**PRINCIPLE:**

The Piccolo Xpress chemistry analyzer provides quantitative in-vitro determinations of clinical chemistry analytes in lithium-heparinized whole blood.

**SCOPE:**  This procedure applies to UPMC Hillman Cancer Center – Hanover Laboratory.

**SPECIMEN:**

The minimum required sample is ~ 100 microliter of heparinized whole blood or control material. Whole blood samples obtained by venipuncture must be homogenous before transferring sample to the reagent disc. Patient specimens must include patient’s full name, date of birth, date and time and collector’s initials. Gently invert collection tube prior to sample transfer. Whole blood samples should be run immediately or within 60 minutes. Use only LITHIUM HEPARIN (light green stopper) evacuated specimen collection tubes. If another tube type is sent, it must be sent to the UPMC Hanover hospital laboratory for analysis. Start test within 10 minutes of transferring sample to reagent disc.

**MATERIALS:**

1. Piccolo Xpress analyzer
2. Piccolo Xpress Comprehensive Metabolic Reagent Disc
3. Bioresource Technology (BRT) Verification Samples
4. Bioresource Technology (BRT) Liquid Assayed Chemistry + Lipid Control
5. 100 microliter pipette and disposable tips
6. Gloves and lab coat
7. Lithium heparin green top tubes

**Reagent Disk Storage/Stability**

* Store reagent discs in their sealed pouches at 2 – 8OC.
* 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. Document new expiration date and time on disc if not used immediately and if pouch is not opened.
* A disc unused after 20 minutes of opening a pouch must be discarded.
* Do not use a reagent disc from a damaged pouch.
* Reagent disc may be used until the expiration date indicated on the package when stored at 2 – 8OC.
* The expiration date is encoded in the bar code of the reagent disc. If an expired disc is used, an error message will occur.
* Please refer to Appendix A for Piccolo Comprehensive Metabolic Reagent Disc information for test methods and test specific interferences.
* Note, the eGFR calculation listed in the disc information sheet is suppressed from the instrument. eGFR calculation occurs at the Laboratory Information System.

**SAFETY:** All specimens and instruments should be considered biohazardous and

Universal Precautions should always be followed.

**CALIBRATION / QUALITY CONTROL / MAINTENANCE:**

1. Daily Quality Control

* iQC is done daily. The iQC results are obtained by utilizing recall results and selecting iQC to print. Attach the printout to the Daily iQC Log Sheet for the appropriate instrument serial number.
* Room temperature and humidity need to be monitored daily during operating hours. Operating range for Piccolo is 15 to 32OC and for humidity, 8 to 80% non-condensing.

1. Weekly Quality Control

* 2 levels of external liquid control are stored frozen (-20OC) until ready for use and are performed weekly. BRT Liquid Assayed Chemistry controls are good until their expiration date when stored frozen. Controls can be stored in the refrigerator for 2 weeks. Thaw controls at room temperature for one hour. Control level 1 or 2 is selected and lot# of control is entered after loading the reagent disc. Both levels of control are required to be analyzed when any of the following occur:
* For each new shipment or lot # of reagent. Reagents need to be parallel checked (old lot versus new lot or shipment) before placing new lot or shipment into service.
* When test results do not match patient symptoms as determined by the ordering physician.
* When training or retraining new operators.
* When laboratory conditions change with temperature or humidity. Acceptable ranges for temperature and humidity are listed on the charts in the maintenance book.
* QC must discarded at the end of the shift once opened.
* Patient results cannot be reported until QC is within acceptable range, either the daily iQC or liquid external controls. For any failures, the technologist is required to rerun the QC, in the case of liquid controls, obtain a new set to rerun. If rerun is acceptable, document on the QC log or in the computer for liquid controls. If the rerun does not work, notify the supervisor. All patient specimens should be sent to the UPMC Hanover laboratory for processing until the problem is resolved and QC is within acceptable limits.

1. New Lots / Shipments of Reagent Discs
   * New lot numbers of reagent discs must be QC’d and checked against the in use lot using a patient sample prior to use for patient testing.
   * New shipments of an in-use lot of reagent discs must be QC’d prior to use for patient testing.
   * Refer to the Abaxis Piccolo New Lot / Shipment Validation form for further instruction.
2. Calibration/Verification - Verification is performed every 6 months (3 levels) **OR**

* When indicated by quality control material
* When the instrument is moved
* After major part, major service or major software upgrade
* To satisfy local regulatory requirements
* Whenever lab conditions change
* When test results do not match patient symptoms as determined by the ordering physician.

1. Maintenance

* Check the air filter on the back of the instrument monthly and clean at least every 6 months or more often if needed.
* If cleaning of the analyzer is necessary, use only a mild non-abrasive cleaner.

**PROCEDURE:**

**Patient Testing**

1. Dispense the sample: Use a micropipette (included with the Piccolo Xpress) or an MLA pipette to dispense approximately 100 uL of well mixed sample into the disc via the sample chamber. (Sample should be gently inverted at least 10 times to ensure sample is homogenous).
2. Press **ANALYZE** on the touch screen to open the disc drawer.
3. Place the disc in the recessed area in the drawer.
4. Press **CLOSE** on the touch screen. The analyzer then closes the drawer.
5. Enter the patient’s accession number for the sample then press **DONE**.
6. The analyzer then checks the disc type and begins processing the sample.
7. When the sample is finished processing, the analyzer stores the results and shows that the analysis is complete.
8. By default, the analyzer automatically prints the results of the analysis and the results will interface into EPIC Beaker. Place the instrument printout on the patient sample log.
9. Press **OPEN** to open the disc drawer.
10. Remove the reagent disc from the drawer.
11. When finished testing, press **CLOSE** to close the drawer and return the analyzer to standby mode.
12. To analyze another sample, dispense the sample and repeat the above procedure.

**Start-up, Shutdown and If Inoperable**

1. To start the Piccolo press the round opaque plastic button on the lower right side of the Piccolo. It will turn blue.
2. To shut down the Piccolo hold the round opaque plastic button in until the blue light goes out. The Piccolo should be shut down at the end of the day.
3. If inoperable, credit all Piccolo orders and reorder and perform at the hospital laboratory using the main chemistry analyzers.

**INTERPRETATION:**

1. **Patient Normal Ranges:**

Alanine Aminotransferase (ALT) 10 – 47 U/L

Albumin (ALB) 3.3 – 5.5 g/dL

Alkaline Phosphatase (ALP) Male 53 – 128 U/L

Alkaline Phosphatase (ALP) Female 42 – 141 U/L

Aspartate Aminotransferase (AST) 11 – 38 U/L

Calcium (CA) 8.0 – 10.3 mg/dL

Chloride (CL-) 98 – 108 mmol/L

Creatinine (CRE) 0.6 – 1.2 mg/dL

Glucose (GLU) 73 – 118 mg/dL

Potassium (K+) 3.6 – 5.1 mmol/L

Sodium (NA+) 128 – 145 mmol/L

Total Bilirubin (TBIL) 0.2 – 1.6 mg/dL

Total Carbon Dioxide (tCO2) 18 – 33 mmol/L

Total Protein (TP) 6.4 – 8.1 g/dL

Blood Urea Nitrogen (BUN) 7 – 22 mg/dL

1. **Piccolo Linearity:**

Alanine Aminotransferase (ALT) 21 – 1386 U/L

Albumin (ALB) 2.2 – 5.6 g/dL

Alkaline Phosphatase (ALP) 29 – 1841 U/L

Aspartate Aminotransferase (AST) 20 – 1417 U/L

Calcium (CA) 4.3 – 14.5 mg/dL

Chloride (CL-) 83 –128 mmol/L

Creatinine (CRE) 0.5 – 15.4 mg/dL

Glucose (GLU) 29 – 639 mg/dL

Potassium (K+) 2.0 – 8.0 mmol/L

Sodium (NA+) 113 – 161 mmol/L

Total Bilirubin (TBIL) 0.4 – 4.8 mg/dL

Total Carbon Dioxide (tCO2) 10 – 35 mmol/L

Total Protein (TP) 3.6 – 9.8 g/dL

Blood Urea Nitrogen (BUN) 5 – 102 mg/dL

Note: If the analyte concentration is above the linearity, the print card will indicate “>” sign at the upper limit and an asterisk “\*” after the number, e.g. ALT >1663\* U/L. If lower than the linearity, a “<” will be printed with an asterisk, e.g. ALT <10\* U/L. For values that are grossly beyond the linearity, “~~~” will be printed instead of a result. Any time “~~~” appears on a print card, repeat the sample and if still out of linearity, send the specimen to the UPMC Hanover laboratory for testing and confirmation.

1. **Critical Values (Adults only)**

|  |  |  |
| --- | --- | --- |
| **Test** | **Low Critical Value** | **High Critical Value** |
| Blood Urea Nitrogen (BUN) | N/A | 100 mg/dl |
| Sodium (NA) | 120 mEq/L | 160 mEq/L |
| Potassium (K+) | 2.8 mEq/L | 6.5 mEq/L |
| CO2 | 10 mEq/L | 40 mEq/L |
| Calcium | 6 mg/dl | 13 mg/dl |
| Glucose | 40 mEq/L | 600 mg/dl |

1. For any analyte that exceeds the linearity, notify the ordering physician of the delay, and send to the UPMC Hanover laboratory for testing by placing on a packing list.
2. Any sample generating a critical value, notify the ordering physician of the delay, tell them you have a preliminary critical value and that the sample will be sent to the hospital laboratory for confirmation.
3. Normal anion gaps are -4 to 12. If the AGAP is lower than -4 repeat the test. If still lower than -4, send to the hospital laboratory for confirmation. The anion gap is calculated using the following equation:

Anion Gap = (Na + K) – (Cl + CO2)

1. Any sample that has interfering substances or you are unable to obtain a result, notify the ordering physician of the delay, credit the order, reorder for the Carlisle hospital laboratory and send to the hospital laboratory for analysis.
2. Any time you encounter the error “Confirm low recoveries” please rerun the specimen to see if the error clears or have the testing performed at the hospital laboratory. This error may indicate a short or diluted sample or problematic specimen which affected the Piccolo methodology.
3. Every 6 months verification samples need to be performed and the results must be within manufacturers ranges listed below.

* ALB ± 0.3 g/dL
* ALP ± 10 U/L or 15%
* ALT ± 9 U/L or 17.5%
* AST ± 8 U/L or 15.0%
* BUN ± 3 mg/dL or 10.5%
* CA ± 1.3 mg/dL
* CL ± 4 mmol/L or 7.5%
* CRET ± 0.5 mg/dL or 7.5%
* GLU ± 4.5 mg/dL or 5%
* K ± 0.8 mmol/L or 3%
* NA ± 2 mmol/L or 5%
* TBIL ± 0.3 mg/dL or 10%
* TCO2 ± 6mmol/L or 10%
* TP ± 1 g/dL or 5%

**RESULT REPORTING:**

Results are interfaced via the LIS.

**LIMITATIONS:**

1. The only anticoagulant recommended for use is lithium heparin. Do not use sodium heparin.
2. Samples with hematocrits in excess of 62-65% packed cell volume may give inaccurate results.

Note: Samples with high hematocrits may be reported as hemolyzed.

1. Any result for a particular test that exceeds the linearity range of the piccolo is to be performed by the UPMC Carlisle laboratory on the main Chemistry analyzers.
2. 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 these interferents. “HEM”, “LIP”, or “ICT” respectively is printed on the result card of the result.
3. Refer to Appendix A in the operator’s manual for reagent disc details, including principles of reactions, interfering substances and linearity of methods.
4. Enrollment in PT programs will be sufficient scope to reflect the extent and complexity of testing performed in the Laboratory. PT samples will be given to the technologist in the lab for that day. All PT samples will be tested in the same manner as routine patient testing. Proficiency testing is never referred to an outside laboratory and communication about the survey is prohibited.
5. The use of the CMP cartridge on the ABAXIS Piccolo is CLIA waived.

**ATTACHMENTS: N/A**

**REFERENCES:**

1. ABAXIS Piccolo Xpress Operators’ Guide

**Document History**

|  |  |  |
| --- | --- | --- |
| Date of Origination and Document Control Number | HCC 0010  April 20, 2022 | Method implementation. |
| John R Samuel, MT(ASCP) |
| Revision History/ Biennial Review: |  |  |
| Revision History/ Biennial Review: |  |  |
| Revision History/ Biennial Review: |  |  |
| Revision History/ Biennial Review: |  |  |