REPORT

Title:	Method Comparison SD LipidoCare Lipid Profile vs Siemens ADVIA 2400
Version no.:	1.0
Prepared by:	Kari Roald **Date:** 28.10.2013

SUMMARY

The purpose of this study was to compare the results obtained with SD LipidoCare Lipid Profile on SD LipidoCare Analyzer, with results obtained with Siemens ADVIA 2400 at Fürst Medisinske Laboratorium.

Finger stick whole blood samples and corresponding serum samples have been included from 45 donors, in addition to 7 EDTA-whole blood samples and corresponding serum samples. All finger stick and EDTA-whole blood samples have been analysed by SD LipidoCare Lipid Profile. The serum samples have been analysed by Siemens ADVIA 2400 at Fürst Medical laboratory.

Deming regression results for SD LipidoCare® Lipid Profile (finger stick samples and EDTA whole blood samples) compared to Siemens ADVIA 2400 (serum). Results in mg/dL.

	Slope	Y-intercept	Correlation coefficient (r^2)	95% CI Slope	95% CI Y-intercept
Chol	0.86	34	0.93	0.79 to 0.93	19 to 49
HDL	0.77	15	0.87	0.69 to 0.86	10 to 20
Trig	0.96	-1	0.98	0.92 to 1.00	-9 to 6
LDL	0.90	16	0.77	0.75 to 1.05	-4 to 35
Non-HDL	0.84	28	0.88	0.75 to 0.92	13 to 42
Chol/HDL	0.73	0.87	0.79	0.62 to 0.84	0.41 to 1.33

Deming regression results for SD LipidoCare® Lipid Profile (finger stick samples only) compared to Siemens ADVIA 2400 (serum). Results in mg/dL.

	Slope	Y-intercept	Correlation coefficient (r^2)	95% CI Slope	95% CI Y-intercept
Chol	1.02	5	0.93	0.93 to 1.10	-12 to 21
HDL	0.76	15	0.89	0.67 to 0.84	10 to 20
Trig	1.04	-9	0.95	0.97 to 1.11	-19 to 1
LDL	1.10	-5	0.83	0.94 to 1.26	-25 to 14
Non-HDL	1.03	2	0.88	0.91 to 1.15	-15 to 20
Chol/HDL	0.83	0.55	0.83	0.72 to 0.95	0.08 to 1.02

CONTENTS

1 OBJECTIVE

The purpose of this study was to compare the results obtained with SD LipidoCare Lipid Profile on SD LipidoCare Analyzer, with results obtained with Siemens ADVIA 2400 at Fürst Medisinske Laboratorium.

Finger stick whole blood and EDTA whole blood were analysed with SD LipidoCare Lipid Profile, and compared to the corresponding serum analysed on Siemens ADVIA 2400 at Fürst Medisinske Laboratorium.

2 DOCUMENTATION OF TRAINING

All participants involved in this study have been trained prior to start.

3 EQUIPMENT, REAGENTS AND MATERIALS

Table 3.1 Equipment, reagents and materials for SD LipidoCare Lipid Profile used in the study

Equipment, reagents, controls, materials	Material no.	Serial / Lot no.
LipidoCare analyzer	02LA10G	LA01808AA0297
LipidoCare Lipid Profile test strip LipidoCare Lipid Profile test strip Codechip	02LS10A	LS1013003
Capillary Tubes	90CT10	2291
Capillary Plungers	90CTP10	2351
LipidoCare Check Strip	N/A (Supplied with analyzer)	N/A

Table 3.2 Equipment, general, used in the study

Equipment	Instrument no.
Centrifuge, Jouan CR3i	Z-981
Freezer, -40°C	DUD-100-31
Pipette with tips	DUD-400-051 DUD-400-167
Siemens ADVIA 2400 Chemsitry System	CA 12450054

Table 3.3 Reagents, general, used in the study

Reagents	Lot no.
BD Vacutainer® collecting tubes with gel for serum, Ref. 367953	2096053
Standard vein puncture equipment	N/A
Vitrex, Alcohol swabs, ref. 520213	20120209
Lancets for finger stick	N/A
Sample tubes with caps, 0.5 mL, Sarstedt, ref. 72.730	2083201
BD Mictotainer® Contact Activated Lancer, ref. 366594	T3X72G2

Table 3.4 Sample material used in the study

Sample materials	Sample ID /Lot no.
Capillary whole blood and corresponding serum	13-2078 to 13-2083, 13-2097 to 13-2102, 13-2112 to 13-2124, 13-2150 to 13-2164, 13-2262 to 13-2276
EDTA whole blood and corresponding serum	13-2270 to 13-2276

4 PROCEDURE

4.1 Comparison of SD LipidoCare vs Siemens ADVIA 2400

The study was performed by 4 persons on 7 operating days over a period of 3 weeks. The study was performed according to the protocol and described below.

The samples were collected in-house, from external donors and received from external laboratories.

Finger stick whole blood samples and corresponding serum samples have been included from 45 donors, in addition to 7 EDTA-whole blood samples and corresponding serum samples. All finger stick and EDTA-whole blood samples have been analysed by SD LipidoCare Lipid Profile. The serum samples have been analysed by Siemens ADVIA 2400 at Fürst Medical laboratory.

The LipidoCare Check strip was measured each test day by SD LipidoCare Lipid Profile. The Cholestech LDX Multianalyte control L1 and L2 were measures in singleton each test day by the SD LipidoCare® Lipid Profile.

5 RESULTS

5.1 Validity criteria

The Controls must be within the allowed ranges for all analytes before analysis of patient samples can be initiated.

If the control results are outside the validity criteria, try to identify the error and implement possible corrective actions. Repeat the measurement.

5.2 Acceptance criteria

No claimed acceptance criteria.
This is an evaluation study and the results will be reported.

6 RESULTS

6.1 Results - Validity control

The results from testing of Cholestech LDX® Multianalyte Controls (L1 and L2) with SD LipidoCare® Lipid Profile for validity control were within the validity criteria.

6.2 Results Raw data

Results from SD LipidoCare® Lipid Profile and Fürst Medical laboratory (Siemens ADVIA 2400) are shown in appendix 1.

The numbers of samples measured within and outside the measuring range for each analyte are shown in table 7.1. The numbers of samples with not valid (NV) results for LDL, non-HDL and Chol/HDL are a consequence of the numbers of samples outside the measuring range for Chol, HDL and/or Trig and therefore no calculation of LDL, non-HDL and Chol/HDL have been performed.

The ranges per sample type are shown in table 7.2.

Table 7.1 Number of samples within and outside the measuring range for Chol, HDL, Trig, LDL, non-HDL and Chol/HDL.

Method	Parameter	Chol	HDL	Trig	LDL	Non-HDL	Chol/HDL
LipidoCare	Within	52	50	50	46	50	50
	Below	0	0	2	//////	//////	//////
	Above	0	2	0	//////	//////	//////
	NV	0	0	0	6	2	2

Table 7.2 Analyte ranges and measuring ranges (in brackets) for the samples included in the study.

Method	Chol	HDL	Trig	LDL	Non-HDL	Chol/HDL
LipidoCare	154-308 (100-450)	36-89 (25-95)	54-530 (45-650)	65-194	81-253	2.1-6.1

6.3 Comparison of SD LipidoCare® Lipid Profile (finger stick) to Siemens ADVIA 2400 (serum) using Deming regression

Finger stick samples (including EDTA whole blood sample) have been analysed by SD LipidoCare® Lipid Profile and compared with serum samples analysed with Siemens ADVIA 2400 using Deming regression. The comparison results are presented in table 7.3 and 7.4. There are no specifications for the results.

Figure 7.1 to 7.12 show the graphic presentation of the Deming regression SD LipidoCare® Lipid Profile with Siemens ADVIA 2400 for Cholesterol, HDL Cholesterol, Triglycerides, LDL Cholesterol, non-HDL Cholesterol and the Chol/HDL ratio respectively.

Table 7.3 Deming regression results for SD LipidoCare® Lipid Profile (finger stick samples and EDTA whole blood samples) to Siemens Advia 2400 (serum). Results in mg/dL.

	Slope	Y-intercept	Correlation coefficient (r^2)	95% CI Slope	95% CI Y-intercept
Chol	0.86	34	0.93	0.79 to 0.93	19 to 49
HDL	0.77	15	0.87	0.69 to 0.86	10 to 20
Trig	0.96	-1	0.98	0.92 to 1.00	-9 to 6
LDL	0.90	16	0.77	0.75 to 1.05	-4 to 35
Non-HDL	0.84	28	0.88	0.75 to 0.92	13 to 42
Chol/HDL	0.73	0.87	0.79	0.62 to 0.84	0.41 to 1.33

Table 7.4 Deming regression results for SD LipidoCare® Lipid Profile (finger stick samples only) to Siemens Advia 2400 (serum). Results in mg/dL.

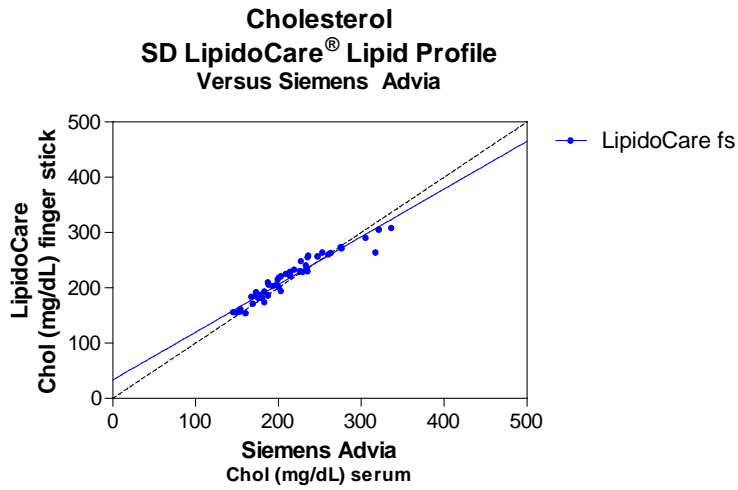|	Slope	Y-intercept	Correlation coefficient (r^2)	95% CI Slope	95% CI Y-intercept
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Trig	1.04	-9	0.95	0.97 to 1.11	-19 to 1
LDL	1.10	-5	0.83	0.94 to 1.26	-25 to 14
Non-HDL	1.03	2	0.88	0.91 to 1.15	-15 to 20
Chol/HDL	0.83	0.55	0.83	0.72 to 0.95	0.08 to 1.02

Figure 7.1 Cholesterol results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood, including 7 EDTA whole blood samples. Results in mg/dL.
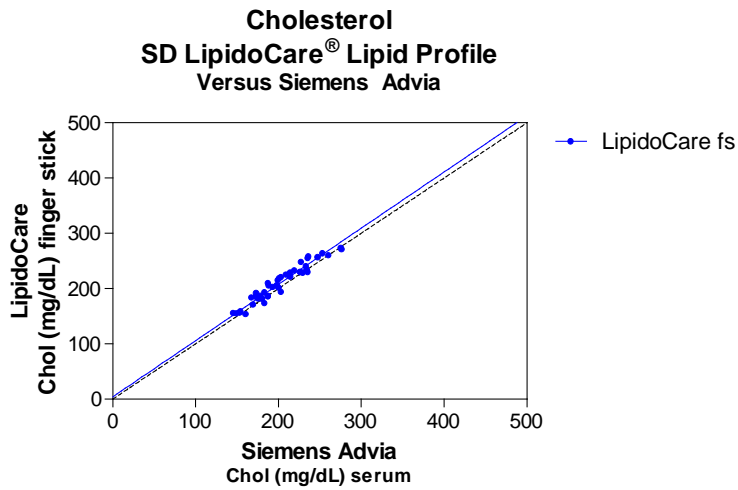

Figure 7.2 Cholesterol results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood only. Results in mg/dL.
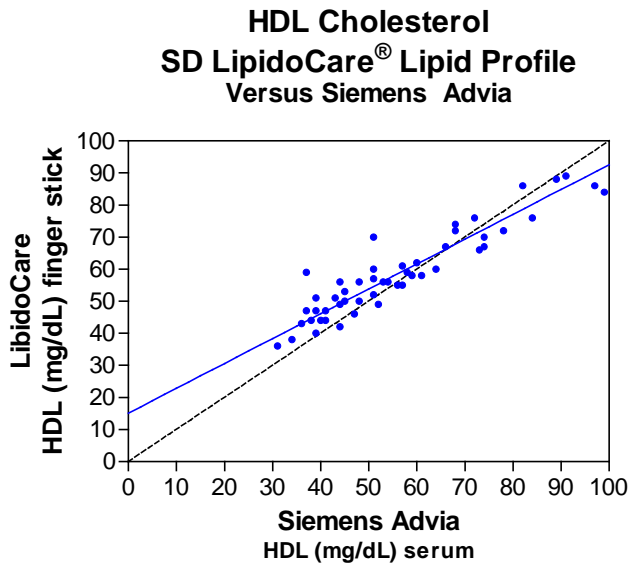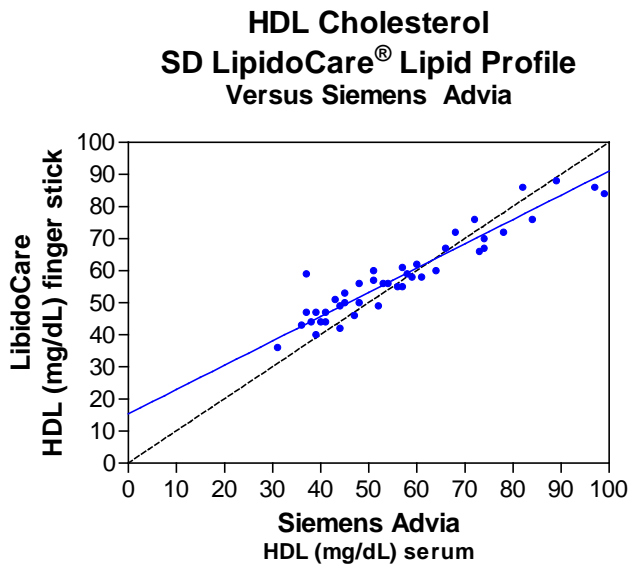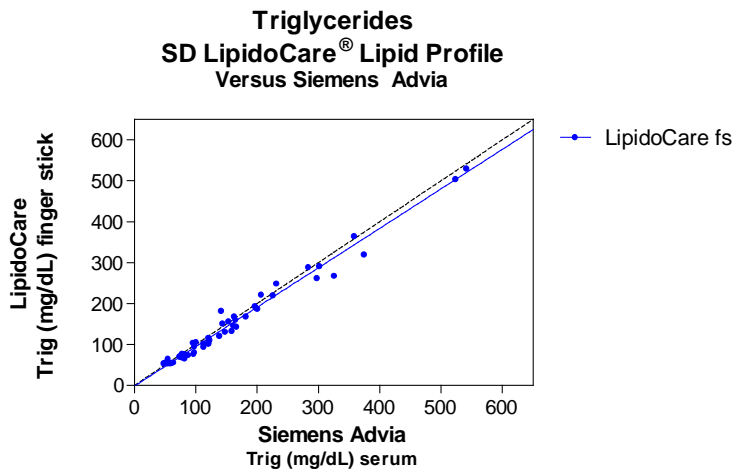
**HDL Cholesterol
SD LipidoCare® Lipid Profile
Versus Siemens Advia**

Figure 7.3 HDL-Cholesterol results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood, including 7 EDTA whole blood samples. Results in mg/dL.
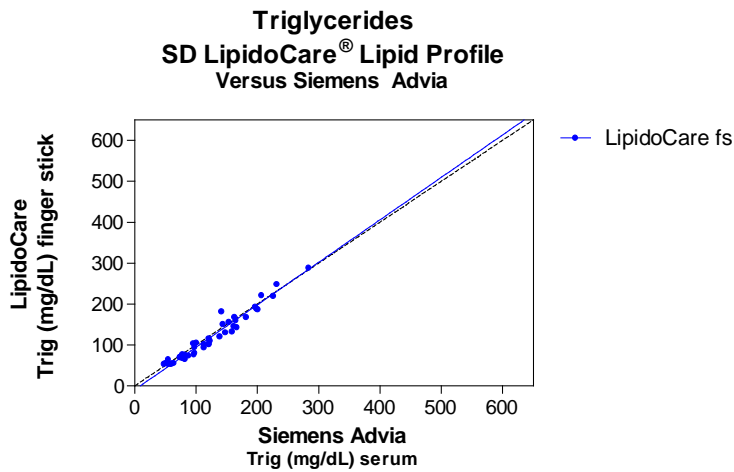
**HDL Cholesterol
SD LipidoCare® Lipid Profile
Versus Siemens Advia**

Figure 7.4 HDL-Cholesterol results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood only. Results in mg/dL.

Triglycerides
SD LipidoCare® Lipid Profile
Versus Siemens Advia

Figure 7.5 Triglyceride results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood, including 7 EDTA whole blood samples. Results in mg/dL.

Triglycerides
SD LipidoCare® Lipid Profile
Versus Siemens Advia

Figure 7.6 Triglyceride results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood only. Results in mg/dL.
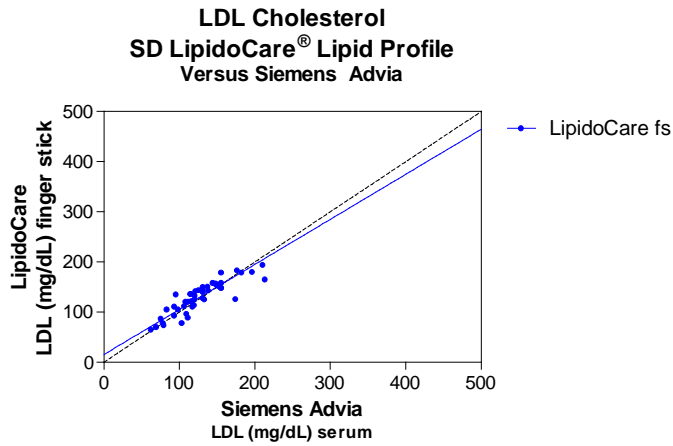
Figure 7.7 LDL-Cholesterol results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood, including 7 EDTA whole blood samples. Results in mg/dL.
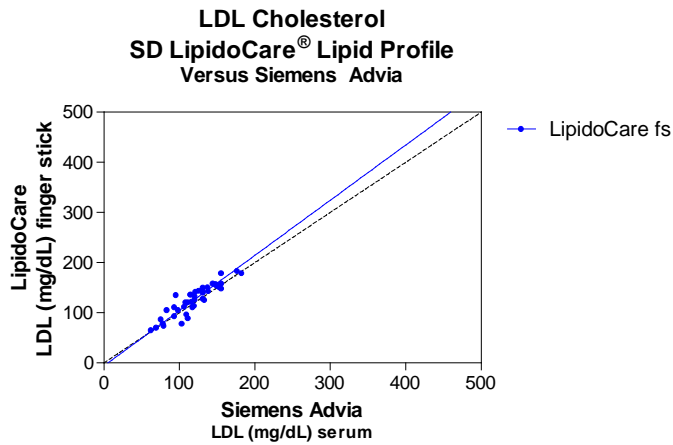

Figure 7.8 LDL-Cholesterol results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood only. Results in mg/dL.
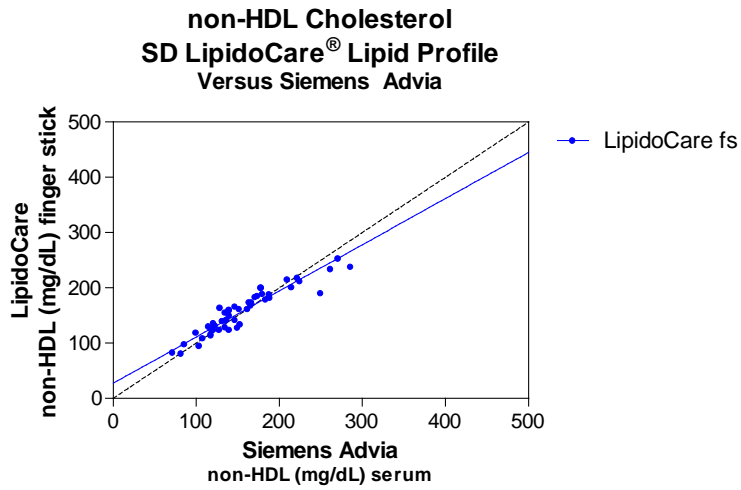
non-HDL Cholesterol
SD LipidoCare® Lipid Profile
Versus Siemens Advia

Figure 7.9 non-HDL results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood, including 7 EDTA whole blood samples. Results in mg/dL.
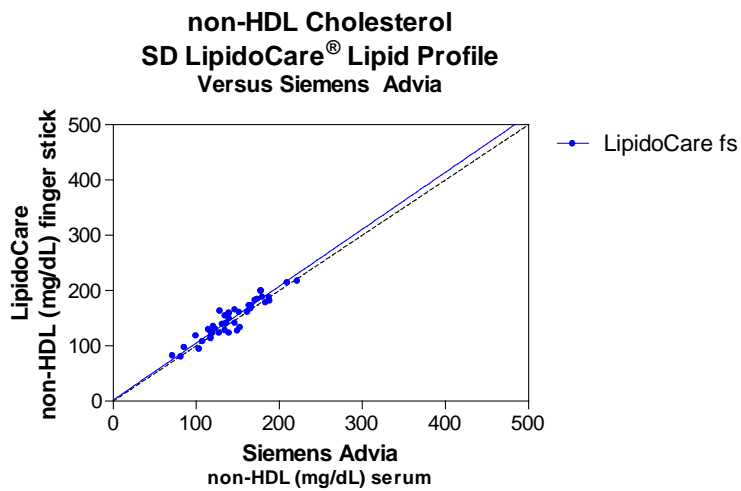
non-HDL Cholesterol
SD LipidoCare® Lipid Profile
Versus Siemens Advia

Figure 7.10 non-HDL results; SD LipidoCare® Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood only. Results in mg/dL.
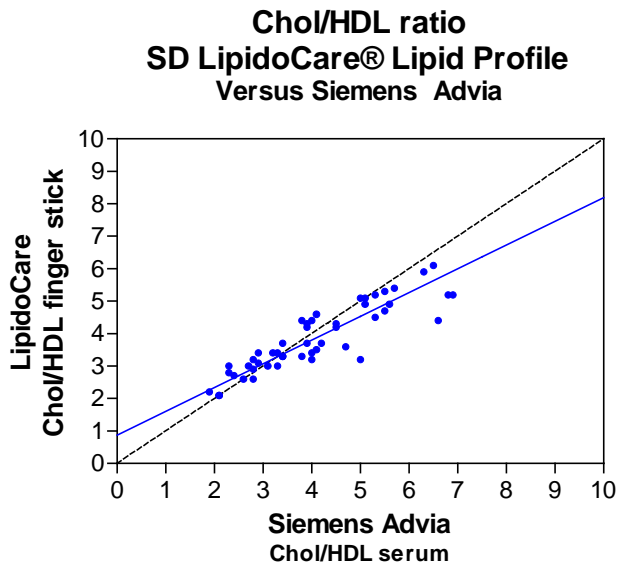
Figure 7.11 Chol/HDL results; SD LipidoCare[®] Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood, including 7 EDTA whole blood samples. Results in mg/dL.
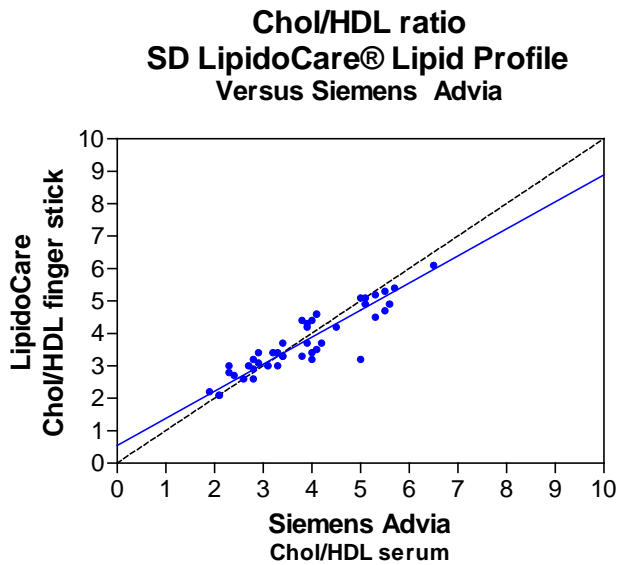

Figure 7.12 Chol/HDL results; SD LipidoCare[®] Lipid Profile compared to serum with Siemens ADVIA 2400 in finger stick whole blood only. Results in mg/dL.

7   CONCLUSION

Finger stick whole blood samples and corresponding serum samples have been included from 45 donors, in addition to 7 EDTA-whole blood samples and corresponding serum samples. All finger stick and EDTA-whole blood samples have been analysed by SD LipidoCare Lipid Profile. The serum samples have been analysed by Siemens ADVIA 2400 at Fürst Medical laboratory.

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Chol/HDL	0.83	0.55	0.83	0.72 to 0.95	0.08 to 1.02

8   APPENDICES

The following appendices are part of the report:

Appendix number	Title
Appendix 1	Results from SD LipidoCare® Lipid Profile and Siemens ADVIA 2400