Evaluation Report

Eurolyser K+ Potassium test kit (VT0280, VT0281)

on solo and CUBE-VET analysers

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Report created on 15th January 2018
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Specimens

The specimens for sample correlation were taken from a local university from dogs, cats and rabbits and were fresh li-heparin plasma or serum samples. Samples were aliquoted and tested with the reference method (Arkray Spotchem EL) and frozen right after testing.

For all other tests the following controls have been used:

Control:
Euronorm: 4.28 mmol/l
Lot: 811601

Sample volume: 20 µl

Equipment

- Eurolyser CUBE-VET: Cc14822 Cc14825 Cb12910
- Eurolyser solo analyser: Ae5050 Ae5052 Ae5053

- Test kits: VT0280, VT0281: LOT 1803-1, 1811-1

- Reagent:
  R1_90: 1000 µl
  R2: no R2

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1. Introduction and Scope

Potassium is the most important cation in the intracellular liquid. It represents a crucial buffer within the cell. Potassium facilitates nerve conduction as well as muscle function and maintains the osmotic pressure. Abnormal potassium levels influence the breathing muscle stimulation and heart muscle function.

Elevated potassium levels (hyperkalaemia) occur with kidney insufficiency, urinary tract obstruction, respiratory or metabolic acidosis and hypoadrenocorticism, as well as excessive haemolysis in cats, horses, cattle and several dog breeds.

Usually, reduced potassium levels (hypokalaemia) are the result of excessive salt loss caused by severe diarrhea or regurgitation.

Low potassium values on the other hand correlate with insufficient food intake (anorexia, especially in cats), malabsorption and severe burns.

1.1 Method comparison
Testing the correlation between the K+ potassium measurement results in the Eurolyser analyser from serum/plasma and the results of the Arkray Spotchem EL.
1.2 Reproducibility
Characterization of the reproducibility of the Eurolyser K+ potassium test.
1.3 Stability testing

Principle:
Immunoturbidimetric detection at 546 nm.

2. Comparison Study

Eurolyser vs Arkray Spotchem EL

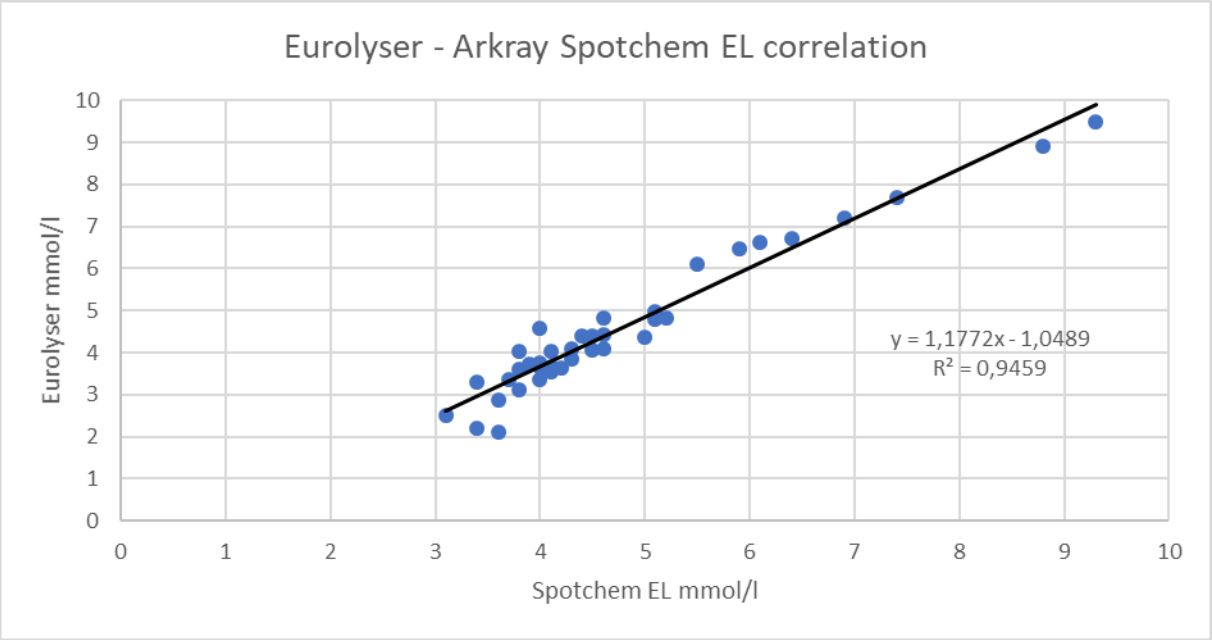
The comparison study is based on the correlation between the results of the Eurolyser K+ Potassium assay and the Arkray Spotchem EL.

38 samples (from various species) 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 K+ Potassium and Arkray Spotchem EL.

Accepted Slope k = 0.8 – 1.2

Sample N°	Sample species	Eurolyser instrument	Spotchem EL mmol/l	Eurolyser mmol/l
1	Cat	Ae5050	3.1	2.51
2	Dog	Ae5052	3.4	2.20
3	Cat	Ae5053	3.4	3.30
4	Cat	Cc14822	3.6	2.87
5	Cat	Cc14825	3.6	2.12
6	Dog	Cb12910	3.7	3.37
7	Cat	Ae5050	3.8	3.11
8	Cat	Ae5052	3.8	3.61
9	Cat	Ae5053	3.8	4.04
10	Cat	Cc14822	3.9	3.74
11	Cow	Cc14825	4.0	4.58
12	Dog	Cb12910	4.0	3.35
13	Cat	Ae5050	4.0	3.76
14	Cat	Ae5052	4.0	3.66
15	Dog	Ae5053	4.1	3.67
16	Cat	Cc14822	4.1	3.55
17	Cat	Cc14825	4.1	4.02
18	Cat	Cb12910	4.2	3.63
19	Cat	Ae5050	4.3	4.09
20	Dog	Ae5052	4.3	3.84
21	Cat	Ae5053	4.4	4.40
22	Dog	Cc14822	4.5	4.39
23	Dog	Cc14825	4.5	4.06
24	Dog	Cb12910	4.6	4.81
25	Cat	Ae5050	4.6	4.43
26	Dog	Ae5052	4.6	4.08
27	Dog	Ae5053	5.5	6.11
28	Cat	Cc14822	5.0	4.37
29	Dog	Cc14825	5.1	4.97
30	Dog	Cb12910	5.1	4.78
31	Dog	Ae5050	5.2	4.81
32	Dog	Ae5052	6.1	6.62
33	Cat	Ae5053	5.9	6.48
34	Dog	Cc14822	9.3	9.50
35	Rabbit	Cc14825	7.4	7.70
36	Rabbit	Cb12910	6.4	6.70
37	Rabbit	Ae5050	6.9	7.20
38	Dog	Ae5052	8.8	8.90



Sample correlation:
The result for the correlation between Arkray Spotchem EL and Eurolyser is the linear regression function:

y (Eurolyser) = 1.1772x (Spotchem EL) - 1.0489 and a **R^2 = 0.9459**

the following reference ranges are applicable:

Dog:	3.5 – 5.1 mmol/l
Cat:	3.0 – 4.8 mmol/l
Rabbit:	3.7 – 6.3 mmol/l
Guinea pig:	4.5 – 8.8 mmol/l
Cattle:	3.5 – 4.5 mmol/l
Horse:	2.8 – 4.5 mmol/l
Pig:	4.0 – 5.0 mmol/l

3. Reproducibility (within-run precision)

Two controls have been tested 20 times and the CV value was calculated (tested with solo and CUBE-VET analysers):

Sample #	Instrument	Control 1 mmol/l	Control 2 mmol/l
1	Ae5050	4.92	8.22
2	Ae5052	4.61	7.35
3	Ae5053	4.80	7.36
4	Cc14822	5.04	7.37
5	Cc14825	4.62	7.76
6	Cb12910	4.97	8.08
7	Ae5050	4.83	7.67
8	Ae5052	4.92	7.30
9	Ae5053	4.59	7.90
10	Cc14822	4.95	7.44
11	Cc14825	4.74	7.65
12	Cb12910	5.01	7.82
13	Ae5050	4.84	8.25
14	Ae5052	4.92	8.16
15	Ae5053	5.14	7.70
16	Cc14822	4.98	7.58
17	Cc14825	5.02	8.12
18	Cb12910	4.85	8.21
19	Ae5050	4.97	7.56
20	Ae5052	4.75	7.52
mean		**4.87**	**7.75**
Stdev		**0.15**	**0.33**
CV		**3.11%**	**4.20%**

The CV values are 3.11% and 4.20% for the 2 control levels.

4. Stability Test

Reagent stability was tested via real time stability test, more than 9 months after initial testing (day 1).

Initial test: 09.04.2018
Stability after 9 months: 15.01.2019

Recovery:

Day	mmol/l	% recovery
1	4.28	100%
282	4.42	103%

The real time stability test suggests that a 12 month test kit stability can be confirmed.

5. Limit of Quantitation (LOQ)

LOQ is determined as the lowest sample run that displays a CV value < 20%.

	Control dilution 1	Control dilution 2
Mean	1.68 mmol/l	0.42 mmol/l
CV	6.32%	21.94%

Based on these results the LOQ is set to 0.6 mmol/l.

6. Interferences in Plasma

Haemolytic and lipaemic samples results in false high K+ values and must therefore not be used.

7. Summary

The Eurolyser K+ Potassium test kit designed for solo and CUBE-VET analysers has a good correlation to the Arkray Spotchem EL.
The reproducibility and stability of the test are very good.