

Evaluation of the Ability of Non-laboratorians to Perform Lipid Testing with the ABAXIS Piccolo® Point-of-Care Instrument

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Abstract

Guidelines have been established defining the characteristics of testing systems necessary to ensure accuracy and reliability of test results when the analysis is performed by non-laboratorians. We evaluated the accuracy and reliability of lipid testing performed by non-laboratorians using the ABAXIS Piccolo. Our goals were to assess the ability of laypeople to obtain accurate and reliable test results.

We evaluated the ability of 63 individuals, without prior laboratory experience, to perform analysis of total and HDL cholesterol, and triglycerides. The study was conducted on 3 separate days at different sites with approximately 20 subjects recruited at each location. Each participant analyzed (in singlicate) 3 separate pools containing various concentrations of analyte. Prior to performing testing, participants were given written instructions that explained how to load the reagent disc with sample, place the disc in the instrument, and run the analysis. The results generated by the 63 non-laboratorians are as follows:

Summary of Test Results

	Level 1			Level 2			Level 3		
	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)
Mean	144.2	29.4	83.4	198.4	44.4	205.6	245.1	58.9	152.7
SD	4.23	0.96	2.47	4.58	1.44	1.82	3.30	1.16	2.29
%CV	2.9	3.3	3.0	2.3	3.2	0.9	1.3	2.0	1.5

Following the conclusion of all testing, subjects completed a questionnaire on the ease of use of the Piccolo. 94% of participants reported the directions of the test procedure to be "clear and easy to follow;" the remainder found the directions "somewhat unclear," but they were still able to follow them. Greater than 94% of participants found instrument operation and overall testing to be "easy," with the remainder reporting the level of operation as "somewhat easy." Somewhat more challenging was pipette use; 87% of participants found pipette manipulation to be "easy." Addition of sample to the reagent disc was described as "easy" by 82% and "somewhat easy" by 16%. One individual found this step to be "difficult."

In summary, use of the Piccolo by non-laboratorians results in accurate and precise test results; lipid test precision met NCEP guidelines. The majority of users report the instrument to be easy to operate.

Introduction

Guidelines established by the National Cholesterol Education Program (NCEP) state that all individuals be tested for total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides, with the frequency of testing based on the presence of other risk factors. The practical difficulties of performing periodic testing on all individuals necessitates that access to testing be as easy as possible. Testing that can be reliably performed by operators not experienced in clinical laboratory techniques helps ensure wide availability of lipoprotein testing. In addition, methods used to measure blood lipids must be accurate, reliable, and comparable to reference methods. We evaluated the ABAXIS Piccolo lipid panel for accuracy, precision, and ease-of-use when testing is performed by individuals with no prior laboratory experience.

A. The Lipid Panel Reagent Disc is intended for quantitative determination of total cholesterol (CHOL), high-density lipoprotein cholesterol (HDL), and triglycerides (TRIG).

1. Low-density lipoprotein cholesterol (LDL), very low-density lipoprotein cholesterol (VLDL), and a total cholesterol/high-density lipoprotein cholesterol ratio (TC/H) are calculated by the analyzer.

2. Heparinized whole blood, heparinized plasma, or serum may be used.

B. The ABAXIS Piccolo system consists of (see picture):

1. The Piccolo Point-of-Care Blood Analyzer

- It is 24.2 cm (9.5 in) high, 15.3 cm (6 in) wide, and 29.2 cm (11.5 in) deep.
- It weighs 6.9 kg (15 pounds).

Introduction (cont.)

2. Single-use disposable reagent discs

- A clear plastic disc, 8 cm in diameter and 2 cm in depth
- The reagent disc contains an aqueous diluent in the center and dry reagent beads in cuvettes around the disc periphery.
- Plasma separation, mixing, and critical volumetric measurements are performed by the disc.
- Fluid flow within the disc is controlled by centrifugal and capillary forces.
- The test system requires approximately 90 μ L of sample (whole blood, serum, or plasma).



C. Current instruments available for point-of-care (POC) testing have limited capability for analyzing multiple analytes, simultaneously. However, the Piccolo analyzer can provide up to 14 simultaneous results, depending on the reagent disc selected.

D. The Piccolo analyzer provides push button, walk-away convenience making the system highly suitable for POC applications.

E. The Abaxis Lipid Panel Disc has received Cholesterol Reference Method Laboratory Network (CRMLN) certification for accuracy using accepted reference methods for CHOL and HDL. While no certification is currently available in the United States for triglycerides, the Abaxis TRIG assay correlated very well with a triglycerides assay in a laboratory standardized for triglycerides through the CDC-NHLBI Lipid Standardization Program

F. A multi-center study of non-laboratorian testing was organized in three non-clinical laboratory settings.

Materials and Methods

We evaluated the ease of use and performance of the Piccolo Lipid Panel Disc by non-clinical laboratory personnel in field studies.

Outline of field studies:

1. Testing was done at 3 non-clinical sites.
2. 21 untrained people performed testing at each site (total subjects=63).
3. Subjects were recruited from the general population. Individuals with professional laboratory training were excluded. The subjects were representative of the general population with respect to gender, age, education, and occupation.
4. Participants were asked to perform lipid testing on three different samples, following the provided written instructions, only.
5. The samples consisted of three serum pools prepared with "low," "medium," and "high" levels of each of the three analytes [Total Cholesterol (CHOL), High-Density Lipoprotein Cholesterol (HDL) and Triglycerides (TRIG)].
6. The samples were designated as Levels 1, 2, & 3 and were tested in random order.

Table 1. Target Levels of Sample Pools

Sample (Level)	Total Cholesterol Target Mean (mg/dL)	HDL Target Mean (mg/dL)	Triglycerides Target Mean (mg/dL)
1	150	30	85
2	200	45	200
3	250	60	150

7. The samples were tested on 3 separate Piccolos by each subject.

8. The data were pooled and precision was calculated.

Demographic Data

Demographic information is summarized below. The study included both genders, various age groups, various educational levels, and various occupations.

Table 2. Demographic Profile of Study Subjects

Factor	Site 1	Site 2	Site 3	Totals
Gender				
Male	10	7	7	24
Female	11	14	14	39
Totals	21	21	21	63
Age				
18-25	2	4	4	10
26-45	10	12	13	35
46-62	9	5	4	18
Totals	21	21	21	63
Education				
High School Degrees	3	7	3	13
Associates Degrees	6	3	1	10
Bachelors Degrees	12	7	16	35
Advanced Degrees	0	4	1	5
Totals	21	21	21	63
Occupation				
Student	1	4	2	7
Administrative/Clerical	6	3	11	20
Professional	8	6	7	21
Sales and Service	1	1	0	2
Manufacturing	3	0	0	3
Other	2	7	1	10
Totals	21	21	21	63

Participants' Impressions

After results were recorded, subjects were asked to complete questionnaires soliciting their impressions and opinions of the Piccolo test and its procedure. The results (combined for all three sites) demonstrated overwhelming ease of use for the test and the written instructions. The responses to the questions are detailed below.

"In your opinion, were the directions in the TEST PROCEDURE..."

Scoring	Description	# of Responses
1	Clear and easy to follow	59
2	Somewhat unclear, but could be followed	4
3	Unclear and difficult to follow	0

"In your opinion, was using the SAMPLE DISPENSER..."

Scoring	Description	# of Responses
1	Easy	55
2	Somewhat easy	8
3	Difficult	0

"In your opinion, was ADDING SAMPLE TO THE SAMPLE PORT..."

Scoring	Description	# of Responses
1	Easy	52
2	Somewhat easy	10
3	Difficult	1

"In your opinion, was USING THE KEYPADS AND BUTTONS..."

Scoring	Description	# of Responses
1	Easy	61
2	Somewhat easy	2
3	Difficult	0

Participants' Impressions (cont.)

"In your opinion, was TESTING WITH THE PICCOLO was ..."

Scoring	Description	# of Responses
1	Easy	59
2	Somewhat easy	4
3	Difficult	0

From these responses to the questionnaire by the 63 untrained users, testing the Lipid Panel Disc with the Piccolo was found to be "easy" or "somewhat easy" with a preponderance of untrained users indicating "easy."

Precision Data

Tables 3–5 present the results obtained from each of the three sites. At each site, 21 untrained individuals tested each of three samples once. Table 6 summarizes the data from all three sites and all 63 untrained users.

The data in Tables 3–6 indicate that the measured values and precision achieved at each site were quite similar. Precision of the combined data exceeds NCEP guidelines for precision for each of the three analytes at all three levels.

Table 3. Results by Untrained Users at Site 1

	Level 1			Level 2			Level 3		
	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)
X	145.0	29.5	84.1	199.9	45.1	206.5	245.9	59.4	153.4
SD	4.10	0.93	3.68	6.15	1.73	2.20	3.30	1.16	1.29
%CV	2.8	3.1	4.4	3.1	3.8	1.1	1.3	2.0	0.8
n	21	21	21	21	21	21	21	21	21

Table 4. Results by Untrained Users at Site 2

	Level 1			Level 2			Level 3		
	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)
X	143.1	29.7	82.9	197.0	44.2	205.5	243.6	58.8	151.4
SD	5.48	1.01	1.49	1.69	1.00	1.29	3.01	1.03	1.66
%CV	3.8	3.4	1.8	0.9	2.2	0.6	1.2	1.8	1.1
n	21	21	21	21	21	21	21	21	21

Table 5. Results by Untrained Users at Site 3

	Level 1			Level 2			Level 3		
	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)
X	144.4	29.0	83.2	198.2	43.9	204.9	245.8	58.3	153.1
SD	2.60	0.86	1.48	4.49	1.28	1.49	3.19	1.06	3.05
%CV	1.8	3.0	1.8	2.3	2.9	0.7	1.3	1.8	2.0
n	21	21	21	21	21	21	21	21	21

Table 6. Summary of Combined Data From All Three Sites

	Level 1			Level 2			Level 3		
	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)	CHOL (mg/dL)	HDL (mg/dL)	TRIG (mg/dL)
X	144.2	29.4	83.4	198.4	44.4	205.6	245.1	58.9	152.7
SD	4.23	0.96	2.47	4.58	1.44	1.82	3.30	1.16	2.29
%CV	2.9	3.3	3.0	2.3	3.2	0.9	1.3	2.0	1.5
n	63	63	63	63	63	63	63	63	63

Accuracy and Traceability

Cholesterol Reference Method Laboratory Network (CRMLN) Certification

The Piccolo Total Cholesterol and HDL assays have met the requirements for certification of accuracy and precision by the Cholesterol Reference Method Laboratory Network (CRMLN), which is coordinated by the Centers for Disease Control. The certification process evaluates the accuracy of method calibration and precision, helping to assure reliable classification of patients based on the NCEP cut-points.

Accuracy of the Piccolo assays for total cholesterol and HDL cholesterol were established by completing the certification process of the CRMLN. A key part of the CRMLN certification is linear regression analysis of the Piccolo assay compared with an established reference method.

The accuracy of the Total Cholesterol Assay compared to the Abell-Kendall reference method is indicated by the correlation coefficient (R^2) of 0.996, slope of 1.061, and intercept of -18.3 mg/dL. Within-run ($n=20$) precision for the Piccolo Total Cholesterol Assay was determined to be 1.3% at 236 mg/dL.

For the Piccolo HDL Assay compared to the HDL reference method, precipitation followed by Abell-Kendall cholesterol assay, the correlation coefficient (R^2) was 0.974, slope of 0.910, and intercept of 5.2 mg/dL. Within-run precision ($n=20$) for the Piccolo HDL Assay was determined to be 2.9% at 54.8 mg/dL.

CRMLN certification is not yet available in the United States for triglyceride assays. The Piccolo TRIG assay was compared to the Bayer TRIG method, as performed by a CRMLN laboratory using reference standards provided by the CDC. The performance characteristics were: correlation coefficient (R^2) was 0.998, slope of 0.983, and intercept of 8.2 mg/dL. Total ($n=160$) imprecision for the Piccolo TRIG Assay was determined to be 2.6% at a concentration of 206.8 mg/dL, and 1.5% at 163.7 mg/dL.

These data confirm the accuracy of the Piccolo Lipid Panel.

Conclusions

- We found the ABAXIS Piccolo to be accurate and precise, even when used by individuals with no prior laboratory experience.
- The vast majority (94%) of non-laboratorian participants found the Piccolo to be easy to operate.
- Precision and accuracy of results obtained by the untrained operators was similar to those that might be expected in a clinical laboratory with testing performed by technologists experienced in laboratory testing.
- Increased awareness by individuals of health-related issues such as lipoprotein status, and the need for periodic assessment of these risk factors, makes it essential that methods for important biochemical constituents be readily available.
- The Piccolo lipid methods have been shown to be easy to use, rapid, accurate and precise, even when testing is performed by non-laboratorians. These attributes should help allow testing to be performed in other settings and enable greater access of individuals to lipoprotein testing.

Note: On July 9th, 2004, the FDA granted "CLIA Waiver" to the Piccolo Lipid Panel. The data contained in this poster were included in the petition for waived status.