

OREGON HEALTH & SCIENCE UNIVERSITY
Hospitals and Clinics
Point of Care

**Comprehensive Metabolic Panel
by Abaxis Piccolo Express**

Principle

The Piccolo Point-of-Care Chemistry Analyzer provides quantitative determinations of clinical chemistry analytes in heparinized whole blood, serum, or plasma. Each patient test utilizes single-use disposable reagent discs composed of multiple reaction cuvettes containing test-specific lyophilized reagent beads. The chemical reactions carried out within each cuvette are designed to produce a reaction that absorbs light at known wavelengths. Analyte concentrations are then calculated from this light absorbance data.

Only the Comprehensive Metabolic Panel (CMP) reagent discs will be utilized. Each of these reagent discs test for the following analytes:

Glucose (Gluc)
Urea Nitrogen (BUN)
Creatinine (Cre)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Total CO₂ (TCO₂)
Calcium (Ca)
Total Bilirubin (TBil)
Total Protein (TP)
Albumin (Alb)
Alkaline Phosphatase (ALP)
Aspartate Aminotransferase (AST)
Alanine Aminotransferase (ALT)

Specimen Requirements

1. Lithium heparinized whole blood is the only acceptable specimen.
2. Specimens must be tested within 60 minutes of collection.
3. A sample size of 90-120 µL is required.

Interferences

1. The analyzer detects for and suppresses results when the precision is significantly affected (>10%) by hemolysis, lipemia, or icterus. Suppressed results due to hemolysis, lipemia, or icterus are displayed as “HEM”, “LIP”, or “ICT” in place of the analyte concentration. If suppressed results are present:
 - a. Insert a result card when prompted.
 - b. Examine the sample indices printed at the bottom of the result card to determine if more than one interferent is affecting results. The sample is rated for the hemolysis, lipemia, and icterus interferences using the following scale:

0	Clear
1+	Slight
2+	Moderate
3+	Gross
 - c. If gross hemolysis (3+) is the interferent, a new sample is necessary and can be rerun on the Piccolo or sent to the Core Lab for testing.
 - d. For lipemic and icteric specimens a new specimen will likely not solve the problem. Send an appropriate requisition along with a properly labeled green-top lithium heparin specimen to the core lab for testing.
2. Specimens with any level of hemolysis (HEM 1+,2+, or 3+) may demonstrate falsely elevated potassium (K+) results. If results are suspect, a new specimen should be obtained and rerun on the Piccolo.
3. Samples with a hematocrit in excess of 60% packed red cell volume may have certain analyte results reported on the result card as “HEM”. These specimens must be sent to the Core Lab for proper testing.
4. A result may be suppressed when any of the internal QC steps detect an abnormal condition or analyte concentrations outside of the linear range of the assay. Suppressed results due to abnormal conditions are displayed as a row of black diamonds (◆◆◆). If results are displayed as a row of black diamonds, rerun the test using a new reagent disc or send the specimen to the core lab for testing.
 - a. If a patient or Liquid Quality Control specimen gives any suppressed results, an error report card can be printed and sent to the POC coordinator.
5. Insufficient sample volume or clotted specimens will result in run cancellations. If a run is cancelled insert a result card to print the cancellation report. Press “EXIT” to acknowledge the message and open the drawer. Check the disc for insufficient volume or a clotted sample.
 - a. If the cause is insufficient sample volume, then load a new reagent disc and rerun the specimen.
 - b. If the cause is a clot, then collect a new specimen and run that new specimen on a new reagent disc.
 - c. Send the cancellation report printed on the result card to the POC coordinator.

If at anytime any result is suppressed and a specimen is sent to the Core Lab, the testing done on the Piccolo cannot be billed for. An entire CMP should be done in the Core Lab.

Analytical Measurement Range (Linearity)

Analyte	AMR
Glucose (Gluc)	25-700 mg/dL
Urea Nitrogen (BUN)	2-170 mg/dL
Creatinine (Cre)	0.2-20 mg/dL
Sodium (Na)	110-170 mmol/L
Potassium (K)	1.5-8.0 mmol/L
Chloride (Cl)	80-135 mmol/L
Total CO ₂ (TCO ₂)	5-40 mmol/L

Analyte	AMR
Calcium (Ca)	4.5-15.0 mmol/L
Total Bilirubin (TBil)	0.1-30 mg/dL
Total Protein (TP)	3-11 g/dL
Albumin (Alb)	2.0-6.5 g/dL
Alkaline Phosphatase (ALP)	10-1900 U/L
Aspartate Aminotransferase (AST)	10-1500 U/L
Alanine Aminotransferase (ALT)	10-1500 U/L

Results exceeding the Piccolo's measurable range are displayed as either a greater than (>) or less than (<) symbol. Any result for a particular test that exceeds the Piccolo's measurable range is to be sent to the Core Lab for testing.

Reference Ranges

	Age	Male	Female
Glucose- mg/dL	0-1 day	40-60	40-60
	1 day- 150 yrs	60-99	60-99
BUN mg/dL	0-2 months	4-15	4-15
	2 months – 2 yrs	5-15	5-15
	2 yrs- 150 yrs	6-20	6-20
Creatinine mg/dL	0- 2 months	0.31-0.92	0.31-0.92
	2 months – 1 yr	0.16-0.39	0.16-0.39
	1 yr – 3 yrs	0.17-0.35	0.17-0.35
	3 yrs – 5 yrs	0.26-0.42	0.26-0.42
	5 yrs – 7 yrs	0.29-0.48	0.29-0.48
	7 yrs – 9 yrs	0.34-0.55	0.34-0.55
	9 yrs – 11 yrs	0.32-0.64	0.32-0.64
	11 yrs – 13 yrs	0.42-0.71	0.42-0.71
Sodium mmol/L	13 yrs – 18 yrs	0.46-0.81	0.46-0.81
	18 yrs – 150 yrs	0.70-1.30	0.60-1.10
Sodium mmol/L		134-143	134-143
Potassium mmol/L		3.4-5.0	3.4-5.0
Chloride mmol/L		97-108	97-108
Total CO ₂ mmol/L		23-31	23-31
Total Calcium mg/dL	0 – 1 week	7.5-10.5	7.5-10.5
	1 week – 150 yrs	8.6-10.2	8.6-10.2
Total Bilirubin mg/dL	0 – 1 day	1.4-8.7	1.4-8.7

	Age	Male	Female
Total Bilirubin Cont.	1 day – 2 days	3.4-11.5	3.4-11.5
	2 days – 5 days	1.5-12.0	1.5-12.0
	5 days – 150 yrs	0.3-1.2	0.3-1.2
Total Protein g/dL	0 – 1 week	4.5-7.0	4.5-7.0
	1 week – 2 yrs	5.0-7.5	5.0-7.5
	2 yrs – 16 yrs	5.9-8.2	5.9-8.2
	16 yrs – 150 yrs	6.1-7.9	6.1-7.9
Albumin g/dL	0 – 1 yr	2.7-5.0	2.7-5.0
	1 year – 150 yrs	3.5-4.7	3.5-4.7
ALP U/L	0 – 3 years	85-270	85-270
	3 yrs – 11 yrs	125-445	125-470
	11 yrs – 13 yrs	170-415	90-355
	13 yrs – 15 yrs	110-440	60-195
	15 yrs – 19 yrs	55-220	42-110
	19 yrs – 60 yrs	53-128	42-98
	60 yrs – 150 yrs	56-119	53-141
AST U/L	0 – 12 years	24-47	24-47
	12 yrs – 16 yrs	18-36	18-36
	16 yrs – 150 yrs	15-41	15-41
ALT U/L		13-48	13-48

Critical/Alert Values

Critical alert values are those results demonstrating such variance from normal as to represent a pathophysiological state with potential of being life threatening unless action is taken quickly. These results must be immediately reported to the care provider and be documented in the test record as to who was contacted, the time of contact, the person making contact, and if relevant, that the results were read back.

Critical/Alert Value			
		Low	High
Glucose	mg/dL	≤50	≥500
Glucose (0-1month)	mg/dL	≤40	≥300
BUN	mg/dL	None	None
Creatinine	mg/dL	None	None
Sodium	mmol/L	≤120	≥160
Potassium	mmol/L	≤2.5	≥6.0
Chloride	mmol/L	None	None
Total CO ₂	mmol/L	≤12	≥40
Total Calcium	mmol/L	≤7.0	≥13
Total Bilirubin (Neonate)	mg/dL	None	≥15
Total Protein	g/dL	None	None
Albumin	g/dL	None	None
ALP	U/L	None	None
AST	U/L	None	None
ALT	U/L	None	None

Quality Control

The Piccolo Point-of-Care Chemistry Analyzer performs multiple internal quality checks with each reagent disc. These quality checks are collectively called “intelligent QC” (iQC). When the iQC confirms that all parameters are within expected ranges, “INST QC: OK” and “CHEM QC: OK” are printed on the result card. If the analyzer detects any internal quality control errors, those results affected will be suppressed and a row of black diamonds (◆◆) will be displayed in place of the analyte concentration.

Daily iQC

Each day of patient testing, immediately after the first patient test, an iQC report must be printed, reviewed, and placed in the Piccolo logbook. To print an iQC report:

1. From the ‘Home’ screen, press the “Recall” (file folder) button.
2. Press the “Last Disc” button. Or
3. Press the “▲, ▼” keys to select patient records (control if that was run).
4. Press ‘Print’ button.
5. Press the “iQC” button to select iQC records.

6. The iQC report is printed. Adhere this to the iQC log.
7. Press the "Home" button return to the standby mode.

Liquid quality control

When a new lot of reagent discs arrives and each month thereafter, two levels of liquid quality controls (LQC) must be tested. To perform LQC testing:

1. Use a micropipette to dispense approximately 100 μ L of LQC into the reagent disc sample port.
2. Insert the loaded reagent disc into the instrument.
3. Enter your operator ID.
4. Select Control.
5. Select the correct control level
 - a. Control Level 1
 - b. Control Level 2
6. Select 1 or 2 at the Control Level ID.
7. When test is complete, the result will print.
8. Attach the LQC printout to the LQC log sheet and compare all results to the target range printed. Analytes outside target ranges will have an asterisks (*) by it
9. If any results fall outside of target range, that level of LQC must be reran with a new reagent disc.
10. Repeat above steps for the other level of LQC.
11. Both levels of LQC must have all results within the target ranges. Contact the POC coordinator if results do not fall within target range on the second attempt. Document all action taken on the LQC log sheet.

Patient Testing Procedure

1. Using proper personal protective equipment, collect a green-top lithium heparin tube; do not forget to mix it.
2. Label the specimen just as you would if it were to be sent to the Core Lab.
3. Remove a reagent disc from the refrigerator.
4. Use a micropipette to dispense approximately 100 μ L of patient specimen into the reagent disc sample port.
5. Insert the loaded reagent disc into the instrument.
6. Enter your operator ID.
7. Select 'Patient'.
8. Select male or female.
9. Enter the patient MR # using the numeric keys when prompted.
10. Insert a result card into the instrument when prompted (after the run is completed).
11. Examine the results **paying particular attention to the indicies** printed near the bottom of the results. The HEM index must be less than 3+. All 3+ HEM specimens must be recollected and reran.
12. Attach the printed result card to the Patient Result Form to be placed in the patient record. This form must also have a patient ID sticker attached to it.

Calculations

None.

Reporting Results

Attach the printed result card to the Patient Result Form to be placed in the patient record. This form must also have a patient ID sticker attached to it. This form must also be scanned into the electronic medical record, as thermally printed results, result cards, are not acceptable for a permanent record.

Patient results displaying an asterisk next to the result indicate results outside of the established normal reference range.

Exclamation marks printed next to each result are intended to notify the user of a possibly diluted or otherwise contaminated specimen. Patient specimens demonstrating these exclamation marks should be reviewed carefully. A new specimen may be indicated if results are lower than expected.

Review the patient results for any critical/alert values. Critical/Alert values are printed on the Patient Result Form next to the area where the result card is to be placed. Report any critical/alert values to the provider immediately and document this in the patient's record.

Calibration Verification

Calibration Verification is performed via patient correlations. Two patients will be tested both by the Piccolo and Core Lab every month.

Reagents

1. Reagent discs:
 - a. No preparation needed.
 - b. Each single-use disposable reagent disc contains dry test-specific reagent beads. See the package insert provided with each box of reagent discs for full details on reagent bead composition.
 - c. Store all cartridges in the refrigerator at a temperature between 2 to 8°C (35 to 46°F). **Do not allow cartridges to freeze.**
2. Piccolo Liquid Assayed Controls (LQC) Levels I and II.
 - a. Piccolo LQC material is prepared from human serum to which purified biochemical material, chemicals, drugs, preservatives, and stabilizers have been added. This material must be handled with the same precautions used with patient specimens.
 - b. Storage:
 - i. Frozen: LQC material is stable until the expiration date when stored unopened at -20°C or colder.
 - ii. Thawed: When LQC material is thawed and stored at 2-8°C, all analytes will be stable for 14 days with the following exceptions: ALT, AST, CK, and Total Bilirubin may decrease.
 - iii. Avoid repeated freezing and thawing of LQC material.

References

1. Piccolo Point-of-Care Chemistry Analyzer Operator's Manual, 2007.
2. Piccolo Guide to Laboratory Quality Compliance, 2007.

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