SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k120662

B. Purpose for Submission:

Addition of capillary whole blood as a sample matrix to a previously cleared device (k023640)

C. Measurand:

HDL cholesterol in capillary heparinized whole blood

D. Type of Test:

Quantitative enzymatic colorimetric end point test

E. Applicant:

Abaxis Inc.

F. Proprietary and Established Names:

Piccolo® HDL Capillary Test System

G. Regulatory Information:

- Regulation section:

  21 CFR 862.1475; Lipoprotein test system

2. Classification:

   Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(9)

3. Product code:

   JHM, HDL Lipoprotein test system

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Piccolo HDL Test System used with the Piccolo xpress Chemistry Analyzer is intended for the *in vitro* quantitative determination of HDL in capillary (fingerstick) heparinized whole blood in a clinical laboratory setting or point-of-care location.

   Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   The Piccolo xpress Chemistry Analyzer

I. Device Description:

The Piccolo@ Lipid Panel Reagent Disc (which contains the Piccolo@ HDL Test System) is designed to separate a heparinized whole blood sample into plasma and blood cells. The disc meters the required quantity of plasma and diluent, mixes the plasma with diluent, and delivers the mixture to the reaction cuvettes along the disc perimeter. The diluted plasma mixes with the reagent beads, initiating the chemical reactions that are then monitored by the Piccolo xpress Chemistry Analyzer.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   The Piccolo HDL Test System for whole blood, serum and plasma
   Cobas HDL-Cholestrol Plus 3rd generation

2. Predicate 510(k) number(s):

   k033610

3. Comparison with predicate:

Similarities and Differences		
Characteristics	**Proposed k120662** The Piccolo HDL Test System	**Predicate k033610** Cobas HDL-Cholestrol Plus 3rd generation
Intended Use	Quantitative analysis of HDL	Same
Methodology	Quantitative enzymatic colorimetric end point test, making use of dextran/sulfate precipitation, centrifugation, and PEG-modified enzymes.	Same
Sample Type	Lithium heparinized whole blood, serum and plasma	Lithium heparinized and K-EDTA plasma and serum
Measuring Range	15 -100 mg/dL	3 -120 mg/dL
Reagent Form	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer	Liquid
Same size	100 ul	2.5 ul
Calibration	Bar code with factory Calibrated lot specific data	Calibrated periodically using calibrators supplied by vendor

K. Standard/Guidance Document Referenced:

1. CLSI. Method comparison and bias estimation using patient samples; approved guideline, 2nd ed. CLSI Document EP9-A2-IR. Wayne, PA: 2010.
2. CLSI. Procedures and devices for the collection of diagnostic capillary blood specimens; approved guideline, 61th ed. CLSI Document H04-A6. Wayne, PA: 2008.

L. Test Principle:

The Piccolo HDL – Capillary Test System (which contains the Piccolo HDL Test System) is designed to separate a heparinized whole blood sample into plasma and blood cells without operator intervention when run on the Abaxis analyzer. The disc meters the required quantity of plasma and diluent, mixes the plasma with diluent, and delivers the mixture to the reaction cuvettes along the disc perimeter. The diluted plasma mixes with the reagent beads, initiating the chemical reactions that are then monitored by the analyzer.

The Abaxis HDL assay is a precipitation method that utilizes polyethylene glycol-modified cholesterol esterase (PEG-CE) and cholesterol oxidase (PEG-CO) for additional specificity. Minute quantities of reagents are formed into lyophilized microspheres and placed in reaction cuvettes along the periphery of the reagent disc. Microspheres are made using proprietary technology developed by Abaxis.

M. Performance Characteristics:

1. Analytical performance

a. Precision and Reproducibility

Serum and plasma precision has been established in the original submission for k023640. Additional whole blood precision studies were performed by running 5 patient samples seven times each across 4 Piccolo analyzers over a period of 3 hours, as shown in the table below:

	HDL				
Sample	**#1**	**#2**	**#3**	**#4**	**#5**
Average, mg/dL	53.1	73.9	55.8	41.0	52.6
SD	1.5	1.3	1.8	1.6	1.5
%CV	2.8	1.7	3.3	3.8	2.9
n	28	28	28	28	28

The precision results were found to be equivalent to the performance using serum samples.

Accuracy of the Piccolo method for HDL was established by completing the certification process of the CRMLN.

b. Linearity

Previously established in k023640

c. Traceability and Expected values for controls, calibrators, or methods

Previously established in k023640

d. Detection Limit

Previously established in k023640

e. Analytical specificity:

An interference study was performed for endogenous interferents: hemoglobin, bilirubin and triglyceride and it was found that capillary blood determinations for HDL are slightly more sensitive to lipemia than previously determined as shown in the table below:

Hemolysis (Hemoglobin, mg/dL)	**Icterus** (Bilirubin, mg/dL)	**Lipemia** (Triglycerides, mg/dL)
400	20	360

Please see original submission for k023640 for the interference by exogenous substances

f. Assay cut-off

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison study was conducted at three point-of-care sites as per CLSI EP9-A2. A total of 559 capillary whole blood samples were tested both on the Piccolo HDL Test using the Piccolo xpress Analyzer and on the predicate device, the Roche HDL Test using a Roche Cobas 6000 analyzer. The results are shown in the tables below:

Site 1

Parameters (Roche on X Axis)	**Linear Regression**	**Deming Regression**
N	187	187
Slope (95% CI)	0.98 (0.96 to 1.01)	1.00 (0.97 to 1.03)
Intercept (95% CI)	-0.3 (-1.5 to 1.0)	-1.0 (-2.3 to 0.3)
Correlation Coefficient (R^2)	0.970	0.970
Std. Error of the Estimate (SEE)	2.6	2.6

Site 2

Parameters (Roche on X Axis)	**Linear Regression**	**Deming Regression**
N	182	182
Slope (95% CI)	1.00 (0.97 to 1.03)	1.02 (0.99 to 1.05)

Intercept (95% CI)	-2.6 (-4.0 to -1.2)	-3.5 (-5.1 to -1.9)
Correlation Coefficient (R^2)	0.966	0.966
Std. Error of the Estimate (SEE)	2.4	2.4

Site 3

Parameters (Roche on X Axis)	**Linear Regression**	**Deming Regression**
N	190	190
Slope (95% CI)	0.99 (0.97 to 1.02)	1.02 (0.99 to 1.05)
Intercept (95% CI)	-2.4 (-4.0 to -0.8)	-3.5 (-5.0 to -2.0)
Correlation Coefficient (R^2)	0.958	0.958
Std. Error of the Estimate (SEE)	2.9	2.9

All sites combined:

Parameters (Roche on X Axis)	**Linear Regression**	**Deming Regression**
N	559	559
Slope (95% CI)	0.99 (0.97 to 1.01)	1.01 (0.99 to 1.03)
Intercept	-1.6 (-2.4 to -0.8)	-2.6 (-3.4 to -1.7)
Correlation Coefficient (R^2)	0.962	0.962
Std. Error of the Estimate (SEE)	2.7	2.7

b. Matrix comparison:

This submission is for capillary whole blood from finger stick.

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Consensus-based cutpoints for the HDL have been established by the National Cholesterol Education Program (ATP III report) as follows:

Desirable	>= 60 mg/dL
CVD Risk Factor	<40 mg/dL

National Cholesterol Education Program Expert Panel. Third report of National Cholesterol Education Program (NCEP) Expert Panel and Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (ATP III). NIH Publication. Bethesda, MD: National Heart, Lung and Blood Institute. 2002

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete to supports a substantial equivalence decision.