piccolo xpress®
chemistry analyzer

WAIVED COMPLIANCE BINDER

3240 Whipple Road, Union City, CA 94587

Dear Abaxis Customer:

Abaxis is committed to be a leader in delivering superior quality products that meet customer requirements on time, every time. The Piccolo® Xpress Chemistry Analyzer used with the waived reagent discs will provide first-class Point-of-Care service to your practice.

This Waived Compliance Binder was created to serve you and your laboratory as you document patient testing, quality control testing, and fulfill the requirements of CLIA. Our goal is to assist you in every way possible to ensure your needs are met and all documentation is efficient and readily available.

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

TRAINING 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.

DAILY IQC: Daily documentation of the internal process of the instrument is fundamental to reporting accurate patient results.

CONTROLS: Abaxis recommends the use of controls to be tested every 30 days. Additional information is enclosed.

CONTROLS IQC: Internal checks documented during the testing of Quality Control runs.

CONTROLS PACKAGE INSERTS: Please place the package insert from the current lot number of controls in this section. Package insert found in control box. Please keep for 2 years.

REFRIGERATOR TEMPERATURE LOG: To ensure you are storing your reagents as required, please log your storage refrigerator temperature in this section.

PATIENT REFERENCE LOG: This log is supplied as a courtesy for your laboratory practice. Good Laboratory Practice is to have a unique patient identifier for all samples collected.

Piccolo® PACKAGE INSERTS: Please add the package inserts for all the reagent discs used. These can be obtained from the Reference Center located at https://www.abaxis.com or from Abaxis Technical Support at 1-800-822-2947.

Additionally, please check your air filter monthly and clean 2 times per year.

Please let us know how we can assist you in any way.

Best Regards,

ABAXIS Human Health, Customer Service, & Technical Support

Welcome to Waived Testing Methodology

Waived Testing- Whole Blood Only

Waived Tests- As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result". The FDA determines the criteria for these tests.

Laboratory Requirements

- In order to operate under the waived laboratory protocol, you must have a valid CLIA certificate. A certificate of waiver is the minimum requirement to perform waived testing. **Please contact your state CLIA office if you have questions concerning your application or state license requirements. Refer to CLIA brochure # 6 for more information (www.cms.hhs.gov/CLIA/).**
- Pay the certificate fee every two years.
- Follow the manufacturer's instructions for the waived tests performed.
- Notify your state agency of any changes to your CLIA status such as the addition of moderately complex tests.
- Permit inspections by a CMS agent. Your laboratory, however, will not be subject to a routine survey or inspection.

Following Manufacturer's Instructions

Follow manufacturer's instructions for chemistry analysis by following the instructions in the package inserts. Please read the package inserts before performing the tests. Additional reference for testing procedure is found in Section 3 of the Piccolo Xpress Operator's Manual.

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.***

PACKAGE INSERT

Disc 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 microliter 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 stopper) 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 (see package insert).

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.
- **Any result for a particular test that exceeds the assay range should be analyzed by another approved test method.**
- Physiological interferents (hemolysis, icterus and lipemia) cause changes in the reported concentrations of some analytes.
- The Piccolo suppresses any results that are affected by >10% interference from interferents- hemolysis, lipemia or icterus. "HEM", "LIP", or "ICT" respectively, is printed on the result card in place of the result.

OPERATORS MANUAL

Performing external quality control:

- *At least every 30 days.*
- *Whenever lab conditions change.*
- *When training or retraining personnel.*
- *When test results do not match patient symptoms.*
- *With EACH new lot number of reagent disc used.*
    - Use the RUN CONTROLS 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.
- For Waived Only Laboratories, daily documentation of the internal functions (iQC) of the Piccolo® is necessary. THIS CAN BE COMPLETED AFTER UTILIZING ANY REAGENT PANEL. (See Operator's Manual for complete instrument instructions).
    - 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 Waived Compliance Reference Binder.

Facility Name _____

S/N(s) _____

Setup and Training Checklist For ***Waived Only*** Testing

3240 Whipple Road
Union City, CA 94587
Phone 800-822-2947 • Fax 887-349-2087
PN 100-9032 Rev. E

Introduction to the Training Checklist

This training checklist for waived only testing will assist you as a reference guide during the initial setup and operation of the Piccolo Xpress® Chemistry Analyzer. After following this checklist, you will be able to operate the Piccolo Xpress® Chemistry Analyzer, run controls and report accurate results. Review each reference listed as you follow the checklist through each of the topics covered.

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.

Getting Started:

Please check off all items that have arrived.

NOTE: IF ANY COMPONENTS OR MATERIALS ARE MISSING, PLEASE CONTACT ABAXIS CUSTOMER SERVICE AT: 1- 800 - 822 – 2947

Materials Provided & Set up Information

- ❑ Power Cord
- ❑ Power Supply
- ❑ Belkin Surge Protector
- ❑ Mini Pipette (100 UL Gray)
- ❑ Disposable tips for the Mini Pipette, (Qty 96)
- ❑ Thermal Paper Roll
- ❑ Abaxis Driver CD
- ❑ Piccolo Xpress Reference Guide
- ❑ USB A To B Cable
- ❑ Fan Filter
- ❑ Warranty Card
- ❑ **Lab Key Operator** - Identify and ensure attendance of the main operator for the Piccolo; this individual must be in attendance for the entire training procedure. Technical Support will follow-up with this individual following the initial training.

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 Piccolo Reagent Discs

Installing the Piccolo®

Prior to installation: Please download and print the Operator's Manual from the Abaxis website, https://www.abaxis.com. Store the manual with the Piccolo Waived Compliance Binder.

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

- ❑ Plug the analyzer into the surge protector and set up the analyzer, as per the manual instructions.

CAUTION: Do not plug the analyzer into the same circuit as a centrifuge, refrigerator, or any high current devices.

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 2.7, page 2-9

- ❑ Power on the analyzer as per the manual instructions.

Reference: Operator's Manual Section 4.6, pages 4-15, Section 9.4, pages 9-3, 9-4

- ❑ Record the analyzer's serial number and software version. From the main menu, press the settings icon (hand) followed by the analyzer information icon (Piccolo with question mark).

Analyzer's Serial Number(s) _____

Software Version _____

(If the software is not current, follow the instructions in the Operator's Manual.)

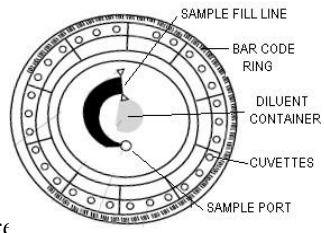
Reference: Operator's Manual Section 7.6, Page 7-4

- ❑ Reinitialize the analyzer as per the manual instructions.

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

- ❑ To change the date and time, from the home screen, press the settings icon (hand), press date and time icon (clock), and follow the prompts.

Disc Handling



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

- ❑ Review disc structure, function, proper storage, and disc handling.
- ❑ Using the training materials provided, allow the trainee time to practice with the pipette and discs. Observe proper techniques before continuing.
- ❑ **Do not overfill** the disc. Only a one time dispense is required to fill the sample chamber.
- ❑ **Wipe off** any residue of sample left on top using lint free wipe.
- ❑ Store discs at **2-8 °C (36-46 °F)** in the refrigerator. Keep a thermometer in the refrigerator to monitor temperature daily.

- ❑ Discs are meant to be used cold and immediately after removing from the refrigerator.
- ❑ Once the pouch is open, the disc needs to be used within **20 minutes.**
- ❑ Once the sample is placed into the disc, it needs to be run within **10 minutes**.
- ❑ Do not use a disc that has been dropped.
- ❑ Report any suspicious shipment or shipping delays to Abaxis. The discs are temperature sensitive.

CAUTION: Do not expose discs opened or unopened to direct sunlight or temperatures above 32 °C (90 °F).

Control Handling

Reference: Control Package Insert

- ❑ Always refer to your Chemistry Control product insert for the most recent information on the controls you are using with your Piccolo.
- ❑ Store controls in the freezer at a constant temperature of **≤ - 15°C (5°F).**
- ❑ Controls are to be treated just like you treat a patient specimen.
- ❑ Thaw controls at room temperature for **1 hour** before using.
- ❑ **Do not refreeze** the controls. Discard the controls in biohazard waste after use.

Running Controls

Reference: Operator's Manual Section 4.15 pages 4-31 to 4-34

- ❑ Review Abaxis' recommendation on control testing.
    - ❑ At least **every 30 days** or with **each new lot number of disc panels**, whichever occurs first.
    - ❑ When training or retraining of personnel is indicated.
    - ❑ Whenever laboratory conditions have changed significantly.
    - ❑ When test results do not match patient symptoms or clinical findings.

IMPORTANT: If control results are out of range, repeat one time. If still out of range, call Piccolo Technical Support. **DO NOT REPORT RESULTS** if controls are outside the control reference range.

Running Controls (continued)

- ❑ Open the disc pouch before drawing up the sample. Place the disc on the counter.
- ❑ Remove (one) Level 1 vial and (one) Level 2 vial controls from the freezer **1 hour** in advance of running the test. Place vials on a counter away from the light.

  Record Control Lot # _____
- ❑ Mix Level 1 **gently** by using a slow windshield wiper motion (10-15 times), then set the vial upright and gently swirl it several times, then tap the top of the vial a few times.
- ❑ Place a tip on the pipette. Depress the plunger of the pipette and place it in the Level 1 control solution and **slowly** release the plunger (avoid air bubbles); 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 sample dispenser into the sample port at a 45° angle.
- ❑ Slowly push the plunger down so the sample fills the chamber and reaches the arrows. (Avoid air bubbles in the sample chamber)
- ❑ Ensure the entire sample is out of the tip and has flowed into the port.
- ❑ 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 pipette and discard into a biohazard waste container.
- ❑ Keeping the prepared disc flat with the bar code facing up, press **"Analyze"** on the touch screen to open the instrument drawer. **The disc does not need to be turned to any particular direction.**
- ❑ Place the disc (bar code facing up) in the drawer.
- ❑ Select sample type **"Control"** on the touch screen.
- ❑ **Enter Control ID** (enter the Control's Lot #). Use the right arrow → on the touch screen for the dash. For Example: Enter 1112025 - 1 (for Control Lot # 1112025 Lev 1)
- ❑ When the control run is completed and results have printed, compare the Level 1 control results with the control product insert values for the control Level 1 lot number you are using.
- ❑ Ensure all control results are within the expected values shown for each analyte in the product insert for the control lot number.
- ❑ If any value is out of range, repeat testing of the panel with the opened control vial.
- ❑ If the control values are again out of range after repeating once, contact **Abaxis Piccolo Technical Service 1-800-822-2947.**
- ❑ When all values have been confirmed as correct, discard the used control vials into a biohazard waste container.
- ❑ Place all control results on the **"Data Collection Form – Controls"** located in the Waived Compliance binder under the tab labeled **"Control Data"**.
- ❑ Repeat the steps listed above for control Level 2.

Pipette Handling Precautions

- ❑ Do not release the plunger abruptly when drawing up the sample into the pipette tip. This can cause the sample to move up into the pipette and contaminate it.
- ❑ Once the pipette is filled with the sample, it must remain upright.
- ❑ Do not use a malfunctioning (sticky) pipette or one that has become internally contaminated. If this occurs, call Abaxis Piccolo Technical Service.

Printing Control iQC

Reference: Operator's Manual Section 5.1, pages 5-2 to 5-9

- ❑ While the controls are running, review the intelligent Quality Control brief **(iQC**).
- ❑ After testing controls, recall the results from the **Last Disc**.
- ❑ Select **Print** (or transmit to external printer).
- ❑ Select **iQC**; the iQC report will print.
- ❑ Place all control iQC results on the **"Data Collection Form – Controls iQC" located** in the Waived Compliance binder under the tab labeled **"Control iQC"**.

Sample Collection & Handling

Reference: Operator's Manual, Section 3.1, page 3-2 to 3-5

- ❑ Venipuncture sample collection.
  Other(s) _____
- ❑ Always follow the correct procedures for the proper collection of blood specimens. CLSI procedures **H03-A6**: Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture and **H18-A4**: Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests. CLSI website**: www.clsi.org**
- ❑ Collect the sample in a **Green Top Lithium Heparin** tube only (without gel).
- ❑ Use the correct size gauge needle **(21-23 gauge)** during collection in order to avoid hemolysis (rupturing of red blood cells).
- ❑ Follow the correct order of use of tubes for blood collection**: Red, Green,** and then. **Purple** (in order to avoid EDTA contamination of samples).
- ❑ Fill the tube (3ml) at least ¾ full **(up to the fill line).**
- ❑ As soon as the blood is collected, invert the tube **gently** to mix **(8-10 times).**
- ❑ Do not have the patient pump their fist before or during the collection of blood.
- ❑ Tourniquet time should not exceed more than 1 minute.
- ❑ Run **whole blood** only.
- ❑ Do not centrifuge or spin the sample.
- ❑ Sample must be analyzed within **60 minutes** from the time it is collected.
- ❑ Do not place the sample on a mixer or rocker.
- ❑ Do not refrigerate the sample.

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 following the testing procedure below.
- ❑ Retrieve and print iQC data information on the first patient each day after the Piccolo is turned on for the day (or shift).
- ❑ Remember to follow good laboratory practices. Use the same techniques and sample precautions as when running controls.
- ❑ Review and verify the patient information on the printout.

Testing Procedure

Reference: Operator's Manual, Section 3.2, pages 3-4 to 3-5; Section 3.3, pages 3-6 to 3-10 and Piccolo Easy-Start Guide

- ❑ Review preparing the reagent disc.
- ❑ Run the patient sample following the same initial steps that were used when running the controls.
- ❑ Open the disc pouch before drawing up the sample with the pipette (place the disc on the counter).

- ❑ Tilt the sample tube at a slight angle (to avoid contaminating the pipette), then insert the pipette tip 2-3mm below the surface of the sample.
- ❑ Once filled with sample, the pipette should be maintained upright**.**
- ❑ After placing the sample into the disc, place the disc (bar code facing up) in the drawer.
- ❑ Select sample type **"Patient"** on the touch screen.
- ❑ Enter Patient ID (Patient ID#).
- ❑ When the sample is finished, **"Analysis Complete"** and **"Open"** appear on the screen, remove the disc from the drawer and dispose of in a biohazard waste container.

Interpreting Results

Reference: Operator's Manual, Section 3.5.1, Pages 3-12 to 3-16 and Section 7

- ❑ Review **Piccolo Xpress - Results Interpretation** (see pg. 13 & 14).
- ❑ Review **>** and **<** signs. Indicates results are out of the dynamic range.
- ❑ Review three **tildes. (~ ~ ~)** Indicates results that cannot be determined. This is known as chemistry suppression.
- ❑ Review the asterisk **(*)**. Indicates the results are outside of the reference 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.**
    - ❑ **LIP** indicates Lipemia (fat in the blood). High lipemia may be due to diet. Ensure that the patient has fasted at least 12 hours before collection.
    - ❑ **HEM** indicates Hemolysis (rupturing of red blood cells). If the sample is identified as hemolytic, collect a new sample.
    - ❑ **ICT** indicates Icterus (bilirubin in the blood).
    - ❑ Review sample indices 0, 1+, 2+, 3+ (qualitative).
- ❑ **<u>Repeat any unexpected test result(s)</u>.** Review whenever test results do not match patient 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.

Recording Daily iQC (QC of Internal Functions)

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

- ❑ After testing the first patient of the day, recall (folder icon) the results from the **Last Disc**.
- ❑ Select **Print** (or transmit to external printer).
- ❑ Select **iQC**; the iQC report will print.
- ❑ Place iQC report in the **"Daily iQC"** log located in the Waived Compliance Binder.
- ❑ **Daily documentation of the internal functions of the Piccolo® is necessary.**

Recall Results

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

- ❑ Recall and print records. (Folder Icon)
- ❑ Recall Patient iQC (on the first patient of the day).
- ❑ Review viewing or printing error records.

Maintenance

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

- ❑ The Piccolo representative would demonstrate maintenance techniques at initial setup.
- ❑ Review cleaning the analyzer exterior, printer, air filter & pipette.
- ❑ Pipette maintenance. You may use a 5% bleach solution only to clean the outside of the pipette. The pipette is not autoclavable.

CAUTION: **Do not soak the pipette** in any solutions as this may cause it to malfunction. Dispose of the pipette if has been internally contaminated with sample.

- ❑ Review installing the software CD-ROM and software update program. Periodically, Abaxis will mail a new revision of software (CD-ROM format). It will be necessary to update the software version of the analyzer. It is important to make this change as soon as practical. Not changing the software may lead to problems in running the discs.

Waived Compliance Binder & Test Information

- ❑ Review the sections in the **Waived Compliance Binder.**
- ❑ Remove the Customer Care Sticker from the Waived Compliance Binder, peel the protective backing off the sticker and affix the sticker to the side of the instrument where it will be most visible.
- ❑ Always keep the package inserts of discs and controls for each lot number for at least two years to capture target range values for later reference in the Waived Compliance binder.
- ❑ Be sure to test using **ONLY CLIA Waived** discs. Check the Abaxis website, **https://www.abaxis.com,** for a list of the current Waived disc panels.
- ❑ Review **Master Analyte List** (see pg. 11). Waived and Non-Waived tests are listed in alphabetical order along with their reference and dynamic ranges.

Proficiency Testing Guidance

(Only for Waived labs deciding to participate in Proficiency Testing)

CLIA guidelines, specifically Subpart H of the regulations, outline the requirements for participation in Proficiency Testing (PT). CLIA Website: **wwwn.cdc.gov/clia/regs/subpart_h.aspx**

- ❑ Abaxis recommends the College of American Pathology **(CAP) Web: www.cap.org** or American Proficiency Institute **(API) Web: www.api-pt.com**
- ❑ Your Abaxis Regional Sales Manager or your distributor sales representative 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 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.

- ❑ The longer that PT material remains thawed, the greater the likelihood that PT results obtained by a laboratory will be incorrect. 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.

Connecting to a Computer / LIS/EMR

Reference Operator's Manual Section 10, Pages 10-1 to 10-11

The current LIS / EMR Software: _____

(Print software name)

- ❑ If the LIS/EMR Software is not capable of importing an Adobe pdf file, a middle-ware software program will need to be used in order to establish a connection.
- ❑ Transmitting to Laboratory Information Systems or Electronic Medical Records – Contact Abaxis Technical Support

Connecting Other Accessories

- ❑ **USB Keyboard** – Allows the use of alphanumeric characters.
- ❑ **External Printer** – Contact Abaxis Technical Support for printer compatibility.
- ❑ **Barcode Reader** – Contact Abaxis Technical Support for barcode reader specifics.

Important Information *** COMPLETE AT INSTALLATION ***

- ❑ Complete **Setup & Training Completion Sign-off** sheet. Fax or e-mail a copy of this checklist to Abaxis Customer Service. **E-Fax 1 - 877 – 349 – 2087**

- ☐ Complete the **Warranty Card.** Mail, fax, or e-mail the Warranty Card to Abaxis Customer Service:

Abaxis Inc.,
3240 Whipple Rd, Union City, CA 94587
E-mail: ab-piccolotechsupport@zoetis.com
Customer Service: E-Fax 1 - 877 – 349 – 2087

- ❑ **Chemistry Controls and Piccolo Reagent Discs**
  To place an order, please call sales representative or distributor**.**

- ❑ Review the Disc Credit procedure **"Disc Cancellation Letter and Credit Sheet."**
  (Located in the Waived Compliance Binder under the Checklist tab).

- ❑ Retain completed and signed checklist for verification of training. Place this document in the Waived Compliance Binder.

Customer Support

- ❑ **Use Abaxis Technical Support – 1-800-822-2947.** (Please wait for voice commands)
  - For questions regarding technical assistance, troubleshooting, error reports and software upgrades.

Master Analyte List

Master Analyte List

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

			REFERENCE INTERVALS	DYNAMIC RANGES		
CLIA STATUS	Analyte	Symbol	Common units	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- Methyte 8 Panel CLIA WAIVED
6- General Chemistry 6 CLIA WAIVED
13- General Chemistry 13 CLIA WAIVED
ML+ CRP-Methyte Plus CRP

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

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:

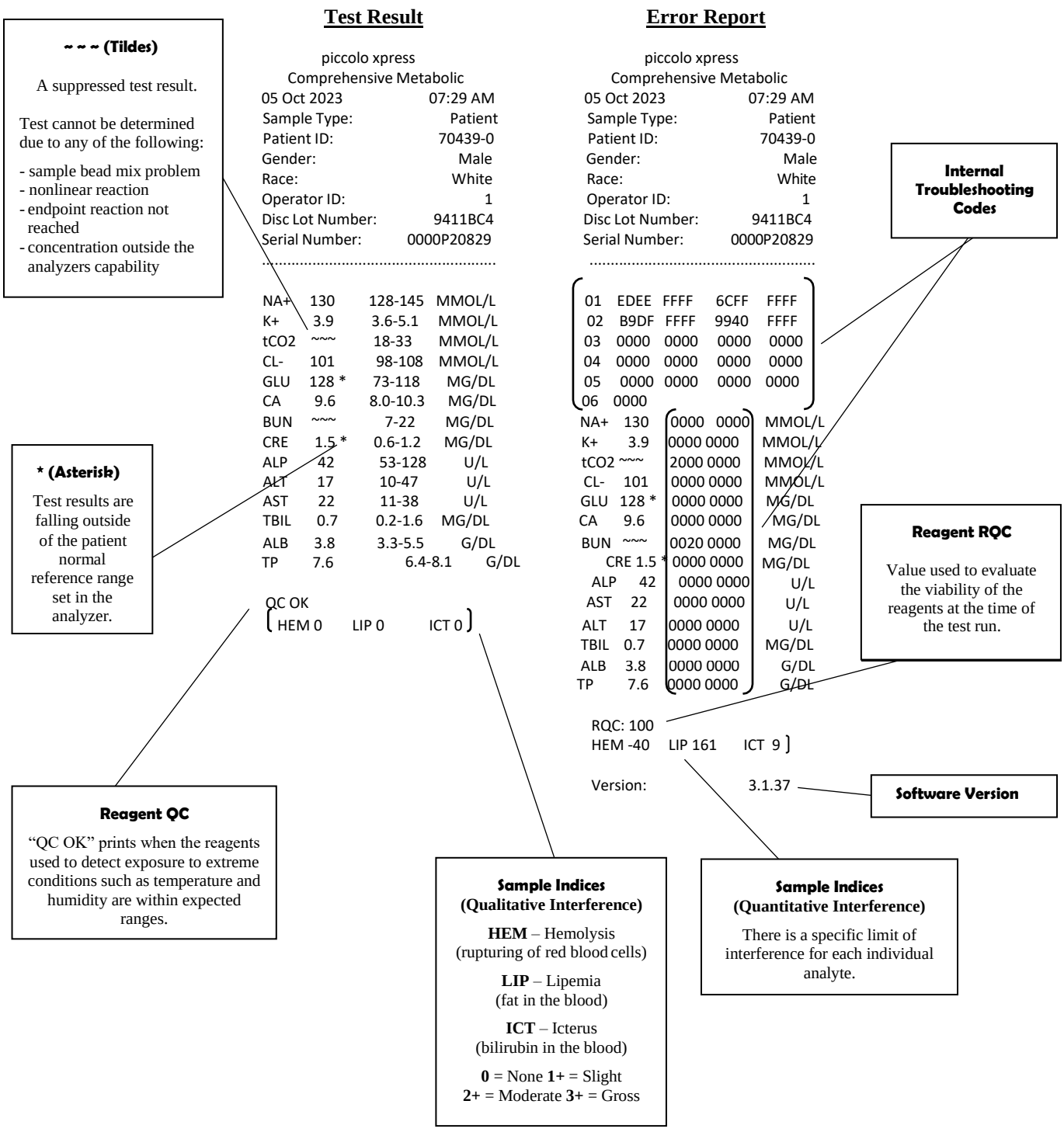
1. Every 30 days
2. Whenever lab conditions change
3. When training or retraining of personnel
4. When test results do not match patient symptoms
5. With EACH new lot number of reagent discs

100-7130-2 Rev. A

ABAXIS

Piccolo Xpress - Results Interpretation

Example (A)



Piccolo Xpress - Results Interpretation

Example (B)

Test Result

piccolo xpress
Comprehensive Metabolic
05 Oct 2023 07:29 AM
Sample Type: Patient
Patient ID: 70439-0
Gender: Male
Race: Unknown
Operator ID: 1
Disc Lot Number: 9411BC4
Serial Number: 0000P20829
.....
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
05 Oct 2023 03:27 PM
Sample Type: Patient
Patient ID: 71805 – 0
Disc Lot Number: 0353BA3
Serial Number: 0000P20829
.....
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: 3.1.37
403D Sample Mix Error

4XXX

Disc Cancellation
4 Digit Error Code &
Error Message

Example (D)

Error Report

piccolo xpress
Lipid Panel
05 Oct 2023 01:27 PM
Sample Type: Patient
Patient ID: 33258 - 0
Disc Lot Number: 0353BA3
Serial Number: 0000P20829
.....
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 3.1.37

LIP

(Lipemic Interference)

Lipemia has adversely affected the result of this test.

Setup and Training Completion Sign-off

Please FAX or E-mail the completed Waived Training Checklist to:

Customer Service: E-Fax 1 - 877 – 349 – 2087
E-mail: ab-piccolotechsupport@zoetis.com

Trainer: _____ (Please Print)

Date: _____

Clinic Name: _____ (Please Print)

Address: _____

City: _____

State: _____

Zip code: _____

Analyzer Serial #(s) _____

Trainer's Signature: _____

Customer Signature: _____ (Lab Key Contact - **Main Operator**)

Phone Number: _____

Ext. _____

Phone number: _____

Fax: _____

Email: _____

Certificate of Training

A Certificate of Training will be mailed to the following individuals at the address listed above.

Trainee(s) **PLEASE PRINT** legibly for ease of translation.

(First Name, Last Name -Title)

_____ _____

_____ _____

_____ _____

_____ _____

Disc Cancellation Letter and Credit Sheet for Piccolo®

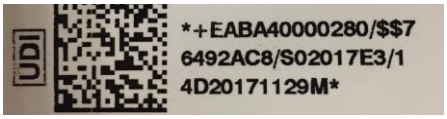
Dear Piccolo Customer,

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 ab-piccolotechsupport@zoetis.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 ab-piccolotechsupport@zoetis.com the error report, a partial result (~~~) or repeated result and the following information to Technical Service (See page 2) within one week 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. Please make copies of this form.

To redeem your credits, contact Abaxis Customer Service at 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: ab-piccolotechsupport@zoetis.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.)

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

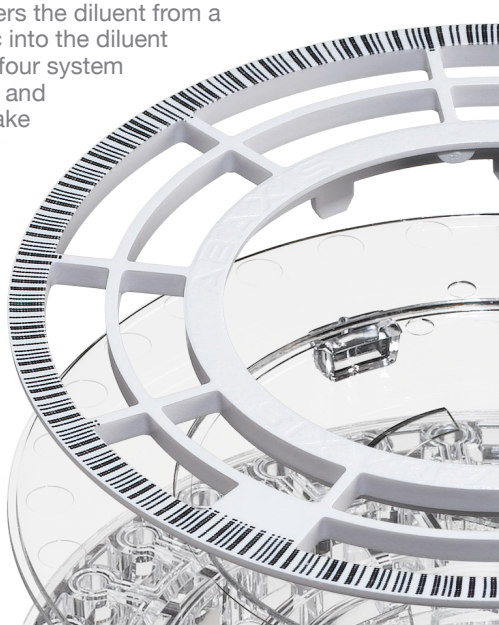
Time-consuming and error-prone reagent calibrations are not required with the Piccolo Xpress® nor is there any chance of using expired reagents. The barcode on the top surface of each disc encodes the type of test panel, the expiration date, and the reagent calibration factors. At the beginning of the 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

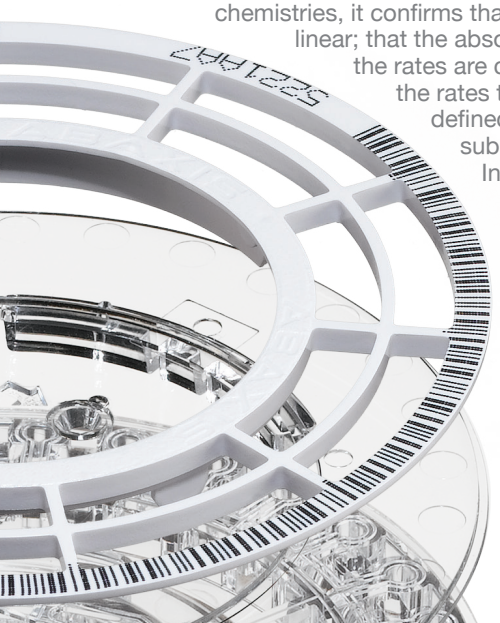
Four system cuvettes are used for reagent and system testing. Chemistry QC reagent beads reveal and quantify any degradation of the analyte-specific reagents in the disc due to suboptimal storage conditions (moisture and temperature). If degradation exceeds a defined level, the run is aborted and an 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

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

Please insert the package insert found in your control box

piccolo xpress chemistry analyzer

DAILY REFRIGERATOR TEMPERATURE LOG

DATE	TEMPERATURE	CHECKED BY:

Reagent disc storage and handling requirements:

1. Store reagent discs in their sealed pouches at 2°-8° C (36-46° F)
2. Reagent discs may be used idrectly from the refrigerator without warming
3. Do not allow discs to remain at room temperature longer than 48 hours prior to use
4. Reagent discs must be used within 20 minutes after opening a pouch
5. Do not use a reagent disc from a damaged pouch

ABAXIS

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

100-7130-5 Rev. B
DCO# 51140 Eff.: 10/06/17

ABAXIS