

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE AND INSTRUMENT TEMPLATE**

A. 510(k) Number: K032311

B. Analyte: Potassium, Calcium, Sodium, Chloride, Blood Gases (PCO₂, PO₂) and pH, Hemoglobin, Hematocrit, Oxygen Saturation, Carboxyhemoglobin, Oxyhemoglobin, Methemoglobin, Deoxyhemoglobin, Lactic Acid, Glucose, Urea Nitrogen.

C. Type of Test: Ion selective electrode – Potassium, Chloride, Sodium, Calcium, Blood gases, pH and Urea Nitrogen
Colorimetric – Glucose
Enzymatic – Lactic Acid

D. Applicant: Jennifer Tribbett
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Patient Care Division
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E. Proprietary and Established Names: Proprietary Name: The Roche OMNI S Analyzer. Established name – Fully automated Critical Care Analyzer for the measurement of pH, Blood gases, electrolytes, Hematocrit, hemoglobin, glucose, lactate, urea/BUN, total hemoglobin, Oxygen saturation, oxy - deoxy-carboxy and methemoglobin

F. Regulatory Information:

1. Regulation section: 862.1600, 862.1145, 862.1665, 862.1170, 862.1120, 862.1450, 862.1345, 862.1770, 864.5620, 864.5600, 864.7425, 864.7500

2. Classification: Class II

3. Product Code: Potassium - CEM, Calcium - JFP, Sodium - JGS, Chloride - CGZ, Blood Gases (PCO₂, PO₂) and pH - CHL, Hemoglobin - GKR, Hematocrit - GKF, Oxygen saturation, Carboxyhemoglobin - GHS, Oxyhemoglobin - GGZ, Methemoglobin - KHG, Deoxyhemoglobin - GKA, Lactic Acid - KHP, Glucose- CGA, Urea Nitrogen - CDS.

4. Panel: 75, 81

G. Intended Use:

1. Intended use(s): The Roche Diagnostics Omni S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PCO₂, PO₂, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin in samples of whole blood, serum, plasma, and aqueous solutions as appropriate.

2. Indication(s) for use: The Roche Diagnostics Omni S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PCO₂, PO₂, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin in samples of whole blood, serum, plasma, and aqueous solutions as appropriate.

3. Special condition for use statement(s): none

4. Special instrument Requirements: none

H. Device Description: The Roche Omni S is an analyzer with an integrated AutoQC drawer option. Depending upon combination and configuration, the following parameters can be measured in whole blood, serum, plasma, acetate and bicarbonate containing dialysis solutions and QC materials.

I. Substantial Equivalence Information:

1. Predicate device name(s): Omni Modular Analyzer and Omni C Analyzer

2. Predicate K number(s): Omni Modular Analyzer (K990092) and Omni C Analyzer (K013373)

3. Comparison with predicate:

Similarities & Differences		
Item	Device	Predicate
Intended use	The Roche Diagnostics Omni S Analyzer is intended to be used for the measurement of	The Roche Diagnostics Omni Modular Analyzer is intended to be used for the measurement of

Parameters measured	<p>pH, PCO₂, PO₂, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin in samples of whole blood, serum, plasma, and aqueous solutions as appropriate.</p> <p>pH, PCO₂, PO₂, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen</p>	<p>pH, PCO₂, PO₂, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, sulfhemoglobin, and methemoglobin in samples of whole blood, serum, plasma, and aqueous solutions as appropriate.</p> <p>The Roche Diagnostics Omni C Analyzer is intended to be used for the measurement of pH, PCO₂, PO₂, sodium, potassium, ionized calcium, chloride, hematocrit, total hemoglobin, and oxygen saturation, in samples of whole blood, serum, plasma, and aqueous solutions as appropriate.</p> <p>Roche Diagnostics Omni Modular Analyzer: pH, PCO₂, PO₂, sodium, potassium, ionized</p>
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a. Linearity/assay reportable range: Linearity was established by utilizing the NCCLS Document EP6-P.

Tonometered whole blood: Whole blood was tonometered at 37°C to various levels of gravitometrically prepared gases with CO₂ and O₂ concentrations certified to 0.03% absolute by the manufacturer. Expected and observed values were corrected to 760 mmHg.

Aqueous solutions : Expected values for the aqueous solutions were based on weighted samples.

NIST Standards: NIST standards are precise serums with accredited target values.

Hematocrit: Measurements for the hemofuge, which represents the gold standard for hematocrit measurements, was used as expected values for hematocrit results.

The linearity for each analyte was described as follows:

PO₂ – slope 0.9904-1.0097 Intercept +/- 0.857 Correlation 0.9998
 Range 0 – 800mmHg
 PCO₂ – slope 0.9898 – 1.0103 Intercept +/- 1.225 Correlation 0.9999
 Range 4 – 200mmHg
 pH – slope 0.9825 – 1.0178 Intercept +/- 0.133 Correlation 0.998
 Range 6.0 – 8.0
 Hct– slope 0.997 – 1.003 Intercept +/- 0.620 Correlation 0.999
 Range 10 80%
 Sodium – slope 0.988 – 1.012 Intercept +/- 0.365 Correlation 0.9999
 Range 20 – 250mmol/L
 Potassium – slope 0.960 – 1.042 Intercept +/- 0.109 Correlation 0.9999
 Range 0.2 - 20 mmol/L
 Ion. Calcium – slope 0.975 – 1.026 Intercept +/- 0.024 Correlation 0.9999
 Range 0.1 – 4.0 mmol/L
 Chloride – slope 0.959 – 1.043 Intercept +/- 2.908 Correlation 0.9999
 Range 20 – 250 mmol/L
 Glucose – slope 0.919 – 1.088 Intercept +/- 1.773 Correlation 0.998
 Range 0.5 – 40 mmol/L
 Lactate – slope 0.961 – 1.041 Intercept +/- 0.191 Correlation 0.9989
 Range 0.2 – 20 mmol/L
 Urea – slope 0.979 – 1.021 Intercept +/- 0.198 Correlation 0.9991
 Range 0.5 – 30 mmol/L
 Total Hgb – slope 0.9892 – 1.0109 Intercept +/- 0.0833 Correlation 0.9904
 Range 3 - 25 g/dl
 SO₂ – slope 0.99999 – 1.00001 Intercept +/- 0.856 Correlation 0.9874
 Range 50 – 100%

b. Traceability (controls, calibrators, or method): Tonometered whole blood, aqueous solutions, NIST standards

c. Detection limit: : Detection Limits for analytes on the Omni S Analyzer are defined on the Omni S Analyzer as the linear range of each assay. The assays performed on the Omni S are measured with established normal and critical ranges for each

analyte. These ranges fall well within the linearity of the respective assays.

d. Analytical specificity: Tonometered whole blood: Whole blood was tonometered at 37°C to various levels of gravimetrically prepared gases with CO₂ and O₂ concentrations certified to 0.03% absolute by the manufacturer. Expected and observed values were corrected to 760 mmHg.

Aqueous solutions : Expected values for the aqueous solutions were based on weighted samples.

NIST Standards: NIST standards are precise serums with accredited target values.

Hematocrit: Measurements for the hemofuge, which represents the gold standard for hematocrit measurements, was used as expected values for hematocrit results.

e. Assay cut-off: The assay cut-off is established as the linearity range of the Roche Omni S for each analyte.

2. Comparison studies:

a. Method comparison with predicate device:). External testing was conducted to demonstrate the correlation of the Omni S analyzer to legally marketed devices in a clinical setting, operated by personnel trained to perform and report these analyses. Specimens analyzed were remnant from patient samples of whole blood, serum and plasma collected from routine analysis on existing instrumentation.

The Omni S has incorporated the same blood gas modules, ISE modules, total hemoglobin and Oxygen saturation, MSS chamber sensors for BUN/urea nitrogen as with the predicate devices. For lactate and glucose the Omni S utilizes Braunstein technology. The correlations to the predicate devices are as follows:

pH, Comparison Instrument - Omni Modular, Slope/Intercept -
 $Y = -0.063 + 1.009 * X$, Bias +0.007, Corr. Coeff. [r] = 0.990, #
 samples = 134

pH, Comparison Instrument - Radiometer 725, Slope/Intercept –
 $Y = -0.496 + 0.933 * X$, Bias +0.003, Corr. Coeff. [r] = 0.990, #
 samples = 99

pO₂, Comparison Instrument - Omni Modular, Slope/Intercept -
 $Y = -0.643 + 1.031 * X$, Bias +1.6, Corr. Coeff. [r] = 0.987, #
 samples = 136, Unit (mmHG)

pO₂, Comparison Instrument - Radiometer 725, Slope/Intercept
 – $Y = -4.433 + 1.013 * X$, Bias +6.6, Corr. Coeff. [r] = 0.996, #
 samples = 137, Unit (mmHG)

pCO₂, Comparison Instrument - Omni C, Slope/Intercept - $Y = -1.452 + 1.038 * X$, Bias +1.6, Corr. Coeff. [r] = 0.987, # samples = 129, Unit (mmHG)

pCO₂, Comparison Instrument - Radiometer 725,
 Slope/Intercept - $Y = -0.301 + 1.000 * X$, Bias +0.4, Corr. Coeff.
 [r] = 0.988, # samples = 144, Unit (mmHG)

tHb, Comparison Instrument - Radiometer 725, Slope/Intercept
 – $Y = 0.581 + 1.083 * X$, Bias +2.0, Corr. Coeff. [r] = 0.814, #
 samples = 96, Unit (g/dl)

Sodium, Comparison Instrument - Omni Modular,
 Slope/Intercept – $Y = -13.193 + 1.106 * X$, Bias +0.9, Corr. Coeff.
 [r] = 0.948, # samples = 108, Unit (mmol/L)

Sodium, Comparison Instrument - Radiometer 725,
 Slope/Intercept – $Y = -2.143 + 1.106 * X$, Bias +0.9, Corr. Coeff.
 [r] = 0.972, # samples = 107, Unit (mmol/L)

Potassium, Comparison Instrument - Omni Modular,
 Slope/Intercept – $Y = -0.126 + 1.020 * X$, Bias -1.4, Corr. Coeff.
 [r] = 0.986, # samples = 131, Unit (mmol/L)

Potassium, Comparison Instrument - Radiometer 725,
 Slope/Intercept - $Y = -2.143 + 1.106 * X$, Bias +0.9, Corr. Coeff.
 [r] = 0.972, # samples = 107, Unit (mmol/L)

Calcium, Comparison Instrument - Omni Modular,
 Slope/Intercept – $Y = -0.039 + 1.024 * X$, Bias -0.8, Corr. Coeff.
 [r] = 0.941, # samples = 131, Unit (mmol/L)

Calcium, Comparison Instrument - Radiometer 725,
 Slope/Intercept - $Y = -0.096 + 1.073 * X$, Bias -1.1, Corr. Coeff.
 [r] = 0.981, # samples = 98, Unit (mmol/L)

Chloride, Comparison Instrument - Omni Modular,
 Slope/Intercept – $Y = -12.459 + 1.118 * X$, Bias -0.7, Corr. Coeff.
 [r] = 0.960, # samples = 139, Unit (mmol/L)

Chloride, Comparison Instrument - Radiometer 725,
Slope/Intercept - $Y = 17.100 + 0.800 * X$, Bias -4.0, Corr. Coeff. [r] = 0.965, # samples = 98, Unit (mmol/L)

SO₂, Comparison Instrument - Omni Modular, Slope/Intercept –
 $Y = 10.066 + 0.903 * X$, Bias 1.1, Corr. Coeff. [r] = 0.991, #
samples = 130, Unit (%)

SO₂, Comparison Instrument - Radiometer 725,
Slope/Intercept - $Y = -3.969 + 1.037 * X$, Bias -4.0, Corr. Coeff. [r]
= 0.904, # samples = 102, Unit (%)

MetHb, Comparison Instrument - Omni Modular, Deviation of
mean -0.3% abs, # samples = 129

MetHb, Comparison Instrument - Radiometer 725, , Deviation
of mean +0.2% abs, # samples = 131

COHb, Comparison Instrument - Omni Modular, Deviation of
mean 0.7% abs, # samples = 130

COHb, Comparison Instrument - Radiometer 725, , Deviation of
mean +0.1% abs, # samples = 132

Hct, Comparison Instrument - Omni Modular, Slope/Intercept –
 $Y = 0.100 + 1.00 * X$, Bias 0.4, Corr. Coeff. [r] = 0.967, # samples
= 132, Unit (%)

Hct, Comparison Instrument - Radiometer 725, Slope/Intercept
- $Y = -0.689 + 1.040 * X$, Bias 0.6, Corr. Coeff. [r] = 0.946, #
samples = 141, Unit (%)

Glucose, Comparison Instrument - Omni Modular,
Slope/Intercept – $Y = -0.461 + 1.034 * X$, Bias -3.9, Corr. Coeff.
[r] = 0.938, # samples = 134, Unit (mmol/L)

Glucose, Comparison Instrument - Radiometer 725,
Slope/Intercept - $Y = -0.867 + 1.201 * X$, Bias 5.2, Corr. Coeff. [r]
= 0.986, # samples = 107, Unit (mmol/L)

Urea, Comparison Instrument - Omni Modular, Slope/Intercept –
 $Y = -0.343 + 0.850 * X$, Bias -10.8, Corr. Coeff. [r] = 0.957, #
samples = 122, Unit (mmol/L)

Urea, Comparison Instrument - Cobas Mira, Slope/Intercept -
 $Y = -0.001 + 0.887 * X$, Bias -11.1, Corr. Coeff. $[r] = 0.981$, #
 samples = 129, Unit (mmol/L)

Lactate, Comparison Instrument - Omni Modular,
 Slope/Intercept – $Y = -0.200 + 1.000 * X$, Bias -9.5, Corr. Coeff.
 $[r] = 0.936$, # samples = 136, Unit (mmol/L)

Lactate, Comparison Instrument - Cobas Mira, Slope/Intercept
 - $Y = -0.297 + 1.074 * X$, Bias -3.0, Corr. Coeff. $[r] = 0.968$, #
 samples = 137, Unit (mmol/L)

b. Matrix comparison: The Omni S Analyzer utilizes the same
 sample types – whole blood, serum, plasma and aqueous
 material (QC material and dialysis fluids) as previously cleared on
 the predicate device, the Omni C analyzer (k013373)

3. Clinical studies:

a. Clinical sensitivity: None stated

b. Clinical specificity: None stated

*c. Other clinical supportive data (when a and b are not
 applicable):* None

4. Clinical cut-off: None stated

5. Expected values/Reference range: A complete listing of critical values
 and expected values are provided in the technical manual of the Omni
 S. The values reflect normal or expected ranges including ranges for
 neonates, children and adults as needed. Additionally, explanations of
 typical disease states with each critical value for each assay is
 provided. These ranges and supportive documentation are derived
 from previously established literature. Specifically: “Critical Care
 Testing: A Quick Reference Guide” by Andrew St. John First edition
 2001, Tietz “Textbook of Clinical Chemistry” third edition 1999, and
 “Labor und Diagnose” Lothar Thomas, fifth expanded edition 2000.

M. Instrument Name: Roche Diagnostics Omni S Analyzer

N. System Descriptions:

1. Modes of Operation: Routine, STAT

2. Software: The Roche Omni S utilizes a PC based interface to the user
 with a touch sensitive color matrix display and a barcode reader for input

and display of data. Additional microcontrollers controls all operations of the Roche Omni S. Lower level tasks are done by a network of micro-controllers. The micro-controller network is responsible for data acquisition and sensor/actuator handling. The programming languages are standard for this type of task.

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes or No

3. Sample Identification: Samples are identified via Bar Code or manual entry.
4. Specimen Sampling and Handling: Samples are a combination of whole blood, serum, plasma and aqueous solution (QC or dialysate). Samples are introduced via capillary tubes, syringes and sealed containers.
5. Assay Types: Ion selective Electrode, Enzymatic, MSS chamber sensors for BUN/urea nitrogen, for lactate and glucose the Omni S utilizes Braunstein technology.
6. Reaction Types: ISE, Enzymatic, MSS chamber sensors for BUN/urea nitrogen as the predicate devices. For lactate and glucose the Omni S utilizes Braunstein technology.
7. Calibration: The instrument automatically calibrates every 8, 12 Or 24hours (default) established by the user. This calibration includes: wavelength calibration of the polychromator, cleaning with internal cleaning solution, Automatic conditioning of the Na⁺ probe, Calibration of the mixing system and 2 point calibration of all parameters. Calibration of the O₂ sensor is done every 30 minutes with ambient air and a zero point solution. O₂ is recalibrated after every measurement. User can calibrate any parameter by performing a user activated calibration in the instrument software. Calibrators are sold separately.
8. Quality Control: Quality Control material is sold separately and consists of the following materials Combitrol TS+ (k032453), Auto-trol+ (AutoQC material) (k032453), Combitrol Plus B and Auto-trol Plus B (AutoQC Material) (k032453). QC target ranges are included with each lot of QC material. Each analyte tested has three levels of QC range. QC timing is established by the user via the user interface.

O. Other Supportive Instrument Performance Characteristics Data Not Covered In The "L. Performance Characteristics" Section Of The SE Determination Decision Summary. The Roche Diagnostics Omni S Analyzer performs the following assays: Potassium, Calcium, Sodium,

Chloride, Blood Gases (PCO₂, PO₂) and pH, Hemoglobin, Hematocrit, Oxygen Saturation, Carboxyhemoglobin, Oxyhemoglobin, Methemoglobin, Deoxyhemoglobin, Lactic Acid, Glucose, and Urea Nitrogen. Hemoglobin, Hematocrit, Deoxyhemoglobin, Carboxyhemoglobin, Oxyhemoglobin, Methemoglobin and Deoxyhemoglobin are regulated by the Office of InVitro Diagnostics Division of Hematology and Immunology. These assays were referred to the division for consultation. The results of that consultation are included with the review.

- P. Conclusion:** Based upon the information provided, I recommend that the Roche Diagnostics Omni S Analyzer be found substantially equivalent to the respective predicate devices.