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PERFORM Operating Document

Use and Maintenance of Chemistry Analyzer Piccolo Xpress

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Revision History

Version	Reason for Revision	Date
04	Create a more condensed version	11/May/2020

1. Introduction

The PERFORM Centre Clinical Analysis suite has an Abaxis Piccolo Xpress which is a bench top chemistry analyzer providing blood chemistry results for human samples. The Piccolo Xpress is a compact, portable clinical chemistry system designed for on-site patient testing. It delivers routine multi-chemistry and electrolyte test results quickly and easily.

2. Definition of Terms and Abbreviations

QC	Quality Control
CLIA	Clinical Laboratory Improvement Amendments
NCCLS	National Committee for Clinical Laboratory Standards
µL	Microliter
Piccolo Xpress	Piccolo Blood Chemistry Analyzer or Piccolo Xpress Chemistry Analyzer

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3.Overview of Piccolo Xpress

3.1 Performance

- A fully automated system with walk away operation.
- Uses a small sample size (90-120ul of whole blood, serum or plasma). Only **lithium heparin** tubes are suitable with this analyzer.
- Results are available in approximately 12 minutes. The instrument monitors the reactions simultaneous using nine wavelengths and calculates the results from the absorbance data.
- The built-in intelligent Quality Control meets CLIA and NCCLS requirements for daily control testing.
- The Piccolo Xpress delivers up to 31 individual tests including CLIA-waived lipids, liver enzymes and glucose monitoring.
- Results are provided in a "hard copy" self-adhesive report or can be quickly transferred to a printer, computer or data management system.
- On-board intelligent Quality Control system performs continuous QC checks during the complete analytical process to ensure accurate results.
- Bar coded self-contained reagent discs are self-calibrating and monitors panel information,
- Multi-analytes panel results include alpha-numeric patient information, analyte concentrations, reference ranges, sample integrity indices and QC performance.
- Stores up to 5000 patient and control results on-board.
- No special operating skills are needed to run the Piccolo Xpress.
- Easy to use color touch screen guides the operator through the process.
- Flexible alpha – numeric data entry options and analyzer settings.
- Self-contained, disposable reagent discs are easy to handle.

3.2 Training requirements

Prior to using the Piccolo Xpress individuals should:

- Read and sign this POD.
- Undergo appropriate Piccolo Xpress training with the Clinical Analysis Suite Supervisor.

3.3 Relevant Documents

- Piccolo Xpress Operator's Manual (available on a CD)
- Piccolo Xpress training video
- Piccolo Xpress waived compliance binder

4. Piccolo Operation

4.1 General recommendations

- The diluent container in the reagent disc is automatically open when the analyzer drawer closes. A disc with an opened diluent container cannot be re-used. Ensure that the sample or control has been place into the disc before closing the drawer.

- Used reagent discs contain human body fluids. Follow good laboratory safety practices when handling and disposing of used discs.
- The reagent discs are plastic and may crack or chip if dropped. Never use a dropped disc as it may spray biohazardous material throughout the interior of the analyzer.
- Reagent beads may contain acids or caustic substances. Operator does not come in direct contact with the reagent beads when following the recommended procedures. In the event that the beads are handled (e.g., cleaning up after dropping and cracking a reagent disc), avoid ingestion, skin contact, or inhalation of the reagent beads.

4.2 Instructions for reagent discs handling

- Reagent discs may be use directly from the refrigerator without warming. Do not allow discs sealed in their foil pouches to remain at room temperature longer than 48 hours prior to use. A disc not used within 20 minutes of opening the pouch should be discarded. Never store it back into the fridge once the pouch has been opened.
- Handle the discs by holding on the edges to avoid smudging on the optical surface. Use lint-free paper (eg. Kimwipes) to remove any spillage on the discs.
- Run samples within 10 minutes of loading them into the reagent disc. NEVER remove samples that have been loaded into the disc to try and re-introduce it into the disc.
- Refer to the Piccolo Xpress Operator's Manual for more detailed instructions.

4.3 Storage

Store reagent discs in their sealed pouches at 2-8°C (36-46°F). Do not expose opened or unopened discs to direct sunlight or temperatures above 32°C (90°F). Reagent discs may be used until the expiration date included on the package. The expiration date is also encoded in the bar code printed on the bar code ring. An error message will appear on the Piccolo Xpress Display if the reagents have expired.

5. Procedure

5.1 Limitations of Procedure

- Only lithium heparinized blood, plasma or serum may be use with this disc due to the susceptibility of falsely high LD values from ruptured blood cells. **Use only lithium heparin (green stopper) evacuated specimen collection tubes for plasma samples.** Use no-additive (red stopper) evacuated specimen collection tubes or serum separator tubes (red or red/black stopper) for serum samples.

- Do not shake the collection tube; shaking may cause hemolysis. Hemolysis will cause erroneously high results in potassium and lactate dehydrogenase assays.

- Abaxis has performed studies demonstrating that EDTA, fluoride, oxalate, and any anticoagulant containing ammonium ions will interfere with at least one chemical contained in the Piccolo Basic Metabolic Panel Plus Disc.

- Whole blood samples must be homogenous before transferring sample to reagent disc. Gently invert collection tube prior to transferring a sample to the disc. Note that whole blood samples should be analyzed within an hour of collection. Plasma and serum samples can be stored in the fridge for 7 days and >30 days at -20 or -80°C freezers. Verify the stability of your analyte prior to storing samples.

- 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.

- Physiological interferents (hemolysis, icterus and lipemia) cause changes in the reported concentrations of some analytes.

- If performing any glucose or lipid analysis, participants should be fasted for at least 12 hours to obtain more accurate results.

- Any result for a particular test that exceeds the assay range should be analyzed by another approved test method or sent to a referral laboratory. Do not dilute the sample and run it again on the Piccolo Blood Chemistry Analyzer.

- Warning: Extensive testing of the Piccolo has shown that, in very rare instances, sample dispensed into the reagent disc may not flow smoothly into the sample chamber. Due to the uneven flow, an inadequate quantity of sample may be analyzed and several results may fall outside the reference ranges. The sample may be re-run using a new reagent disc.

5.2 Operation

5.2.1 Calibration

The Piccolo is calibrated by the manufacturer before shipment. The bar code printed on the bar code ring provides the analyzer with disc-specific calibration data.

5.2.2 Quality Control

Performance of the Piccolo can be verified by running controls at least every 30 days or whenever the laboratory conditions have changed significantly (ex. Piccolo moved to a new location, changes in temperature control…), when training personnel, with each new lot of reagent discs. If control values are out of range after repeating once, **contact Abaxis Technical Service.**

Use the RUN CONTROL option to store control results separately from patient results in the analyzer's memory. The results are printed automatically. These results can be recalled later as needed.

Controls recommended by Abaxis are listed in the Piccolo operator's manual. Other human serum or plasma-based controls may not be compatible.

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Piccolo is very easy to operate in 3 simple steps:

Step 1: Add Sample

Collect 100 µl of whole blood, serum or plasma, or control. For controls, thaw for 1 hour at room temperature. Gently mix before reading. Find the arrow below the center of the disc at the 6 o'clock position. It points towards a small hole that is the sample port. Dispense the entire sample by smoothly pushing down on the plunger. The single use, disposable disc contains all the reagents and diluent necessary to perform a complete fixed multi-test panel. Start the test within 10 minutes of transferring the sample into the reagent disc.

Step 2: Insert Disc

Press the yellow [ANALYZE] box on the touch screen to open the instrument drawer. Place the disc, barcode facing up, into the drawer. Press the blue [CLOSE] box at the bottom on the touch screen to close the drawer and begin analysis. Select [Patient or Control] on the touch screen and type identification numbers then press done. The screen will read "Analyzing sample". In approximately 12 minutes, results are ready.

Step 3: Read Results

Wait until the message on the screen reads "Analysis complete" and then press [OPEN] on the touch screen to open the drawer, remove the used disc and place in a biohazardous waste container. Press [CLOSE] on the touch screen to close the drawer. Complete panel results including patient demographics, chemistry concentrations, reference ranges, sample integrity indices and iQC are available on the full color display, printed on a self-adhesive print out, transmitted to an external printer, computer or LIS/EMR system. The Piccolo Xpress analyzer will store on-board up to 5000 patient and quality control results.

5.3 Data acquisition and Results Interpretation

Results are print out on the result paper (Abaxis part no. 100-7127) from Piccolo Xpress. Stick the results in your laboratory notebook. Use the PATIENT option to store patient results separately from control results in the analyzer memory. Results outside of 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 "~~~" is print when a result cannot be determined; the value is suppress. The report can also be transmitted to the computer using Abaxis data manager.

5.4 Preventive maintenance

5.4.1 Weekly

Clean the analyzer's external case and display at least weekly. Clean the analyzer with a soft cloth, dampened with a mild, non-abrasive detergent or cleaning solution, such as Simple Green®, a 10% bleach solution, or a 30% isopropyl alcohol solution.

Do not spray or pour any detergents, solutions or other liquids directly onto the analyzer. Dampen a soft cloth or disposable paper towel with the detergent and apply to the analyzer.

Cleaning the Display

Clean the analyzer's screen periodically using a soft, lint-free cloth dampened with a glass-cleaning fluid or window cleaner. The screen can be disinfected using a 10% bleach solution: apply the solution to a lint free cloth, then wipe the screen.

CAUTION: Do not use any cleaner containing alcohol. Do not spray cleaner directly onto

the display and dampen the cloth instead.

Cleaning Spills

Observe universal precautions when cleaning spills on the analyzer. Use a 10% bleach solution (1 part household bleach plus 9 parts water) to disinfect spills and wipe with damp lint-free cloth or paper towel

5.4.2 Annually

The air filter in the back of the analyzer should be cleaned at least twice per year. Check the air filter more often than twice per year if the analyzer is located in an environment with excessive dust or dirt.

To clean the air filter:

1. Unplug the analyzer and remove the power cord from the back of the analyzer.
2. Grasp the black mesh filter in the circular opening and remove it.
3. Wash the filter in warm soapy water and dry completely.
4. Place the clean, dry filter flat in the circular opening and push the sides of the filter behind the edges of the circular opening.
5. Plug the power cord into the back of the analyzer.
6. Plug the power cord into the power source, and press the Power button on the front of the analyzer. The analyzer will perform a diagnostic self-test. It may take up to another four minutes for the heaters to bring the analyzer disc chamber to operating temperature.

5.5 Data Transmission and Reporting

1. Turn on the computer and open Abaxis Data Manager.
2. Specify a Save Folder Path.

5.5.1 Piccolo Xpress Configuration

1. Connect the USB Cable to the Analyzer
2. Connect the USB Cable to the PC
3. Turn ON the Analyzer, if it is not already on
4. Home > Hand > More options >Analyzer> Choose XML > Home

Note: For entering Patients Ids, age, DOB, Doctor's name etc., report modifications settings in Piccolo can be changed by clicking Home> Hand> Bulb> advanced> Data Entry Options.

5.5.2 Transmit Results

1. Home > Folder >Last Disc/Rotor> Print> Select Xmit > Results
2. Locate Save Folder Path in the Abaxis Data Manager Settings
3. Open a file created by the Abaxis Data Manager

Note: Do not close the Abaxis Data Manager when Piccolo Xpress is transmitting the results.