510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. 510(k) Number
   k131126

2. Applicant:
   OPTI Medical Systems, Inc.

3. Contact:
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4. Date prepared: June 14, 2013

5. Proprietary and Established Names
   OPTI® CCA-T52

6. Regulatory Information

<table>
<thead>
<tr>
<th>Product Code Name</th>
<th>Regulation</th>
<th>Product Code</th>
<th>Class</th>
<th>Classification Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACID, LACTIC, ENZYMATIC METHOD</td>
<td>862.1450</td>
<td>KHP</td>
<td>I</td>
<td>CHEMISTRY (75)</td>
</tr>
<tr>
<td>ELECTRODE MEASUREMENT, BLOOD GASES (PCO₂, PO₂) AND BLOOD pH</td>
<td>862.1120</td>
<td>CHL</td>
<td>II</td>
<td>CHEMISTRY (75)</td>
</tr>
<tr>
<td>SYSTEM, HEMOGLOBIN, AUTOMATED</td>
<td>864.5620</td>
<td>GKR</td>
<td>II</td>
<td>HEMATOLOGY (81)</td>
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<tr>
<td>OXIMETER, WHOLE BLOOD</td>
<td>864.7500</td>
<td>GLY</td>
<td>II</td>
<td>HEMATOLOGY (81)</td>
</tr>
<tr>
<td>ELECTRODE, ION SPECIFIC, POTASSIUM</td>
<td>862.1600</td>
<td>CEM</td>
<td>II</td>
<td>CHEMISTRY (75)</td>
</tr>
<tr>
<td>ELECTRODE, ION SPECIFIC, CALCIUM</td>
<td>862.1145</td>
<td>JFP</td>
<td>II</td>
<td>CHEMISTRY (75)</td>
</tr>
<tr>
<td>ELECTRODE, ION SPECIFIC, SODIUM</td>
<td>862.1665</td>
<td>JGS</td>
<td>II</td>
<td>CHEMISTRY (75)</td>
</tr>
<tr>
<td>ELECTRODE, ION SPECIFIC, CHLORIDE</td>
<td>862.1170</td>
<td>CGZ</td>
<td>II</td>
<td>CHEMISTRY (75)</td>
</tr>
<tr>
<td>ELECTRODE, ION SPECIFIC, UREA NITROGEN</td>
<td>862.1770</td>
<td>CDS</td>
<td>II</td>
<td>CHEMISTRY (75)</td>
</tr>
<tr>
<td>GLUCOSE OXIDASE, GLUCOSE</td>
<td>862.1345</td>
<td>CGA</td>
<td>II</td>
<td>CHEMISTRY (75)</td>
</tr>
</tbody>
</table>

7. Purpose of Submission
   OPTI Medical has designed and tested a new model (OPTI® CCA-T52) of the OPTI® Critical Care Analyzer (OPTI® CCA-TS) previously cleared for use with k993837 for the IVD measurement of pH, pCO₂, pO₂, Na⁺, K⁺, Ca²⁺, Cl⁻, Glucose, BUN (urea), thb and SO₂ and cleared for use with k093280 for lactate when used with OPTI cassettes containing the blood sample and sensors designed to interact with the analyzer to measure the parameters. Changes were made to the analyzer only in order to update the electronic hardware to prevent obsolescence as electronics evolve, to modify the software to operate the analyzer with modified hardware, and change the software architecture to accommodate the hardware changes and provide for modular programming in the future. No changes were made to the algorithms used to calculate parameter values. Other modifications were made to the analyzer as outlined in the table below to update the look of the new model and improve manufacturing and shipping efficiencies.

   OPTI Medical conducted studies to ensure that the OPTI® CCA-T52 model analyzer reports equivalent results when used with the same cassettes as the OPTI® CCA-TS model analyzer predicate. The
performance tests completed are summarized here. Please note that since cassettes and the sensors used in the cassettes are unchanged from the cleared analyzer, testing specific to the cassette and the sensor chemistry such as interference studies and limit of detection studies were not repeated in this submission.

8. **Predicate Device**

OPTI® CCA-TS Critical Care Analyzer (k993837).

9. **Device Description**

The OPTI® CCA-TS2 is a modified model of the legally marketed OPTI® CCA-TS analyzer system. The OPTI® CCA-TS2 analyzer system uses the same technology and operating principles to perform the same intended uses as the OPTI® CCA-TS cleared with k993837. Optical fluorescence and reflectance technology is used to perform the parameter measurements outlined in the intended use. The technology is the same as that employed in previous models of OPTI products.

The OPTI® CCA-TS2 analyzer is sold separately from disposable cassettes containing sensors that interact with an *in-vitro* blood or plasma/serum sample aspirated into the cassette by the analyzer system. The disposable cassettes are designed and manufactured by OPTI Medical Systems, Inc. for exclusive use with OPTI Analyzers. The parameters reported by the analyzer system are determined by the sensors contained within each cassette style. Various styles of cassettes are available to report up to six combinations of blood gases, electrolytes and metabolites for each sample aspirated into the cassette. Each cassette style is bar-coded with calibration information determined for each lot of cassettes prior to release.

10. **Intended Use**

The OPTI CCA-TS2 system when used with disposable cassettes containing parameter specific sensors is intended to be used for the measurement of pH, pCO2, pO2, Na+, K+, Ca++, Cl-, Glucose, BUN (urea), lactate, tHb, and SO2 in samples of whole blood, and pH, Na+, K+, Ca++, Cl-, Glucose and BUN (urea) in serum and plasma, in a clinical laboratory setting or point of care locations.

- Measurements of blood gases (pCO2, pO2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.
- Lactate (lactic acid) measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).
- Total hemoglobin (tHb) measurement is used to determine the hemoglobin content of human blood.
- Oxygen saturation (SO2) measurement is used to determine the oxygen capacity of the hemoglobin.
- Potassium (K+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
- Calcium (Ca++) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
- Sodium (Na+) measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
- Chloride (Cl-) measurements are used in the diagnosis and treatment of electrolyte and...
metabolic disorders such as cystic fibrosis and diabetic acidosis.

- Urea nitrogen (an end-product of nitrogen metabolism) measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

11. Indications for Use
Same as Intended Use above.

12. Substantial Equivalence Information
Both the OPTI CCA-TS2 system and the predicate OPTI CCA-TS system use identical disposable cassettes containing electrolyte sensors to measure and report in-vitro results. The CCA-TS2 model is designed to use the same technology as that employed in the CCA-TS model with updated electronics and other changes to reduce manufacturing costs and add features desired by end users.

A comparison of the similarities and differences between the devices is provided in the following tables:

<table>
<thead>
<tr>
<th>Similarities for OPTI® CCA-TS2 analyzer system:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feature</td>
</tr>
<tr>
<td>Intended use</td>
</tr>
<tr>
<td>Measured Parameter</td>
</tr>
<tr>
<td>Sample Type</td>
</tr>
<tr>
<td>Reportable ranges</td>
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<tr>
<td>Sample Volume</td>
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<tr>
<td>Test consumable</td>
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<tr>
<td>Feature</td>
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<td>-------------------------------</td>
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<tr>
<td>Test consumable storage</td>
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<tr>
<td>Measurement sequence</td>
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<tr>
<td>Measurement time</td>
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<tr>
<td>Measurement Temperature</td>
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<tr>
<td>Error detection</td>
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<tr>
<td>Measurement Principle</td>
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<tr>
<td>Differences for OPTI® CCA-TS2 analyzer system:</td>
</tr>
<tr>
<td>Electronics - PC board</td>
</tr>
<tr>
<td>Component updates to avoid obsolescence</td>
</tr>
<tr>
<td>Power supply</td>
</tr>
<tr>
<td>Battery</td>
</tr>
<tr>
<td>Feature</td>
</tr>
<tr>
<td>------------------------------</td>
</tr>
<tr>
<td>Exterior Case</td>
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<tr>
<td>Optics module</td>
</tr>
<tr>
<td>Software</td>
</tr>
<tr>
<td>User features</td>
</tr>
<tr>
<td>Gas bottle and pressure regulator</td>
</tr>
<tr>
<td>Quality control</td>
</tr>
<tr>
<td>External communications</td>
</tr>
</tbody>
</table>

Modifications made to the OPTI® CCA-TS analyzer design to produce the OPTI® CCA-TS2 analyzer did not change the technological characteristics of the device and were found to be functionally equivalent.

13. Standard/Guidance Documents Referenced
- Evaluations of Precision Performance of Quantitative Measurement in Methods; Approved Guideline (CLSI guideline EP5-A2, volume 24, Number 25)
- User Verification of Performance for Precision and Trueness; Approved Guideline (CLSI guideline EP15-A2 Volume 25, Number 17)
- Method Comparison and Bias Estimation using Patient Samples; Approved Guideline (CLSI guideline EP9-A2, Volume 15, Number 19)
- Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements (IEC 61010-1)
- Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety
requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications (IEC 62133 Ed. 2.0 b:2012)

- Electrical Equipment for measurement, control and laboratory use – EMC requirements Part 2-6: Particular requirements – In-vitro diagnostic (IVD) medical equipment (IEC 61326-2-6)

14. Performance Characteristics

The modified analyzer design was assembled and tested with unchanged design cassettes with sensors to determine whether any of the design changes affected the performance, safety, or efficacy of the device. In-house studies were conducted with each type of sensor available for use on the OPTI® CCA-TS analyzer.

Method Comparison

Whole blood samples were measured across the measurement range on three OPTI CCA-TS analyzers and three OPTI CCA-TS2 analyzers at the internal site. Regression was calculated using the Ordinary linear fit method. Correlation statistics for each parameter / sensor design are presented here:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Slope (95% Confidence)</th>
<th>Intercept</th>
<th>Correlation Coefficient ($R^2$)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>6.927 to 7.705 pH units</td>
<td>0.97 (0.97 to 0.98)</td>
<td>0.18</td>
<td>0.998</td>
<td>126</td>
</tr>
<tr>
<td>pH (dry sensor)</td>
<td>6.961 to 7.648 pH units</td>
<td>1.00 (0.98 to 1.01)</td>
<td>0.04</td>
<td>0.996</td>
<td>63</td>
</tr>
<tr>
<td>Sodium (Na+)</td>
<td>109.0 to 179.4 mmol/L</td>
<td>0.99 (0.98 to 0.99)</td>
<td>1.57</td>
<td>0.999</td>
<td>45</td>
</tr>
<tr>
<td>Potassium (K+)</td>
<td>0.9 to 8.1 mmol/L</td>
<td>1.01 (1.00 to 1.01)</td>
<td>-0.01</td>
<td>0.999</td>
<td>54</td>
</tr>
<tr>
<td>Calcium (Ca++)</td>
<td>0.28 to 2.21 mmol/L</td>
<td>1.00 (0.99 to 1.01)</td>
<td>0.00</td>
<td>0.999</td>
<td>54</td>
</tr>
<tr>
<td>Chloride (Cl-)</td>
<td>64.4 to 145.7 mmol/L</td>
<td>0.98 (0.97 to 0.99)</td>
<td>0.87</td>
<td>0.999</td>
<td>45</td>
</tr>
<tr>
<td>Glucose</td>
<td>69.4 to 361.3 mg/dL</td>
<td>0.99 (0.95 to 1.02)</td>
<td>-0.44</td>
<td>0.983</td>
<td>54</td>
</tr>
<tr>
<td>BUN (urea)</td>
<td>5.5 to 103.2 mg/dL</td>
<td>1.01 (1.00 to 1.02)</td>
<td>-0.20</td>
<td>0.999</td>
<td>45</td>
</tr>
<tr>
<td>pCO2</td>
<td>14.3 to 198.9 mmHg</td>
<td>0.97 (0.97 to 0.98)</td>
<td>0.87</td>
<td>0.999</td>
<td>117</td>
</tr>
<tr>
<td>pCO2 (dry)</td>
<td>14.7 to 87.9 mmHg</td>
<td>1.00 (0.99 to 1.02)</td>
<td>-1.13</td>
<td>0.995</td>
<td>63</td>
</tr>
<tr>
<td>pO2</td>
<td>13.5 to 639.3 mmHg</td>
<td>0.98 (0.98 to 0.98)</td>
<td>-1.82</td>
<td>0.999</td>
<td>144</td>
</tr>
<tr>
<td>pO2 (dry)</td>
<td>10.7 to 656.6 mmHg</td>
<td>0.99 (0.99 to 1.00)</td>
<td>0.36</td>
<td>0.999</td>
<td>66</td>
</tr>
<tr>
<td>Lactate</td>
<td>0.7 to 13.8 mmol/L</td>
<td>1.01 (0.99 to 1.03)</td>
<td>0.08</td>
<td>0.994</td>
<td>45</td>
</tr>
<tr>
<td>tHb</td>
<td>7.7 to 21.2 g/dL</td>
<td>1.01 (0.99 to 1.03)</td>
<td>-0.09</td>
<td>0.996</td>
<td>45</td>
</tr>
<tr>
<td>SO2</td>
<td>71.5 to 99.9 %</td>
<td>1.03 (1.01 to 1.06)</td>
<td>-3.54</td>
<td>0.992</td>
<td>63</td>
</tr>
</tbody>
</table>
Plasma/serum samples were measured across the measurement range on three OPTI CCA-TS analyzers and three OPTI CCA-TS2 analyzers. Correlation statistics for each parameter / sensor design are presented here:

OPTI CCA-TS2 vs. Predicate in plasma/serum samples

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Slope (95% Confidence)</th>
<th>Intercept</th>
<th>Correlation Coefficient ($R^2$)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>6.814 to 7.741 pH units</td>
<td>0.97 (0.97 to 0.98)</td>
<td>0.21</td>
<td>0.999</td>
<td>108</td>
</tr>
<tr>
<td>Sodium (Na+)</td>
<td>104.1 to 176.7 mmol/L</td>
<td>0.98 (0.98 to 0.99)</td>
<td>1.91</td>
<td>0.998</td>
<td>90</td>
</tr>
<tr>
<td>Potassium (K+)</td>
<td>1.60 to 7.45 mmol/L</td>
<td>0.99 (0.99 to 1.00)</td>
<td>0.02</td>
<td>0.999</td>
<td>99</td>
</tr>
<tr>
<td>Calcium (Ca++)</td>
<td>0.39 to 2.75 mmol/L</td>
<td>0.98 (0.98 to 0.99)</td>
<td>0.02</td>
<td>0.999</td>
<td>99</td>
</tr>
<tr>
<td>Chloride (Cl-)</td>
<td>64.7 to 146.1 mmol/L</td>
<td>0.97 (0.96 to 0.97)</td>
<td>2.50</td>
<td>0.999</td>
<td>45</td>
</tr>
<tr>
<td>BUN (urea)</td>
<td>5.4 to 92.9 mg/dL</td>
<td>1.03 (1.01 to 1.05)</td>
<td>-0.53</td>
<td>0.995</td>
<td>45</td>
</tr>
<tr>
<td>Glucose</td>
<td>35.9 to 288.6 mg/dL</td>
<td>1.00 (0.98 to 1.01)</td>
<td>-2.32</td>
<td>0.997</td>
<td>54</td>
</tr>
</tbody>
</table>

In addition to the in-house studies, method comparison studies in whole blood samples were repeated at 4 different POC sites to confirm that the OPTI CCA-TS2 performs with functional equivalence to the OPTI CCA-TS analyzer. Method comparison results obtained at the 4 POC sites were very similar to the results obtained at the internal site.

**Precision/Reproducibility**

Multi-day, in-house, precision testing was performed in accordance with CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. Samples consisted of three levels of aqueous quality control solution for the testing (OPTI Check Level 1, Level 2 and Level 3 manufactured by Bionostics Inc., Acton, Massachusetts). Testing was performed over at least 10 days, 4 runs per day, with a minimum of 2 OPTI CCA-TS2 analyzers.

**Precision OPTI CCA-TS2 with controls**

<table>
<thead>
<tr>
<th>Days run</th>
<th>OPTI-Check Level 1</th>
<th>OPTI-Check Level 2</th>
<th>OPTI-Check Level 3</th>
<th>OPTI-Check Level 1</th>
<th>OPTI-Check Level 2</th>
<th>OPTI-Check Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Average</td>
<td>71.6</td>
<td>100.0</td>
<td>137.7</td>
<td>73.5</td>
<td>103.5</td>
<td>139.1</td>
</tr>
<tr>
<td>Within Run St.Dev ($S_w$)</td>
<td>1.3</td>
<td>1.4</td>
<td>1.4</td>
<td>1.4</td>
<td>0.9</td>
<td>1.4</td>
</tr>
<tr>
<td>Within Run %CV</td>
<td>1.8%</td>
<td>1.4%</td>
<td>1.0%</td>
<td>1.8%</td>
<td>0.9%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Between Run St.Dev ($S_{br}$)</td>
<td>0.0</td>
<td>0.9</td>
<td>1.0</td>
<td>0.0</td>
<td>0.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Between Run %CV</td>
<td>0.0%</td>
<td>0.9%</td>
<td>0.7%</td>
<td>0.0%</td>
<td>0.4%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Between Day St.Dev ($S_{bd}$)</td>
<td>0.8</td>
<td>0.0</td>
<td>0.6</td>
<td>1.1</td>
<td>0.9</td>
<td>1.4</td>
</tr>
<tr>
<td>Between Day %CV</td>
<td>1.1%</td>
<td>0.0%</td>
<td>0.4%</td>
<td>1.5%</td>
<td>0.9%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Total Precision St.Dev ($S_T$)</td>
<td>1.5</td>
<td>1.7</td>
<td>1.8</td>
<td>1.6</td>
<td>1.3</td>
<td>2.0</td>
</tr>
<tr>
<td>Total %CV</td>
<td>2.1%</td>
<td>1.7%</td>
<td>1.3%</td>
<td>2.2%</td>
<td>1.3%</td>
<td>1.5%</td>
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<tr>
<td></td>
<td>PCO2 (mmHg)</td>
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<td>Dry PCO2 (mmHg)</td>
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<tr>
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<td>OPTI-Check</td>
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<tr>
<td></td>
<td>Level 1</td>
<td>Level 2</td>
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<tr>
<td>Days run</td>
<td>20</td>
<td>20</td>
<td>20</td>
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<tr>
<td>Total Average</td>
<td>74.5</td>
<td>45.0</td>
<td>24.8</td>
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<tr>
<td>Within Run St.Dev ($S_w$)</td>
<td>0.8</td>
<td>0.3</td>
<td>0.3</td>
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<tr>
<td>Within Run %CV</td>
<td>1.1%</td>
<td>0.7%</td>
<td>1.1%</td>
<td></td>
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<tr>
<td>Between Run St.Dev ($S_p$)</td>
<td>0.2</td>
<td>0.2</td>
<td>0.1</td>
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<tr>
<td>Between Run %CV</td>
<td>0.2%</td>
<td>0.5%</td>
<td>0.5%</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Between Day St.Dev ($S_d$)</td>
<td>0.4</td>
<td>0.3</td>
<td>0.2</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Between Day %CV</td>
<td>0.5%</td>
<td>0.6%</td>
<td>0.8%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Precision St.Dev ($S_T$)</td>
<td>0.9</td>
<td>0.5</td>
<td>0.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total %CV</td>
<td>1.3%</td>
<td>1.0%</td>
<td>1.5%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

|                  | pH          |                  | Dry pH          |
|                  | OPTI-Check  | OPTI-Check       | OPTI-Check      |
|                  | Level 1     | Level 2          | Level 3         |
| Days run         | 20          | 20               | 20              |
| Total Average    | 7.151       | 7.415            | 7.624           |
| Within Run St.Dev ($S_w$) | 0.003    | 0.006            | 0.005           |
| Within Run %CV   | 0.0%        | 0.1%             | 0.1%            |
| Between Run St.Dev ($S_p$) | 0.001   | 0.002            | 0.002           |
| Between Run %CV  | 0.0%        | 0.0%             | 0.0%            |
| Between Day St.Dev ($S_d$) | 0.003  | 0.003            | 0.004           |
| Between Day %CV  | 0.0%        | 0.0%             | 0.1%            |
| Total Precision St.Dev ($S_T$) | 0.005  | 0.007            | 0.007           |
| Total %CV        | 0.1%        | 0.1%             | 0.1%            |

|                  | Na+ (mmol/L) |                  | K+ (mmol/L)    |
|                  | OPTI-Check  | OPTI-Check       | OPTI-Check     |
|                  | Level 1     | Level 2          | Level 3        |
| Days run         | 20          | 20               | 20             |
| Total Average    | 126.1       | 143.7            | 156.5          |
| Within Run St.Dev ($S_w$) | 0.6      | 0.7              | 0.4            |
| Within Run %CV   | 0.4%        | 0.5%             | 0.3%           |
| Between Run St.Dev ($S_p$) | 0.2   | 0.0              | 0.0            |
| Between Run %CV  | 0.2%        | 0.0%             | 0.0%           |
| Between Day St.Dev ($S_d$) | 0.3  | 0.1              | 0.4            |
| Between Day %CV  | 0.3%        | 0.1%             | 0.3%           |
| Total Precision St.Dev ($S_T$) | 0.7    | 0.7              | 0.6            |
| Total %CV        | 0.6%        | 0.5%             | 0.4%           |

<p>|                  | Ca++ (mmol/L) |                  | Cl- (mmol/L)   |
|                  | OPTI-Check   | OPTI-Check       | OPTI-Check     |
|                  | Level 1      | Level 2          | Level 3        |
| Days run         | 20          | 20               | 20             |
| Total Average    | 1.57        | 1.27             | 0.79           |
| Within Run St.Dev ($S_w$) | 0.01      | 0.01             | 0.01           |
|                  |              |                  | 95.3           |
|                  |              |                  | 10.71          |
|                  |              |                  | 115.6          |
| Total %CV        | 0.6%        | 0.5%             | 0.6%           |</p>
<table>
<thead>
<tr>
<th>Ca++ (mmol/L)</th>
<th>Cl- (mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OPTI-Check</strong></td>
<td><strong>OPTI-Check</strong></td>
</tr>
<tr>
<td>Level 1</td>
<td>Level 2</td>
</tr>
<tr>
<td>Within Run %CV</td>
<td>0.9%</td>
</tr>
<tr>
<td>Between Run St.Dev ($S_r$)</td>
<td>0.01</td>
</tr>
<tr>
<td>Between Run %CV</td>
<td>0.4%</td>
</tr>
<tr>
<td>Between Day St.Dev ($S_{dd}$)</td>
<td>0.02</td>
</tr>
<tr>
<td>Between Day %CV</td>
<td>1.2%</td>
</tr>
<tr>
<td>Total Precision St.Dev ($S_t$)</td>
<td>0.02</td>
</tr>
<tr>
<td>Total %CV</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Glucose (mg/dL)</th>
<th>BUN (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OPTI-Check</strong></td>
<td><strong>OPTI-Check</strong></td>
</tr>
<tr>
<td>Level 1</td>
<td>Level 2</td>
</tr>
<tr>
<td>Days run</td>
<td>10</td>
</tr>
<tr>
<td>Total Average</td>
<td>40.5</td>
</tr>
<tr>
<td>Within Run St.Dev ($S_w$)</td>
<td>1.6</td>
</tr>
<tr>
<td>Within Run %CV</td>
<td>3.9%</td>
</tr>
<tr>
<td>Between Run %CV</td>
<td>1.1</td>
</tr>
<tr>
<td>Between Day St.Dev ($S_{dd}$)</td>
<td>1.4</td>
</tr>
<tr>
<td>Between Day %CV</td>
<td>3.5%</td>
</tr>
<tr>
<td>Total Precision St.Dev ($S_t$)</td>
<td>2.4</td>
</tr>
<tr>
<td>Total %CV</td>
<td>5.9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lactate (mmol/L)</th>
<th>tHb (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OPTI-Check</strong></td>
<td><strong>OPTI-Check</strong></td>
</tr>
<tr>
<td>Level 1</td>
<td>Level 2</td>
</tr>
<tr>
<td>Days run</td>
<td>20</td>
</tr>
<tr>
<td>Total Average</td>
<td>1.02</td>
</tr>
<tr>
<td>Within Run St.Dev ($S_w$)</td>
<td>0.06</td>
</tr>
<tr>
<td>Within Run %CV</td>
<td>5.6%</td>
</tr>
<tr>
<td>Between Run %CV</td>
<td>0.00</td>
</tr>
<tr>
<td>Between Day St.Dev ($S_{dd}$)</td>
<td>0.04</td>
</tr>
<tr>
<td>Between Day %CV</td>
<td>3.4%</td>
</tr>
<tr>
<td>Total Precision St.Dev ($S_t$)</td>
<td>0.07</td>
</tr>
<tr>
<td>Total %CV</td>
<td>6.4%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SO2 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OPTI-Check</strong></td>
</tr>
<tr>
<td>Level 1</td>
</tr>
<tr>
<td>Days run</td>
</tr>
<tr>
<td>Total Average</td>
</tr>
<tr>
<td>Within Run St.Dev ($S_w$)</td>
</tr>
<tr>
<td>Within Run %CV</td>
</tr>
<tr>
<td>Between Run %CV</td>
</tr>
<tr>
<td>Between Day St.Dev ($S_{dd}$)</td>
</tr>
<tr>
<td>Between Day %CV</td>
</tr>
<tr>
<td>Total Precision St.Dev ($S_t$)</td>
</tr>
<tr>
<td>Total %CV</td>
</tr>
</tbody>
</table>
In addition, within-run precision testing was performed in-house in accordance with CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. Samples consisted of three levels of whole blood spiked or diluted to give three levels of each of the analytes. Testing was performed in one day with 10 repeats at each blood level on one OPTI CCA-T52 analyzer. Results of the studies run are shown in the tables below:

**Precision OPTI CCA-TS2 with whole blood**

### Blood Gases

<table>
<thead>
<tr>
<th></th>
<th>Standard Sampling PO2 (mmHg)</th>
<th>60μL Sampling PO2 (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Blood Level 1</td>
<td>Whole Blood Level 2</td>
</tr>
<tr>
<td>Total Average</td>
<td>54.8</td>
<td>90.3</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>%CV</td>
<td>0.97%</td>
<td>0.52%</td>
</tr>
</tbody>
</table>

### Dry PO2 (mmHg)

<table>
<thead>
<tr>
<th></th>
<th>Standard Sampling PO2 (mmHg)</th>
<th>60μL Sampling PO2 (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Blood Level 1</td>
<td>Whole Blood Level 2</td>
</tr>
<tr>
<td>Total Average</td>
<td>55.9</td>
<td>91.8</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.6</td>
<td>0.5</td>
</tr>
<tr>
<td>%CV</td>
<td>1.02%</td>
<td>0.57%</td>
</tr>
</tbody>
</table>

### Standard Sampling PCO2 (mmHg)

<table>
<thead>
<tr>
<th></th>
<th>Standard Sampling PCO2 (mmHg)</th>
<th>60μL Sampling PCO2 (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Blood Level 1</td>
<td>Whole Blood Level 2</td>
</tr>
<tr>
<td>Total Average</td>
<td>21.4</td>
<td>46.2</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>%CV</td>
<td>1.60%</td>
<td>0.90%</td>
</tr>
</tbody>
</table>

### Dry PCO2 (mmHg)

<table>
<thead>
<tr>
<th></th>
<th>Standard Sampling PCO2 (mmHg)</th>
<th>60μL Sampling PCO2 (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Blood Level 1</td>
<td>Whole Blood Level 2</td>
</tr>
<tr>
<td>Total Average</td>
<td>19.6</td>
<td>44.4</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.357</td>
<td>0.316</td>
</tr>
<tr>
<td>%CV</td>
<td>1.82%</td>
<td>0.71%</td>
</tr>
</tbody>
</table>

### Standard Sampling pH (mmHg)

<table>
<thead>
<tr>
<th></th>
<th>Standard Sampling pH (mmHg)</th>
<th>60μL Sampling pH (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Blood Level 1</td>
<td>Whole Blood Level 2</td>
</tr>
<tr>
<td>Total Average</td>
<td>7.134</td>
<td>7.341</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.004</td>
<td>0.006</td>
</tr>
<tr>
<td>%CV</td>
<td>0.05%</td>
<td>0.08%</td>
</tr>
<tr>
<td>Dry pH (mmHg)</td>
<td>Whole Blood</td>
<td>Whole Blood</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
</tr>
<tr>
<td>Total Average</td>
<td>7.174</td>
<td>7.352</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.011</td>
<td>0.019</td>
</tr>
<tr>
<td>%CV</td>
<td>0.16%</td>
<td>0.26%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SO2</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>Total Average</td>
<td>79.5</td>
<td>96.8</td>
<td>99.9</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.2</td>
<td>0.1</td>
<td>0.0</td>
</tr>
<tr>
<td>%CV</td>
<td>0.21%</td>
<td>0.05%</td>
<td>0.00%</td>
</tr>
</tbody>
</table>

Electrolytes, Glucose and BUN

<table>
<thead>
<tr>
<th>Na+ (mmol/L)</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>Total Average</td>
<td>136.5</td>
<td>167.4</td>
<td>112.7</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.4</td>
<td>0.2</td>
<td>0.4</td>
</tr>
<tr>
<td>%CV</td>
<td>0.26%</td>
<td>0.13%</td>
<td>0.33%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>K+ (mmol/L)</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>Total Average</td>
<td>3.6</td>
<td>8.1</td>
<td>2.1</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.0</td>
<td>0.0</td>
<td>0.1</td>
</tr>
<tr>
<td>%CV</td>
<td>0.38%</td>
<td>0.26%</td>
<td>2.49%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cl- (mmol/L)</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>Total Average</td>
<td>104.1</td>
<td>141.3</td>
<td>57.5</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>1.2</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>%CV</td>
<td>0.28%</td>
<td>0.73%</td>
<td>0.51%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ca++ (mmol/L)</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>Total Average</td>
<td>1.2</td>
<td>2.6</td>
<td>0.8</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>%CV</td>
<td>0.35%</td>
<td>0.40%</td>
<td>0.59%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Glucose</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>Total Average</td>
<td>82.7</td>
<td>166.1</td>
<td>34.6</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>3.8</td>
<td>8.2</td>
<td>2.4</td>
</tr>
<tr>
<td>%CV</td>
<td>4.65%</td>
<td>4.91%</td>
<td>6.94%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BUN</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>Total Average</td>
<td>6.03</td>
<td>26.61</td>
<td>85.59</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.03</td>
<td>0.25</td>
<td>0.97</td>
</tr>
<tr>
<td>%CV</td>
<td>0.53%</td>
<td>0.93%</td>
<td>1.13%</td>
</tr>
</tbody>
</table>
### Lactate

<table>
<thead>
<tr>
<th></th>
<th>Whole Blood Level 1</th>
<th>Whole Blood Level 2</th>
<th>Whole Blood Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Average</strong></td>
<td>3.85</td>
<td>1.13</td>
<td>6.17</td>
</tr>
<tr>
<td><strong>Standard Deviation</strong></td>
<td>0.14</td>
<td>0.05</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>%CV</strong></td>
<td>3.76%</td>
<td>4.42%</td>
<td>3.16%</td>
</tr>
</tbody>
</table>

### tHb

<table>
<thead>
<tr>
<th></th>
<th>Whole Blood Level 1</th>
<th>Whole Blood Level 2</th>
<th>Whole Blood Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Average</strong></td>
<td>7.5</td>
<td>17.7</td>
<td>12.1</td>
</tr>
<tr>
<td><strong>Standard Deviation</strong></td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>%CV</strong></td>
<td>2.59%</td>
<td>1.34%</td>
<td>1.86%</td>
</tr>
</tbody>
</table>

### Linearity / Reportable range

The linearity of the OPTI CCA-TS2 system was determined using the experimental protocol recommended in CLSI guideline EP15-A2, User Verification of Performance for Precision and Trueness; Approved Guideline. Linearity data was collected versus the OPTI CCA-TS analyzer predicate using standard aqueous linearity solutions (CVC123 manufactured by RNA Medical, Devons, MA) and whole blood samples that included points just outside the measurement range and points inside the range. Each of the levels of samples was run on two (2) OPTI CCA-TS and two (2) OPTI CCA-TS2 analyzers. The linear regression correlation between analyzers using each individual measurement is summarized below:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Sample type</th>
<th>Range</th>
<th>Slope (95% Confidence)</th>
<th>Intercept</th>
<th>Correlation Coefficient ($R^2$)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH (60μL sample)</td>
<td>Whole Blood</td>
<td>6.391 to 8.044 pH units</td>
<td>0.97 (0.96 to 0.97)</td>
<td>0.26</td>
<td>0.999</td>
<td>81</td>
</tr>
<tr>
<td>pH (120 μL)</td>
<td>Whole Blood</td>
<td>6.404 to 8.011 pH units</td>
<td>0.98 (0.97 to 0.98)</td>
<td>0.16</td>
<td>1.000</td>
<td>81</td>
</tr>
<tr>
<td>pH (dry sensor)</td>
<td>Whole Blood</td>
<td>6.477 to 7.915 pH units</td>
<td>0.99 (0.98 to 1.00)</td>
<td>0.09</td>
<td>0.998</td>
<td>81</td>
</tr>
<tr>
<td>pH (60μL sample)</td>
<td>CVC123</td>
<td>6.915 to 7.638 pH units</td>
<td>0.98 (0.98 to 0.99)</td>
<td>0.14</td>
<td>1.000</td>
<td>24</td>
</tr>
<tr>
<td>pH (120 μL)</td>
<td>CVC123</td>
<td>6.912 to 7.646 pH units</td>
<td>0.96 (0.96 to 0.97)</td>
<td>0.26</td>
<td>0.999</td>
<td>48</td>
</tr>
<tr>
<td>pH (dry sensor)</td>
<td>CVC123</td>
<td>6.971 to 7.631 pH units</td>
<td>0.98 (0.97 to 0.99)</td>
<td>0.16</td>
<td>0.999</td>
<td>24</td>
</tr>
<tr>
<td>PCO2 (60μL sample)</td>
<td>Whole Blood</td>
<td>6.2 to 256.6 mmHg</td>
<td>0.98 (0.98 to 0.99)</td>
<td>0.65</td>
<td>1.000</td>
<td>81</td>
</tr>
<tr>
<td>PCO2 (120μL)</td>
<td>Whole Blood</td>
<td>7.4 to 205.7 mmHg</td>
<td>0.98 (0.98 to 0.99)</td>
<td>0.45</td>
<td>1.000</td>
<td>72</td>
</tr>
<tr>
<td>PCO2 (dry)</td>
<td>Whole Blood</td>
<td>2.2 to 207.9 mmHg</td>
<td>1.01 (1.00 to 1.02)</td>
<td>-1.19</td>
<td>0.999</td>
<td>81</td>
</tr>
<tr>
<td>Parameter</td>
<td>Sample type</td>
<td>Range</td>
<td>Slope (95% Confidence)</td>
<td>Intercept</td>
<td>Correlation Coefficient ($R^2$)</td>
<td>n</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------</td>
<td>------------------</td>
<td>------------------------</td>
<td>-----------</td>
<td>--------------------------------</td>
<td>----</td>
</tr>
<tr>
<td>PCO2 (60µL sample)</td>
<td>CVC123</td>
<td>13.9 to 85.8 mmHg</td>
<td>0.98 (0.97 to 0.99)</td>
<td>0.35</td>
<td>1.000</td>
<td>30</td>
</tr>
<tr>
<td>PCO2 (120µL)</td>
<td>CVC123</td>
<td>13.3 to 90.5 mmHg</td>
<td>0.98 (0.98 to 0.99)</td>
<td>0.88</td>
<td>0.999</td>
<td>60</td>
</tr>
<tr>
<td>PCO2 (dry)</td>
<td>CVC123</td>
<td>15.9 to 87.8 mmHg</td>
<td>0.99 (0.98 to 1.00)</td>
<td>-0.04</td>
<td>1.000</td>
<td>30</td>
</tr>
<tr>
<td>PO2 (60µL sample)</td>
<td>Whole Blood</td>
<td>6.8 to 711.2 mmHg</td>
<td>0.99 (0.99 to 1.00)</td>
<td>-3.10</td>
<td>0.999</td>
<td>90</td>
</tr>
<tr>
<td>PO2 (120µL)</td>
<td>Whole Blood</td>
<td>8.9 to 707.0 mmHg</td>
<td>0.99 (0.98 to 0.99)</td>
<td>-2.57</td>
<td>1.000</td>
<td>90</td>
</tr>
<tr>
<td>PO2 (dry)</td>
<td>Whole Blood</td>
<td>9.1 to 656.6 mmHg</td>
<td>0.99 (0.99 to 1.00)</td>
<td>0.43</td>
<td>0.999</td>
<td>72</td>
</tr>
<tr>
<td>PO2 (60µL sample)</td>
<td>CVC123</td>
<td>62.7 to 451.0 mmHg</td>
<td>0.97 (0.97 to 0.98)</td>
<td>0.29</td>
<td>0.999</td>
<td>30</td>
</tr>
<tr>
<td>PO2 (120µL)</td>
<td>CVC123</td>
<td>60.9 to 487.1 mmHg</td>
<td>0.98 (0.97 to 0.99)</td>
<td>0.90</td>
<td>0.999</td>
<td>60</td>
</tr>
<tr>
<td>PO2 (dry)</td>
<td>CVC123</td>
<td>60.8 to 476.3 mmHg</td>
<td>0.98 (0.97 to 0.99)</td>
<td>2.55</td>
<td>1.000</td>
<td>30</td>
</tr>
<tr>
<td>Sodium (Na+)</td>
<td>Whole Blood</td>
<td>93.4 to 204.4 mmHg</td>
<td>1.00 (0.99 to 1.01)</td>
<td>-0.18</td>
<td>1.000</td>
<td>63</td>
</tr>
<tr>
<td>Sodium (Na+)</td>
<td>CVC123</td>
<td>116.2 to 163.8 mmol/L</td>
<td>1.01 (0.99 to 1.02)</td>
<td>-0.68</td>
<td>0.998</td>
<td>36</td>
</tr>
<tr>
<td>Potassium (K+)</td>
<td>Whole Blood</td>
<td>0.39 to 10.09 mmol/L</td>
<td>1.00 (1.00 to 1.01)</td>
<td>0.00</td>
<td>1.000</td>
<td>72</td>
</tr>
<tr>
<td>Potassium (K+)</td>
<td>CVC123</td>
<td>1.19 to 6.98 mmol/L</td>
<td>0.99 (0.99 to 1.00)</td>
<td>0.10</td>
<td>1.000</td>
<td>48</td>
</tr>
<tr>
<td>Calcium (Ca++)</td>
<td>Whole Blood</td>
<td>0.158 to 3.372 mmol/L</td>
<td>0.99 (0.99 to 0.99)</td>
<td>0.01</td>
<td>1.000</td>
<td>72</td>
</tr>
<tr>
<td>Calcium (Ca++)</td>
<td>CVC123</td>
<td>0.20 to 2.67 mmol/L</td>
<td>1.01 (1.00 to 1.02)</td>
<td>-0.00</td>
<td>0.999</td>
<td>30</td>
</tr>
<tr>
<td>Chloride (Cl-)</td>
<td>Whole Blood</td>
<td>42.9 to 175.0 mmol/L</td>
<td>0.99 (0.98 to 1.00)</td>
<td>-0.21</td>
<td>0.999</td>
<td>63</td>
</tr>
<tr>
<td>Chloride (Cl-)</td>
<td>CVC123</td>
<td>85.9 to 135.0 mmol/L</td>
<td>0.96 (0.94 to 0.98)</td>
<td>2.93</td>
<td>0.998</td>
<td>30</td>
</tr>
<tr>
<td>Glucose</td>
<td>Whole Blood</td>
<td>12.5 to 455.6 mg/dL</td>
<td>1.02 (1.00 to 1.05)</td>
<td>-4.19</td>
<td>0.991</td>
<td>63</td>
</tr>
<tr>
<td>Glucose</td>
<td>CVC123</td>
<td>81.8 to 303.6 mg/dL</td>
<td>0.98 (0.94 to 1.03)</td>
<td>1.87</td>
<td>0.993</td>
<td>18</td>
</tr>
<tr>
<td>BUN (urea)</td>
<td>Whole Blood</td>
<td>2.63 to 142.93 mg/dL</td>
<td>1.00 (0.99 to 1.01)</td>
<td>0.08</td>
<td>0.999</td>
<td>63</td>
</tr>
<tr>
<td>Lactate</td>
<td>Whole Blood</td>
<td>0.17 to 17.81 mmol/L</td>
<td>1.04 (1.02 to 1.06)</td>
<td>-0.02</td>
<td>0.996</td>
<td>55</td>
</tr>
<tr>
<td>Lactate</td>
<td>CVC123</td>
<td>0.77 to 15.3 mmol/L</td>
<td>1.03 (1.00 to 1.06)</td>
<td>-0.14</td>
<td>0.995</td>
<td>30</td>
</tr>
<tr>
<td>tHb</td>
<td>Whole Blood</td>
<td>4.37 to 26.13 g/dL</td>
<td>0.99 (0.98 to 1.01)</td>
<td>0.10</td>
<td>0.998</td>
<td>63</td>
</tr>
<tr>
<td>SO2</td>
<td>Whole Blood</td>
<td>55.5 to 99.9 %</td>
<td>0.96 (0.94 to 0.98)</td>
<td>3.23</td>
<td>0.991</td>
<td>72</td>
</tr>
</tbody>
</table>
The linearity data support the following reportable range claims:

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>6.6 - 7.8 pH units</td>
</tr>
<tr>
<td>PCO2</td>
<td>10 - 200 mm Hg</td>
</tr>
<tr>
<td>PO2</td>
<td>10 - 700 mm Hg</td>
</tr>
<tr>
<td>Na+</td>
<td>100 - 180 mmol/L</td>
</tr>
<tr>
<td>K+</td>
<td>0.8 - 9.99 mmol/L</td>
</tr>
<tr>
<td>Ca++</td>
<td>0.2 - 3.0 mmol/L</td>
</tr>
<tr>
<td>Cl-</td>
<td>50 - 160 mmol/L</td>
</tr>
<tr>
<td>Glu</td>
<td>30 - 400 mg/dL</td>
</tr>
<tr>
<td>BUN/Urea</td>
<td>208 - 112.0 mg/dL</td>
</tr>
<tr>
<td>Lac</td>
<td>0.3 - 17.5 mmol/L</td>
</tr>
<tr>
<td>tHb</td>
<td>5 - 25 g/dL</td>
</tr>
<tr>
<td>SO2</td>
<td>60 - 100%</td>
</tr>
</tbody>
</table>

Limit of Blank, Limit of Determination and Limit of Quantitation

No changes were made to the electrolyte sensors installed in the disposable cassettes used on both the OPTI CCA-TS2 device and the predicate OPTI CCA-TS so evaluation of limits of detection does not apply to the analyzer change.

Analytical Specificity / Interferences

No changes were made to the electrolyte sensors installed in the disposable cassettes used on both the OPTI CCA-TS2 device and the predicate OPTI CCA-TS. Evaluation of interferences was not performed since the analysis was done previously in k993837.

Traceability

The parameters measured and reported by the OPTI CCA-TS2 device are calibrated and tested for release using primary and secondary standards that are traceable to NIST or other recognized standards (where no NIST standard is available of practical) as outlined in this table:
<table>
<thead>
<tr>
<th>Analyte</th>
<th>Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO2</td>
<td>Definition of SI unit by French: Conférence générale des poids et mesures (CGPM), International Siggaard-Andersen Model</td>
</tr>
<tr>
<td>Glu</td>
<td>Standard reference material, NIST SRM 965</td>
</tr>
<tr>
<td>BUN</td>
<td>Standard reference material, NIST SRM 909</td>
</tr>
<tr>
<td>Lactate</td>
<td>Gravimetric working calibrator prepared from sodium L-lactate &gt;99% purity</td>
</tr>
</tbody>
</table>

15. Electromagnetic Compatibility and Electrical Safety
Electromagnetic Compatibility and electrical safety tests were performed on the OPTI® CCA-TS2 model to show compliance with current standards applicable for the device. Performance verification studies were performed using the modified device with all cassette styles and modified consumables and calibration methods to demonstrate performance equivalence.

16. Software Verification and Validation
The software driving the analyzer has been updated according to internal design control and verification procedures of the Quality System at OPTI Medical Systems, Inc. to ensure changes did not impact the measurements reported by the analyzer system.

17. Conclusion
Analysis of the method comparison data collected during internal and POC site studies for this device presented in this 510(k), together with the linearity and precision data collected during internal and POC studies demonstrates that the OPTI CCA-TS2 device is safe, effective, and substantially equivalent to the OPTI CCA-TS predicate device.
August 22, 2013

OPTI Medical Systems, Inc.
C/O Len Owens
235 Hembree Park Drive
ROSWELL GA 30076

Re: K131126

Trade/Device Name: OPTI CCA-TS2
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: KHP, CHL, GKR, GLY, CEM, JFP, JGS, CGZ, CDS, CGA
Dated: July 11, 2013
Received: July 16, 2013

Dear Mr. Owens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 801); labeling (21 CFR Part 807); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for
the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): k131126

Device Name: OPTI CCA-TS2

Indications for Use: -
The OPTI CCA-TS2 system when used with disposable cassettes containing parameter specific sensors is intended to be used for the measurement of pH, pCO₂, pO₂, Na⁺, K⁺, Ca²⁺, Cl⁻, Glucose, BUN (urea), lactate, tHb, and SO₂ in samples of whole blood, and pH, Na⁺, K⁺, Ca²⁺, Cl⁻, Glucose and BUN (urea) in serum and plasma, in a clinical laboratory setting or point of care locations.

- Measurements of blood gases (pCO₂, pO₂) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.
- Lactate (lactic acid) measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).
- Total hemoglobin (tHb) measurement is used to determine the hemoglobin content of human blood.
- Oxygen saturation (SO₂) measurement is used to determine the oxygen capacity of the hemoglobin.

Prescription Use X AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S
Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)

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· Potassium (K⁺) measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
· Calcium (Ca²⁺) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
· Sodium (Na⁺) measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
· Chloride (Cl⁻) measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
· Urea nitrogen (an end-product of nitrogen metabolism) measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.
· Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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