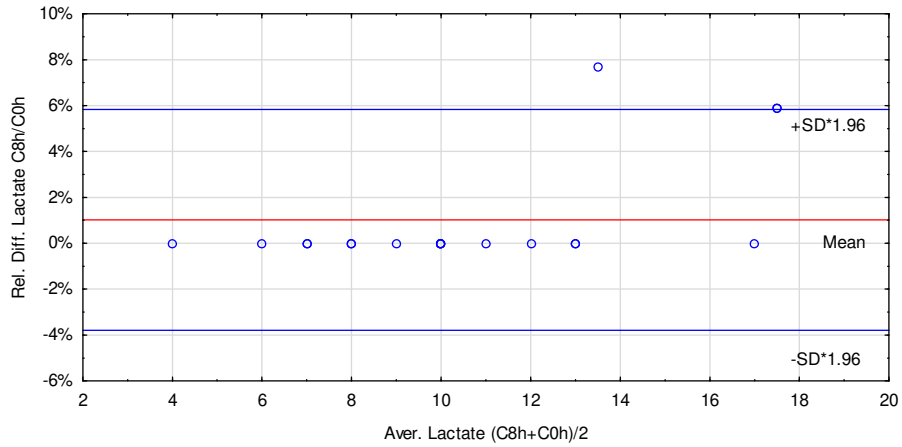## Bland Altman: Lactate [mg/dl] B0h/B8h

Bland Altman: Lactate [mg/dl] B0h/B24

Bland Altman: Lactate [mg/dl] C0h/C8h

Bland Altman: Lactate [mg/dl] C0h/C24