CLIA Waiver by Application Approval Determination

Decision Summary

A. Document Number

CW200007

B. Parent Document Number

k200865

C. CLIA Waiver Type:

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

D. Applicant

Abaxis, Inc.

E. Proprietary and Established Names

Piccolo® Potassium Test System

F. Measurand (analyte)

Potassium

G. Sample Type(s)

Lithium heparinized venous whole blood

H. Type of Test

Quantitative, enzymatic colorimetric assay

I. Test System Description

The Piccolo® Potassium Test System consists of the Piccolo Xpress® chemistry analyzer and single-use disposable reagent discs designed to separate a lithium 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 lyophilized microsphere reagent beads contained in the cuvettes, initiating the chemical reactions that are then monitored by the analyzer. The Piccolo® Potassium Test System dry reagent contains pyruvate kinase

(0.01 U), lactate dehydrogenase (0.27 U), adenosine diphosphate (36 µg), phosphoenolpyruvate (57 µg) and nicotinamide adenine dinucleotide (48 µg).

All performance studies for the Potassium® Test System in this submission were conducted on the Piccolo Xpress® Chemistry Analyzer using the Piccolo® Comprehensive Metabolic Panel (CMP) disc. The potassium test included in the Piccolo® CMP disc is representative for the potassium assay found in the currently marketed CLIA waived Piccolo reagent discs that include the potassium assay: Piccolo® Comprehensive Metabolic Panel, Piccolo® Basic Metabolic Panel, Piccolo® Electrolyte Panel, Piccolo® Renal Function Panel, and Piccolo® MetLyte 8 Panel.

This device was previously cleared (K992140) and CLIA waived (K992140/A002) for use with lithium heparinized venous whole blood samples. The current submission is for a modification to the calibration of the Piccolo® Potassium Test run on the Piccolo Xpress® chemistry analyzer. The modification did not impact the simplicity, risk analysis, fail-safe mechanisms, external control material and flex studies that were previously reviewed in K992140/A002.

J. Demonstrating "Insignificant Risk of an Erroneous Result" –Accuracy

1. Clinical Study Design

An abbreviated clinical study was conducted to verify that the performance established in K992140/A002 of the previously waived Piccolo® Potassium Test System in the hands of the intended users (untrained operators) has not changed.

Clinical Study Site
A clinical study was conducted at one representative CLIA waived site in the U.S.

Operators
A total of three operators who were representative of CLIA waived operators (untrained operators) participated in the clinical study. Operators had no laboratory training or prior knowledge of the system operation. The education level ranged from high school to college. The operators performed the testing using the Easy-Start Guide.

Subjects (patients)
A total of one hundred and thirty (130) venous whole blood samples drawn into lithium heparinized tubes were immediately tested for potassium using one lot of the CMP reagent disc on six Piccolo Xpress® chemistry analyzers. Thirteen (13) contrived samples (10%) in the extreme high and low ranges were tested to cover the entire measuring range. After the initial testing, the whole blood was processed to plasma, frozen, and shipped to a central reference laboratory for duplicate testing by the Siemens VISTA integrated system (VISTA ISE) K+ method (k051087).

2. Comparative Method

The comparative method (CM), the Siemens VISTA integrated system (VISTA ISE) K+ method using plasma samples, is traceable to a true reference method of known accuracy. Testing was performed with the Siemens VISTA ISE in duplicate in a moderately/highly complex central reference clinical laboratory by trained laboratory professionals. The average of 2 measurements was used for comparison.

3. Allowable Total Error (ATE) and Limit of Erroneous Results (LER)

The allowable total error (ATE) for Potassium was set to ±0.5 mmol/L.

The limit of erroneous results (LER) for Potassium was set to ±0.7 mmol/L.

4. Data Analysis of the Clinical Study

The following data analyses were performed:

- Percent candidate device results within ATE and LER, along with 95% confidence intervals (CI) were calculated.
- Total error (an interval for the 95% differences between the candidate device results and CM result) was calculated.
- Deming weighted regression analysis was performed. The average of the two CM values was used as the x-axis and the individual candidate device values were used as the y-axis in the regression analysis.
- Biases at the lower and upper limits of the reference interval for venous whole blood were estimated.

Results of ATE and LER analysis are presented below:

	Estimate	95%CI
ATE (± 0.5 mmol/L)	98.5% (128/130) total samples were within ATE	(94.6%; 99.6%)
	98.3% (115/117) native patient samples were within ATE	(94.0%, 99.5%).
LER (±0.7 mmol/L)	0.0% (0/130) total samples were outside of ± 0.7 mmol/L	(0.0%; 2.9%)

95% Total Error, an interval that has 95% of differences between the Piccolo results and the CM results, was from -0.39 mmol/L to 0.40 mmol/L.

Results of regression analysis are presented below:

Sample type	N	Slope (95% CI)	Intercept	R^2
Heparinized venous whole blood	130	0.99 (0.931 to 1.043)	0.13 (-0.095 to 0.35)	0.969

The reference range study data supports the reference interval of 3.6 – 5.1 mmol/L for venous whole blood (see k200865). Bias at X=3.6 was 0.09 mmol/L and bias at X=5.1 was 0.08 mmol/L.

The results support that the performance of the Piccolo® Potassium Test System (contained in the Piccolo® Comprehensive Metabolic Panel) at CLIA waived sites has not changed.

5. Questionnaire Results

The three operators were asked to complete a 6-question questionnaire that polled their opinions of the procedural steps to address ease of use. The multiple-choice responses were presented as a 5-point scale, where rankings ranged from "strongly agree" (5) to "strongly disagree" (1). Results from the questionnaire demonstrated that the Piccolo® Potassium Test on the Piccolo Xpress® Analyzer continues to be simple to use for the operator.

K. Labeling for Waived Devices

The labeling consists of:

1. Package Insert
2. Easy Start Guide
3. Quick Reference Guide

The following elements are appropriately present:

1. The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.
2. The reading level of the Easy-Start Guide and Quick Reference Guide, as determined by the Flesch-Kincaid program within Microsoft Word, has been written at no higher than a 7th grade reading level. Pictures and diagrams have been provided, as appropriate.
3. The Quick Reference Guide, package insert, and Easy-Start Guide identify the test as CLIA waived and contain a statement that a Certificate of Waiver is required to perform the test in a waived setting and contain information on how users can obtain a certificate.

4. The Quick Reference Guide, package insert, and Easy-Start Guide contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1).
5. The Quick Reference Guide provides instructions for conducting quality control procedures.

L. Conclusion:

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.