

Evaluation Report

Eurolyser Haemoglobin Test Kit (ST0190) on the Smart Analyser

Location

Location: Eurolyser Diagnostica GmbH
Operators: Michael Gruber
Date: 01.08.2009

Specimens

Samples taken from the daily routine of 5 days (02/07/2009 to 07/07/2009), from the routine lab of a doctor's office for internal medicine and paediatrics in Hallein/Austria.

Equipment

- Eurolyser SMART 546 Analyser: Ab 0833

- Test kit Haemoglobin ST0190 LOT 8132



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1. Scope and goals of the evaluation

1.1 Method comparison

Testing the correlation between the HGB measurement results in the SMART 546 analyser from EDTA whole blood and the results of the Nihon Kohden Celltac E analyser in the laboratory of Eurolab Medizintechnik GmbH Austria.

1.2 Imprecision

Characterisation of the precision of the SMART HGB test at 2 levels

1.3 Day/Day variation - Stability testing

2. Quality Control

To check the correctness, the QC kit provided by Medisynthana/Germany LOT HD08132 was used.

3. Test processing with the SMART system:

The reagent kit contains all the materials required to carry out the tests.

Pipette 20µl sample with SMART pipette into SMART cuvette

Apply ERS cap and place cuvette into analyser - Start measurement

4. Method comparison:

The method comparison was carried out with 40 samples from the pool of the 2 doctor's offices in the range of 10-21 g/dl. For values on the upper linearity range, 5 EDTA samples have been centrifuged and the plasma was taken partially out to higher the HGB content.

The R^2 value of the linear regression was determined, as well as the k and d value, according to the formula $y=kx+d$ (y =SMART HGB and x = CELLTAC E) Measurements have been performed at the Eurolab laboratories in Hallein/ Austria directly by Ing. Ricky Hirscher

Sample Seq	HGB Celltac E HBCN Methode	HGB SMART	Sample material
1	10.9 g/dl	11.3 g/dl	EDTA
2	11.4 g/dl	10.5 g/dl	EDTA
3	13.3 g/dl	13.6 g/dl	EDTA
4	9.9 g/dl	9.2 g/dl	EDTA
5	14.7 g/dl	15.0 g/dl	EDTA
6	15.3 g/dl	15.0 g/dl	EDTA
7	11.9 g/dl	11.6 g/dl	EDTA
8	19.1 g/dl	19.3 g/dl	EDTA
9	19.2 g/dl	18.9 g/dl	EDTA
10	18.2 g/dl	18.0 g/dl	EDTA
11	14.3 g/dl	14.6 g/dl	EDTA
12	11.2 g/dl	10.9 g/dl	EDTA
13	12.9 g/dl	13.2 g/dl	EDTA
14	14.5 g/dl	14.8 g/dl	EDTA
15	15.3 g/dl	15.0 g/dl	EDTA
16	16.2 g/dl	16.0 g/dl	EDTA
17	17.0 g/dl	17.4 g/dl	EDTA
18	9.9 g/dl	9.3 g/dl	EDTA
19	9.8 g/dl	8.8 g/dl	EDTA
20	11.3 g/dl	10.8 g/dl	EDTA
21	12.2 g/dl	11.8 g/dl	EDTA
22	14.1 g/dl	13.8 g/dl	EDTA
23	16.0 g/dl	15.3 g/dl	EDTA
24	18.1 g/dl	17.6 g/dl	EDTA
25	13.2 g/dl	12.7 g/dl	EDTA
26	11.1 g/dl	10.8 g/dl	EDTA
27	11.8 g/dl	11.2 g/dl	EDTA
28	19.2 g/dl	18.4 g/dl	EDTA
29	15.3 g/dl	16.0 g/dl	EDTA
30	18.2 g/dl	18.5 g/dl	EDTA
31	14.0 g/dl	14.4 g/dl	EDTA
32	15.0 g/dl	14.5 g/dl	EDTA
33	15.1 g/dl	14.5 g/dl	EDTA
34	16.3 g/dl	16.0 g/dl	EDTA
35	14.4 g/dl	13.9 g/dl	EDTA
36	19.0 g/dl	18.3 g/dl	plasma removed
37	21.0 g/dl	20.1 g/dl	plasma removed
38	29.9 g/dl	26.3 g/dl	plasma removed
39	28.1 g/dl	26.3 g/dl	plasma removed
40	31.1 g/dl	27.0 g/dl	plasma removed

Table 1: HGB values for fresh EDTA whole blood from SMART, compared with CELLTAC

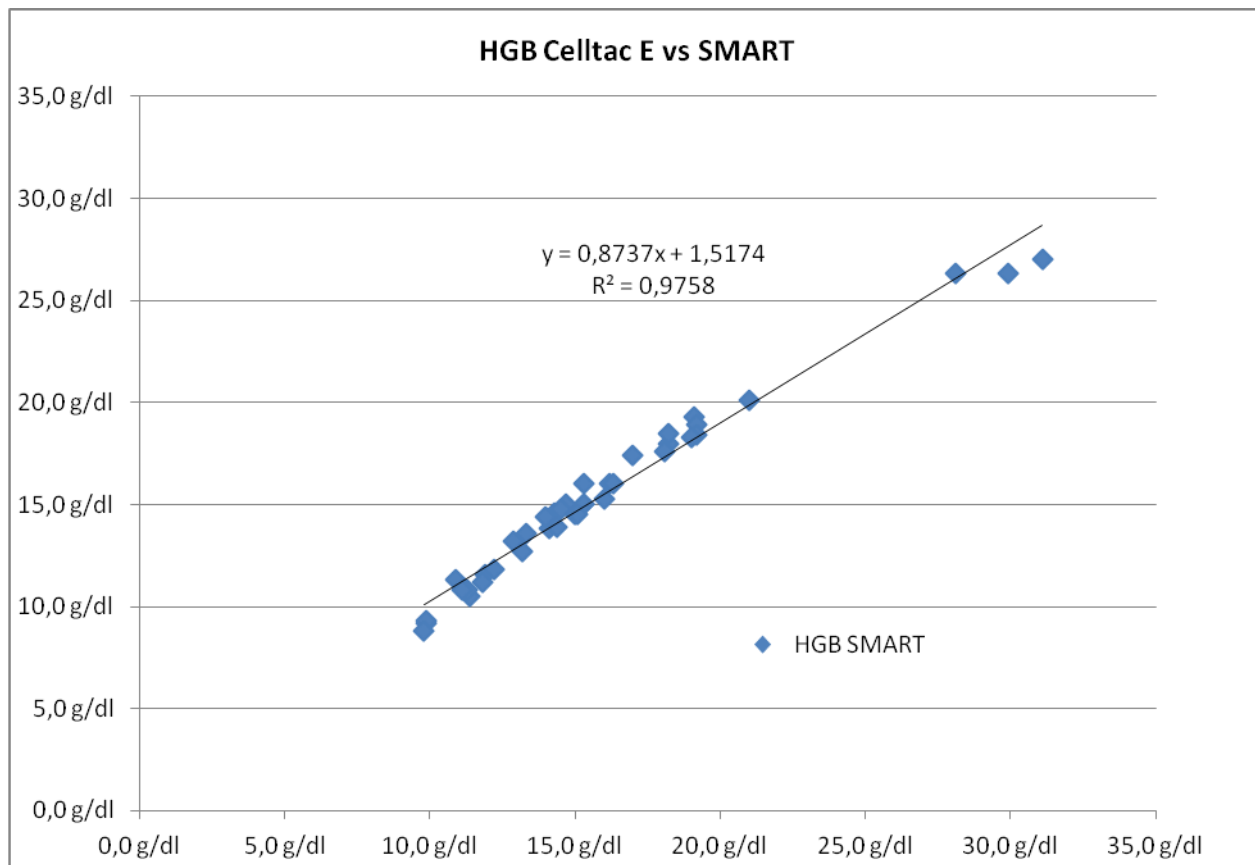
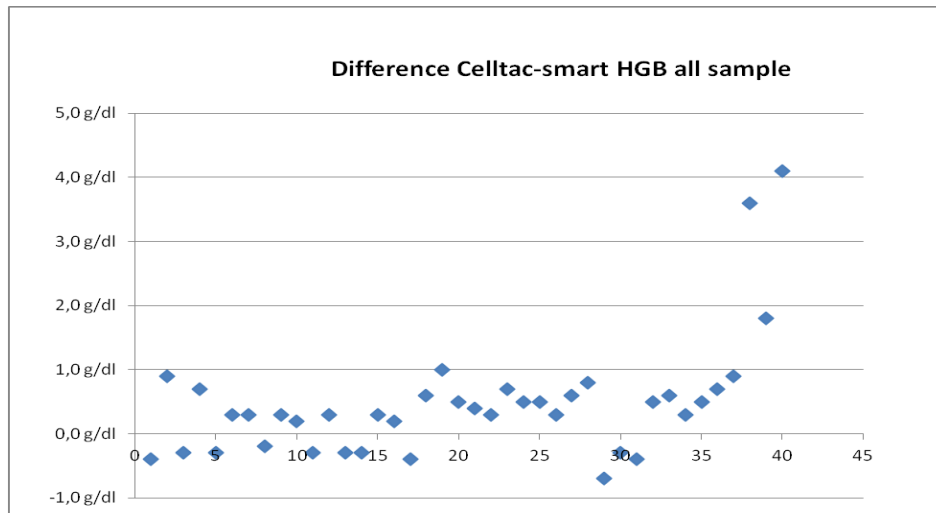


Chart 1: Correlation between SMART HGB (y) and Celltac (x)
 $R^2=0.9758$ $Y=kx+d=0.8737x+0.9758$

Sample Seq	HGB Celltac E HBCN method	HGB SMART	Difference
1	10.9 g/dl	11.3 g/dl	-0.4 g/dl
2	11.4 g/dl	10.5 g/dl	0.9 g/dl
3	13.3 g/dl	13.6 g/dl	-0.3 g/dl
4	9.9 g/dl	9.2 g/dl	0.7 g/dl
5	14.7 g/dl	15.0 g/dl	-0.3 g/dl
6	15.3 g/dl	15.0 g/dl	0.3 g/dl
7	11.9 g/dl	11.6 g/dl	0.3 g/dl
8	19.1 g/dl	19.3 g/dl	-0.2 g/dl
9	19.2 g/dl	18.9 g/dl	0.3 g/dl
10	18.2 g/dl	18.0 g/dl	0.2 g/dl
11	14.3 g/dl	14.6 g/dl	-0.3 g/dl
12	11.2 g/dl	10.9 g/dl	0.3 g/dl
13	12.9 g/dl	13.2 g/dl	-0.3 g/dl
14	14.5 g/dl	14.8 g/dl	-0.3 g/dl
15	15.3 g/dl	15.0 g/dl	0.3 g/dl
16	16.2 g/dl	16.0 g/dl	0.2 g/dl
17	17.0 g/dl	17.4 g/dl	-0.4 g/dl
18	9.9 g/dl	9.3 g/dl	0.6 g/dl
19	9.8 g/dl	8.8 g/dl	1.0 g/dl
20	11.3 g/dl	10.8 g/dl	0.5 g/dl
21	12.2 g/dl	11.8 g/dl	0.4 g/dl
22	14.1 g/dl	13.8 g/dl	0.3 g/dl
23	16.0 g/dl	15.3 g/dl	0.7 g/dl
24	18.1 g/dl	17.6 g/dl	0.5 g/dl
25	13.2 g/dl	12.7 g/dl	0.5 g/dl
26	11.1 g/dl	10.8 g/dl	0.3 g/dl
27	11.8 g/dl	11.2 g/dl	0.6 g/dl
28	19.2 g/dl	18.4 g/dl	0.8 g/dl
29	15.3 g/dl	16.0 g/dl	-0.7 g/dl
30	18.2 g/dl	18.5 g/dl	-0.3 g/dl
31	14.0 g/dl	14.4 g/dl	-0.4 g/dl
32	15.0 g/dl	14.5 g/dl	0.5 g/dl
33	15.1 g/dl	14.5 g/dl	0.6 g/dl
34	16.3 g/dl	16.0 g/dl	0.3 g/dl
35	14.4 g/dl	13.9 g/dl	0.5 g/dl
36	19.0 g/dl	18.3 g/dl	0.7 g/dl
37	21.0 g/dl	20.1 g/dl	0.9 g/dl
38	29.9 g/dl	26.3 g/dl	3.6 g/dl
39	28.1 g/dl	26.3 g/dl	1.8 g/dl
40	31.1 g/dl	27.0 g/dl	4.1 g/dl

Difference Table



Difference plot for all samples

5. Imprecision:

The imprecision of the SMART HGB was determined with 2 different levels of a commercial HGB control (Medisynthana Germany), each sample was tested 20 times.

No	15g/dl	6g/dl
1	14.5 g/dl	6.2 g/dl
2	15.0 g/dl	6.0 g/dl
3	15.2 g/dl	5.8 g/dl
4	15.4 g/dl	6.3 g/dl
5	15.3 g/dl	6.2 g/dl
6	15.5 g/dl	6.0 g/dl
7	15.3 g/dl	5.7 g/dl
8	15.8 g/dl	6.4 g/dl
9	15.1 g/dl	5.7 g/dl
10	15.3 g/dl	6.1 g/dl
11	15.5 g/dl	6.3 g/dl
12	15.3 g/dl	6.1 g/dl
13	15.8 g/dl	6.0 g/dl
14	15.1 g/dl	5.9 g/dl
15	15.0 g/dl	6.1 g/dl
16	15.8 g/dl	6.2 g/dl
17	14.6 g/dl	5.9 g/dl
18	15.3 g/dl	5.7 g/dl
19	15.4 g/dl	6.2 g/dl
20	15.7 g/dl	6.1 g/dl
mean	15.3 g/dl	6.0 g/dl
stabw	0.35	0.20
cv	2.27%	3.36%

6. Day-to-day variance with Medisynthana control level 2

Stability test		day 0	day2	day5	day7	day14	day21
01/07/2009	HGB	result	result	result	result	result	result
Medisynthana level 2	15.0	15.3	15.7	14,6	15.0	15.1	15.0

7. Summary:

The HGB test kit used in the SMART analyser has a good correlation to the haematology analyser Celltac-Nihon Kohden.

The precision is good for a point-of-care system.

External QC material values have been confirmed closed to target values for low and high controls.

The method used in the SMART system is also mentioned in a *** WHO study and is known as an excellent HGB method:

*** *International collaborative assessment study of the AHD575 method for the measurement of blood haemoglobin N.M.M Moharram, Aouad, Busaidy, Fabricius, Heller, Wood Wolf, Heuck*

Salzburg 01/08/2009

