

Evaluation Report

Eurolyser Ferritin Test Kit (ST0170) on the Smart Analyser

Location

Location: Eurolyser Diagnostica GmbH
Operators: Michael Gruber
Date: 21.09.2009

Specimens

Samples taken from the daily routine of 4 days (07/09/2009 to 10/09/2009) from hospital samples.

Equipment

- Eurolyser SMART Analyser:	Ab 1035	Ab 1033	Ab 0853
- Test kit Ferritin	ST0170	LOT 6010	



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1. Scope and goals of the evaluation

1.1 Method comparison

Testing the correlation between the Ferritin measurement results in the SMART 700/340 analyser from serum samples and the results of the Ferritin method of the clinical chemistry bench top analyser CCA180 in combination with the Dialab Ferritin assay.

1.2 Imprecision

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

2. Reference Analyser

CCA180 bench top analyser manufactured by Akatech GmbH-Austria

Dialab Ferritin test kit LOT ferd006

QC materials

To check the correctness, the ferritin QC kit provided by Dialab Austria was used.

3. Test processing with the SMART system:

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

Allow cuvettes at least 10 minutes to warm up to room temperature

Pipette sample with SMART pipette (50 µl) into SMART cuvette

Apply ERS cap and place cuvette into analyser - Start measurement

4. Method comparison:

The method comparison was carried out with 23 samples from the pool of the hospital "Barmherzige Brüder" in the range of 28 ng/ml and 630 ng/ml ferritin.

The R² value of the linear regression was determined, as well as the k and d value, according to the formula $y=kx+d$ (y=SMART HCY and x= HPLC) Measurements have been performed at the site of Eurolyser Diagnostica GmbH, Bayernstrasse 11a.

The chart and raw data are in the appendix.

Sample	CCA180 Dialab Ferritin Assay	SMART 700/340 Ferritin Assay
1	28 ng/ml	38 ng/ml
2	30 ng/ml	48 ng/ml
3	50 ng/ml	69 ng/ml
4	100 ng/ml	98 ng/ml
5	105 ng/ml	120 ng/ml
6	110 ng/ml	125 ng/ml
7	115 ng/ml	130 ng/ml
8	120 ng/ml	120 ng/ml
9	133 ng/ml	132 ng/ml
10	141 ng/ml	138 ng/ml
11	145 ng/ml	155 ng/ml
12	160 ng/ml	166 ng/ml
13	250 ng/ml	220 ng/ml
14	270 ng/ml	250 ng/ml
15	330 ng/ml	350 ng/ml
16	360 ng/ml	320 ng/ml
17	400 ng/ml	390 ng/ml
18	410 ng/ml	395 ng/ml
19	550 ng/ml	555 ng/ml
20	560 ng/ml	600 ng/ml
21	600 ng/ml	675 ng/ml
22	620 ng/ml	680 ng/ml
23	630 ng/ml	699 ng/ml

Table 1: Ferritin values for fresh serum from SMART, compared with Dialab ferritin Assay on CCA180 bench top analyser

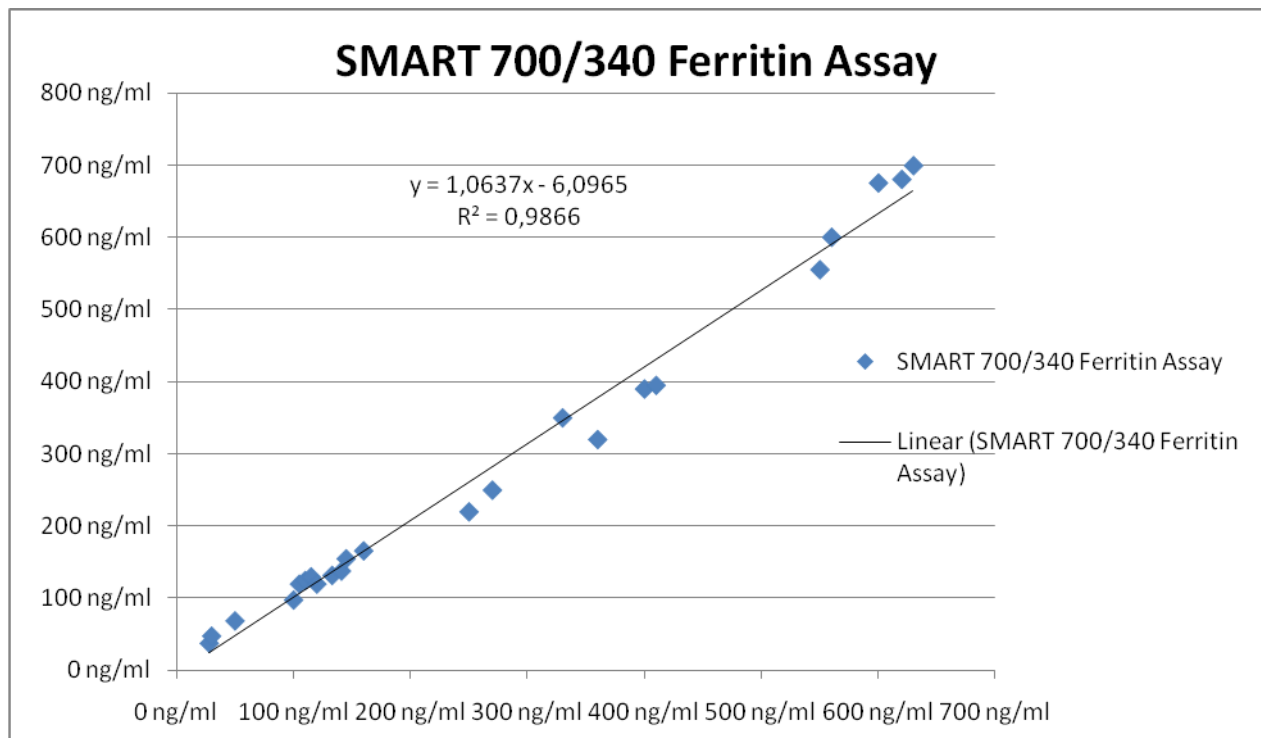


Chart 1:
Correlation between SMART Ferritin (y) and CCA180 (x)
 $R^2=0.9866$ $Y=kx+d=1.0637-6.0965$

Sample	CCA180 Dialab Ferritin Assay	SMART 700/340 Ferritin Assay	Difference CCA180-SMART
1	28 ng/ml	38 ng/ml	-10 ng/ml
2	30 ng/ml	48 ng/ml	-18 ng/ml
3	50 ng/ml	69 ng/ml	-19 ng/ml
4	100 ng/ml	98 ng/ml	2 ng/ml
5	105 ng/ml	120 ng/ml	-15 ng/ml
6	110 ng/ml	125 ng/ml	-15 ng/ml
7	115 ng/ml	130 ng/ml	-15 ng/ml
8	120 ng/ml	120 ng/ml	0 ng/ml
9	133 ng/ml	132 ng/ml	1 ng/ml
10	141 ng/ml	138 ng/ml	3 ng/ml
11	145 ng/ml	155 ng/ml	-10 ng/ml
12	160 ng/ml	166 ng/ml	-6 ng/ml
13	250 ng/ml	220 ng/ml	30 ng/ml
14	270 ng/ml	250 ng/ml	20 ng/ml
15	330 ng/ml	350 ng/ml	-20 ng/ml
16	360 ng/ml	320 ng/ml	40 ng/ml
17	400 ng/ml	390 ng/ml	10 ng/ml
18	410 ng/ml	395 ng/ml	15 ng/ml
19	550 ng/ml	555 ng/ml	-5 ng/ml
20	560 ng/ml	600 ng/ml	-40 ng/ml
21	600 ng/ml	675 ng/ml	-75 ng/ml
22	620 ng/ml	680 ng/ml	-60 ng/ml
23	630 ng/ml	699 ng/ml	-69 ng/ml

Table 2: Difference of all samples

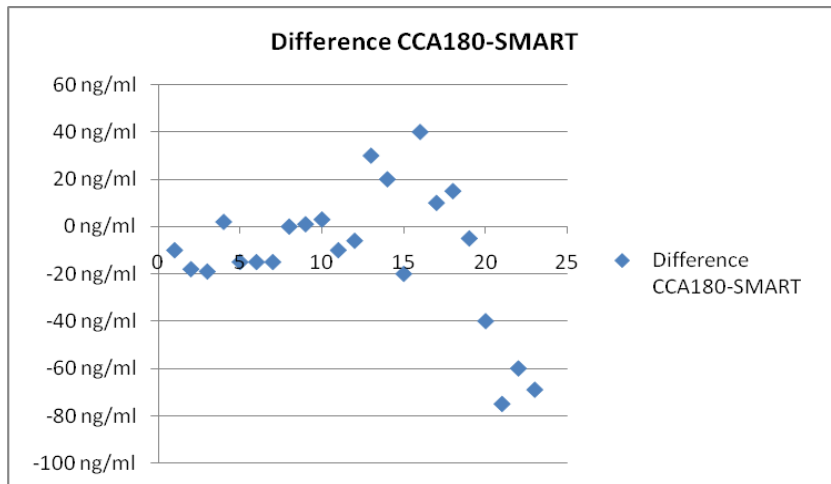


Chart 2: Difference plot for all samples (serum)

5. Imprecision:

The imprecision of the SMART Ferritin was determined with 2 different control levels (low-high Dialab Control)

No	SMART Control Low	Control High
1	81	250
2	81	271
3	75	244
4	83	266
5	79	276
6	88	296
7	78	269
8	80	255
9	84	240
10	85	233
11	78	272
12	75	278
13	72	279
14	78	276
15	81	270
16	80	272
17	73	265
18	75	267
19	73	269
20	71	268
21	70	264
22	78	263
23	81	264
24	85	265
25	78	266
mean	78.48	265
Stabw	4.673685198	13.21022331
cv	5.96%	4.98%

Table 3: within run precision

8. Summary:

The **Ferritin method** used in the SMART analyser has a good correlation to the Dialab Ferritin Assay if the whole range of the assay is taken in consideration.

Sensitivity of the Ferritin assay is an issue on samples lower 100ng/ml.

A separate sensitivity study should be performed as soon as volumes of the involved reagents within the smart cartridge can be reduced to increase sensitivity.

The precision is acceptable for a point-of-care system with
cv=5.96% low level (78 ng/ml) cv=4.98% high level (265 ng/ml).

Salzburg 21/09/2009



Michael Gruber