Evaluation Report

Eurolyser Lactate test kit (VT0220, VT0221)

on solo analysers

Location: Eurolyser Diagnostica GmbH
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Report created on 17th July 2017
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Specimens

The specimens for sample correlation were taken from a local university from horses and were fresh li-heparin blood samples which have been centrifuged within 15 minutes after taking the blood. Plasma was aliquoted and tested with the reference method (Lactate Gen.2 on a Cobas c501) and deep frozen right after testing with Cobas c501.

The plasma was kept a maximum of 8 days at -20 °C and after thawing tested with the solo and CUBE|vet analysers.

For all other tests the following controls have been used:

Control low:
Euronorm: 1.29 mmol/l
Lot: 811601

Control high:
Diacon-P: 3.52 mmol/l
Lot: 821601

Sample volume: 20 µl

Equipment

- Eurolyser CUBE|vet analyser: Cc14822 Cc14825 Cb12910
- Eurolyser solo analyser: Ae5050 Ae5052 Ae5053 Bd18113

- Test kits: VT0220, VT0221: LOT 20170707_1

- Reagent:
  R1_90: 1000 µl
  R2: no R2

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1. Introduction and Scope

Lactate production is a normal physiologic process which occurs in all animals. Lactate is a result of anaerobic metabolism and its presence does not indicate any particular disease. Elevated lactate levels can be used as an indicator of significant metabolic derangement usually caused by hypoxia or hypoperfusion.
Elevated lactate levels can be used as an indication for e.g. shock (hypovolemic, cardiogenic), local hypoperfusion (splanchnic ischaemia, aortic thromboembolism), hypoxaemia, severe anaemia, carbon monoxide intoxication, excessive muscular activity, sepsis, severe liver disease and diabetes mellitus. Further, lactate measurements can be carried out to determine the performance of racing animals.

1.1 Method comparison
Testing the correlation between the lactate measurement results in the Eurolyser analyser from plasma and the results of the Roche Lactate Gen.2 measured on a Cobas c501.
1.2 Reproducibility
Characterization of the reproducibility of the Eurolyser lactate test at 2 levels
1.3 Stability testing

Principle:
Colorimetric detection at 546 nm.

2. Comparison Study

Eurolyser vs Roche (Cobas c501)

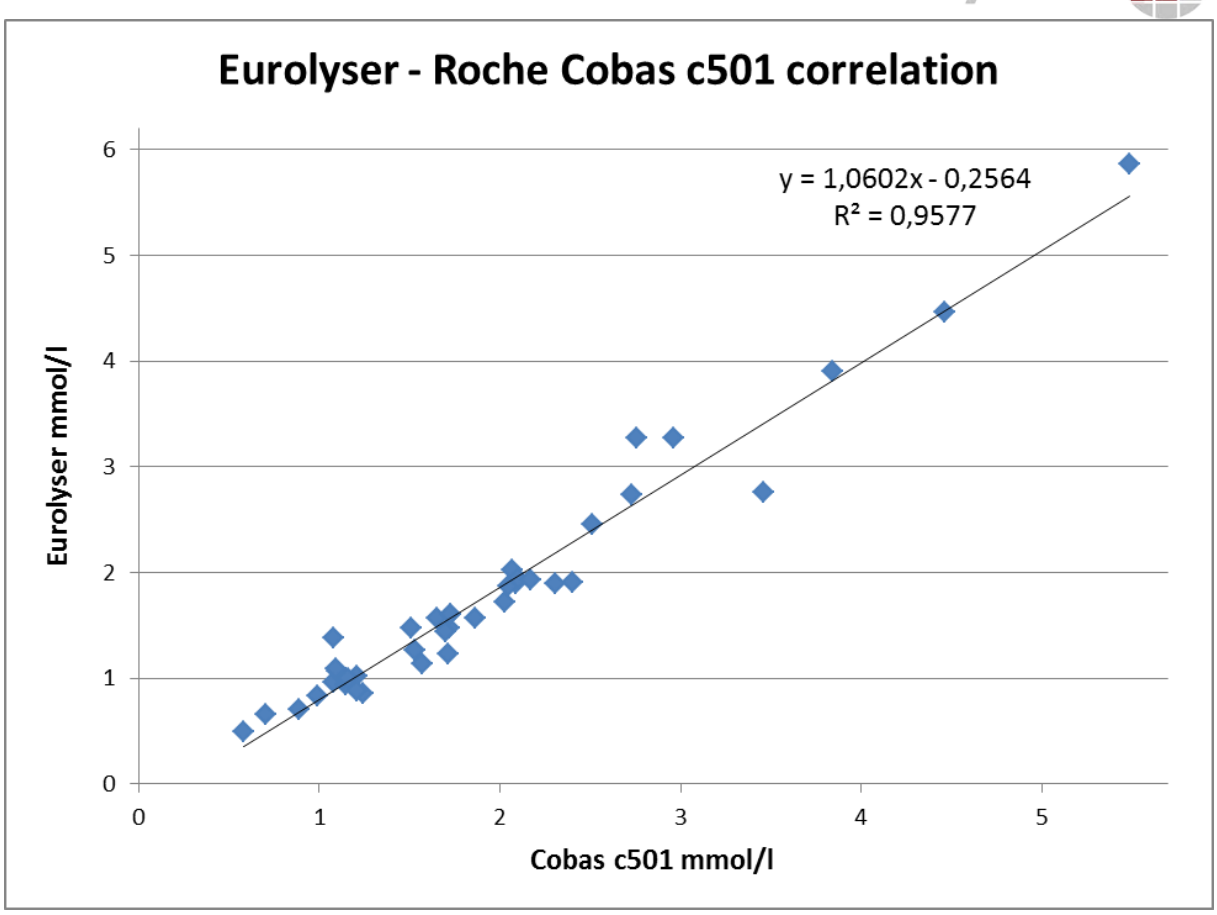
The comparison study is based on the correlation between the results of the Eurolyser Lactate assay and the Roche Lactate Gen.2 assay measured on a Cobas c501.

40 samples have been analysed on Solo and CUBE|vet analysers.

The acceptance criterion for this comparison study is a coefficient of determination **$R^2 > 0.90$** obtained from linear regression between the Eurolyser Lactate and the Roche Cobas lactate.

Accepted Slope k = 0.9 – 1.1

Sample N°	Eurolyser instrument	Roche Cobas 501c mmol/l	Eurolyser mmol/l
1	Cc14822	1,08 mmol/l	0,96 mmol/l
2	Cc14825	2,76 mmol/l	3,27 mmol/l
3	Cb12910	3,46 mmol/l	2,76 mmol/l
4	Ae5050	1,65 mmol/l	1,57 mmol/l
5	Ae5052	1,10 mmol/l	1,07 mmol/l
6	Ae5053	1,21 mmol/l	1,02 mmol/l
7	Bd18113	2,73 mmol/l	2,73 mmol/l
8	Cc14822	5,49 mmol/l	5,86 mmol/l
9	Cc14825	0,70 mmol/l	0,66 mmol/l
10	Cb12910	2,09 mmol/l	1,89 mmol/l
11	Ae5050	1,53 mmol/l	1,27 mmol/l
12	Ae5052	1,86 mmol/l	1,57 mmol/l
13	Ae5053	2,05 mmol/l	1,87 mmol/l
14	Bd18113	1,71 mmol/l	1,23 mmol/l
15	Cc14822	1,15 mmol/l	0,94 mmol/l
16	Cc14825	0,58 mmol/l	0,50 mmol/l
17	Cb12910	2,03 mmol/l	1,72 mmol/l
18	Ae5050	2,40 mmol/l	1,91 mmol/l
19	Ae5052	2,96 mmol/l	3,27 mmol/l
20	Ae5053	1,72 mmol/l	1,47 mmol/l
21	Bd18113	2,31 mmol/l	1,89 mmol/l
22	Cc14822	1,14 mmol/l	1,00 mmol/l
23	Cc14825	0,89 mmol/l	0,70 mmol/l
24	Cb12910	1,70 mmol/l	1,44 mmol/l
25	Ae5050	4,46 mmol/l	4,46 mmol/l
26	Ae5052	1,24 mmol/l	0,86 mmol/l
27	Ae5053	2,07 mmol/l	2,02 mmol/l
28	Bd18113	1,09 mmol/l	1,09 mmol/l
29	Cc14822	1,73 mmol/l	1,60 mmol/l
30	Cc14825	1,16 mmol/l	1,00 mmol/l
31	Cb12910	1,08 mmol/l	1,38 mmol/l
32	Ae5050	2,10 mmol/l	1,94 mmol/l
33	Ae5052	1,21 mmol/l	0,88 mmol/l
34	Ae5053	2,51 mmol/l	2,45 mmol/l
35	Bd18113	3,84 mmol/l	3,90 mmol/l
36	Cc14822	2,17 mmol/l	1,93 mmol/l
37	Cc14825	1,73 mmol/l	1,60 mmol/l
38	Cb12910	1,51 mmol/l	1,47 mmol/l
39	Ae5050	1,57 mmol/l	1,14 mmol/l
40	Ae5052	0,99 mmol/l	0,83 mmol/l



Sample correlation:
The result for the correlation between Roche and Eurolyser is the linear regression function:

y (Eurolyser) = 1.0602x (Cobas) - 0.2564 and a **R^2 = 0.9577**

3. Reproducibility (within-run precision)

Controls have been tested 20 times and the CV value was calculated (tested with solo and CUBE|vet analysers):

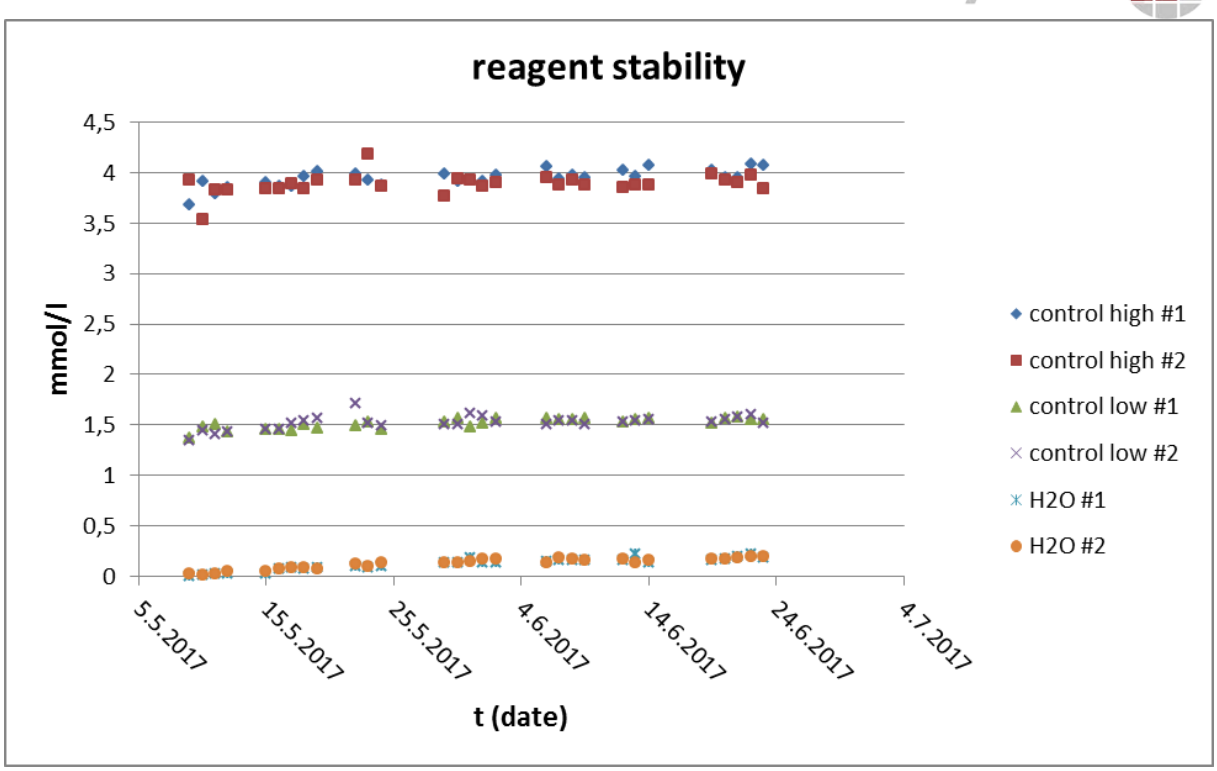
Sample #	instrument	Control low	Control high
1	Cc14822	1,50	3,88
2	Cc14825	1,48	3,82
3	Cb12910	1,51	3,89
4	Ae5050	1,54	3,85
5	Ae5052	1,51	3,98
6	Ae5053	1,46	3,86
7	Bd18113	1,47	3,77
8	Cc14822	1,47	3,76
9	Cc14825	1,48	3,88
10	Cb12910	1,51	3,88
11	Ae5050	1,48	3,85
12	Ae5052	1,40	3,83
13	Ae5053	1,46	3,82
14	Bd18113	1,48	3,82
15	Cc14822	1,45	3,85
16	Cc14825	1,54	4,05
17	Cb12910	1,49	3,92
18	Ae5050	1,51	3,88
19	Ae5052	1,51	3,83
20	Ae5053	1,52	3,91
Average		**1.49**	**3.87**
Stdev		**0.03**	**0,07**
CV		**2.10%**	**1.69%**

The CV values are 2.1% for the control low as well as 1.69% for the control high.

4. Stability Test

Reagent stability was recorded over 7 weeks, during this time cuvettes have been stored at room temperature.

Cuvettes prepared on: 08.05.2017
Measurement date: 09.05.2017 – 23.06.2017



	Control low	Control high
average	1.52	3.92
stdev	0.06	0.10
CV (%)	**3.98%**	**2.47%**

The reagent shows very good stability reflected in low CV values in case of storage at room temperature over 7 weeks.

5. Interferences in Plasma

no interference up to:

Ascorbic acid	30 mg/dl
Bilirubin	60 mg/dl
Triglyceride	2000 mg/dl
Haemoglobin	1000 mg/dl
Dopamine	10 mg/l
L-Dopamine	20 mg/l
Methyldopamine	10 mg/l
Glycolic acid	1200 mg/l

6. Summary

The Lactate test kit designed for solo and CUBE|vet analysers has a good correlation to the Lactate Gen.2 from Roche measured on a Cobas c501.
The reproducibility and stability of the test are very good.