

Piccolo[®] Electrolyte Panel



For In Vitro Diagnostic Use and For Professional Use Only
Customer and Technical Service: 1- 800-822-2947
Customers outside the US: +49 6155 780 210

Applicable to US customers only
CLIA Waived: Use lithium heparin whole blood, only
Moderate Complexity: Use lithium heparin whole blood, lithium heparin plasma, or serum



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1. Intended Use

The Piccolo[®] Electrolyte Panel, used with the Piccolo[®] blood chemistry analyzer or the Piccolo Xpress[®] chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of chloride, potassium, sodium, and total carbon dioxide in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

For US Customers Only

The tests on this panel are waived under CLIA '88 regulations. If a laboratory modifies the test system instructions, then the tests are considered high complexity and subject to all CLIA requirements. For CLIA waived labs, only lithium heparin whole blood may be tested. For use in moderate complexity labs, lithium heparinized whole blood, lithium heparinized plasma, or serum may be used.

A CLIA Certificate of Waiver is needed to perform CLIA waived testing. A Certificate of Waiver can be obtained from the Centers for Medicare & Medicaid Services (CMS). Please contact the Commission on Laboratory Accreditation (COLA) at 1-800-981-9883 for assistance in obtaining one.

2. Summary and Explanation of Tests

The Piccolo Electrolyte Panel and the Piccolo blood chemistry analyzer comprise an *in vitro* diagnostic system that aids the physician in diagnosing the following disorders:

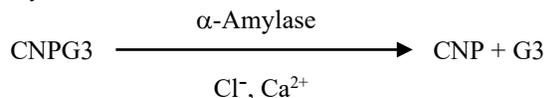
Chloride:	Dehydration, prolonged diarrhea and vomiting, renal tubular disease, hyperparathyroidism, burns, salt-losing renal diseases, overhydration and thiazide therapy.
Potassium:	Renal glomerular or tubular disease, adrenocortical insufficiency, diabetic ketacidosis, excessive intravenous potassium therapy, sepsis, panhypopituitarism, in vitro hemolysis, hyperaldosteronism, malnutrition, hyperinsulinism, metabolic alkalosis and gastrointestinal loss.
Sodium:	Dehydration, diabetes insipidus, loss of hypotonic gastrointestinal fluids, salt poisoning, selective depression of sense of thirst, skin losses, burns, sweating, hyperaldosteronism, CNS disorders, dilutional, depletion and delusional hyponatremia and syndrome of inappropriate ADH secretion.
Total carbon dioxide:	Primary metabolic alkalosis and acidosis and primary respiratory alkalosis and acidosis.

As with any diagnostic test procedure, all other test procedures including the clinical status of the patient, should be considered prior to final diagnosis.

3. Principle of Procedure

Chloride (Cl⁻)

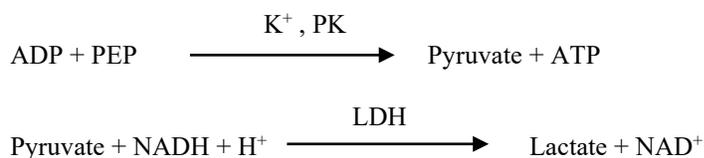
The method is based on the determination of chloride-dependent activation of α -amylase activity. Deactivated α -amylase is reactivated by addition of the chloride ion, allowing the calcium to re-associate with the enzyme. The reactivation of α -amylase activity is proportional to the concentration of chloride ions in the sample. The reactivated α -amylase converts the substrate, 2-chloro-*p*-nitrophenyl- α -D-maltotriose (CNP3) to 2-chloro-*p*-nitrophenol (CNP) producing color and α -maltotriose (G3). The reaction is measured bichromatically and the increase in absorbance is directly proportional to the reactivated α -amylase activity and the concentration of chloride ion in the sample.¹



Potassium (K⁺)

Spectrophotometric methods have been developed that allow the measurement of potassium concentration on standard clinical chemistry instrumentation. The Abaxis enzymatic method is based on the activation of pyruvate kinase with potassium and shows excellent linearity and negligible susceptibility to endogenous substances.^{2,3,4} Interference from sodium and ammonium ion are minimized with the addition of Kryptofix and glutamine synthetase, respectively.²

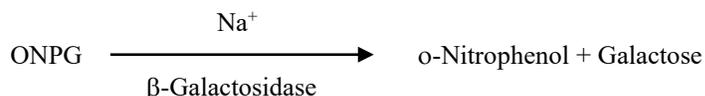
In the coupled-enzyme reaction, pyruvate kinase (PK) dephosphorylates phosphoenolpyruvate (PEP) to form pyruvate. Lactate dehydrogenase (LDH) catalyzes conversion of pyruvate to lactate. Concomitantly, NADH is oxidized to NAD⁺.



The rate of change in absorbance difference between 340 nm and 405 nm is due to the conversion of NADH to NAD⁺ and is directly proportional to the amount of potassium in the sample.

Sodium (Na⁺)

Colorimetric and enzymatic methods have been developed that allow the measurement of sodium concentration on standard clinical chemistry instrumentation.^{5,6,7} In the Abaxis enzymatic reaction, β -galactosidase is activated by the sodium in the sample. The activated enzyme catalyzes the reaction of o-nitrophenyl- β -D-galactopyranoside (ONPG) to o-nitrophenol and galactose.

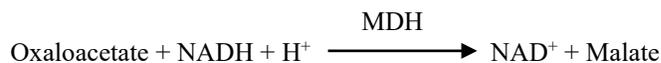


Total Carbon Dioxide (tCO₂)

Total carbon dioxide in serum or plasma exists as dissolved carbon dioxide, carbamino derivatives of proteins, bicarbonate and carbonate ions and carbonic acid. Total carbon dioxide can be measured by pH indicator, CO₂ electrode and spectrophotometric enzymatic methods, which all produce accurate and precise results.^{8,9} The enzymatic method is well suited for use on a routine blood chemistry analyzer without adding complexity.

In the enzymatic method, the specimen is first made alkaline to convert all forms of carbon dioxide (CO₂) toward bicarbonate (HCO₃⁻). Phosphoenolpyruvate (PEP) and HCO₃⁻ then react to form oxaloacetate and phosphate in the presence of phosphoenolpyruvate carboxylase (PEPC). Malate dehydrogenase (MDH) catalyzes the reaction of oxaloacetate and reduced nicotinamide adenine dinucleotide (NADH) to NAD⁺ and malate. The rate of change in absorbance due to the conversion of NADH to NAD⁺ is directly proportional to the amount of tCO₂ in the sample.





4. Principle of Operation

See the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Operator's Manual, for the Principles and Limitations of the Procedure.

5. Description of Reagents

Reagents

Each Piccolo Electrolyte Panel contains dry test-specific reagent beads (described below). A dry sample blank reagent (comprised of buffer, surfactants, excipients, and preservatives) is included in each disc for use in calculating concentrations of chloride (CL⁻), potassium (K⁺), sodium (NA⁺), and total carbon dioxide (tCO₂). Each disc also contains a diluent consisting of surfactants and preservatives.

Table 1: Reagents

Component	Quantity/Disc
Adenosine-5'-diphosphate	13.9µg
Amylase	0.036U
Calcium acetate	25.2µg
2-Chloro-4-nitrophenyl – alpha-maltotrioxide (CNP3)	52.5µg
Citric acid, trisodium salt	567µg
Ethylenediaminetetraacetic acid (EDTA)	182µg
Ethylene glycol-bis(β-aminoethyl ether)-N,N,N',N'-tetraacetic acid (EGTA)	3.7µg
β-Galactosidase	0.0046U
4,7,13,16,21,24-Hexaoxa-1,10-diazabicyclo[8.8.8]hexacosane (Kryptofix 222)	0.3µg
Lactate dehydrogenase	0.3U
Magnesium acetate	15µg
Malate dehydrogenase (porcine heart)	0.1U
N-acetyl cysteine	15.3µg
β-Nicotinamide adenine dinucleotide, reduced (NADH)	21µg
α-Oxoglutarate	7.9µg
4,7,13,16,21-Pentaoxa-1,10-diazabicyclo[8.8.5]tricosane (Kryptofix 221)	84µg
Phosphoenol pyruvate	34µg
Phosphoenol pyruvate carboxylase	0.001U
Pyruvate kinase	0.01U
Buffers, surfactants, excipients and preservatives	

Warnings and Precautions

- For *In vitro* Diagnostic Use
- The diluent container in the reagent disc is automatically opened when the analyzer drawer closes. A disc with an opened diluent container can not be re-used. Ensure that the sample or control has been placed 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.¹⁰ See the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Operator's Manual for instructions on cleaning biohazardous spills.
- 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. The operator does not come into 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.

Instructions for Reagent Handling

Reagent discs may be used 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. Open the sealed foil pouch, remove the disc and use according to the instructions provided in the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Operator's Manual. A disc not used within 20 minutes of opening the pouch should be discarded.

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 blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Display if the reagents have expired.

Indications of Reagent Disc Instability/Deterioration

A torn or otherwise damaged pouch may allow moisture to reach the unused disc and adversely affect reagent performance. Do not use a disc from a damaged pouch.

6. Instrument

See the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Operator's Manual for complete information on use of the analyzer.

7. Sample Collection and Preparation

Sample collection techniques are described in the "Sample Collection" section of the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Operator's Manual.

- The minimum required sample size is ~100 µL of heparinized whole blood, heparinized plasma, serum or control material. The reagent disc sample chamber can contain up to 120 µL of sample.
- Whole blood samples obtained by venipuncture must be homogeneous before transferring a sample to the reagent disc. Gently invert the collection tube several times just prior to sample transfer. Do not shake the collection tube; shaking may cause hemolysis.
- Hemolysis may cause erroneously high results in potassium assays. This problem may go undetected when analyzing whole blood (release of potassium from as few as 0.5% of the erythrocytes can increase the potassium serum level by 0.5 mmol/L). In addition, even unhemolyzed specimens that are not promptly processed may have increased potassium levels due to intracellular potassium leakage.¹¹
- Whole blood venipuncture samples should be run within 60 minutes of collection.¹² The sample may be separated into plasma or serum and stored in capped sample tubes at 2-8°C (36-46°F), if the sample cannot be run within 60 minutes.
- Use only lithium heparin (green stopper) evacuated specimen collection tubes for whole blood or plasma samples. Use no-additive (red stopper) evacuated specimen collection tubes or serum separator tubes (red or red/black stopper) for serum samples.
- Start the test within 10 minutes of transferring the sample into the reagent disc.
- The concentration of total carbon dioxide is most accurately determined when the assay is done immediately after opening the tube and as promptly as possible after collection and processing of the blood in the unopened tube. Ambient air contains far less carbon dioxide than does plasma, and gaseous dissolved carbon dioxide will escape from the specimen into the air, with a consequent decrease in carbon dioxide value of up to 6 mmol/L in the course of 1 hour.¹³

8. Procedure

Materials Provided

- One Piccolo Electrolyte Panel PN: 400-1022 (a box of discs PN: 400-0022)

Materials Required but not Provided

- Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer
- Sample transfer pipettes (fixed volume approximately 100 µL) and tips are provided with each Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer and may be reordered from Abaxis.
- Commercially available control reagents recommended by Abaxis (contact Abaxis Technical Support for approved control materials and expected values).
- Timer

Test Parameters

The Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer operates at ambient temperatures between 15°C and 32°C (59-90°F). The analysis time for each Piccolo Electrolyte Panel is less than 14 minutes. The analyzers maintain the reagent disc at a temperature of 37°C (98.6°F) over the measurement interval.

Test Procedure

The complete sample collection and step-by-step operating procedures are detailed in the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Operator's Manual.

Calibration

The Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer is calibrated by the manufacturer before shipment. The bar code printed on the bar code ring provides the analyzer with disc-specific calibration data. See the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Operator's Manual.

Quality Control

See Section 2.4 of the Piccolo blood chemistry analyzer Operator's Manual or Section 6 (Calibration and Quality Control) of the Piccolo Xpress chemistry analyzer Operator's Manual. Performance of the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer can be verified by running controls. For a list of approved quality control materials with acceptance ranges, please contact Abaxis Technical Support. Other human serum or plasma-based controls may not be compatible. Quality control materials should be stored as per the package-insert included with the controls.

If control results are out of range, repeat one time. If still out of range, call Technical Support. Do not report results if controls are outside their labeled limits. See the Piccolo blood chemistry analyzer or Piccolo Xpress chemistry analyzer Operator's Manual for a detailed discussion on running, recording, interpreting, and plotting control results.

Waived Laboratories: Abaxis recommends control testing as follows:

- at least every 30 days
- whenever the laboratory conditions have changed significantly, e.g. Piccolo moved to a new location or changes in temperature control
- when training or retraining of personnel is indicated
- with each new lot (CLIA waived tests in waived status labs)

Non-Waived Laboratories: Abaxis recommends control testing to follow federal, state, and local guidelines.

9. Results

The Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer automatically calculates and prints the analyte concentrations in the sample. Details of the endpoint and rate reaction calculations are found in the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Operator's Manual.

Interpretation of results is detailed in the Operator's Manual. Results are printed onto result cards or paper rolls supplied by Abaxis. The result cards or paper rolls have an adhesive backing for easy placement in the patient's files.

10. Limitations of Procedure

General procedural limitations are discussed in the Piccolo blood chemistry analyzer Operator's Manual or the Piccolo Xpress chemistry analyzer Operator's Manual.

- The only anticoagulant **recommended for use** with the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer is **lithium heparin**. Abaxis has performed studies demonstrating that EDTA, fluoride, oxalate, and any anticoagulant containing ammonium ions will interfere with at least one chemistry contained in the Piccolo Electrolyte Panel. Do not use sodium heparin.
- Samples with hematocrits in excess of 62-65% packed red cell volume (a volume fraction of 0.62-0.65) may give inaccurate results. Samples with high hematocrits may be reported as hemolyzed. These samples may be spun down to get plasma then re-run in a new reagent disc.
- **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 or the Piccolo Xpress chemistry analyzer.**

Warning: Extensive testing of the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer 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.

Interference

Substances were tested as interferents with the analytes. Human serum pools were prepared. The concentration at which each potential interferent was tested was based on the testing levels in CLSI EP7-P.¹⁴

Effects of Endogenous Substances

- Physiological interferents (hemolysis, icterus and lipemia) cause changes in the reported concentrations of some analytes. The sample indices are printed on the bottom of each printout to inform the operator about the levels of interferents present in each sample.
- The Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer suppresses any results that are affected by >10% interference from hemolysis, lipemia or icterus. “HEM”, “LIP”, or “ICT” respectively, is printed on the printout in place of the result.
- Extremely elevated amylase levels (>9,000 U/L) will have a significant effect, >10% increase, on the chloride result. The concentration of amylase is not evaluated by the Piccolo system for each specimen.
- The potassium assay in the Piccolo system is a coupled pyruvate kinase (PK) / lactate dehydrogenase (LDH) assay. Therefore, in cases of extreme muscle trauma or highly elevated levels of creatine kinase (CK), the Piccolo may recover a falsely elevated potassium (K⁺) value. In such cases, unexpected high potassium recoveries need to be confirmed utilizing a different methodology.
- For maximum levels of endogenous substances contact Abaxis Technical Support.

Effects of Exogenous and Therapeutic Substances

- Thirty-five exogenous and therapeutic substances were selected as potential interferents for Abaxis test methods based on recommendations by Young.¹⁵ Significant interference is defined as greater than $\pm 10\%$ shift in the result for a normal range specimen. Human serum pools were supplemented with known concentrations of the drugs or chemicals and then analyzed. Please see Table 2 for a list of exogenous and therapeutic substances evaluated. **Please see TABLE 3 for a list of analytes where interference was observed.**

Table 2: Exogenous and Therapeutic Substances Evaluated

Potential Interferent	Highest Concentration Tested (mg/dL unless otherwise specified)
Acetaminophen	100
Acetoacetate	102
Acetylsalicylic Acid	50
Ampicillin	30
Ascorbic acid	20
Caffeine	10
Calcium Chloride	20
Cephalothin (Keflin)	400
Chloramphenicol	100
Cimetidine	16
Dopamine	19
Epinephrine	1
Erythromycin	10
Glutathione	30
Hydrochlorothiazide	7.5
Ibuprofen	50
Isoniazide	4
α -Ketoglutarate	5
Ketoprofen	50
L-dopa	5
Lidocaine	1
Lithium Lactate	84
Methicillin	100
Methotrexate	0.5
Metronidazole	5
Nafcillin	1
Nitrofurantoin	20
Oxacillin	1
Oxaloacetate	132
Penicillin G	100
Phenytoin (5,5-Diphenylhydantion)	3
Proline	4
Pyruvate	44
Rifampin	0.5
Salicylic Acid	50
Sulfadiazine	150
Sulfanilamide	50
Theophylline	20

Please see Table 3 for a list of analytes where interference was observed.

Table 3: The following substances showed greater than $\pm 10\%$ shift in the result for a normal range specimen.

	Concentration Which Produces > 10% Interference	% Interference^A Observed
Potassium		
Penicillin G	100	17% inc.
Sulfadiazine	150	12% dec.
Sodium		
Cephalothin	400	12% inc.
Methotrexate	0.5	11% inc.
Penicillin G	100	10% inc.
Total Carbon Dioxide		
Acetaminophen	100	11% inc.
Ascorbic Acid	20	12% dec.
Cephalothin	400	13% inc.
Cimetidine	16	19% dec.
Erythromycin	10	21% dec.
Lidocaine	1	23% inc.
Methotrexate	0.5	80% dec.
Nitrofurantoin	20	13% inc.
Salicylic Acid	50	17% dec.
Sulfadiazine	150	25% dec.

^A Dec. = decreased concentration of the specified analyte; Inc. = increased concentration of the specified analyte

- For the Chloride assay, bromide at toxic levels (≥ 15 mmol/L) can cause a significant effect ($> 10\%$ increase), on the chloride result. Iodide at very high concentrations (30 mmol/L, highest level tested) has no effect. Normal physiological levels of bromide and iodide do not interfere with the Piccolo Chloride Test System.

11. Expected Values

Samples from approximately 140 adult males and females were analyzed on the Piccolo blood chemistry analyzer to determine the reference interval. These ranges were calculated based on the 95% reference interval estimated from the combined (overall) values obtained from the reference subjects.¹⁶ It is recommended that your office or institution establish normal ranges for your particular patient population.

Table 4: Piccolo Reference Intervals

Analyte	Common Units	SI Units
Chloride (CL⁻)	98-108 mmol/L	98-108 mmol/L
Potassium (K⁺)	3.6-5.1 mmol/L	3.6-5.1 mmol/L
Sodium (NA⁺)	128-145 mmol/L	128-145 mmol/L
Total Carbon Dioxide (tCO₂)	18-33 mmol/L	18-33 mmol/L

12. Performance Characteristics

Linearity

The chemistry for each analyte is linear over the dynamic range listed below when the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer is operated according to the recommended procedure (refer to the Piccolo blood chemistry analyzer or the Piccolo Xpress chemistry analyzer Operator's Manual).

Table 5: Piccolo Dynamic Ranges

Analyte	Common Units	SI Units
Chloride (CL ⁻)	80-135 mmol/L	80-135 mmol/L
Potassium (K ⁺)	1.5-8.5 mmol/L	1.5-8.5 mmol/L
Sodium (NA ⁺)	110-170 mmol/L	110-170 mmol/L
Total Carbon Dioxide (tCO ₂)	5-40 mmol/L	5-40 mmol/L

If the analyte concentration is above the measuring range (dynamic range), but less than the system range, the printout will indicate a “>” sign at the upper limit and an asterisk after the number, e.g. CL⁻ >135* mmol/L. If lower than the dynamic range, a “<” will be printed with an asterisk, e.g. CL⁻ <80* U/L. For values that are grossly beyond the measurement range (system range), “~~~” will be printed instead of a result. Any time “~~~” appears on a printout, collect a new sample and rerun the test. If results for the second sample are suppressed again, please call Abaxis Technical Support.

Sensitivity (Limits of Detection)

The lower limit of the reportable (dynamic) range for each analyte is: chloride 80 mmol/L; potassium 1.5 mmol/L; sodium 110 mmol/L; and total carbon dioxide 5 mmol/L.

Precision

Precision studies were conducted using CLSI EP5-A guidelines¹⁷ with modifications based on CLSI EP18-P¹⁸ for unit-use devices. Results for within-run and total precision were determined using two levels of commercially available control materials. The studies made use of multiple instruments and two reagent disc lots. Potassium and total carbon dioxide testing was performed at two sites over 20 days; sodium testing was performed at one site over 20 days; chloride testing was done at two sites over a period of five days.

Results of precision studies are shown in Table 6.

Table 6: Precision

Analyte	Sample Size	Within-Run	Total
Chloride (mmol/L)			
<u>Control 1</u>	N = 160		
Mean		97.8	97.8
SD		1.63	1.74
CV		1.7	1.7
<u>Control 2</u>			
Mean		113.6	113.6
SD		1.97	2.22
CV		1.7	2.0
Potassium (mmol/L)			
<u>Control 1</u>	N = 120		
Mean		6.12	6.12
SD		0.32	0.32
CV		5.2	5.7
<u>Control 2</u>			
Mean		4.10	4.10
SD		0.24	0.26
CV		5.9	6.3
Sodium (mmol/L)			
<u>Control 1</u>	N = 80		
Mean		143.5	143.5
SD		2.28	2.28
CV		1.6	1.6
<u>Control 2</u>			
Mean		120.0	120.0
SD		2.13	2.13
CV		1.8	1.8

Table 6: Precision (continued)

Analyte	Sample Size	Within-Run	Total
Total Carbon Dioxide (mmol/L)			
<u>Control 1</u>	N = 120		
Mean		21.4	21.4
SD		2.29	2.29
CV		10.7	10.7
<u>Control 2</u>			
Mean		10.5	10.5
SD		0.90	0.90
CV		8.6	8.6

Correlation

Serum samples were collected and assayed on the Piccolo blood chemistry analyzer and by comparative methods. In some cases, high and low supplemented samples were used to cover the dynamic range. The samples were chosen to meet the distribution values in CLSI EP9-A guideline.¹⁹ Representative correlation statistics are shown in Table 7.

Table 7: Correlation of Piccolo Blood Chemistry Analyzer with Comparative Method(s)

	Correlation Coefficient	Slope	Intercept	SEE	N	Sample Range (mmol/L)	Comparative Method
Chloride (mmol/L)	0.978	0.982	-1.1	1.84	120	71-118	Vitros 950
Potassium (mmol/L)	0.969	0.863	0.6	0.14	58	2.0-6.8	Radiometer KNA™ 2
Sodium (mmol/L)	0.937	0.782	27.7	3.79	113	116-154	Radiometer KNA™ 2
Total Carbon Dioxide (mmol/L)	0.947	0.903	2.4	0.84	60	6-39	Cobas Fara

Results of Untrained User Study

An “untrained user” study was conducted in which participants were given only the test instructions and asked to perform testing of 3 discs with blinded randomized samples. The samples consisted of serum pools prepared at three levels for each of the four analytes: chloride, potassium, sodium, and total carbon dioxide. The participants were not given any training on the use of the test. A total of approximately 60 participants were enrolled from 3 sites, representing a diverse demographic (educational, age, gender, etc) population.

Tables below present the summary of the performance for each analyte.

Chloride (CL⁻)

	Level 1	Level 2	Level 3
N	62	62	62
Mean	94.6	106.0	115.5
%CV	1.8	1.4	1.5
Observed Range	90 – 100	102 – 108	110 – 119
Percent of Results in the Range ± 2.4%	91.9% 57/62 95%CI: 82.2% to 97.3%	96.8% 60/62 95%CI: 88.8% to 99.6%	95.2% 59/62 95%CI: 86.5% to 99.0%

* This percent is based on the premise that one cannot distinguish properly between normal and abnormal values when errors are greater than one-quarter of the normal range. The range of (98 mmol/L - 108 mmol/L) was considered.

Potassium (K⁺)

	Level 1	Level 2	Level 3
N	62	62	62
Mean	3.4	5.7	7.2
%CV	3.3	2.5	2.0
Observed Range	3.2 – 3.7	5.2 – 5.9	6.7 – 7.5
Percent of Results in the Range ± 8.6%	100% 62/62 95%CI: 94.2% to 100%	100% 62/62 95%CI: 94.2% to 100%	100% 62/62 95%CI: 94.2% to 100%

Sodium (NA⁺)

	Level 1	Level 2	Level 3
N	62	62	62
Mean	122.1	140.8	157.5
%CV	1.0	0.8	1.0
Observed Range	118 – 127	138 – 143	154 – 162
Percent of Results in the Range ± 3.1%	98.4% 61/62 95%CI: 91.3% to 100%	100% 62/62 95%CI: 94.2% to 100%	100% 62/62 95%CI: 94.2% to 100%

Total Carbon Dioxide (tCO₂)

	Level 1	Level 2	Level 3
N	62	62	62
Mean	20.3	27.6	34.4
%CV	5.1	4.6	3.7
Observed Range	18 – 23	23 – 30	32 – 38
Percent of Results in the Range ± 14.7%	100% 62/62 95%CI: 94.2% to 100%	98.4% 61/62 95%CI: 91.3% to 100%	100% 62/62 95%CI: 94.2% to 100%

13. Symbols



Use By



Catalog Number



Batch Code



In Vitro Diagnostic Medical Device



Consult Instructions For Use



Manufacturer



Do Not Reuse



X Number of Test Devices in Kit



Manufacturing Sequence



Serial Number



Caution



Temperature Limitation

PN:
Part Number



Authorized Representative In the European Community



Denotes conformity to specified European directives



UDI Barcode structure in Health Industry Bar Code (HIBC) standard format



Unique Device Identifier (UDI) in human and machine-readable form used to adequately identify medical devices through their distribution and use



Separate waste collection for this electronic item indicated; Equipment manufactured / placed on the market after 13 August 2005; Indicates compliance with Article 14(4) of Directive 2012/19/EU (WEEE) for the European Union (EU).

14. Bibliography

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2. Berry MN, et al. Enzymatic determination of potassium in serum. *Clin Chem* 1989;35:817-20.
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