

DEPMEDS LABORATORY PROCEDURES
DEPARTMENT OF CLINICAL SUPPORT SERVICES
U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
FORT SAM HOUSTON, TEXAS 78234-6137

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STANDARD OPERATING PROCEDURE

17 July 2002

Piccolo Point-of-Care Blood Analyzer

1. PRINCIPLE:

Chemical reactions occur between dry reagent beads and aqueous diluents contained in the Piccolo™ Reagent Disc and added sample. These reactions produce chromophores that are measured photometrically by the Piccolo Point of Care Blood Analyzer. The microprocessor then calculates the concentration of the analytes.

The operator introduces a heparinized whole blood sample (or heparinized plasma, serum, or control) into the reagent disc. The operator then places the disc in the analyzer and enters the appropriate identification. The analyzer spins the specimen to separate whole blood into cells and plasma. During this time, the disc is heated to 37° C.

2. SPECIMEN:

- a. Lithium heparin is the only anticoagulant recommended for use with the Piccolo.
- b. Accepts heparinized whole blood, heparinized plasma, or serum samples.
- c. Samples can be collected by finger puncture or venipuncture.

Use biohazard precautions and wear Personal Protective Equipment (PPE) when handling or pipetting body fluids or products.
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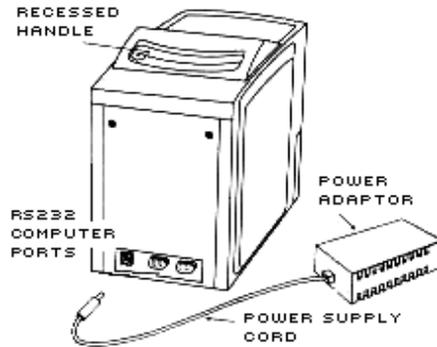
- 1) Finger puncture: Place in reagent disc immediately after collection.
 - 2) Venipuncture: Analyze samples collected within 60 minutes of collection.
- d. Sample size of 90uL is required to run the reagent disc. The disc sample chamber can contain up to 120uL sample.

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- e. A serum sample should be run within 5 hours of centrifugation. If this is not possible, the sample should be refrigerated in a [stoppered](#) container at 2-8° C (36-46° F) for no longer than 48 hours. A sample can be stored at 10° C for up to five weeks in a freezer that does not have a self defrost cycle.
3. REAGEANTS AND MATERIALS:
- a. Piccolo Point-of –Care Blood Analyzer
 - b. Power adapter
 - c. Start up kit
 - d. Operator’s Manual
 - e. Control Solution
 - f. Reagent rotor
 - g. 100uL pipette
 - h. 100uL pipette tips
 - i. Record cards
 - j. Powder free glove
 - k. Kim wipes
4. SETUP AND POWER SUPPLY
- a. Unpack the Analyzer and Accessories
 - (1) Place the box of reagent rotors in refrigerator immediately upon arrival.
(2-8° C, 36-46° F)
 - (2) Remove analyzer from box and place on level surface.
 - b. Set-up the Analyzer and Electrical Connections.
 - (1) Attach AC supply cord (with electrical wall plug) to power adapter.
 - (2) Attach DC power supply cord to (RS232 Computer ports) back of the Piccolo.

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- (3) Plug AC supply cord into grounded electrical outlet.
- (4) Make sure all connections are secured.
- (5) The Piccolo Analyzer will automatically turn on when plugged in to the electrical outlet. The analyzer display will show the following messages:

“PERFORMING SELF-TEST”

“HEATING DISC CHAMBER TO OPERATING TEMPERATURE”

“OPEN DRAWER TO RUN ROTOR”

NOTE: You will have to push the OPEN/CLOSE key on the keypad to open the drawer. Open when ready to load a disc.



- (6) Troubleshooting- Refer to the Operator’s Manual, Section 10, Troubleshooting. If the troubleshooting guide does not correct your problem call Abaxis Technical Services at **800-822-2947**.

c. Setting System Parameters

- (1) The following procedures are performed using the MENU key. The drawer must be closed in order to access these special functions.

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- (a) Set time and date. See Operator's Manual, Section 8.3 Changing Date and Time for details. The analyzer is pre-set to Pacific Time.

NOTE: Date and time must be accurately set. The analyzer uses this information to determine reagent dating when reading the bar-coded rotor prior to sample analysis.

- (b) Measurement units. The analyzer is pre-set to report results in common units (e.g., *mg/dL*). You may choose to change the units to SI units (e.g., *mmol/L*). To change units see Operator's Manual, Section 8.6, "Selecting Units."

5. REAGENTS STORAGE AND HANDLING

- a. Store reagents discs in their pouches at 2-8° C (36-46° F).
- b. A disc can be used directly from the refrigerator without warming.
- c. Do not exposed disc, in or out of the foil pouch to direct sunlight or temperature above 32° C (90° F).
- d. Reagents disc 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 bar.
- e. Inspect the unopened foil pouch for tears and punctures. A torn or damaged pouch may allow moisture to reach the disc and adversely affect reagent performance.
- f. Open the disc pouch at the notch on the top right edge of the package.
- g. Disc not used within 20 minutes of opening the pouch should be discarded.
- h. Discs are fragile, handle with care. Do not tap the disc on the table or workbench to fill the sample port. Do not use a disc that has been dropped.
- i. Handle disc only at the edges to avoid smudges on the optical surfaces. Use a lint free tissue to remove blood from the disc surface.
- j. Write patient identification number on the disc surface in the space indicated in the figure below. Do not write anywhere else in the disc.
- k. Hold reagent discs flat after introducing the sample or to avoid spillage.
- l. The used disc can be replaced in the pouch for disposal.

Warning: Used reagents disc contain body fluids. Follow good laboratory working practices. Handle all used disc as if they are contaminated with hepatitis or other infectious diseases.

6. CALIBRATION

The Piccolo Point-of-Care Chemistry Analyzer is calibrated by the manufacture before shipment. The bar code printed on the back ring provides the analyzer with disc-specific calibration data. (See the Piccolo Chemistry Analyzer Operator's Manual, Section 7).

7. QUALITY CONTROL

- a. Performance of the Piccolo Point-of-Care Chemistry Analyzer can be verified by running controls. Controls recommended by Abaxis are listed in the Piccolo Chemistry Analyzer Operator's Manual, section 13. Run at least a low and high control once per day on all analytes in use. The laboratory should also use some type of trend analysis (Levi-Jennings, running mean, etc.) to detect developing biases. If detected, biases must be corrected prior to further patient testing. All QC interventions must be thoroughly documented.
- b. The analyzer hardware performs a self-test with each power-on to ensure that optics, flash lamp, memory function, and circuit board components are functioning properly.
- c. System QC methods are included in the reagent disc to provide information on analyzer accuracy and linearity and disc chemistry performance during each analysis.
- d. Special beads are included in each reagent disc to detect environmental conditions such as temperature and humidity.
- e. The message "QC OK" is printed on the results card when results from these beads are within the expected ranges. If the QC is not within limits, no results card is printed and a "RUN CANCELED" message is shown on the display.

8. SPECIMEN COLLECTION

- a. The minimum required sample size is 100 μ L of heparinized whole blood, heparinized plasma, serum or serum control.
- b. Whole blood samples obtained by venipuncture must be homogeneous before transferring a sample to the reagent disc.
- c. Whole blood venipuncture samples should be run with 60 minutes of collection. Precautions:

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- (1) Glucose concentrations decrease approximately 5-12 mg/dL in 1 hour in uncentrifuged samples stored at room temperature.
- (2) Refrigerated whole blood samples can cause significant change in concentrations of glucose, and creatinine. The sample may be separated into plasma or serum and stored in capped sample tubes at 2-8° C.

- d. Use lithium heparin (green stopper) evacuated specimen collection tubes for whole blood or plasma samples.
- e. Use no additive (red stopper) evacuated specimen collection tubes or serum separator tubes (red/black stopper) for serum samples.

9. TESTING PROCEDURES

- a. Wear power-free gloves while operating the Piccolo Point-of-Care Blood Analyzer. Powder may adversely affect the analyzer optical system.
- b. If necessary, power up the analyzer power (by pressing the power key) The analyzer display will show the following messages:

“PERFORMING SELF-TEST”

- c. The analyzer may require additional time for the heaters to warm the disc chamber to operating temperature. During the warming period, the display reads:

“HEATING DISC CHAMBER TO OPERATING TEMPERATURE”

- d. After reaching operating temperature, the message reads:

“OPEN DRAWER TO RUN ROTOR”

(1) Preparing the reagent disc

- (a) Remove a sufficient number of foil reagent disc pouches from the refrigerator. Reagent discs may be used directly from the refrigerator without warming.
- (b) Inspect the unopened foil pouch for tears and punctures.
- (c) Examine the desiccant packet contained in the pouch. The strip on the

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back of the packet should be **BLUE**. A **PINK** strip indicates the reagent disc has been exposed to excess moisture. Discard.

- (d) Remove the reagent disc from the pouch with thumb and middle finger. Be careful not to touch the bar code ring located on the top of the disc.

A disc not used within 20 minutes of opening the pouch should be discarded.

- (e) Label disc with patient identification number.

(2) Dispense the sample

- (a) Use a micropipette or other transfer device to dispense approximately 100 μ L of sample into the disc via the sample port.

NOTE: Whole blood samples should be homogeneous prior to inoculating the disc. Gently invert the collection tube several times before filling the transfer device. Do not shake the sample, shaking may cause sample hemolysis.

- (b) Expel air bubbles from the tip of the micropipette.
- (c) Place the pipette in the sample port and tilt the device until it is perpendicular to the disc surface.
- (d) Push down in the plunger with slow, continuous motion.
- (e) Take care not to overfill the sample chamber. A 90 μ L sample will fill the sample chamber and form a line between the two arrows molded on the disc.
- (f) After dispensing the sample, discard the pipette tip in the biohazard container.
- (g) Tilt the disc at an angle of 45 degrees so that the sample fills line is lower than the port. This will cause any sample or control remaining in the sample port to flow into the sample chamber.

NOTE: Do not tap the disc on the table or workbench to empty the sample port as this may damage the disc.

- (h) Wipe up any spilled blood with a lint free tissue. Discard contaminated tissue.
- (i) Maintain disc in a flat position while loading the drawer.

(3) Running a patient sample.

- (a) The analyzer must be in standby mode to begin the procedure.
- (b) Use the numeric and arrow keys to enter patient, operator, and physician IDs while the analysis is proceeding.

The → key inserts a dash; the ← key deletes the characters to the left.

(c) This message is displayed when there is not a reagent disc in the drawer and the drawer is closed. Stand by mode.

“OPEN DRAWER TO RUN A DISC”

(d) Press OPEN. The following messages are displayed sequentially.

**“OPENING DRAWER TO START
ANALYSIS”**

(e) Place disc in the round hole in the drawer and press CLOSE. The display reads:

“CLOSING DRAWER...”

(f) The analysis begins when the drawer closes.

(g) By default, the range set for the previous sample is displayed. The reference range set for the current sample must be selected for correct interpretation of results. Use the numeric key to select the correct reference range set. Press “ENTER” when the correct number appears to the right of “SELECT SET”.

**SELECT: _X
1- MALE 2-FEMALE
3- SPECIAL
ENTER to accept**

(h) Press 1, 2, and 3, to select the reference range set appropriate for the sample being run.

(i) Enter patient identification number.

**INPUT PATIENT #
PRESS ENTER WHEN FINISHED**

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(j) Input the patient identification number up to 14 characters using the numeric keypad and press ENTER when the patient identification number is correct.

(k) Enter the operator identification number. (Up to three characters)

INPUT OPERATOR #
PRESS ENTER WHEN FINISHED

(l) To change the operator identification number, use the numeric keypad to enter the correct number. Use the back arrow key to make corrections. Press **ENTER** when the number is correct.

(m) Enter the physician identification number (up to three characters). Once again, the identification number shown on the display is that entered for the previous sample.

INPUT DOCTOR #
PRESS ENTER WHEN FINISHED

(n) Changing DOCTOR #: same as step (l)

(4) Automatic sample processing

(a) The analyzer processes the sample with no further input. Sample processing takes <15 minutes. The analyzer displays the following message, including patient ID number and time remaining to complete the analysis.

RESULTS READY IN
XX:XX
FOR PATIENT #:
XXXXXXX

(b) Sample processing is complete when the analyzer beeps and displays the message:

ANALYSIS COMPLETE.
OPEN DRAWER OR INSERT CARD TO PRINT RESULTS.

(c) The analyzer stores the results internally and automatically transmits them to the RS232 port. If you do not choose to print the results, press

OPEN, continue to step 11. If you choose to print results, press OPEN and insert the results card in the result card slot. The display reads:

- (5)

PRINTING RESULTS

REMOVE CARD

(a) Place the result card in the result card slot. Remove the card when directed to do so on the display. These message appear sequentially:

- | |
|-------------------------|
| PRINTING RESULTS |
|-------------------------|
- | |
|--------------------|
| REMOVE CARD |
|--------------------|

(b) As you remove results card, the drawer will open automatically and these messages appear sequentially.

- | |
|-----------------------|
| OPENING DRAWER |
|-----------------------|
-
- | |
|-------------------------------------|
| REMOVE DISC AND CLOSE DRAWER |
|-------------------------------------|

(c) Remove the reagent disc from the drawer. You may place the disc back into its foil pouch before disposal.

(6) To return the analyzer to standby mode, remove the reagent disc from the drawer and dispose of it, following your lab’s biohazard procedures. Press CLOSE and the analyzer will return to standby mode.

10. RESULTS

- a. The Piccolo Point-of-Care Blood Analyzer automatically calculates and prints the analyte concentrations in the sample. Details of the end point and rate reaction calculations are found in the Operator’s Manual.
- b. Interpretation of results is detailed in the Operator’s Manual, Section 5.5. Results are printed onto result cards supplied by Abaxis. The result cards have an adhesive backing for easy placement in the patient’s files.

Indices- hemolysis, lipemia, and icterus are printed at the bottom of each result card. 0 (clear), 1+ (slight), 2+ (moderate) and 3+ (gross)
 When results falls outside the linear range, contains interferences, or is considered inaccurate, it is flagged according to the condition noted:

FLAG	CONDITION	ACTION
>	Results falls above the displayed concentration value, which Represents the high end of the reportable range of the test.	Report as “Greater than”-

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<	Results falls below the displayed concentration value, which represents the low end of the reportable range of the test.	Report as "Less than"
HEM, LIP, ICT	Indices- hemolysis, lipemia, and icterus	Collect a new fasting sample.
◆◆◆	Inaccurate results.	Retest with a new disc. If flag again, contact Abaxis.

11. FACTORS AFFECTING RESULTS

- a. Contaminated equipment.
- b. QNS-quantity not sufficient.
- c. Expired disc(s).
- d. Reagent storage.

12. INSTALLING A NEW SOFTWARE CARD

- a. Remove the power cord from the back of the analyzer.
- b. Remove the rear panel by loosening the two Phillips head screws at the top of the panel.
- c. Remove the Phillips head screw and the software card-retaining bracket to expose the access slot.

NOTE: The bracket screw is very small. Carefully remove the screw to avoid losing it.

- d. Firmly push the black button in the upper portion of the access slot.
- e. The card ejects itself. Insert the new version software and with the printed label facing toward the center of the analyzer
- f. Push the card firmly until it clicks into place.
- g. Hook the lip on the bottom of the retaining bracket inside the bottom of the access slot.
- h. Replace the screw and software card retaining bracket.
- i. Replace the rear panel and tighten the two screws at the rear panel.
- j. Plug the power cord into the back of the analyzer.
- k. The analyzer performs a self-test and programs itself. The entire procedure takes about 10 minutes.

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NOTE: An error code will appear if the software card is not properly installed or if the card is faulty. Refer to the trouble shooting section of your Operator's Manual.

- j. Allow the analyzer to reach operating temperature (<15 minutes). When the "Open drawer to run a rotor" message is displayed, you will know you have successfully changed the software card.
- k. Place your old software card into the enclosed postage paid envelope and mail it back to Abaxis.
- m. You must contact the Abaxis customer services to subscribe your unit and equipment for further software updates. **1-800-822-2947**.
- n. The technical service representative will ask for: description of the problem, if any; the analyzer serial number and software version number.
- o. Serial number and software version numbers can be accessed through the MENU key. A complete description can be found in the Operator's Manual.

13. REFERENCES

Piccolo™ Point-of-Care Blood Analyzer Operator's Manual, PN: 100-7008 Rev. E, © 1995 Abaxis Corporation

Abaxis, Inc.

1-800-822-2947

Customer Service and Technical Support.

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Reviewed 16 AUG 02

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NCOIC, DEPMEDS