510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k120664

B. Purpose for Submission:

Modification of a previously cleared device (k023639) to add a new matrix (capillary whole blood)

C. Measurand:

Triglycerides

D. Type of Test:

Quantitative, Colorimetric

E. Applicant:

Abaxis Inc.

F. Proprietary and Established Names:

Piccolo Triglycerides – Capillary Test System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JGY	Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(4)	21 CFR 862.1705 Triglyceride test system	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

Please see indication use below.

2. Indication(s) for use:

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

   Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism, or various endocrine disorders.

3. Special conditions for use statement(s):

   For prescription use

4. Special instrument requirements:

   Piccolo xpress Chemistry Analyzer

I. Device Description:

The Piccolo Triglycerides – Capillary Test System is composed of an 8 cm diameter single-use device constructed from three ultrasonically welded injection molded parts. The base and middle layers are formed of polymethylmethacrylate plastic and create the chambers, cuvettes, and passageways for processing the whole blood and mixing the resulting heparinized plasma with diluent and reagents. The top layer, referred to as the bar code ring, is molded from ABS (acrylonitrile, butadiene, and styrene) plastic. The bar code ring is imprinted with a bar code containing disc-specific calibration information and also functions to trap small blood spills, preventing contamination of the analyzer, and to protect the disc optical surfaces from fingerprints.

In the center of the disc there is a molded high-density polyethylene plastic container holding approximately 480 µL of diluent. The diluent container is sealed with polyethylene-laminated foil. Spherical lyophilized reagent beads are placed in the cuvettes during disc manufacture. Cuvettes are made in five different depths. As part of the optical system, the specific depth, or pathlength, is chosen to compliment the reagent sensitivity and analyte concentrations of each test.

The test is performed by means of an enzymatic reaction that leads to a change in color. The measurement of the intensity of the color is directly proportional to the concentration of triglycerides in the sample.

Upon completion of the analysis, the disc, containing the diluted heparinized plasma and blood cells, may be placed back into its foil pouch and is disposed of in a biohazard container.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Cobas Triglycerides Test

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

k893973

3. Comparison with predicate:

	Piccolo Triglycerides – Capillary Test on Abaxis Chemistry Analyzer (Candidate Device – k120664)	**Roche Triglycerides Test on the Cobas 6000 Analyzer (Predicate – k893973)**
Intended Use	Quantitative analysis of Triglycerides	Same
Methodology	Enzymatic endpoint reaction	Same
Sample Type	Lithium heparinized capillary whole blood,	Lithium heparin and potassium EDTA plasma and serum
Dynamic Range Lower Limit	20 mg/dL	8.85 mg/dL
Reagents	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer	Liquid reagent
Temperature of Reaction	37°C	Same
Calibration	Bar code with factory calibrated lot specific data	Calibrated periodically using calibrators supplied by vendor
Assay Range	20–500 mg/dL	8.85–885 mg/dL
Testing Environment	Professional use	Same
Sample Size	Approx 100 µL	2 µL

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP09-A2- IR Method of comparison and bias estimation using patient samples 07/2010

CLSI H04-A6 – Procedures and devices for the collection of diagnostic capillary blood specimens 09/2008

L. Test Principle:

The Piccolo Triglycerides – Capillary Test System will initially be contained on the Lipid Panel – Capillary Reagent Disc. The disc is designed to separate a heparinized whole blood sample into plasma and blood cells when run on the Abaxis analyzer. This is achieved automatically within the analyzer without operator intervention. 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 acceptable sample that may be run on the Piccolo Lipid Panel – Capillary Reagent Disc is heparinized whole blood from capillary (fingerstick) collection.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Point of care precision was previously established in k023639.

Additional precision studies were performed using 5 whole blood samples over a 3-hour time frame using at least 4 different analyzers for each of 7 time points. A total of 20 analyzers were used. The table below summarizes the data.

Summary of Whole Blood Precision

Sample 1	mg/dL
Average	210.3
sd	1.9
%CV	0.9
Sample 2	mg/dL
Average	78.3
sd	2.4
%CV	3.1
Sample 3	mg/dL
Average	232.1
sd	2.4
%CV	1.0

Average	82.7
sd	2.3
%CV	2.8
Sample 5	mg/dL
Average	219.0
sd	1.9
%CV	0.8

b. Linearity/assay reportable range:

Previously established in k023639

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Previously established in k023639

d. Detection limit:

Previously established in k023639

e. Analytical specificity:

Previously established in k023639

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Roche Triglycerides Test (k893973) was used as the predicate method, using recommended applications and procedures on a Roche Cobas 6000 analyzer. Five hundred eighty eight capillary (fingerstick) samples were assayed in parallel by both the test and predicate methods and the results compared by Deming regression. The studies were performed at three point-of-care sites. The range tested was 36 to 496 mg/dL which spans the assay range of 20- 500 mg/dL. No samples were altered (spiked or diluted). Data for each site and combined data are shown below:

Site 1:

Parameters	Statistics
Piccolo Triglycerides – Capillary: Singlicate Values, N	201
Roche Triglycerides Assay: Average of Duplicates, N	201
Piccolo Triglycerides – Capillary: Mean	170.5
Roche Triglycerides Assay: Mean	173.7
Piccolo Triglycerides – Capillary: Std. Dev.	97.5

Roche Triglycerides Assay: Std. Dev	100.2
Piccolo Triglycerides – Capillary: Range of Samples	42 - 496
Roche Triglycerides Assay: Range of Samples	39.0 – 528.0

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	201	201
Slope (95% CI)	0.97 (0.96 to 0.98)	0.97 (0.96 to 0.99)
Intercept (95% CI)	1.8 (0.0 to 3.6)	1.5 (-0.7 to 3.6)
Correlation Coefficient (R^2)	0.996	0.996
Std. Error of the Estimate (SEE)	6.4	6.4

Calculated Recovery of the Abaxis Triglycerides – Capillary Assay

	Predicate Device Concentration mg/dL	Calculated Piccolo Recovery from Linear Regression Data Above mg/dL	Bias mg/dL	% Bias
Piccolo Triglycerides - Capillary	150	147.3	-2.7	-1.8%
	200	195.8	-4.2	-2.1%

Site 2:

Parameters	Statistics
Piccolo Triglycerides – Capillary: Singlicate Values, N	191
Roche Triglycerides Assay: Average of Duplicates, N	191
Piccolo Triglycerides – Capillary: Mean	156.4
Roche Triglycerides Assay: Mean	158.2
Piccolo Triglycerides – Capillary: Std. Dev.	90.6
Roche Triglycerides Assay: Std. Dev	94.6
Piccolo Triglycerides – Capillary: Range of Samples	44 - 479

Roche Triglycerides Assay: Range of Samples	41.0 – 498.5

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	191	191
Slope (95% CI)	0.95 (0.94 to 0.97)	0.96 (0.94 to 0.97)
Intercept (95% CI)	5.3 (3.2 to 7.3)	4.8 (2.4 to 7.2)
Correlation Coefficient (R^2)	0.994	0.994
Std. Error of the Estimate (SEE)	7.4	7.4

Calculated Recovery of the Abaxis Triglycerides – Capillary Assay

	Predicate Device Concentration mg/dL	Calculated Piccolo Recovery from Linear Regression Data Above mg/dL	Bias mg/dL	% Bias
Piccolo Triglycerides - Capillary	150	147.8	-2.2	-1.5%
	200	195.3	-4.7	-2.4%

Site 3:

Parameters	Statistics
Piccolo Triglycerides – Capillary: Singlicate Values, N	196
Roche Triglycerides Assay: Average of Duplicates, N	196
Piccolo Triglycerides – Capillary: Mean	139
Roche Triglycerides Assay: Mean	140.2
Piccolo Triglycerides – Capillary: Std. Dev.	72.3
Roche Triglycerides Assay: Std. Dev	75.3
Piccolo Triglycerides – Capillary: Range of Samples	36 - 437
Roche Triglycerides Assay: Range of Samples	33.5 – 447.5

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	196	196
Slope (95% CI)	0.95 (0.93 to 0.97)	0.96 (0.94 to 0.98)
Intercept (95% CI)	5.6 (2.8 to 8.4)	4.5 (1.9 to 7.1)
Correlation Coefficient (R^2)	0.982	0.982
Std. Error of the Estimate (SEE)	9.4	9.4

Calculated Recovery of the Abaxis Triglycerides – Capillary Assay

	Predicate Device Concentration mg/dL	Calculated Piccolo Recovery from Linear Regression Data Above mg/dL	Bias mg/dL	% Bias
Piccolo Triglycerides - Capillary	150	148.1	-1.9	-1.3%
	200	195.6	-4.4	-2.2%

Standard linear regression analysis was used for estimation of the slope, intercept, and correlation coefficient of the combined data in accordance with CLSI EP9-A2. Deming regression analysis was also performed as shown below.

Combined data:

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	588	588
Slope (95% CI)	0.96 (0.95 to 0.97)	0.96 (0.96 to 0.97)
Intercept (95% CI)	4.1 (2.8 – 5.4)	3.5 (2.1 to 4.9)
Correlation Coefficient (R^2)	0.992	0.992
Std. Error of the Estimate (SEE)	7.9	7.9

b. Matrix comparison:

This submission is for capillary whole blood from finger stick. Matrix comparison previously established in k023639.

3. Clinical studies:

   a. Clinical Sensitivity:

   Not applicable

   b. Clinical specificity:

   Not applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

   Not applicable

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

Normal	< 150 mg/dL (< 1.70 mmol/L)
Borderline High	150-199 mg/dL (5.17-6.18 mmol/L)
High	200-499 mg/dL (2.26-5.64 mmol/L)
Very High	> 500 mg/dL (> 5.65 mmol/L)

   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 and supports a substantial equivalence decision.