Eurolyser Diagnostica GmbH Tel. +43 (0) 662 43 21 00
Bayernstrasse 11a Fax. +43 (0) 662 43 21 00 50
5020 Salzburg/Austria www.eurolyser.com

In house EVALUATION SMART Lp (a)

Author:
Michael Gruber
Eurolyser Diagnostica
Bayernstrasse 11-A
5020 Salzburg
AUSTRIA

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1. Scope and goals of the evaluation

1.1 Method comparison
Testing the correlation between the Lp (a) measurement results on the SMART 700/340 analyzer from serum samples and the results of the Lp (a) of the clinical chemistry bench top analyser CCA180 in combination with Audit Diagnostics Lpa Assay.

1.2 Imprecision
Characterization of the precision of the SMART Lpa test at 2 levels of control serum

2. Samples, reagent kits, and consumables

Samples:
Samples taken from the daily routine of 4 days (01/07/2009 to 04/07/2009), from hospital samples in venous sample tubes (Greiner Bio-one).

Reference Analyser:
CCA180 bench top analyser manufactured by Akatech GmbH-Austria
Audit Diagnostics Lpa kit LOT 67686

Material and methods:
SMART 700/340 analyzer with the following serial number, have been taken:

SMART: SNO Ab 1035
SNO Ab 1033
SNO Ab 0853

Reagent kits:
6 packages of Lpa testkit article ST0141 LOT 6768-2, were taken.

The assay is based on the reaction between antigen and antibody.
The reaction forms an insoluble complex producing a turbidity, which is measured spectrophotometically in the smart analyser at 700nm.
The amount of complex formed is directly proportional to the amount of Lp(a) in the sample.
Lp(a) Antigen + Anti-Lp(a) Antibodies Antigen/Antibody complex –→–

The Eurolyser Lpa assay uses latex particles containing rabbit anti-human Lp(a) polyclonal antibody as a reagent. The rabbit anti-human Lp(a) polyclonal antibody is technically isoform sensitive by virtue of the antisera binding to multiple sites of kringle domain IV type 2 (KIV_2) repeats; (The assay can theoretically made nearly isoform independent if the appropriate calibrator system is used. This assay format, like most commercial assays, binds to both free apo(a) and true Lp(a) [i.e., apo(a) covalently bound to apoB-100]; therefore, it is best described as measuring “total apo(a)” rather than “Lp(a).”

QC materials
To check the correctness, the Lp (a) QC kit provided by AUDIT Ireland was used.

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3. Test processing with the SMART system:

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

Warm up cuvettes at least 10 minutes at room temperature

Pipette sample with SMART Pipette (20 µl) 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 hospital "Barmh Brüder" , in the range of 2 mg/dl and 78 mg/dl Lp (a).

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 Lpa and x= CCA180) Measurements have been performed at the site of Eurolyser Diagnostica GmbH Bayernstrasse 11A.

Chart and raw data:.

Sample seq no	CCA180 AUDIT Lpa Assay	SMART 700/340 Lpa assay
1	28 mg/dl	22 mg/dl
2	44 mg/dl	41 mg/dl
3	79 mg/dl	77 mg/dl
4	36 mg/dl	33 mg/dl
5	10 mg/dl	9 mg/dl
6	5 mg/dl	4 mg/dl
7	19 mg/dl	18 mg/dl
8	22 mg/dl	19 mg/dl
9	78 mg/dl	77 mg/dl

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10	33 mg/dl	29 mg/dl
11	77 mg/dl	76 mg/dl
12	22 mg/dl	20 mg/dl
13	11 mg/dl	9 mg/dl
14	23 mg/dl	20 mg/dl
15	2 mg/dl	6 mg/dl
16	5 mg/dl	3 mg/dl
17	3 mg/dl	8 mg/dl
18	5 mg/dl	8 mg/dl
19	10 mg/dl	12 mg/dl
20	22 mg/dl	23 mg/dl
21	39 mg/dl	41 mg/dl
22	66 mg/dl	68 mg/dl
23	56 mg/dl	58 mg/dl
24	53 mg/dl	55 mg/dl
25	33 mg/dl	34 mg/dl
26	32 mg/dl	28 mg/dl
27	11 mg/dl	9 mg/dl
28	22 mg/dl	19 mg/dl
29	19 mg/dl	21 mg/dl
30	28 mg/dl	28 mg/dl
31	36 mg/dl	35 mg/dl
32	47 mg/dl	49 mg/dl
33	22 mg/dl	19 mg/dl
34	39 mg/dl	41 mg/dl
35	37 mg/dl	36 mg/dl
36	34 mg/dl	33 mg/dl
37	22 mg/dl	21 mg/dl
38	31 mg/dl	29 mg/dl
39	33 mg/dl	32 mg/dl
40	39 mg/dl	37 mg/dl

Table 1:
Lpa values for fresh serum from SMART, compared with AUDIT Diagnostics Lpa Assay on CCA180 bench top analyser

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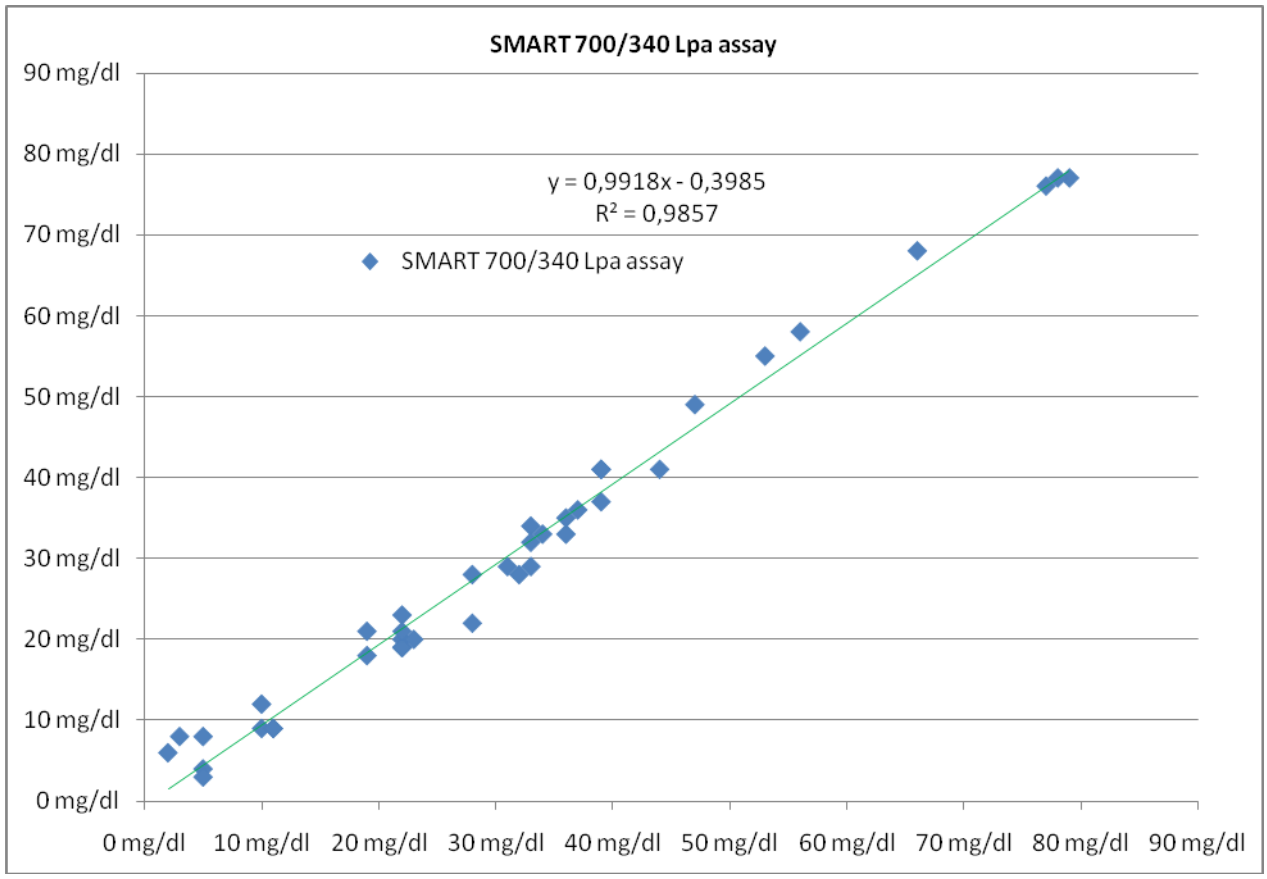

Chart 1:
Correlation between SMART lpa (y) and CCA180 (x)
R^2=0.9857 Y=kx+d=0,9918x-0,3985

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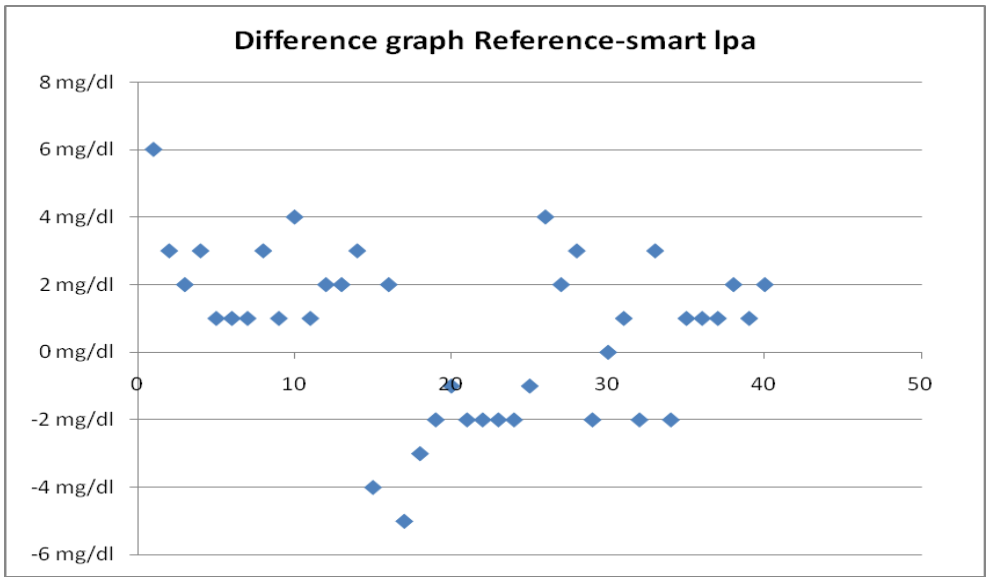
Graph 2: Difference of all samples



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5. Imprecision:

The imprecision of the SMART lpa was determined with 2 different control levels (low-high AUDIT Control 24 mg/dl and 51 mg/dl)

Sample seq no	Lpa low 24	Lpa high 51
1	24 mg/dl	50 mg/dl
2	23 mg/dl	49 mg/dl
3	22 mg/dl	48 mg/dl
4	23 mg/dl	51 mg/dl
5	21 mg/dl	52 mg/dl
6	25 mg/dl	48 mg/dl
7	25 mg/dl	51 mg/dl
8	23 mg/dl	51 mg/dl
9	21 mg/dl	50 mg/dl
10	22 mg/dl	50 mg/dl
11	24 mg/dl	49 mg/dl
12	24 mg/dl	51 mg/dl
13	23 mg/dl	51 mg/dl
14	23 mg/dl	49 mg/dl
15	21 mg/dl	51 mg/dl
16	24 mg/dl	49 mg/dl
17	24 mg/dl	50 mg/dl
18	25 mg/dl	52 mg/dl
19	24 mg/dl	52 mg/dl
20	25 mg/dl	49 mg/dl
mean	23 mg/dl	50 mg/dl
Stabwn	1,30766968	1,23592071
cv	5,6%	2,46%

Table 3: within run precision

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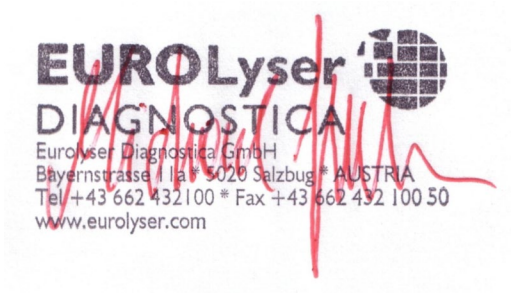
8. Summary:

The Lpa method used in the SMART analyzer has a good correlation to the AUDIT Lpa Assay if the whole range of the assay is taken in consideration.

The cv values for low and high controls are excellent for a point of care analyser.

cv=5,6% low level (24 mg/dl) cv=2,46% high level (51 mg/dl).



Ing. Michael Gruber
Salzburg 10/07/2009