piccolo xpress®
chemistry analyzer

MODERATE COMPLEXITY COMPLIANCE BINDER

3240 Whipple Road, Union City, CA 94587

INTRODUCTION

Abaxis has developed this binder to assist you with your quality compliance program for the Piccolo system.

This Moderately Complex Compliance Binder was created to serve you and your laboratory as you document patient testing, quality control testing, and fulfill the requirements of CLIA.

The Piccolo Moderate Complexity Compliance Binder describes:

1) The establishment of the intelligent Quality Control (iQC) features of the Piccolo system and the intervals between running external liquid Q.C.

2) Describes the minimal verification procedure you will need to complete to bring the Piccolo system "on-board" into your laboratory, or to add new analytes to your existing Piccolo menus.

If you have any questions about your quality compliance program for the Piccolo, please feel free to contact Abaxis Technical Support at 1-800-822-2947. We suggest, however, that you discuss this first with your Lab Director, Lab Consultant and/or a State CLIA office representative.

Please take a moment to review the contents of this binder.

CHECKLIST: The training checklist serves as the document of training for laboratory personnel. It also serves as an orientation for continued use of the instrument.

PERFORMANCE VERIFICATION: Contains explanation on the minimal requirements for the initial verification of the Piccolo along with accompanying data sheets. Abaxis recommends the director contact the state CLIA office or accrediting agency for additional requirements.

- **INITIAL QC:** Contains explanation on the initial QC of the Piccolo and data sheets.

- **6 MONTH VERIFICATION:** Linearity verification can be performed every 6 months, however due to recent CMS/CLIA changes this may be optional. The lab director should check with the state CLIA office or accrediting agency for requirements.

PROFICIENCY TESTING: Contains important information with regards to performing proficiency testing as required by CLIA. Check with the State CLIA office for the number of required annual events.

DAILY IQC: Daily documentation of the internal process of the instrument is fundamental to reporting accurate patient results. (iQC is performed on every disc that runs on the Piccolo and stored automatically in the analyzer for retrieval).

CONTROLS DATA: Lab director should check with state CLIA office or accrediting agency for additional requirements.

PACKAGE INSERTS: Please place the package insert for controls, verification samples, and reagents from the current lot numbers in this section. Package inserts are generally found in the boxes of controls and verification samples. Reagent package inserts can be obtained from http://www.abaxis.com/medical/piccolo/panels-menu or Abaxis Technical Support at 1-800-822-2947.

QUALITY ASSURANCE:

- **IQCP DOCUMENTS:** These documents are supplied as a courtesy for your laboratory practice. These are for use at the discretion of the lab director or lab consultant.

PATIENT SAMPLE: This log is supplied as a courtesy for your laboratory practice. Good laboratory practice is to have unique patient identifiers for all samples.

NOTES: Area to keep troubleshooting notes, repair reports, etc.

Abaxis Recommendations

The package inserts and the operator's manual have the complete listing of testing requirements and recommendations. ***Always refer to the most updated package insert and operator's manual for complete information.***
Please see http://www.abaxis.com/medical/piccolo/panels-menu

PACKAGE INSERT

Storage and Handling requirements:

- Store reagent discs in their sealed pouches at 2-8 °C (36-46 °F).
- Reagent discs may be used directly from the refrigerator without warming.
- Do not allow discs to remain at room temperature longer than 48 hours prior to use.
- A disc unused after 20 minutes of opening a pouch should be discarded.
- Do not use a reagent disc from a damaged pouch.

Sample Collection and Preparation:

- The minimum required sample size is ~100 microliters of heparinized whole blood or control material.
- Whole blood samples obtained by venipuncture must be homogeneous before transferring sample to reagent disc. Gently invert collection tube prior to sample transfer.
- Whole blood samples should be run immediately or within 60 minutes.
- Use only lithium heparin (green top) evacuated specimen collection tubes.
- Start the test within 10 minutes of transferring sample to the reagent disc.

Adhering to the expiration date of the components of the system:

- Reagent disc may be used until the expiration date indicated on the package.
- The expiration date is also encoded in the bar code on the reagent disc. If an expired disc is used, an error message will occur.
- Note the expiration date of the control material package insert as supplied from the manufacturer.

Limitations to Procedure:

- The only anticoagulant recommended for use is lithium heparin. Do not use sodium heparin.
- Samples with hematocrits in excess of 62-65% packed red cell volume may give inaccurate results. Samples with high hematocrits may be reported as hemolyzed and designated as HEM on the results screen and printout.
- **Any result for a particular test that exceeds the assay range should be analyzed by another approved test method.**
- Physiological interferents (hemolysis, lipemia and icterus) cause changes in the reported concentrations of some analytes.
- The Piccolo suppresses any results that are affected by >10% from interferents-hemolysis, lipemia or icterus. "HEM", "LIP", or "ICT" respectively, is printed on the result card in place of the result.

OPERATORS MANUAL

Perform external quality control whenever directed by the Lab Director or Lab Consultant. Use the CONTROL option to store control results separately from patient results in the analyzer memory.

Results

- The results are stored in memory and printed automatically. Results can be recalled and printed later as needed.
- The test result section is printed in four columns:
  - Chemistry name
  - Analyte concentration
  - Reference range
  - Specified units
- Use the PATIENT option to store patient results separately from control results in the analyzer memory.
- Results outside the reference range are indicated by an asterisk (*) next to analyte concentration.
- Results outside the dynamic range are indicated by the 'less than' symbol (<) next to the value, or a 'greater than' symbol (>) printed next to the value.
- The symbols "~~~" are printed when a result cannot be determined; the value is suppressed.
- HEM, LIP, or ICT is printed in place of the analyte concentration of hemolysis, lipemia, or icterus, respectively, when results have been adversely affected by any of these physical interferences.

Performing function checks and maintenance.

- Clean the air filter on the back of the instrument at least twice a year. More frequent cleaning is required in areas with excessive dust or dirt.
- Each reagent disc contains reagents to detect exposure to extreme conditions. The message "QC OK" is printed when results from these reagents are within expected ranges. Otherwise no results are printed and a 'run cancelled' message is shown.
- Daily documentation of the internal functions (iQC) of the Piccolo® is necessary. THIS CAN BE COMPLETED AFTER UTILIZING ANY REAGENT PANEL.
  - After testing the first patient of the day, recall the results from the Last Disc.
  - Select Print (or transmit to external printer).
  - Select iQC; the iQC report will print to be logged in the "Daily IQC" report section in the Moderate Complexity Compliance Binder.

Facility Name _____

S/N(s) _____

Setup and Training Checklist For **Moderate Complexity** Testing

3240 Whipple Road
Union City, CA 94587
Phone 800.822.2947
PN 100-9031 Rev. F

Introduction to the Training Checklist

This training checklist for moderate complexity testing will document important guidance during the setup and operation of the Piccolo Xpress® chemistry analyzer. This checklist will refer to information and instructions in a number of available reference documents, including the Operator's Manual that is sent to the customer in CD format.

Review each reference listed as you follow the checklist through each of the topics covered including Installing the Piccolo, Disc Handling, Sample Handling, Testing Procedure, Laboratory Certification Process, Key Laboratory Certification Contacts, Running controls, Recording Daily iQC® , Testing Verification Samples, Running a Patient Sample, Interpreting Results, Recalling Results, Recording Daily iQC (After the First Patient Sample of the Day), Transmitting Records, Connecting a Computer/Printer, Maintenance, Proficiency Testing Guidance, Additional Information and Support.

It is required to allow the key operator to fully perform each function to document hands on experience with using the Piccolo Xpress Chemistry Analyzer.

Initial Set-Up

- ❑ Please consult with your Piccolo sales representative or distributor for the materials needed for setup
- ❑ While starting the installation process, it is best to locate the controls and verification samples and document proper storage. It is also time to begin the thaw process if not started by the customer.
- ❑ Label and confirm receipt of all pertinent contents as you begin your training. ***If any objects are missing or damaged, contact Piccolo sales representative or distributor for immediate replacement.***
- ❑ Identify and ensure attendance of the Laboratory Key Operator for the Piccolo; this individual must be in attendance for the entire training procedure. (Technical Support will follow-up with this individual.)

Materials Provided

- ❑ Mini Pipette
- ❑ Disposable tips for the Mini Pipette
- ❑ Piccolo Xpress® Operator's Manual CD
- ❑ Abaxis Driver CD
- ❑ Package Inserts CD
- ❑ Piccolo Xpress® Reference Guide
- ❑ Thermal Paper Roll
- ❑ Belkin Surge Protector
- ❑ Power Supply
- ❑ Power Cord
- ❑ USB A/B Cable
- ❑ Fan Filter
- ❑ Warranty Card

Additional Items – Required but not supplied.

- ❑ Patient Sample
- ❑ Boxes of Chemistry Controls
  Each box contains:
  - Level 1 - 6 Vials x 1.0 mL (All Piccolo Panel Analytes)
  - Level 2 – 6 Vials x 1.0 mL (All Piccolo Panel Analytes)
- ❑ Boxes of Verification Samples
  Each box contains:
  - Sample 1 – 3 Vials x 0.5 mL (All Piccolo Panel Analytes)
  - Sample 2 – 3 Vials x 0.5 mL (All Piccolo Panel Analytes)
  - Sample 3 – 3 Vials x 0.5 mL (All Piccolo Panel Analytes)
- ❑ Boxes of Piccolo Reagent Discs

Facility name: _____

Key Lab Contact: _____

Installing the Piccolo

Reference: Operator's Manual, Section 2.3, pages 2-3, 2-4

- ❑ Plug the Piccolo analyzer into a surge protector designed for use with a computer and set up the analyzer, per the manual instructions. Keep the power connector box away from the back of the unit.

Reference: Operator's Manual Section 2.3, pages 2-3, 2-4

- ❑ Power on the analyzer per the manual instructions.

Reference: Operator's Manual Section 4.6, page 4-15

- ❑ **Record the version of software installed-** _____

Reference: Operator's Manual Section 9.4, Pages 9-3, 9-4(or the Maintenance section of this checklist)

  - o **If version is not current, install the new software according to the instructions.**

- ❑ Record the Piccolo serial number.

  Piccolo Serial Number _____

  (When the screen display reads "analyze", in the home screen press settings icon, press analyzer information icon.)

Reference: Operator's Manual Section 7.6, Page 7-4

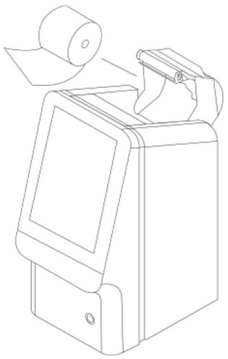
- ❑ Reinitialize the analyzer per the manual instructions.

Reference: Operator's Manual Section 4.7, Pages 4-15, 4-16

- ❑ To change date and time, in the Home screen, press settings icon, press date and time icon (clock). Follow prompts.

Installing the Paper Roll

- ❑ Locate the paper roll compartment situated on top of the Piccolo. Pull the cover up and away from you following the arrow that is marked on top. Place the paper roll into the compartment with the white side facing you and snap down the cover.

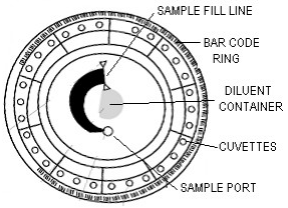


Reference: Operator's Manual Section 2.3, pages 2-3, 2-4

Disc Handling

Reference: Operator's Manual, Sections 2.6 Page, 2-7 to 2-9 and Easy Start Guide

- ❑ Review Disc Structure, Function, Proper Storage and Handling of Discs.
- ❑ After a pouch has been opened, the reagent disc must be used within **20** minutes or discarded.



Sample Handling

Reference: Operator's Manual, Section 3.1, page 3-2, 3-3

- ❑ Review Sample Requirements.
- ❑ Review with Abaxis representative the following helpful tips:
  - How to avoid Hemolysis in the sample.
  - Use plasma in case of suspected high HCT (dehydrated patient where HCT > 60%).
  - Use plasma rather than whole blood in case of suspected grossly lipemic sample. Visually inspect the sample.
  - Review anticoagulant to sample ratio recommendation (sample tubes should be ¾ full for the size of the tube).
  - Reinforce the correct filling of tubes: red, green, blue and then lavender top tubes (in this order).

Testing Procedure

Reference: Operator's Manual, Section 3.2, pages 3-4, 3-5 and Piccolo Easy- Start Guide

- ❑ Review preparing the reagent disc.
- ❑ **Note:** The reagent disc must be used within **20** minutes of opening the foil pouch.
- ❑ **Never** use a reagent disc that has been dropped.

Reference: Operator's Manual, Section 3.3, pages 3-6 to 3-10

- ❑ Review running a patient sample.
- ❑ **Note:** The correct sample type is necessary for results to be interpreted correctly.
- ❑ **Note:** Analysis must begin immediately (no more than 10 minutes) after dispensing the sample into the reagent disc.

Laboratory Certification Process

Verification and Quality Control Sample Handling

- ❑ **ALWAYS** refer to the package inserts of the manufacturer's recommended controls and verification samples for current information on testing with your Piccolo.
- ❑ **Controls and verification samples are to be run as controls**.
- ❑ Thaw controls and verification samples at room temperature for **1 HOUR** before using.

Reference: Moderate Complexity Compliance Binder, Operator's Manual and iQC Tech Brief

- ❑ **Always keep the package inserts of reagent discs, external quality controls and verification samples for each lot number at least two years to capture target range values as a later reference.**
- ❑ Keep these package inserts in a three ring binder.

Key Laboratory Certification Contacts

- ❑ **Commission on Laboratory Accreditation (COLA) 1.800.981.9883**

COLA will assist the POL in the certification and accreditation process.
Please call COLA.

- ❑ Your state or regional CLIA office. See CMS website for listing- **www.cms.gov**.

Running Controls

Reference: Operator's Manual Section 4.15 pages 4-31 to 4-34 and Moderate Complexity Compliance Binder.

- ❑ The verification procedure for accuracy and precision is completed over a period of time to be determined by Lab Director or Lab Consultant's instructions.

- ❑ Remove one level 1 vial and one level 2 vial controls from the freezer **1 hour** in advance of running the test. Store vials away from the light.

  Record Lot # _____

- ❑ Mix the vial GENTLY by using a windshield wiper motion several times, then upright the vial and GENTLY swirl it several times, then tap the top of the vial a few times.

- ❑ Push the pipettor plunger all the way down and place the pipettor in level 1 control solution. Slowly release the plunger; this will draw the control sample up into the pipette tip.

- ❑ Find the arrow below the center of the disc at the 6 o'clock position. It points towards a small hole. This is the sample port.

- ❑ Holding the disc level, place the tip of the pipettor into the sample port at a 45° angle.

- ❑ Push the plunger slowly down so the sample fills the chamber. Sample should meet the two etched arrows at the end of the chamber.

- ❑ Ensure the entire sample is out of the tip.

- ❑ With the plunger still depressed, remove the tip of the sample dispenser from the sample port. Only then release the pressure on the plunger.

- ❑ Remove the used tip from the Pipettor and discard into a biohazardous waste container.

- ❑ Keeping the prepared disc flat, press **ANALYZE** on the touch screen to open the instrument drawer. **The disc does not need to be turned to any particular direction.**

- ❑ Run the control as a "**CONTROL**" from the analyzer touch screen menu.

- ❑ When control run is completed and printed, compare the printout with the product insert values for the control lot number you are using to see if your control results are within the numbers for the analytes.

- ❑ Example: Glucose, expected values for Level I are 59-81 mg/dL. If your result for level 1 reads 65 mg/dL, you are in range and the quality control test for glucose is acceptable.

- ❑ Ensure all control results are within the expected values shown for each analyte in the product insert for the control lot number. Please log and sign the data collection form.

- ❑ If the results are out of the expected value range, open a new vial of controls **(let thaw for 1 hour)** and repeat the control testing for level 1. You can only repeat one time.
- ❑ Place all control print outs in the ***Moderate Complexity Compliance Binder*** for the Piccolo.
- ❑ When you verify that the range values have been met, discard the used controls.
- ❑ Run an unused set of controls every time.
- ❑ Repeat the steps listed above for level 2.
- ❑ While the controls are running, review intelligent Quality Control. (*iQC Tech Brief)*

Reference: Operator's Manual Section 6.2, Pages 6-1 to 6-2, iQC Tech Brief and the Moderate Complexity Compliance Binder.

At the completion of the procedure, submit results to your Lab Director or Lab Consultant for analysis. The Lab Director or Lab Consultant will submit a report of the results for your records.

Recording Daily iQC® (QC of internal functions)

The Piccolo Point-of-Care Chemistry Analyzer incorporates a process called iQC (intelligent Quality Control) that meets established QC standards independently of the operator's skill level. It is a series of automatic checks that verify the chemistry, optics, and electronic functions of the analyzer during each run.

iQC must be recorded daily during the Piccolo chemistry analyzer system validation, and each day during regular patient testing.

The following pages will help you through the process of documenting this important Quality Control feature unique to the Piccolo xpress®.

Reference: Operator's Manual, Section 5.1, pages 5-2 to 5-6, and Moderate Complexity Compliance Binder.

- ❑ After testing, recall the results from the **Last Disc.**
- ❑ Select **Print** (or transmit to external printer).
- ❑ Select iQC; the iQC report will print.
- ❑ Print copy of iQC results – place results on the iQC log sheet.
- ❑ **Print iQC** daily during regular patient testing. (Use iQC log sheets attached for your convenience.)
- ❑ If you have any questions, please contact Abaxis Piccolo Technical Support at 1-800-822-2947.

Verification of Linearity

Reference: Moderate Complexity Compliance Binder

The CLIA Quality System Regulations require the laboratory to validate the manufacturer's performance of accuracy, precision and verify linearity across the reportable range before reporting patient test results. This validation process assures that the instrument is performing in your laboratory as the manufacturer intended.

- ❑ Follow the same handling instructions as with the liquid controls.
- ❑ Remove Verification Vials (Sample 1, Sample 2 and Sample 3) from the freezer ***1 hour in advance of running the test***. Store vials away from the light.

Record Lot # _____

(Use the same lot number of verification samples for the entire verification process.)

- ❑ Run the thawed verification vials on the Piccolo. The total number of verification samples to be run would be decided by either the Laboratory Director or the Laboratory Consultant.
- ❑ Open an unused set of verification samples each day you conduct verification testing.
- ❑ At the end of successful verification testing, provide the results to your laboratory Director or Laboratory Consultant.

Running a Patient Sample

Reference: Operator's Manual, Sections 3.3, Pages 3-6 to 3-10 and Piccolo® Easy-Start Guide.

- ❑ Run a Patient Sample.

Interpreting Results

Reference: Operator's Manual, Section 3.5, Pages 3-12 to 3-16.

- ❑ Review **Piccolo Xpress – Results Interpretation** (see pgs. 15 & 16).
- ❑ Review three **tildes (~ ~ ~)**. Indicates results that cannot be determined. This is known as chemistry suppression.
- ❑ Review the asterisk **(*)**. Indicates the results are outside the reference range.

- ❑ Review < and > signs. Indicates results are out of dynamic range.

- ❑ Review **(!) "Confirm low recoveries".** Indicates that multiple tests are lower than expected. This may indicate fluid distribution issues in the disc causing over dilution or that the sample has been diluted through contamination. Evaluate the sample's integrity repeat or redraw the sample to confirm test results. If the message reoccurs, the sample may be problematic.

- ❑ Review Sample Integrity Alerts.

  HEM indicates Hemolysis (rupturing of red blood cells). If the sample is identified as hemolytic, collect a new sample
  LIP indicates Lipemia (fat in the blood. High lipemia may be due to diet.
  ICT indicates Icterus (bilirubin in the blood)

- ❑ Review sample indicies 0, 1+, 2+, 3+

- ❑ Review any unexpected test result(s). Review whenever test results do not match the patient's symptoms or clinical findings. Any result for a particular test that exceeds the assay range (dynamic range) should be analyzed by another approved testing method or sent to a referral laboratory.

Recalling Results

Reference: Operator's Manual, Section 5, Pages 5-1 to 5-9.

- ❑ Recall and print records.

- ❑ Recall Patient iQC (the first patient of the day).

- ❑ Review viewing or printing error records.

Recording Daily iQC® (After the First Patient of the Day)

Reference: Operator's Manual, Section 5.1, pages 5-2 to 5-6

- ❑ After testing the **first** patient of the day, recall the results from the **Last Disc.**
- ❑ Select **Print** (or transmit to external printer).

- ❑ Select iQC; the iQC report will print to be logged in the daily QC report binder or your Moderate Complexity Compliance Binder.

Transmitting records

Reference: Operator's Manual Section 5.4, Page 5-11, 5.5 & Page 5-9

- ❑ Transmitting patient records to a Personal Computer/Printer

- ❑ Transmitting to Laboratory Information Systems or Electronic Medical Records – Contact Abaxis Technical Support

Reference Operator's Manual Section 5.2, Pages 5-2 to 5-9

- ❑ Transmitting control records

- ❑ Review transmitting error records.

- ❑ Review the **Disc Cancellation and Credit Sheet.**

Connecting a Computer/Printer

Reference Operator's Manual Section 10, Pages 10-1 to 10-10

- ❑ Review connecting an external printer.

- ❑ Review connecting a computer.

- ❑ Review installing the Abaxis Driver.

Maintenance

Reference: Operator's Manual, Sections 9, Pages 9-1to 9-4

- ❑ Review cleaning the analyzer exterior, the air filter.
- ❑ The Piccolo representative demonstrates maintenance techniques at initial setup.

Reference: Operator's Manual Section 9.4, Page 9-3, 9-4

- ❑ Review installing the software CD-ROM and software update program (if not part of the initial set-up described in the beginning of this document).

Note: Periodically, Abaxis will mail a new revision of software (CD-ROM format). It will be necessary to replace the software in the analyzer. It will be important to make this change as soon as practical. Not changing the software may lead to problems in running the reagent discs.

Proficiency Testing Guidance

CLIA guidelines, specifically 42 CFR Part 493, Subpart H of the regulations, outline the requirements for participation in Proficiency Testing (PT).

- ❑ Abaxis recommends the American Proficiency Institute (API) or College of American Pathology (CAP)
- ❑ Your Piccolo sales representative or your distributor will provide you with the contact information to register.

Proficiency Testing Sample Handling

The artificial nature of PT material and behavior differences of analytes as compared to blood means that proper handling of PT material is extremely important.

Analytes in PT materials can be very labile. Since the goal of the proficiency testing process is to assess the accuracy of your laboratory instrumentation, any errors or failures due to deteriorating PT samples should easily be avoided. It is best to follow your surveyors' procedure as early in the process of testing as possible.

- ❑ **The accuracy of results are diminished if testing is delayed until the proficiency due date.** The longer that PT material remains thawed, the greater the likelihood that PT results obtained by a laboratory will be incorrect.
- ❑ Please check the insert of PT materials for optimal procedure and results.
- ❑ It would be best to test a day or so after the sample arrives in the lab.

Proficiency Testing

Reference: Operator's Manual Section 4.15, Pages 4-31to 4-34.

- ❑ Run proficiency-testing samples as ***controls*** e.g.: identify API/ CAP proficiency sample as a control.

- ❑ Contact Piccolo Technical Support if you have any questions about proficiency sample handling procedures or test results at 1-800-822-2947.

Additional Information

- ❑ Piccolo chemistry controls, verification samples and other Piccolo-related materials are ordered through your Piccolo sales representative or distributor.

- ❑ Complete the Warranty Card (Reference Serial Number logged under Installing the Piccolo). Fax or mail the Warranty Card to Abaxis.

- ❑ Complete Setup & Training Completion Sign-off Sheet and fax the completed checklist to Piccolo Customer Service at **1-877-362-0915**.

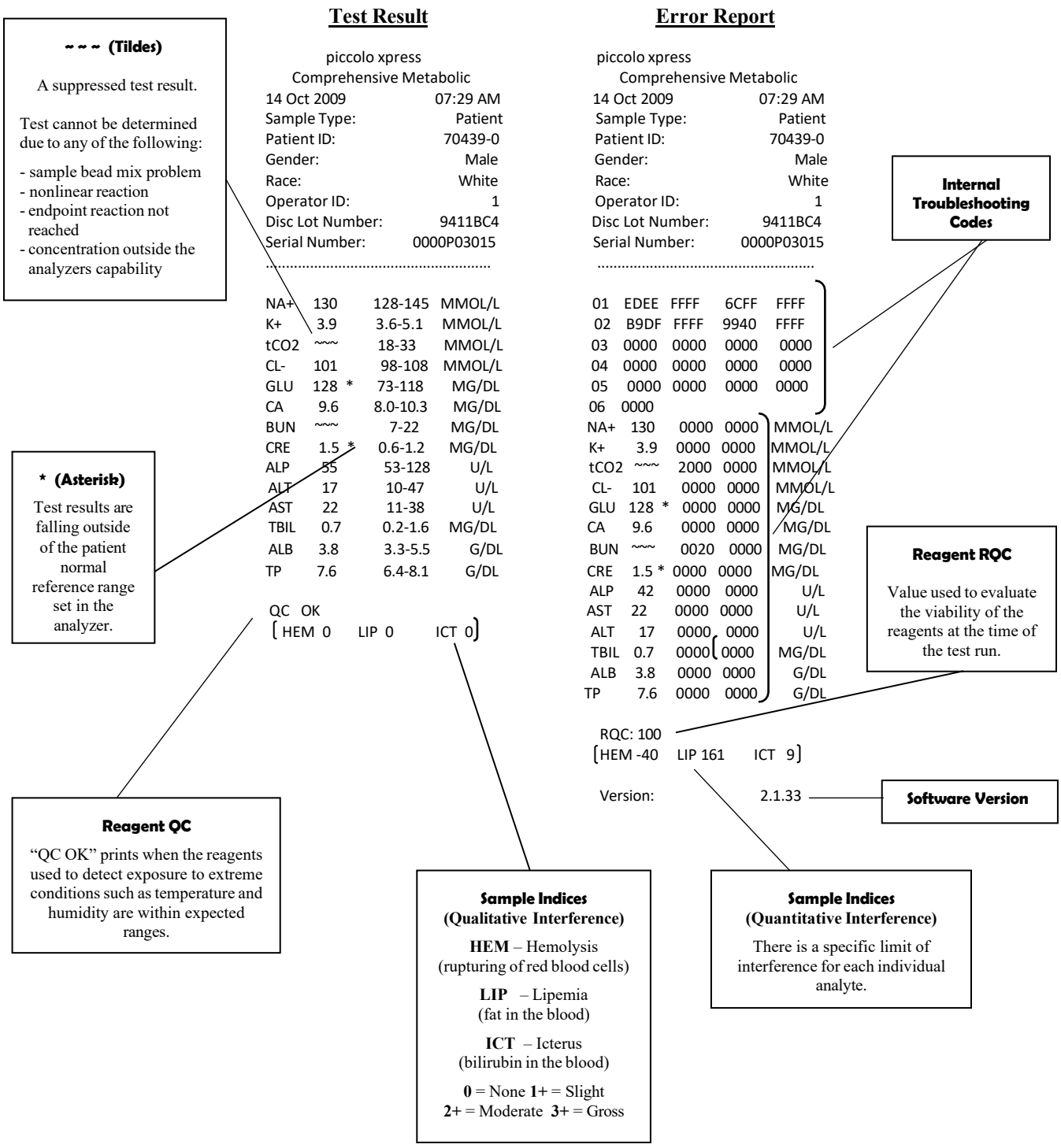
- ❑ Retain completed and signed checklist for confirmation of training.

Support

- ❑ Call Piccolo Technical Support – 1-800-822-2947
  - For questions regarding technical assistance, troubleshooting, and error reports.

Piccolo Xpress - Results Interpretation

Example (A)



Piccolo Xpress - Results Interpretation
Example (B)

Test Result

piccolo xpress
Comprehensive Metabolic
14 Oct 2009 07:29 AM
Sample Type: Patient
Patient ID: 70439-0
Gender: Male
Race: Unknown
Operator ID: 1
Disc Lot Number: 9411BC4
Serial Number: 0000P03015

NA+	~~~	!	128-145	MMOL/L
K+	< 1.5	!	3.6-5.1	MMOL/L
tCO2	11	!	18-33	MMOL/L
CL-	~~~	!	98-108	MMOL/L
GLU	62	!	73 -118	MG/DL
CA	5.6	!	8.0-10.3	MG/DL
BUN	15	!	7-22	MG/DL
CRE	0.7	!	0.6-1.2	MG/DL
eGFR	N/C			ML/MIN
ALP	38	!	53-128	U/L
ALT	18	!	10-47	U/L
AST	20	!	11-38	U/L
TBIL	11	!	18-33	MG/DL
ALB	2.5	!	3.3-5.5	G/DL
TP	3.7	!	3.6-5.1	G/DL

QC OK
HEM 0 LIP 0 ICT 0
! CONFIRM LOW RECOVERIES !

< or >

Test results have exceeded the dynamic range.

eGFR N/C

Estimated Glomerular Filtration Rate (Not Calculated)

This appears when the operator has failed to enter one or more of the following when prompted by the analyzer:

- Age (≥ 18 and ≤ 70)
- Gender
- Race

In addition to the original test result, an error report may print out whenever the eGFR is not calculated.

! Confirm Low Recoveries !

! Indicates that multiple tests are lower than expected. A possible "short or diluted" sample.

Example (C)

Error Report

piccolo xpress
Comprehensive Metabolic
08 Dec 2010 03:27 PM
Sample Type: Patient
Patient ID: 71805 – 0
Disc Lot Number: 0353BA3
Serial Number: 0000P04302

01	B40F	FFFF	6CFF	FFFF
02	B9DF	FFFF	5BAD	B9EF
03	0000	0000	0000	0000
04	0000	0000	0000	0000
05	0000	0000	0000	0000
06	0000			

RQC: 98
HEM ~~~ LIP ~~~ ICT ~~~

Version: 2.1.33
403D Sample Mix Error

4XXX

Disc Cancellation
4 Digit Error Code &
Error Message

Example (D)

Error Report

piccolo xpress
Lipid Panel
14 Jan 2011 01:27 PM
Sample Type: Patient
Patient ID: 33258 - 0
Disc Lot Number: 0353BA3
Serial Number: 0000P04302

01	B40F	FFFF	6CFF	FFFF
02	B9DF	FFFF	5BAD	B9EF
03	0000	0000	0000	0000
04	0000	0000	0000	0000
05	0000	0000	0000	0000
06	0000			

CHOL 225 * 0000 0000 MG/DL
HDL LIP 0400 0000 MG//DL
TRIG 471 * 0000 0000 MG/DL
TC/H ~~~ 0000 0002
LDL LIP 0400 0000 MG/DL
VLDL LIP 0400 0000 MG/DL

RQC: 100
HEM 3 LIP 261 ICT 1

Version 2.1.33

LIP

(Lipemic Interference)

Lipemia has adversely affected the result of this test.

Master Analyte List

Master Analyte List

ABAXIS POINT OF CARE BLOOD LABORATORY SYSTEMS. ANYTIME, ANYWHERE.

CLIA STATUS	Analyte	Symbol	REFERENCE INTERVALS Common units	DYNAMIC RANGES Common units	Usage (abbreviated example)	Panel Found
WAIVED	Alanine Aminotransferase	ALT	10-47 U/L	5-2000U/L	Liver diseases	CMP, LP+, H, 6, 13
WAIVED	Albumin	ALB	3.3- 5.5 g/dL	1-6.5 g/dL	Liver and kidney diseases	CMP, LivP+, R, H, 13
WAIVED	Alkaline Phosphatase- female	ALP	42-141 U/L	5-2400 U/L	Liver, bone, parathyroid, intestinal diseases	CMP, LivP+, H, 13
WAIVED	Alkaline Phosphatase-male	ALP	53-128 U/L	5-2400 U/L	Liver, bone, parathyroid, intestinal diseases	CMP, LivP+, H, 13
WAIVED	Amylase	AMY	14-97 U/L	5-4000 U/L	Pancreatitis	LivP+, 13, B
WAIVED	Aspartate Aminotransferase	AST	11-38 U/L	5-2000 U/L	Liver disease; hepatitis, viral jaundice, shock	LP+, CMP, 6, 13
WAIVED	Calcium	CA	8.0-10.3 mg/dL	4-16.0 mg/dL	Parathyroid, bone, chronic renal diseases	BMP+, CMP, BMP, R, 13
WAIVED	Chloride	CL	98-108 mmol/L	80-135 mmol/L	Dehydration, renal tubular disease	BMP+, BMP, R, E, Met
WAIVED	Cholesterol (TOTAL)	CHOL	SEE CURRENT NCEP GUIDELINES/PI	20-520 mg/dL	Total Cholesterol; risk of CV disease	Lip, LP+
WAIVED	Creatine Kinase- female	CK	30-190 U/L	5-5,000 U/L	MI, progressive muscular dystrophy	Met
WAIVED	Creatine Kinase- male	CK	39-380 U/L	5-5,000 U/L	MI, progressive muscular dystrophy	Met
WAIVED	Creatinine	CRE	0.6- 1.2 mg/dL	0.2- 20 mg/dL	Renal disease	CMP, BMP+, BMP, R, Met, 6, 13, KC
	C-Reactive Protein	CRP	< 7.5 mg/dL	5.0 - 200.0 mg/dL	Inflammation, Infection	ML+ CRP, BMP+
	Direct Bilirubin	DBIL	0 - 0.3 mg/dL	0.1 -15 mg/dL	Liver disorders; hepatitis, gall bladder	H
N/A	Estimated Glomerular Filtration Rate	eGFR	calculated	calculated	Kidney disease	CMP, BMP,13, 6,R,Met,KC, BMP+, ML+ CRP, B, ML12
WAIVED	Gamma Glutamytransferase	GGT	5-65 U/L	5-3000 U/L	Liver disease, alcoholic cirrhosis, liver tumors	LivP+, 6, 13
WAIVED	Glucose	GLU	73-118 mg/dL	10-700 mg/dL	Carbohydrate metabolism, diabetes mellitus	LP+, CMP, BMP+, BMP, R,ML8, 6, 13
WAIVED	High Density Lipoprotein Cholesterol	HDL	SEE CURRENT NCEP GUIDELINES/PI	15-100 mg/dL	High density lipoprotein; transport of cholesterol	Lip, LP+
	Lactate	LAC	0.53-2.10 mmol/L	0.30-9.99 mmol/L	Lactate acidosis, Tissue Hypoxia, Hyperlactatemia	ML12
	Lactate Dehydrogenase*	LD	99-192 U/L	50- 1000 U/L	Liver diseases; viral hepatitis, cirrhosis. Cardiac *small increase seen in serum vs plasma.	BMP+
N/A	Low Density Lipoprotein Cholesterol	LDL	calculated	calculated	Major lipoprotein; contributor to atherosclerosis, CVD	Lip, LP+
	Magnesium	MG	1.6-2.3 mg/dL	0.1- 8.0 mg/dL	Hypormagnesemia and hypermagnesemia	BMP+
N/A	Non High Density Lipoprotein Cholesterol	nHDL	calculated	calculated	Cardiovascular disease	LP+, Lip
WAIVED	Phosphorous - plasma	PHOS	2.2-4.1 mg/dL	0.2-20 mg/dL	Dehydration, diabetes, renal disease	R
WAIVED	Phosphorous- serum	PHOS	2.5-4.1 mg/dL	0.2-20 mg/dL	Dehydration, diabetes, renal disease	R
WAIVED	Potassium	K	3.6- 5.1 mmol/L	1.5-8.5 mmol/L	Renal glomerular or tubular disease	CMP, BMP+, BMP, ML12 R, E, Met , ML+ CRP
WAIVED	Sodium	NA	128-145 mmol/L	110-170 mmol/L	Dehydration, diabetes insipidus	CMP, BMP+, BMP, R, E, Met
WAIVED	Total Bilirubin	TBIL	0.2-1.6 mg/dL	0.1-30 mg/dL	Liver disorders, hepatitis, jaundice, gall bladder	CMP, LivP+, H, 13
WAIVED	Total Carbon Dioxide	tCO2	18-33 mmol/L	5-40 mmol/L	Metabolic or respiratory alkalosis & acidosis	CMP, BMP+, BMP, R, E, Met
N/A	Total Cholesterol/HDL ratio	TC/H	calculated	calculated	Ratio predictive of CVD	Lip, LP+
WAIVED	Total Protein	TP	6.4- 8.1 g/dL	2-14 g/dL	Liver, kidney, bone marrow, metabolic disorders	CMP, LivP+, H, 13
WAIVED	Triglycerides	TRIG	SEE CURRENT NCEP GUIDELINES/PI	20-500 mg/dL	Body's major fuel; Risk of Cardiovascular Disease	Lip, LP+
WAIVED	Urea Nitrogen	BUN	7-22 mg/dL	2-180 mg/dL	Renal & Metabolic diseases	CMP, BMP+, BMP, R, Met, 6, 13, KC
WAIVED	Uric Acid- female	UA	2.2- 6.6 mg/dL	1-15 mg/dL	Renal & Metabolic diseases; renal failure, gout	13
WAIVED	Uric Acid- male	UA	3.6- 8.0 mg/dL	1-15 mg/dL	Renal & Metabolic diseases; renal failure, gout	13
N/A	Very Low Density Lipoprotein Cholesterol	VLDL	calculated	calculated	Very Low Density Lipoproteins. Risk of Cardio Vascular Disease	Lip, LP+

KEY:

LP+- Lipid Panel Plus CLIA WAIVED
Lip- Lipid Panel CLIA WAIVED
CMP- Comprehensive Metabolic Panel CLIA WAIVED
BMP- Basic Metabolic Panel CLIA WAIVED
KC-Kidney Check CLIA WAIVED

BMP+- Basic Metabolic Panel Plus
LivP+- Liver Panel Plus CLIA WAIVED
R- Renal Function Panel CLIA WAIVED
H- Hepatic Panel
ML12-MetLac 12 Panel
B-Biochemistry Panel Plus

E- Electrolyte Panel CLIA WAIVED
Met- Metlyte 8 Panel CLIA WAIVED
6- General Chemistry 6 CLIA WAIVED
13- General Chemistry 13 CLIA WAIVED
ML+ CRP-Metlyte Plus CRP

ABAXIS. Inc. 1-800-822-2947 888-8300 Rev. H

piccolo xpress chemistry analyzer

DAILY IQC

DATE: _____	DATE: _____	DATE: _____
(Attach Results Here)	(Attach Results Here)	(Attach Results Here)
DATE: _____	DATE: _____	DATE: _____
(Attach Results Here)	(Attach Results Here)	(Attach Results Here)

Setup and Training Completion Sign-off

(Please complete: fax or mail upon completion of process prior to leaving the facility.)

Trainer: _____ **Clinic Name:** _____

Date: _____ **Address:** _____

Serial # _____ **City:** _____

State: _____

_____ **Zip code:** _____

Key Contact Name: _____

Trainer Signature: _____ **Signature:** _____

(This is the primary person trained- TS contact.)

Phone Number: _____ **Phone number:** _____

Fax: _____

Email: _____

A Certificate of Training will be mailed to the following individuals:

Please PRINT legibly for ease of transcription.

_____ _____

_____ _____

_____ _____

_____ _____

- ❑ Copy this entire completed checklist and the completed Warranty Card; fax or mail the copy to Abaxis Customer Service.

Abaxis, Inc
3240 Whipple Road, Union City, CA 94587
1-877-349-2087 eFax

Disc Cancellation Letter and Credit Sheet for Piccolo®

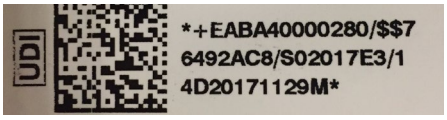
Dear Piccolo Customer,

You may occasionally experience a disc cancellation after using the Piccolo Xpress ® Chemistry Analyzer. To ensure that you receive a reliable test result, the Piccolo is designed with over 100 quality control checks performed on every analysis. If one of the checks does not meet specifications, the disc will cancel.

Cancellations represent a very small percentage of all discs. By tracking all disc cancellations and evaluating the error codes, we are able to provide you with continuous product improvement. Abaxis Technical Support gives credit for cancelled discs, partial results (~~~) or repeated tests when contacted via phone or fax.

If a disc cancels, please follow the procedure below and fax or email the Piccolo Credit Sheet to Abaxis Technical Service to **(877) 349-2087 or tsrmedbox@abaxis.com.**

Per Federal Instructions we are now required to obtain the UDI (48 characters) information from the backside of the disc pouch. Please record this necessary information on the Piccolo Credit Sheet



When a disc cancels, the Piccolo Xpress will display an error code on the screen.

1. **Print the error message using the from the home screen. For more details please reference Section 5 (Recalling Results) and Section 7 (Troubleshooting) of the Operators Manual.**

2. **Fax (877) 349-2087 or email tsrmedbox@abaxis.com the error report, a partial result (~~~) or repeated result and the following information to Technical Service (See page 2) <u>within one week</u> of disc cancellation:**
   - Lot number of Disc
   - Product Name
   - 4 digit error code
   - Sample type (whole blood, plasma, or serum)

Attached is a Piccolo Credit Sheet to help you document the required information on the cancelled disc, partial result (~~~) or repeated result. <u>Please make copies of this form.</u>

To redeem your credits, contact Abaxis Customer Service 800-822-2947, Option 2.

Thank you for your cooperation,

Abaxis Technical Service Department

Piccolo® Credit Sheet

NOTE: Please provide the following information within one week (7 days) of the disc cancellation
Tel# 800-822-2947 Fax# 877-349-2087 Email: tsrmedbox@abaxis.com

Clinic Name and Address:
_____
_____
_____

Sample Type:
[ ] Lithium Heparinized Whole Blood
[ ] Lithium Heparinized Plasma
[ ] Serum (tube type_____)

Sample Information:
[ ] Control [ ] Proficiency Sample [ ] Verification Sample

Description of Problem: _____
_____

UDI#:_____

Affix the Disc Report here.

The following information must be completed.

Message displayed on Piccolo:

Code: _____

Disc Panel Name:
[ ] Basic Metabolic
[ ] Basic Metabolic Plus
[ ] Comprehensive Metabolic
[ ] Electrolyte
[ ] General Chemistry 6
[ ] General Chemistry 13
[ ] Hepatic
[ ] Kidney Check
[ ] Lipid
[ ] Lipid Plus
[ ] Liver
[ ] MetLyte 8
[ ] Renal
[ ] Other _____

Lot #: _____
(Can be found on the disc, the result printout, back of disc pouch, and on the outer box of discs.)

VERIFICATION PROCEDURE

OVERVIEW

The laboratory is responsible for verifying the performance specifications of each non-waived FDA-cleared or approved test system that it introduces, prior to reporting patient test results. The verification of method performance should provide evidence of accuracy, precision and reportable range, as determined by the laboratory director or laboratory consultant. A laboratory may use the manufacturer's performance guidelines, but is responsible for verifying the manufacturer's analytical claims before initiating patient testing.

The laboratory may use the manufacturer's reference ranges provided it is appropriate for the laboratory's patient population. Refer to the specific Panel Package Insert for reference values.

Abaxis has developed an easy-to-use procedure to verify instrument and reagent performance based on testing and analyzing the panels for which you will be reporting results.

The verification procedure is completed over a period of time per Lab Director's or Lab Consultant instructions. The procedure will verify accuracy, precision and reportable range.

At the completion of the procedure, submit results to your Lab Director or Lab Consultant for analysis. The Lab Director or Lab Consultant will submit a report of the results for your records.

Performance verification may be optional and performed every 6 months. The Lab Director or Lab Consultant should contact their State CLIA office or accrediting agency to verify requirements.

If you need assistance contact Technical Service at 1-800-822-2947.

100-7137 Rev. C
DCO# 51140 Eff.: 10/06/17

VERIFICATION PROCEDURE

Running the Verification Samples

Step 1 You will run verification samples on the Piccolo. The total number of sets of verification samples to run would be decided by either the Laboratory Director or the Laboratory Consultant.

Step 2 Locate the box of the manufacturer's recommended verification samples. A package insert is enclosed with the samples. The box contains three separate sets of samples. The samples are labeled for each level and described in the sample package insert

Step 3 Confirm that these samples have been stored and handled as shown in the Package Insert.

Step 4 Bring verification samples to room temperature for approximately 60 minutes.

Step 5 Before testing, gently mix the samples by inverting the vials several times.

Step 6 Before opening the vials, tap the top of each vial gently to ensure that the entire sample is forced to the bottom of the vial.

Step 7 When the samples are fully thawed and mixed, use an Abaxis 0.1cc mini pipette and a clean pipette tip (for each sample) and transfer 100ul of sample to a Piccolo reagent disc and run. Repeat for each sample.

Step 8 Run the Piccolo Verification Samples as "CONTROL" rather than as Patient. If for some reason the results for all analytes on the disc's panel are not reported for that run, simply re-run the sample with a new reagent disc. Do not use the results from the partially reported test run.

Step 9 Following completion of running verification samples or after completion of data collection, properly discard the remaining thawed samples.

Verification Results

Submit results to your Lab Director or Lab Consultant for approval.

6 MONTH VERIFICATION

Verification of linearity may be optional and performed every 6 months. The Lab Director or Lab Consultant should contact their State CLIA office or accrediting agency to verify requirements.

100-7139 Rev. D
DCO# 51140 Eff.: 10/06/17

piccolo xpress chemistry analyzer

DATA COLLECTION FORM VERIFICATION

Piccolo Verif. Study Date _____ /_____ /_____ Instrument serial #_____ Sample ID_____

Day _____

SAMPLE 1

(Attach Results Here)

SAMPLE 2

(Attach Results Here)

SAMPLE 3

(Attach Results Here)

ABAXIS

QUALITY CONTROL

OVERVIEW

intelligent Quality Control (iQC®)

The Piccolo® system includes comprehensive internal quality control features that monitor the Test System, Environment & Operator. These features include monitoring of: instrument performance (electronics and optics), reagent stability, the chemistry reactions, the integrity of the sample, and compliance to the procedural steps. The Piccolo iQC features are in operation with every patient sample. Errors or suppressions are identified by specific codes or messages.

TEST SYSTEM

Test system failures may result from reagent or patient specimen contamination or deterioration, reagent lot variation, reaction temperature fluctuations, inadequate sampling, improper or loss of calibration, electronic or mechanical failure, power supply variances, etc.

ENVIRONMENT

Environmental conditions that may affect test system performance include temperature, airflow, light intensity, humidity, altitude, etc.

OPERATOR

Operator performance that may affect testing includes
improper specimen preparation and handling, incorrect test interpretation, failure to follow the manufacturer's test system instructions, etc. Operator training prior to testing is critical and periodic competency assessment is necessary to ensure continued appropriate test performance.

Detailed information regarding iQC can be found in the Daily iQC tab.

Running the Piccolo Controls

Step 1 You will "run" one set of the Manufacturer's Recommended Controls, at the beginning of each day (once per day) during the entire iQC period; the actual number if iQC days will depend on the decision of the Lab Director or Lab Consultant.

Step 2 **A)** Locate the Manufacturer's Recommended Control materials.
A package insert is generally enclosed with the controls.
B) Confirm the samples have been stored and handled as specified in the package insert.

Step 3 **A)** Bring the controls to room temperature for approximately 60 minutes while protecting the samples from bright lights.
B) Before testing, gently mix the samples by inverting the vial several times.

100-7138 Rev. D
DCO# 51529 Eff.: 02/04/19

C) Before opening the vials, tap the top of each vial gently to ensure that the entire sample is forced to the bottom of the vial.
D) Choose the specific reagent panel which you are testing your patients with for a certain number of days.

Step 4 When the controls are fully thawed and mixed, use an operable Abaxis 0.1 cc minipipette and clean pipette tip (for each control) and transfer 100uL of the level one to a specific Piccolo reagent panel disc and run. * Then add 100 uL of the level two to the same Piccolo reagent panel (new disc) and run. (See Operator's Manual for details). Make sure that a clean pipette tip is used for each control transfer.
*Per CLSI requirements, all controls MUST have the SAME LOT#. Although it is not necessary to use the SAME LOT# of reagent discs, it is preferred that you use discs with the SAME LOT#.

Step 5 Run the controls as "Control" rather than as "Patient" (See the Operator's Manual for details). If for some reason the results for all analytes on the disc's panel are not reported for that run simply re-run the control using a new Piccolo reagent disc. Do not use the results from the partially reported test run. If you need assistance, contact Technical Service at 1-800-822-2947.

You can also refer to the Moderately Complex Checklist for running controls

100-7138 Rev. D
DCO# 51529 Eff.: 02/04/19

piccolo xpress chemistry analyzer

DATA COLLECTION FORM CONTROLS

Piccolo Control Study Date____/_____/_____Instrument serial #_____Control Lot #_____

LOW LEVEL

(Attach Results Here)

HIGH LEVEL

(Attach Results Here)

Controls Tested By: Title _____

Name _____
please print

Signed _____

Controls should be tested:

1. Whenever lab conditions change
2. When training or retraining of personnel
3. When test results do not match patient symptoms
4. With EACH new lot number of reagent discs

ABAXIS

piccolo xpress chemistry analyzer

DATA COLLECTION FORM CONTROLS IQC

Piccolo Control Study Date _____/_____/_____ Instrument serial # _____ Control Lot # _____

LOW LEVEL

(Attach Results Here)

HIGH LEVEL

(Attach Results Here)

Controls Tested By: Title _____

Name _____
please print

Signed _____

ABAXIS

Technical Bulletin

Technical Bulletin for the

piccolo xpress chemistry analyzer

May 1, 2007

ABAXIS TB 07-03

IMPORTANCE OF PROPER HANDLING OF PT SURVEY MATERIALS

Prompt analysis and proper storage of proficiency testing (PT) survey materials are of utmost importance. As a result of the artificial nature of PT materials and the behavior of added analytes, careful attention to storage and usage will ensure more accurate testing results.

Here are some important observations:

Specimens that are analyzed for purposes of Proficiency Testing (PT) differ significantly from blood specimens obtained from actual patients.

- **Sample Matrix**:

Examples of matrix differences include: viscosity of the specimen, the degree to which certain analytes are bound to proteins in the specimen, the color and pH of the specimen.

- **Source and form of analytes present**

For example, many of the enzymes that are present in PT specimens are derived from animal sources such as pigs or cows, while other analytes such as bilirubin are chemically prepared from gallstones, and do not react like true bilirubin. Low concentrations of certain analytes in PT specimens may be achieved by chemical removal of the analyte from the PT material or dilution of the PT material with artificial diluents. High concentrations of some analytes in PT materials are obtained by the addition of exogenous analytes obtained from non-human sources.

- **Stability of the material**

The time that elapses from collection of blood from a patient to analysis with the Piccolo is typically a matter of minutes or hours. In comparison, PT specimens may take weeks to months to prepare, aliquot into individual vials, and ship to customers. Therefore, stability is an important issue for PT materials, and specimens are often modified by the addition of stabilizers to provide a longer shelf life for the material.

The net result of these modifications to PT materials is samples typically do not perform the same way as patient specimens. The complex matrix of PT specimens can produce unique interferences on analyzers that are not normally seen when patient specimens are analyzed. For example, patient specimens that typically show identical results regardless of the type of instrument used to measure the analyte, may show vastly different results when PT material is measured.

NOTE: For this reason, PT material should never be used to assess the comparability of results obtained between different types of analyzers.

Abaxis, Inc.
3240 Whipple Road
Union City, CA 94587
1-800-822-2947

PN 888-3202 Rev. A 5/1/07

Importance of Proficiency Testing Survey Material Handling.

It is important to review the correct storage and usage of your PT Survey sample as soon as it arrives into the Laboratory.

The artificial nature of PT material and behavior differences of analytes as compared to blood means that proper handling of PT material is extremely important.

Analytes in PT materials can be very labile. The longer that PT material remains thawed, the greater the likelihood that PT results obtained by a laboratory will be incorrect.

Since the goal of the proficiency testing process is to access the accuracy of your laboratory instrumentation, any errors or failures due to deteriorating PT samples can easily be avoided. It is best to follow your surveyors' procedure as early in the process of testing as possible.

For example:

PT materials obtained from the **American Proficiency Institute (API),** specify the window of 10 working days from receipt of the survey sample. Although this sample can be refrozen, it is imperative that the sample be processed for analysis as soon as it arrives. Any time the sample is left at temperatures that could compromise the stability, the greater the probability of errors.

During the 10 working days given to complete the PT testing, variables in handling exist with each day. It is likely that some analytes will begin to degrade due to the instability within the PT material. Therefore it would be best to test as soon as the sample arrives in the lab.

PT materials from the **College of American Pathologists (CAP),** often used in the hospital setting, state that their PT material is stable for 7 days following receipt of the survey sample by the laboratory. These samples cannot be refrozen. It should be noted that laboratories are typically given 2-3 weeks to submit their PT testing results to the CAP.

In this case, the probability of accurate results lessens if testing is delayed to the days prior to the due date. Once again it would be best to test as soon as the sample arrives in the lab.

With all the variables that exist with proficiency testing survey samples, prompt analysis and proper storage and handling of PT materials is imperative if laboratories are to achieve success with PT testing.

Abaxis, Inc.
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PN 888-3202 Rev. A 5/1/07

piccolo xpress®
chemistry analyzer

FAST, EASY, ACCURATE ON-SITE CHEMISTRY TESTING

INTELLIGENT QUALITY CONTROL (IQC®) ON THE PICCOLO XPRESS® POINT-OF-CARE CHEMISTRY ANALYZER

The Piccolo Xpress® Point-of-Care Chemistry Analyzer is a lightweight portable instrument that processes whole blood, serum, or plasma samples in self-contained, single-use reagent discs. Along with fully automated processing and onboard data handling, the Piccolo Xpress® incorporates a unique process called iQC ("intelligent Quality Control"). Transparent to the operator, iQC checks the analyzer, the reagent disc, and the sample during each run to verify correct electronic and chemistry performance. iQC automatically suppresses a single chemistry or the entire panel if it detects uncharacteristic performance, and immediately alerts the operator to any problems. From the self-test at power-up to the recording and printing of patient results, the Piccolo Xpress® conducts multiple QC checks automatically with each run. iQC ensures that the operator reports only accurate and reliable results.

Demands for improved patient care and greater cost control are driving profound changes in the structure of health care delivery. Within and outside of traditional hospital environments, evolving technology is permitting some types of diagnostic testing and patient monitoring to move from the clinical laboratory to the near-patient environment. Many health care professionals whose roles have traditionally involved hands-on patient care are now being asked to take a role in clinical chemistry testing as well. Laboratorians, with their training and experience, know that rigorous quality control (QC) is an absolute necessity for accurate test results on which treatment decisions can confidently be based.

The Piccolo Xpress® Point-of-Care Chemistry Analyzer incorporates a process called iQC ("intelligent Quality Control") that meets established QC standards independently of the operator's skill level. iQC is a series of sophisticated automatic checks that verify the chemistry, optics, and electronics functions of the analyzer during each run, and ensures that operators in a wide range of environments report only accurate and reliable results.

ABAXIS

piccolo xpress® chemistry analyzer

HOW IQC® WORKS

In the Piccolo Xpress®, a tiny volume of patient sample is introduced directly into the single-use, self-contained reagent disc, where sample preparation is handled automatically. All reactions, including analyte, reagent, and instrument QC testing, occur in solution within tiny cuvettes on the periphery of the disc. In contrast to most laboratory photometers, which use light of only a single wavelength per measurement, the Piccolo Xpress® generates powerful flashes of full-spectrum white light and measures absorption for each reaction at multiple wavelengths, from ultraviolet to near-infrared. To ensure accurate results, iQC verifies the composition and delivery within the disc of all substances participating in the reactions (chemistry); validates the performance of the light generating and detection components (optics); and audits the conversion of the light absorbance into digital values for use in mathematical algorithms (electronics).

CHEMISTRY AND IQC

Bar code

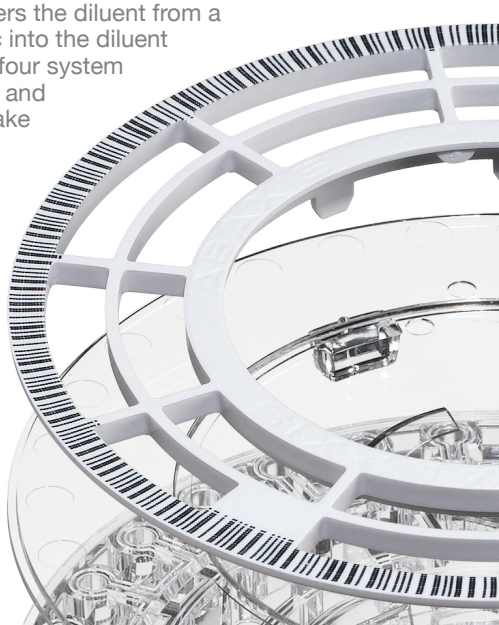
Time-consuming and error-prone reagent calibrations are not required with the Piccolo Xpress® nor is there any chance of using expired reagents. The barcode on the top surface of each disc encodes the type of test panel, the expiration date, and the reagent calibration factors. At the beginning of the run, iQC verifies the integrity of the information in the bar code by the use of a cyclic redundancy check (CRC). It then checks the expiration date of the disc against the analyzer's clock to verify that the expiration date has not been exceeded. The calibration information is transferred into the analyzer's memory to be used in the calculation of results. Disc-specific information is maintained with the system QC data in the analyzer's memory.

Fluidics

The metering and movement of fluids (sample, diluent, and diluted sample) are controlled at all stages of the run by the analyzer's motor and design features of the disc. In several precisely timed cycles, the disc is alternately spun to create centrifugal force, then held still to permit capillary action. These forces synchronize the movement of fluids into and out of the chambers, channels, and cuvettes within the disc as necessary for the correct timing of all reactions. They also control the rate of fluid movement, so that turbulence can be minimized or utilized, as appropriate for a particular function.

At the start of the run, the sample and the diluent are moved along separate but parallel pathways within the disc. The sample (~100 µL of serum, plasma, or whole blood) is drawn by capillary action from the sample port into the application chamber, then through a small channel into the plasma metering chamber. During the first spin cycle, the red cells are separated from whole blood samples and sequestered in a cell trap chamber. The analyzer verifies the presence of adequate sample volume by sensing overflow into the "sufficient-sample" cuvette. iQC will abort the run if the presence of sufficient sample cannot be verified.

Centrifugal force transfers the diluent from a reservoir within the disc into the diluent metering chamber and four system cuvettes where reagent and system iQC reactions take place. (Refer to iQC reactions, below.) The run will also abort if insufficient volume of diluent is detected, or if the reactions indicate reagent degradation.



When spinning stops, capillary forces pull precise quantities of sample and diluent into a mixing chamber. A spin cycle that alternately accelerates and decelerates the disc ensures complete mixing. At the end of this cycle, the aliquot (diluted sample) flows through the exit siphon and along the distribution channel to the reaction cuvettes. The design of the cuvettes permits air to outflow and aliquot to inflow, preventing the formation of air bubbles inside the cuvette and ensuring the correct concentration of the reaction solution. If iQC detects no aliquot in a reservoir beyond the last reaction cuvette, the presence of sufficient aliquot in all reaction cuvettes cannot be verified, and the run will abort. Otherwise, the disc spins alternately clockwise and counterclockwise to dissolve the reagent beads in the diluted sample and start the reactions.

iQC reactions

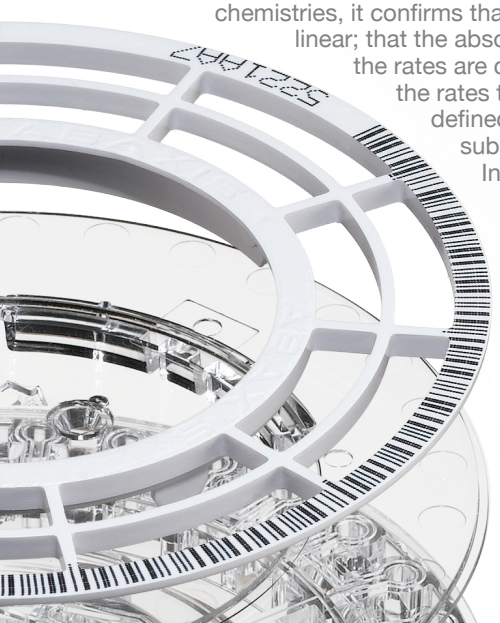
Four system cuvettes are used for reagent and system testing. Chemistry QC reagent beads reveal and quantify any degradation of the analyte-specific reagents in the disc due to suboptimal storage conditions (moisture and temperature). If degradation exceeds a defined level, the run is aborted and an error message is displayed on the analyzer screen. System cuvettes containing a dye are used to verify the accuracy and precision of the instrument. An individual chemistry or the entire panel will be suppressed if any abnormality is detected. System and reagent QC data from each run are stored in the analyzer's memory with the sample results. Standard information storage and retrieval techniques are employed to ensure the integrity of the data. All QC data stored in memory can be called up for review at any time.

Sample evaluation

iQC eliminates the need for visual evaluation of the sample for physical interferents (hemolysis, lipemia, and icterus), a task that may be impossible when dealing with whole blood or a very small sample. The Piccolo Xpress® evaluates the quality of the sample, and reports the measured values for each interferent. Different chemistries within one type of disc may have different sensitivities to physical interferents. If a limit is reached for one or more analytes, results are suppressed for those analytes only; the level of interference is indicated on the Result card. Results for analytes less sensitive to that interferent are reported normally.

Reaction monitoring

iQC monitors the analyte-specific reactions. For rate chemistries, it confirms that the reactions are linear; that the absorbencies from which the rates are calculated, as well as the rates themselves, are within defined ranges; and whether the substrate has been depleted. In endpoint chemistries, the analyzer verifies that all measurements are within the dynamic range of the photometer and that the reaction has reached completion.



OPTICS AND IQC

Controlling and measuring the light

The optical system consists of a xenon arc stroboscopic lamp that generates the incident beam; a family of beam splitters and filters that select defined wavelengths; and photodetectors that convert the light intensity at each wavelength into electric current. The current is routed to one of two microprocessors, which select the signals of interest and send them through variable-gain amplifiers. The amplified signal goes on to the analog-to-digital converter where the light intensity is converted to a digital number that can be used in the calculations.

Because the Piccolo Xpress® measures absorbance at multiple wavelengths, the full spectrum of the reactions can be utilized in the determination of the analyte concentration. For analytes known to be present in a wide range of concentrations in clinical samples, e.g., glucose, chemistries optimized at several different wavelengths can be included on a single disc and results measured simultaneously in the same sample. The ability to measure absorption at several wavelengths gives the Piccolo Xpress® an extremely wide dynamic range.

Signal adjustments

The uniquely designed variable-gain front-end amplifiers define the noise performance of the system and its dynamic range. The dynamic range and the noise performance of the analyzer are optimized through a complex set of measurements that involve both the disc and the electronics.

The brightness of the lamp flash changes very gradually with time and use (declining to 50% intensity after a minimum of 50 million flashes, or 7 years of normal use). These changes are normal and expected, and generally affect all wavelengths more or less equally. However, to retain maximum sensitivity, the analyzer adjusts for those changes. iQC includes a series of flashes through the "minimum-absorbance" cuvette at the beginning of each run that prompts the variable gain amplifiers to adjust for maximum dynamic range (1 to ~64,000). Simultaneously with the adjustment of the gain, the analyzer verifies that the noise associated with the light intensity at any wavelength is within acceptable limits. When changes in the lamp intensity exceed the range of the variable-gain amplifiers for any wavelength, iQC will abort the run and display an error message.

Background noise is ever-present in every system. iQC includes a series of flashes through the "maximum absorbance" cuvette at the beginning of each run to measure the amount of background noise registered by the photometer at each wavelength. Higher than expected background noise at the different wavelengths usually indicates problems associated with the electronics in the analyzer or variable light leaks into the photometer from sources other than the primary light path. These problems can degrade the accuracy and precision of the readings, especially at higher absorbencies. When the level or the noise in the background signal is outside acceptable limits, iQC will abort the run and display an error message. The effect of the inherent flash-to-flash variation in light intensity is eliminated by the use of a reference wavelength. This reference wavelength also minimizes the inherent variability in the disc due to the manufacturing process or introduced by handling (scratches, fingerprints).

ELECTRONICS AND IQC

Microprocessors and memory

The architecture of the instrument consists of two microprocessors: a real-time controller that monitors and controls all the measurements; and an I/O (input/output) controller for memory management, calculations, and data storage. The two processors interact continuously, which allows a very high level of confidence in the workings of the instrument, and consequently in the integrity of the data and in the results. The analyzer stores 5000 results and system QC data.

Software

The analyzer software comprises two matched programs. One program processes the information and controls the measurement engine itself, i.e., it synchronizes the flashing of the lamp with the position of specific cuvettes, and collects the light intensity data for different cuvettes at different times during the run; and it collects all the information generated in the analytical part of the instrument. The second program reports analyte concentrations. It also stores data related to each run (time, date, user ID, patient results, and control data).

Calculations from absorbance data

In normal functioning, each reported absorbance is calculated from a series of 10 flashes through the cuvette. Before being reported, the calculations are verified by a series of rigorous mathematical algorithms programmed into the analyzer software. These algorithms can detect errors in the absorbance data resulting from excess noise in the intensity of the flashes or from abnormalities in the reaction itself, as well as the integrity of the calculations. When such errors are detected, results for a particular analyte, or, in certain cases, for the entire panel, are suppressed. Point-of-care testing is a rapidly evolving area of laboratory diagnostics. iQC on the Piccolo system provides the health care facility with innovative solutions that ensure quality testing while meeting regulatory requirements.

THE PICCOLO® REAGENT DISC IN IQC

The Piccolo reagent disc contains components that are integrated with the optical, electronic, and mechanical functions of the analyzer, and takes part in all phases of the analysis of the sample.

A bar code ring on the top of the disc contains the ID code, lot number, expiration date, and calibration data. The transfer of this data to the analyzer software is verified by a cyclic redundancy check (CRC).

The disc works with the analyzer's optical and electronic components in the calibration of the signals and rigorous checks of system functioning.

Sophisticated fluidics are employed to measure and mix the sample and diluent, and deliver them at precisely the right time to cuvettes located around the disc periphery.

THE CUVETTES HAVE SPECIALIZED FUNCTIONS:

- A minimum-absorbance cuvette is used in signal adjustments that optimize sensitivity
- A maximum-absorbance cuvette is used in quantifying the noise performance of the electronic components to ensure the accuracy of all readings
- 1 cuvette contains reagent beads for chemistry QC
- 2 cuvettes contain dye beads for instrument QC
- 1 "empty" cuvette fills with diluent only, as a control on the system cuvettes
- 21 cuvettes contain test-specific lyophilized reagent beads
- 2 cuvettes verify the presence of sufficient sample and diluent, respectively
- 1 cuvette verifies that diluted sample was delivered to all the reaction cuvettes
- The disc contains miscellaneous reservoirs to isolate excess fluids

Piccolo xpress

Comprehensive Metabolic

12 Jun 2015				03:50 PM
Sample Type:				Patient
Sample ID:				789
Alternate ID:				845
Gender:				Male
Age:				24 Years
Operator ID:				423
Disc Lot Number:				5200D
Serial Number:				0000P02618
Instrument QC:				100
iQC 1:	100	340 nm:		100
iQC 2:	100	405 nm:		100
iQC 3:	100	467 nm:		100
iQC 4:	100	500 nm:		100
iQC 5:	100	515 nm:		100
iQC 6:	100	550 nm:		100
iQC 7:	100	600 nm:		100
iQC 8:	100	630 nm:		100
Range:	90-110			95-105

HOW TO READ THE QC REPORT

Run-specific information is found at the top of the QC Report Instrument QC data are arranged in two columns below the run-specific information. Level 1 iQC 1 through 8 refers to the eight different system checks that the analyzer carries out at the beginning of each run. The allowable values for all components are normalized, with 90% equaling the minimum allowed value and 110% equaling the maximum allowed value. For the run to pass iQC, the values obtained by flashing through the minimum- and maximum-absorbance cuvettes at the beginning of the run must be within these limits for all components.

Level 2 QC data concerns precision. Two system cuvettes contain 1 dye bead and 2 dye beads, respectively. At the beginning of the run, the analyzer calculates the ratio of the absorbances in the 1-bead and the 2-bead cuvettes at all wavelengths. It then averages the ratios and determines the precision of the measurements. The precision is reported to the right of “LEVEL 2.” The values to the right of each specified wavelength indicate the mathematical relationship between the normalized ratio obtained at that wavelength and the average for all wavelengths. For the run to pass iQC, the precision must be between 95 and 105% overall and for each specific wavelength.

The results obtained in the chemistry iQC testing are given at the bottom of the card, along with the minimum acceptable value for this test. Any value above the minimum indicates that the disc was stored correctly and all chemistries in the disc were viable at the time of testing.

HOW TO RECALL AND PRINT THE QC REPORT

System QC data are compiled for each run and stored in the analyzer memory with the run results. For any run that remains in memory, these data can be recalled and a copy of the QC Report can be printed. Refer to the Piccolo Operator’s Manual for instructions on recalling and printing system QC data.

piccolo xpress® chemistry analyzer

SUMMARY OF IQC CHECKS

BAR CODE
- Verifies current dating
- Cyclic redundancy check verifies accurate transfer of the reagent calibration data to the analyzer software

CHEMISTRY
- Confirms the viability of the analyte-specific reagents
- Monitors all reactions in process

FLUIDICS
- Verifies the presence of sufficient sample and diluent
- Verifies the presence of diluted sample in all reagent cuvettes

SAMPLE
- Quantifies physical interferents (hemolysis, lipemia, icterus)
- Suppresses results for any reaction where the limits of sensitivity to an interferent have been exceeded

SIGNAL ADJUSTMENT
- Monitors changes in flash intensity and adjusts for maximum dynamic range
- Monitors the noise associated with the lamp intensity at all wavelengths
- Measures the background noise to detect electrical and other problems
- Uses a reference wavelength to minimize the effect of flash-to-flash intensity variation

SOFTWARE / MEMORY
- The architecture of the two microprocessors optimizes real time performance
- Synchronizes the flashing of the lamp with the position of specific cuvettes
- Detects errors in absorbance data and errors in the calculations

ABAXIS

3240 Whipple Road, Union City, CA 94587 | 1-800-822-2947 | www.piccoloxpress .com

piccolo xpress chemistry analyzer

DAILY IQC

DATE: _____

(Attach Results Here)

DATE: _____

(Attach Results Here)

DATE: _____

(Attach Results Here)

DATE: _____

(Attach Results Here)

DATE: _____

(Attach Results Here)

DATE: _____

(Attach Results Here)

ABAXIS

piccolo xpress chemistry analyzer

DATA COLLECTION FORM CONTROLS

Piccolo Control Study Date____/_____/_____Instrument serial #_____Control Lot #_____

LOW LEVEL

(Attach Results Here)

HIGH LEVEL

(Attach Results Here)

Controls Tested By: Title _____

Name _____
please print

Signed _____

Controls should be tested:

1. Whenever lab conditions change
2. When training or retraining of personnel
3. When test results do not match patient symptoms
4. With EACH new lot number of reagent discs

ABAXIS

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)
PICCOLO XPRESS® CHEMISTRY SYSTEM

The Piccolo Xpress® Chemistry Analyzer has been designed with multiple on-board intelligent quality control (iQC®) features and functions to maintain the overall system integrity and quality of the test results. The iQC system supports the customer by providing solutions to reduce or prevent pre-analytical, analytical, and post- analytical risks of erroneous results. The Piccolo performs both CLIA waived and non-waived tests. This is determined by specific waived or non-waived chemistry test reagent panels available for use with the Piccolo (see: www.piccoloxpress.com/products/panels/menu).

NEW QUALITY CONTROL PROCESS INFORMATION
Effective January 1, 2016, laboratories will have two acceptable QC options for non-waived testing with the Piccolo Xpress Chemistry System:

Option 1. Follow the CLIA regulatory requirements for quality control as written.

Option 2. Implement IQCP as described by CMS found at https://cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

Abaxis Inc., in keeping with the recent changes for quality control frequency adopted by the Centers for Medicare/Medicaid Services (CMS) is providing the following steps and Risk Assessment worksheet to guide your laboratory should you choose to adopt the new "Individualized Quality Control Plan" (IQCP).

DEFINITION
IQCP utilizes a risk based approach to quality control frequency. The laboratory best practice tenants of Quality Control and Quality Assurance monitoring are already familiar processes and should already be practiced in your laboratory. The IQCP is 'individualized' for each laboratory and each non waived test system. This allows the laboratory to consider factors such as environment for example that may be unique to the laboratory or to a particular test system. By adding a documented review or "risk assessment" of the testing process in your laboratory, the final tenant for IQCP will be in place.

DECIDE
Laboratories performing non-waived testing panels with the Abaxis Piccolo Chemistry System have two options:

1. Use the default frequency of quality control as defined by the CLIA regulations. (Note: In this option, liquid quality control must be performed at the frequency defined by the CLIA regulations and not by the manufacturer or lab director).

2. Document an IQCP to demonstrate a different frequency of quality control.

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(Note: The Laboratory Director is responsible for the overall performance and administration of the laboratory. The Laboratory Director is required to review, approve, and sign the IQCP or any Quality Control Plan.)

PROCESS COMPONENTS

The IQCP must incorporate a documented review and assessment by the laboratory of non-waived test systems and processes related to the test system. The laboratory, should it choose to make use of quality control frequency that is different than what is required by CLIA, must provide this documented review to a surveyor. The surveyor will expect the laboratory to have covered assessment and mitigation of associated risks of any non-waived test system. There are five areas of assessment where risk and procedures to mitigate risk must be considered. In addition, review of the test system must be complete for the entire test process, i.e. Pre-Analytical, Analytical, and Post- Analytical.

CLIA/CMS Required Components of IQCP Assessment:

- Test System
- Specimen/Sample
- Testing Personnel
- Environment/Equipment
- Reagent

In addition, each of the categories must encompass an assessment for the entire test process:

- Pre Analytical
- Analytical
- Post Analytical

STEPS TO COMPLETE YOUR IQCP

Should your Laboratory Director elect to adopt an "Individualized Quality Control Plan," the following are key steps to guide the process for gathering documentation to support this decision and your plan. Your information should include regulatory and accreditation requirements for the test system as well as medical requirements (who and how the test will be used), information about how the test is used in your environment (internal to a core lab or external such as a POL or Stat lab) and all information provided by Abaxis Inc. for the Piccolo Xpress Chemistry System. Keep all work such as electronic and liquid quality control comparisons, calibration verification, and other supporting documents. It is recommended you contact Abaxis for technical assistance if your laboratory has not performed and documented a ten day Equivalent Quality Control study (EQC) or manufacturer's recommended validation process using Option 1.

For Abaxis Technical Support assistance call 1-800-822-2947 #2.

STEP 1. GATHER INFORMATION

Gather the information you have available to you on the Piccolo Xpress System. Consider all steps to perform the test in your laboratory environment from beginning to end.

Suggested information includes:

- Training documents and processes

- A prior Electronic Quality Control Study (EQC)
- Ongoing Quality Control documents
- Maintenance records
- Proficiency Testing reports
- Written policies and procedures
- By whom and how the test results will be used (e.g. screening/diagnostic)
- Regulatory / Accreditation requirements
- Piccolo Xpress Moderate Complexity Compliance Binder, Piccolo Xpress Operator's Manual, package inserts, or other literature provided by Abaxis, Inc. and available at "www.piccoloxpress.com."

STEP 2. CATALOG YOUR TESTING PROCESS

Please refer to example provided of Risk Assessment Worksheet that is being provided specifically for the Piccolo Analyzer test system by Abaxis for the CMS required components stated in "Process Components" section previously.

STEP 3: FORMALIZE and DOCUMENT

Using the Risk Assessment Worksheet and working with your Laboratory Director, it is time to formalize and document your plan or "IQCP."

Each laboratory will be different. For example, some laboratories may wish to use more frequent liquid quality control to assess staff in sample handling technique. Other laboratories may choose to implement stricter or more frequent observations for staff performing testing. It is important to consider that many of the solutions may already exist in annual competency assessment, therefore listing this as risk mitigation would be an example of a laboratory solution.

Formalize your plan and have it ready for an inspector. You can provide your laboratory's Risk Assessment Matrix, Other Piccolo Documents, and Actions in preparing an IQCP for your Abaxis Piccolo Chemistry System. Your laboratory IQCP may incorporate more or less information depending on your own environment, policies and procedures.

STEP 4. MONITORING THE PROCESS

Once you have completed your IQCP for the Abaxis Piccolo Chemistry System, the process will need to be monitored for efficacy. Please follow the frequency of review of your IQCP per your laboratory survey organization's requirements and/or your existing policies and procedures.

REFERENCES

1. Piccolo Xpress System Operator's Manual

2. Abaxis Piccolo Xpress Chemistry Analyzer, Moderate Complexity Compliance Binder

3. CLSI EP23A "Laboratory Quality Control Based on Risk Management; Approved Guideline" Volume 31 No. 18, 2012

4. Nichols, James, PhD DABCC "EP23 Laboratory QC Based on Risk Management Update" 2012

5. Nichols, James, PhD DABCC ‘‘Risk Management for Clinical Laboratories,” 2013

6. Yost, Judith A, MA, MT (ASCP), Scott, Keith, MLS (ASCP) CM, “CLIA and EP23 Individualized Quality Control Plan,” CLIA & Centers for Medicare & Medicaid, 2013

7. CLIA Interpretive Guidelines *§493.1226*

8. https://www.cms.gov/regulations-and-guidance/legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

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Example of a "System- Specific Sources of Error" Matrix

Potential Sources of Error	Applicable	Nature of Impact	Training/Lab Procedure Requirements	Applicable Quality Monitoring	Frequency of Monitoring
1 Specimen Collection				Lab to decide all	Lab to decide all
				elements of "A"	elements of "A"
1.1 Contamination					
1.1.1 Alcohol	N	Comment A*	Lab requirement		
1.1.2 Other Cleansing Agent	N	Comment A*	Lab requirement		
1.1.3 Anticoagulants in Lines	N	Comment A*	Lab requirement		
1.1.4 Intravenous Fluids	N	Comment A*	Lab requirement		
1.1.5 Admixture with Other Fluid/Materials	N	Comment A*	Lab requirement		
1.2 Inadequate Sample					
1.2.1 Poor Circulation at Sample Site	N	Comment A*	Lab requirement		
1.2.2 Poor Vascular Access	N	Comment A*	Lab requirement		
1.2.3 Not Enough Collected	N	Comment A*	Lab requirement	Piccolo monitors sample sufficiency	Piccolo monitors every disc
1.2.4 Poor Technique	N	Comment A*	Lab requirement		
1.2.5 Too Much Collected	N	Comment A*	Lab requirement	Excess sample cannot be added	Piccolo monitors every disc
1.3 Hemolysis	Y	Hemolysis is measured and if there is an interference with a method, the results are flagged. Piccolo monitors every disc.		Piccolo monitors every disc	Piccolo monitors every disc
1.4 Incorrect Patient Drawn	N	Comment A*			
1.5 Inappropriate Sample	N	Comment A*			
1.5.1 Arterial vs. Venous vs. Capillary	N	The difference in analyte concentration between arterial and capillary blood is well documented.	Lab requirement		
1.5.2 Whole Blood vs. Plasma	Y	The analyzer accepts both samples.			
1.5.3 Sample in Wrong Container or Syringe/Wrong Additives	N	Comment A*	Lab requirement	The analyzer requires the use of lithium heparin sample collection tubes. If EDTA or sodium heparin is used, those analytes impacted will be flagged	Piccolo monitors every disc
1.5.4 Fasting vs. Nonfasting	N	Comment A*			
1.5.5 Clotted Sample	N	Causes insufficient sample detection that suppresses, flags results and cancels run		Piccolo monitors every disc	Piccolo monitors every disc
1.5.6 Inappropriate Time of Collection	N	Comment A*			
1.6 Patient Condition					
1.6.1 Inappropriate for Testing Method	N	Comment A*			
1.6.2 Oxygen Too Low or Too Unstable	N	Piccolo does not perform blood gas analysis			
1.6.3 Medications Interfere with Method	N	Normal levels of medication do not interfere with the results			
1.6.4 Lipemia	Y	Lipemia is measured and if there is an interference with a method, the results are flagged.		Piccolo monitors every disc	Piccolo monitors every disc
1.6.5 Dilute Urine	N				

* Comment A-satisfactory sample collection, e.g., site cleaning, etc., is the responsibility of the phlebotomist.

1.6.6 Dehydration/ Hemodilution	N	Comment A*			
1.6.7 Shock	N	Comment A*			
1.7 Improper Patient Preparation	N				
2.0 Sample Presentation	Y	Follow CLSI guidelines for sample preparation and handling			
2.1 Incorrect Procedure/ Technique					
2.1.1 Contamination	N	Comment A*			
2.2 Incorrect Sample Presented	N	Comment A*			
2.2.1 Sample Type	N	Comment A*			
2.2.2 Failure to Appropriately Dilute Sample	N	Dilution of sample not required			
2.2.3 Failure to Remove Excess Particulate Matter	N	Instrument automatically centrifuges the sample, spinning off excess matter			
2.2.4 Incorrect Sample Temperature	N	Comment A*			
2.2.5 Improper Handling of Stored Specimen	Y	Follow CLSI guidelines for sample preparation and handling			

* Comment A-satisfactory sample collection, e.g., site cleaning, etc., is the responsibility of the phlebotomist.

Potential Sources of Error	Applicable	Nature of impact	Training/Lab Procedure Requirements	Applicable Quality Monitoring	Frequency of Monitoring
2.3 Long Delay from Collection to Analysis	Y	Elapsed time depends on the method of collection and storage; see product labeling for details.			
2.4 Sample Inadequately Mixed	N	Not required			
2.5 Sample Inadequately Mixed with Reagents	N	Internally monitored		Piccolo monitors every disc	Piccolo monitors every disc
2.6 Inappropriate Amount of Sample					
2.6.1 Insufficient Volume	Y	The analyzer measures the amount of sample. Insufficient sample causes flagging of the results or the run is cancelled.		Piccolo monitors every disc	Piccolo monitors every disc
2.6.2 Excessive Volume	Y	The analyzer measures the amount of sample. Excessive sample results in the flagging of the results or the run is cancelled.		Piccolo monitors every disc	Piccolo monitors every disc
2.7 Introduction of Air Bubbles	Y	If the bubbles reduce the volume of sample below the minimum the run is cancelled.		Piccolo monitors every disc	Piccolo monitors every disc
2.8 Incorrect Patient Identification Entered into Instrument	Y	Manual data every may result in error. A bar code reader can be used for patient identification			
3.0 Instrument/ Reagents					
3.1 Adverse Environmental Conditions					
3.1.1 Temperature	Y	The instrument monitors the temperature and warns the user if it is outside the operating range (no analysis is performed and no results are reported)			
3.1.2 Humidity	N				
3.1.3 Shock/ Vibration	N				
3.1.4 Static Electricity	N				
3.1.5 Radio Frequency Interference/Electromagnetic interference	N	Instrument exceeds requirements for medical equipment			
3.1.6 Light Intensity	N	Optical chamber optically isolated		Piccolo monitors	Piccolo monitors
3.1.7 Barometric Pressure/Altitude	N				
3.1.8 Inadequate Warm- Up Time	N	The instrument will not accept samples until it has reached operating temperature			
3.1.9 Low Power	N	Instrument monitors input power, but operates within a very broad range of voltages			
3.2 Outdated Reagents	N	Discs have bar-coded expiration date. Expired discs will be rejected by the analyzer.		Piccolo monitors every disc	Piccolo monitors every disc
3.3 Improper Reagent Shipment	N	Each disc senses exposure to excessive humidity and/or temperature. If exceeded, results are flagged.		Piccolo monitors every disc	Piccolo monitors every disc
3.4 Improper Reagent Storage	N	Each disc senses exposure to excessive humidity and/or temperature. If exceeded, results are flagged.		Piccolo monitors every disc	Piccolo monitors every disc
3.5 Incorrectly Prepared Reagents	N	Factory packaged, no preparation needed			
3.6 Incorrect Use of Reagents	N	Factory packed, self contained disc			

* Comment A-satisfactory sample collection, e.g., site cleaning, etc., is the responsibility of the phlebotomist.

3.7 Reagent Contamination	N	Factory packaged, sealed discs			
3.8 Deterioration of Reagent lots Over Time	N	Discs have bar-coded expiration date. The analyzer will reject expired discs.		Piccolo monitors every disc	Piccolo monitors every disc
3.9 Lot-to-Lot Variability	N	Reagents are factory calibrated		Piccolo monitors every disc	Piccolo monitors every disc
3.10 Sample Related Reagent Failure					
3.10.1 Interfering Substances	N	Please see package insert		Piccolo monitors every disc	Piccolo monitors every disc
3.10.2 Excessive Analyte Concentrate (hook or prozone effects)	N	If the analyte is outside the system (dynamic) range, results are flagged			
3.10.3 Unusual pH	N				
3.10.4 Unusual Viscosity	N	Flagged			

* Comment A-satisfactory sample collection, e.g., site cleaning, etc., is the responsibility of the phlebotomist.

Potential Sources of Error	Applicable	Nature of impact	Training/Lab Procedure Requirements	Applicable Quality Monitoring	Frequency of Monitoring
3.10.5 Unusual Particulate Load	N				
3.11 Electronic Simulator Malfunction	N	No simulator used			
3.12 Improper Control Shipment	Y	Operator Responsibility Each disposable disc has internal controls.		Piccolo monitors every disc	Piccolo monitors every disc
3.13 Improper Control Storage	Y	Operator Responsibility Each disposable disc has internal controls.		Piccolo monitors every disc	Piccolo monitors every disc
3.14 Inadequate Mixing of Controls	N	Operator Responsibility			
3.15 Improper Calibration	N	Reagents are factory calibrated		Piccolo monitors every disc	Piccolo monitors every disc
3.16 Poor Precision	N	Each disc has internal quality controls		Piccolo monitors every disc	Piccolo monitors every disc
3.17 Poor Accuracy	N	Each disc has internal quality controls		Piccolo monitors every disc	Piccolo monitors every disc
3.17.1 Bias	N	Reagents are factory calibrated		Piccolo monitors every disc	Piccolo monitors every disc
3.17.2 Interference's	Y	See 3.10			
3.18 Incorrect Analysis Mode					
3.18.1 Controls vs. Patient Samples	N	Controls and patient samples are run in exactly the same way			
3.18.2 Incorrect Analyte Selected	N	Disc panel of tests are pre configured			
3.18.3 Incorrectly Programming Parameters	N	Each disc has a barcode with configuration, reagent calibration, lot number and expiration date information			
3.19 Sample Carryover	N	Closed system			
3.20 Instrument Error	N	The instrument performs 100 internal tests before releasing results		Monitored during every disc run	Monitored during every disc run
3.21 Instrument Failure	N	Instrument has extensive internal diagnostics, including a two-processor architecture. Instrument measurement system calibrates itself for every sample analyzed.		Monitored during every disc run	Monitored during every disc run
3.21.1 Software Computation	N	See 3.21			
3.21.2 Drift Between Calibration and Analysis	N	See 3.21			
3.21.3 Loss of Calibration	N	See 3.18.3			
3.21.4 Electronic Instability	N	See 3.1 and 3.21			
3.21.5 Readout Device Error	N	See 3.21			
3.21.6 Loss/ Corruption of Data	N	See 3.21			
3.22 Instrument/ Reagent Performance Not Verified Prior to Use					
3.22.1 Initial Instrument Implementation	Y	Abaxis representative assists laboratory			
3.22.2 Instrument Repair/Maintenance	Y	Minimal maintenance, repairs performed at factory			
3.22.3 Battery Changes	N				
3.22.4 Reagent Lot Changes	N	Each "run" includes calibration & iQC checks			

* Comment A-satisfactory sample collection, e.g., site cleaning, etc., is the responsibility of the phlebotomist.

3.22.5 Routine Use	N				
3.23 Improperly Functioning Instrument Not Removed from Service	Y	In case of an instrument failure, error messages are displayed and the instrument will not accept samples.		Monitored during every disc run	Monitored during every disc run
3.24 Inadequate Instrument Maintenance/ Handling					
3.24.1 Dirty Optics	Y	Instrument monitors integrity of optical system		Monitored during every disc run	Monitered during every disc run
3.24.2 Scratches	N	Optics not accessible to user			
3.24.3 Fogging	N	Measurement chamber is a dry environment			
3.24.4 Instrument Trauma	Y	See 3.21			
3.25 Patient's Personal Equipment Used	N				
3.26 Complicated Procedure	N				
3.27 Incorrect Technique	N				

* Comment A-satisfactory sample collection, e.g., site cleaning, etc., is the responsibility of the phlebotomist.

Potential Sources of Error	Applicable	Nature of impact	Training/Lab Procedure Requirements	Applicable Quality Monitoring	Frequency of Monitoring
4.0 Results/ Readout/ Raw Data					
4.1 Visual Misinterpretation					
4.1.1 Color	N				
4.1.2 Number	N				
4.2 Incorrect Setting for Units of Measure	N	Customer can change from common units to SI units			
4.3 Incorrect Mode Setting	N				
4.3.1 Neonatal vs. Whole Blood v/s Plasma	N	Instrument automatically centrifuges sample. If hematocrit exceeds 62%, instrument will flag results due to hemolysis		Piccolo monitors every disc	Piccolo monitors every disc
4.3.2 Control vs. Patient Sample	N	See 3.18			
4.3.3 Incorrect Programming	N				
4.4 Accidental Loss of Data	N	Instrument stores 70 patient records and 70 control records			
4.5 Calculation Required	N				
5.0 Preliminary Review					
5.1 Improper Interpretation of Control Results	N	Responsibility of Tech reading the card			
5.2 Outlier/ Nonsense Result Not Recognized	N				
5.3 Result Outside of Linear Range Not Recognized		Instrument does not report values outside system (dynamic) range. User is alerted by flags		Piccolo monitors every disc	Piccolo monitors every disc
5.4 Alert Value Not Recognized	N				
5.5 Need for a Confirmatory Sample Not Recognized	N				
5.6 Effect of Preanalytical Variables Not Recognized	N				
5.7 Instrument Malfunction Not Recognized	N				
5.8 Interference Not Recognized	N				
6.0 Integration/ Report into Chart					
6.1 No Result Recorded	N				
6.2 Result Recorded in Incorrect Patient Chart	N				
6.3 Incorrect Information Recorded	N				
6.3.1 Data	N	Responsibility of Tech reading the card			
6.3.2 Time	N	Instrument has real time clock			
6.3.3 Result	N	Instrument stores, prints and/or transmit results to external computer system			

* Comment A-satisfactory sample collection, e.g., site cleaning, etc., is the responsibility of the phlebotomist.

6.4 Information Unreadable	N				
6.5 No Aids for Clinical Interpretation	N				
6.5.1 Reference Range	N	Pre programmed in the instrument and printed with results. Values outside the reference range are flagged.		Piccolo monitors every disc	Piccolo monitors every disc
6.5.2 Alert Limits	N	Pre programmed in the instrument and printed with results. Values outside the reference range are flagged.		Piccolo monitors every disc	Piccolo monitors every disc
6.5.3 Previous Patient Results	N				
6.6 Inconsistent Location of Reporting Result/ Result Difficult to find in Chart	N				
6.7 Result Temporarily Unavailable Due to Reporting Mechanism (computer delay)	N				

* Comment A-satisfactory sample collection, e.g., site cleaning, etc., is the responsibility of the phlebotomist.

Piccolo Maintenance Log

Month
Year

	Day of Month																													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily																															
Refridgerator Temp																															
Freezer Temp																															
Print IQC																															
Initials																															
Weekly																															
Clean Inst Surface Initials																															
Monthly																															
Liquid QC Initials																															
Quarterly																															
Clean Air Filter *Initials*																															
Proficiency Testing *Initials*																															
Semi-Annual																															
Clean Printer *Initials*																															
6 Month Verification *Initials*																															

piccolo xpress chemistry analyzer

PATIENT SAMPLE LOG

PATIENT NAME	DRAW DATE	SAMPLE ID #1	SAMPLE ID #2	OPERATOR ID

Good Laboratory Practice:
1. All samples must be collected in Lithium Heparin tubes
2. Analyze whole blood within 60 minutes of draw
3. Start the test within 10 minutes of transferring sample to disc
4. Test patients under the PATIENT selection on the Piccolo analyzer
5. Enter a unique ID number for each patient sample

Contact Abaxis Technical Support at 1-800-822-2947 if you have questions

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ABAXIS