

Evaluation Report

Eurolyser HGB test kit (VT0150) on solo analysers

Location: Eurolyser Diagnostica GmbH
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Specimens

The specimens for sample correlation were taken from a local university from dogs, cats and horses and were fresh EDTA blood samples. Samples were tested with the reference method (Sysmex XT 2000 IV) and on Solo analysers.

For all other tests the following controls have been used:

Control material:
Dog EDTA whole blood samples

Control low: 8.8 g/dl
Control high: 13.9 g/dl

Sample volume: 20 µl

Equipment

- Eurolyser solo analyser: Ae3629
 - Test kits: VT0150: LOT 1010-1
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1. Introduction and Scope

In routine medical diagnostics, the test may be used for the following purposes: To diagnose anaemia or polyglobulia, to monitor risk groups for iron deficiency, as part of point-of-care testing when acute bleedings or haemorrhages are suspected, at parasitic diseases as well as for quantifying blood loss.

- 1.1 Method comparison
Testing the correlation between the HBG measurement results in the Eurolyser analyser from whole blood and the results of the Sysmex XT 2000 IV.
- 1.2 Reproducibility
Characterization of the reproducibility of the Eurolyser HGB test at 2 levels
- 1.3 Linearity testing

Principle:

Colorimetric test. Photometric measurement of the absorbance at 546 nm wavelength.

2. Comparison Study

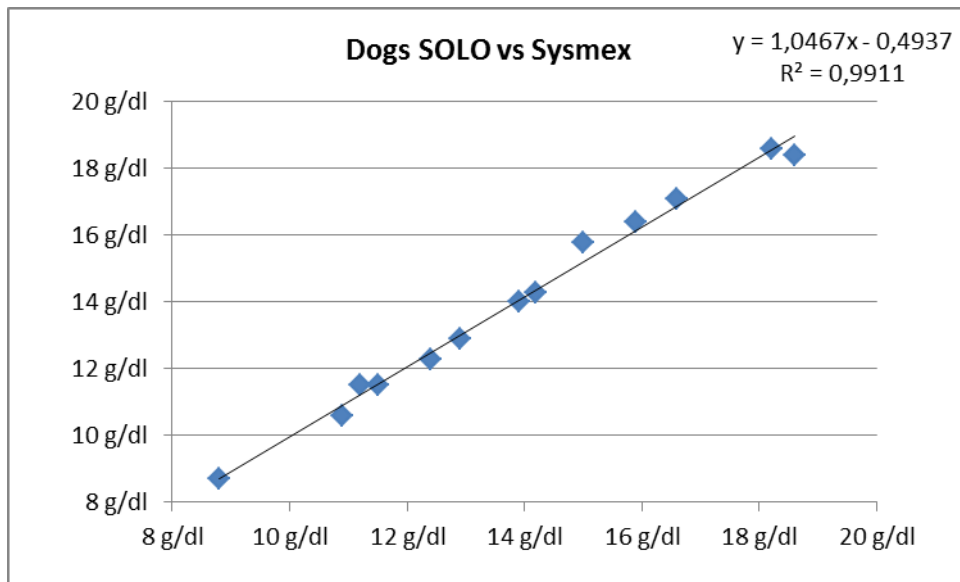
Eurolyser vs Sysmex XT 2000 IV

The comparison study is based on the correlation between the results of the Eurolyser HBG assay and the Sysmex XT 2000 IV.

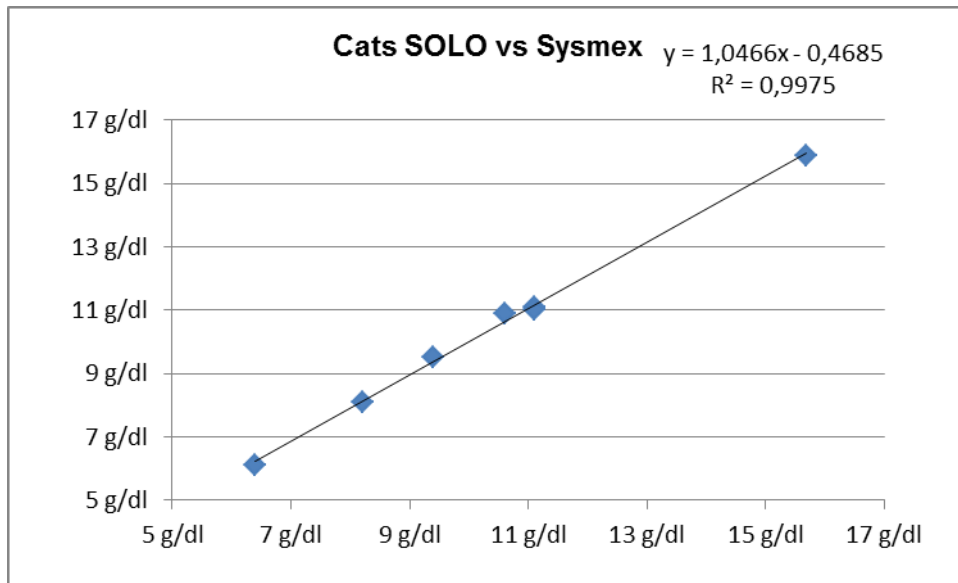
26 samples have been analysed on Solo analysers (13 dogs, 7 cats and 6 horses).

The acceptance criterion for this comparison study is a coefficient of determination $R^2 > 0.90$ obtained from linear regression between the Eurolyser HBG and the Sysmex XT 2000 IV HGB.

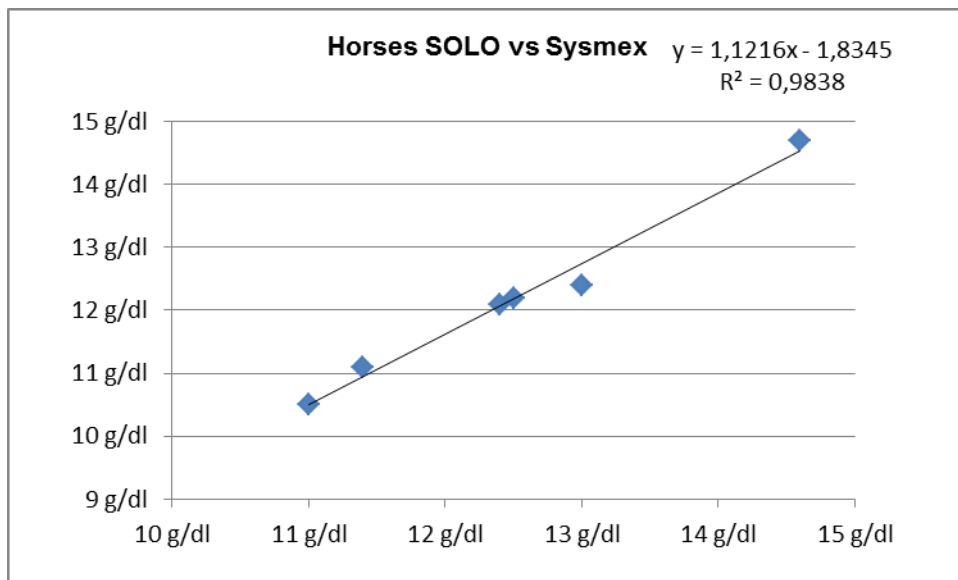
Sample N° (dogs)	Eurolyser instrument	Sysmex XT 2000 IV g/dl	Eurolyser g/dl
1	Ae3629	18,2	18,6
2	Ae3629	11,5	11,5
3	Ae3629	10,9	10,6
4	Ae3629	12,4	12,3
5	Ae3629	16,6	17,1
6	Ae3629	14,2	14,3
7	Ae3629	8,8	8,7
8	Ae3629	15,9	16,4
9	Ae3629	13,9	14,0
10	Ae3629	11,2	11,5
11	Ae3629	18,6	18,4
12	Ae3629	12,9	12,9
13	Ae3629	15,0	15,8



Sample N° (cats)	Eurolyser instrument	Sysmex XT 2000 IV g/dl	Eurolyser g/dl
14	Ae3629	6,4	6,1
15	Ae3629	11,1	11,1
16	Ae3629	15,7	15,9
17	Ae3629	8,2	8,1
18	Ae3629	10,6	10,9
19	Ae3629	11,1	11,0
20	Ae3629	9,4	9,5



Sample N° (horses)	Eurolyser instrument	Sysmex XT 2000 IV g/dl	Eurolyser g/dl
21	Ae3629	11,0	10,5
22	Ae3629	13,0	12,4
23	Ae3629	14,6	14,7
24	Ae3629	12,5	12,2
25	Ae3629	11,4	11,1
26	Ae3629	12,4	12,1



Sample correlation:

The result for the correlation between Sysmex and Eurolyser are the linear regression functions:

Dogs:

y (Eurolyser) = 1.0467x (Sysmex) - 0.4937 and a $R^2 = 0.9911$

Cats:

y (Eurolyser) = 1.0466x (Sysmex) - 0.4685 and a $R^2 = 0.9975$

Horses:

y (Eurolyser) = 1.1216x (Sysmex) - 1.8345 and a $R^2 = 0.9838$

3. Reproducibility (within-run precision)

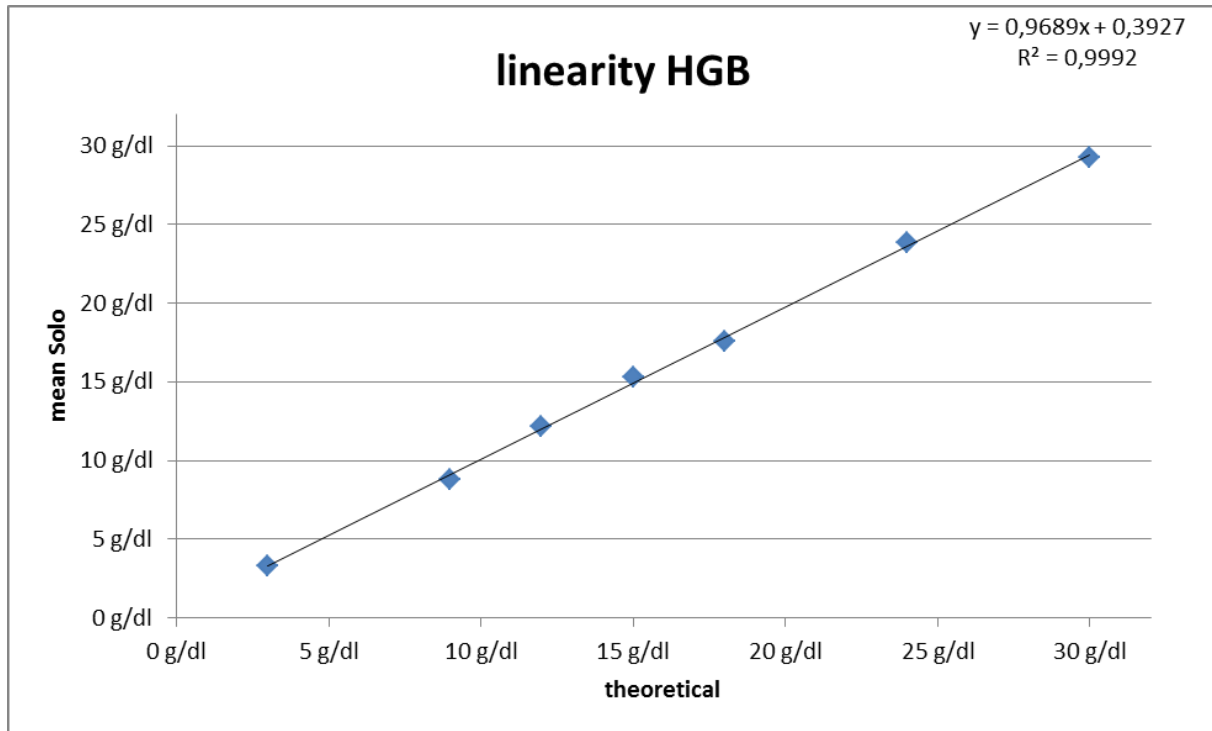
Controls have been tested 20 times and the CV value was calculated (tested with solo analysers):

Sample #	instrument	8.8 g/dl dog	13.9 g/dl dog
1	Ae3629	8,3	13,8
2	Ae3629	8,0	14,4
3	Ae3629	8,2	14,1
4	Ae3629	8,1	14,2
5	Ae3629	7,9	14,3
6	Ae3629	8,3	13,8
7	Ae3629	7,9	13,7
8	Ae3629	8,0	14,1
9	Ae3629	8,1	14,3
10	Ae3629	8,3	14,2
11	Ae3629	8,2	13,7
12	Ae3629	8,3	13,9
13	Ae3629	8,4	14,2
14	Ae3629	8,3	14,4
15	Ae3629	8,4	13,8
16	Ae3629	8,8	13,5
17	Ae3629	8,9	13,5
18	Ae3629	8,8	14,6
19	Ae3629	8,7	14,8
20	Ae3629	8,9	14,1
Average		8,34	14,06
Stdev		0,32	0,3486
CV		3.86%	2.48%

The CV values are 3.86% for the control low as well as 2.48% for the control high.

4. Linearity Test

Pooled EDTA whole blood	Ae3629	Ae3629	Ae3629	
Theoretical	meas 1	meas 2	meas 3	mean
30 g/dl	30,3	28,8	28,8	29,3 g/dl
24 g/dl	23,5	23,6	24,4	23,8 g/dl
18 g/dl	17,8	16,9	18,1	17,6 g/dl
15 g/dl	15,1	15,3	15,5	15,3 g/dl
12 g/dl	11,8	12,5	12,2	12,2 g/dl
9 g/dl	8,8	8,9	8,7	8,8 g/dl
3 g/dl	3,2	3,4	3,3	3,3 g/dl



The test kit shows very good linearity.

5. Summary

The HGB test kit designed for solo analysers has a good correlation to the HGB test from Sysmex measured on a Sysmex XT 2000 IV.

The reproducibility and linearity of the test are very good.