

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

**A. 510(k) Number:**

k100060

**B. Purpose for Submission:**

New device

**C. Measurand:**

Amylase, Albumin, Bicarbonate, Sodium, Potassium, Chloride, and Uric Acid

**D. Type of Test:**

Quantitative, photometric and ion selective electrodes

**E. Applicant:**

Vital Diagnostics

**F. Proprietary and Established Names:**

EON 100 Chemistry Analyzer with Ion Selective Electrode (ISE)  
EON Amylase Reagent  
EON Albumin Reagent  
EON Bicarbonate Reagent  
EON ISE Reagent Pack  
EON Uric Acid Reagent  
EON Calibrator Kit  
EON Carbon Dioxide Calibrator

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.2160 Discrete photometric chemistry analyzer for clinical use  
21 CFR 862.1070 Amylase test system  
21 CFR 862.1035 Albumin test system  
21 CFR 862.1160 Bicarbonate/carbon dioxide test system

21 CFR 862.1665 Sodium test system  
21 CFR 862.1600 Potassium test system  
21 CFR 862.1170 Chloride test system  
21 CFR 862.1775 Uric Acid test system  
21 CFR 862.1150 Calibrator

2. Classification:

Class I  
Discrete photometric chemistry analyzer for clinical use

Class I, reserved  
Uric Acid test system

Class II  
Amylase test system  
Albumin test system  
Bicarbonate/carbon dioxide test system  
Sodium test system  
Potassium test system  
Chloride test system  
Calibrator

3. Product code:

JJE - Analyzer, Chemistry (Photometric, Discrete) for clinical use  
JFJ - Catalytic methods, amylase  
CIX - Bromocresol green dye-binding, albumin  
KHS - Enzymatic, carbon-dioxide  
JGS - Electrode, ion specific, sodium  
CEM - Electrode, ion specific, potassium  
CGZ - Electrode, ion specific, chloride  
KNK - Acid, uric, uricase (colorimetric)  
JIX - Calibrator, Multi-Analyte Mixture  
JIT - Calibrator, Secondary

4. Panel:

Clinical Chemistry - 75

**H. Intended Use:**

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

EON 100 Chemistry Analyzer with Ion Selective Electrode (ISE)

The Eon 100 is a discrete photometric chemistry analyzer for clinical use. It is a device intended for the in-vitro, spectrophotometric determination of general chemistry assays. The Eon 100 has replaceable parts, automated maintenance monitoring and backup of both patient and system data.

The Eon 100 Chemistry Analyzer is intended to be used to assist the clinician with the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease. The Eon 100 includes an optional Ion Selective Electrodes (ISE) module for the measurement of sodium, potassium and chloride in serum and plasma.

The Eon 100 is for in vitro diagnostic use only.

EON Amylase Reagent

An amylase test system is a device intended to measure the quantitative activity of the enzyme amylase in serum and plasma on the EON 100 Chemistry Analyzer. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

EON Albumin Reagent

An albumin test system is a device intended to quantitatively measure the albumin concentration in serum and plasma on the EON 100 Chemistry Analyzer. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

EON Bicarbonate Reagent

A bicarbonate/carbon dioxide test system is a device intended to quantitatively measure bicarbonate/carbon dioxide in serum and plasma on the EON 100 Chemistry Analyzer. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

EON ISE Reagent Pack

A sodium test system is a device intended to quantitatively measure sodium in serum and plasma on the EON 100 Chemistry Analyzer. Measurements obtained by this device 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.

A potassium test system is a device intended to quantitatively measure potassium in serum and plasma on the EON 100 Chemistry Analyzer. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

A chloride test system is a device intended to quantitatively measure the level of chloride in serum and plasma on the EON 100 Chemistry Analyzer. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis

#### EON Uric Acid Reagent

A Uric acid test system is a device intended to quantitatively measure uric acid in serum and plasma on the EON 100 Chemistry Analyzer. Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

#### EON Calibrator Kit

The Eon Calibrator Kit is intended for medical purposes for use in a test system to establish points of reference for albumin, total protein, and uric acid on the EON 100 Chemistry Analyzer that are used in the determination of values in the measurement of substances in human specimens.

#### EON Carbon Dioxide Calibrator

The Eon Carbon Dioxide Calibrator is a device intended for medical purposes for use in the Eon Carbon Dioxide Reagent assay on the EON 100 Chemistry Analyzer to establish points of reference that are used in the determination of values in the measurement of carbon dioxide in serum and plasma.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only. For prescription use.

4. Special instrument requirements:

Vital Diagnostics, EON 100 Chemistry Analyzer with Ion Selective Electrode Module

### **I. Device Description:**

The EON 100 is a random access, fully automated clinical chemistry analyzer intended for the *in vitro*, spectrophotometric determination of general chemistry assays. The EON 100 analyzer consists of the EON 100 software, a carousel system for both reagents and samples, an internal cooling unit, a sample/reagent dispensing arm assembly, an incubation/reading assembly, and a washing station. The EON 100 analyzer also includes an integrated ISE Module. The claimed specimens are serum and lithium heparin plasma.

**J. Substantial Equivalence Information:**

1. Predicate device name:

<b>New Device</b>	<b>Predicate Device</b>	<b>Predicate 510(k)</b>
EON 100 Chemistry Analyzer with Ion Selective Electrode (ISE)	Hitachi 911 System	k921661
EON Amylase Reagent	Cobas alpha-Amylase Liquid Reagent	k882225
EON Albumin Reagent	Cobas Albumin Plus	k901003
EON Bicarbonate Reagent	Cobas Bicarbonate Liquid	k032377
EON ISE Reagent Pack	Medica EasyLyte Analyzer - Na/K/Cl	k963763
EON Uric Acid Reagent	Cobas Uric Acid Plus Reagent	k873363
EON Carbon Dioxide Calibrator	Ammonia/Ethanol/CO2 Calibrator and Controls	k031880
EON Calibrator kit	ATAC Calibrator	k030621

2. Predicate 510(k) number:

Refer to predicate device names above.

3. Comparison with predicate:

<b>Comparison Table: EON 100 Analyzer</b>		
<b>Item</b>	<b>New Device (k100060)</b>	<b>Predicate (k921661)</b>
Intended Use	Intended for in vitro determination of general chemistry assays. It includes an optional ion selective electrode module.	Same
System Principle	Clinical chemistry analyses including endpoint, bi-chromatic end-point, kinetic, and fixed time assays in either random mode or batch mode with routine and urgency (STAT) testing.	Same
Detection method	Spectrophotometric	Same
Calibration	Single and Multi-Standard	Same
Reaction Vessel	80 reusable plastic cuvettes tray	120 semi-disposable plastic

<b>Comparison Table: EON 100 Analyzer</b>		
Item	New Device (k100060)	Predicate (k921661)
		cuvettes
Throughput (without ISE)	150 tests/hour (with ISE: 180)	360 tests/hour (with ISE: 720)
Reagents	Stored on-board	Same
Sample volume	1-300 uL	2-50 uL
Specimen Type	Serum and plasma	Same
Temperature Control	Reaction: 37°C Reagents: 14°C	Reaction: 37°C Reagents: 12°C
Reagent Type/Storage	Liquid. Refrigerated tray with 28 positions.	Liquid. Refrigerated storage for 64 positions
LIS Connectivity	Yes	Yes
Host Interface	RS-232 serial interface	Same
Barcode Reader	Yes	Same

<b>Comparison Table: EON Amylase Reagent</b>		
Item	New Device (k100060)	Predicate (k882225)
Intended Use	Intended to measure the activity of the enzyme amylase	Same
Reagent Configuration/Format	Liquid single reagent, ready for use	Same
Measurement Range	10-1600 U/L	3-1500 U/L

<b>Comparison Table: EON Albumin Reagent</b>		
Item	New Device (k100060)	Predicate (k932950)
Intended Use	Intended to measure the albumin concentration in serum and plasma	Same
Reagent Configuration	Liquid single reagent, ready for use	Same
Measurement Range	1.0-7.0 g/dL	Same

<b>Comparison Table: EON Bicarbonate Reagent</b>		
Item	New Device (k100060)	Predicate (k032377)
Intended Use	Intended to measure bicarbonate in serum and plasma	Same
Reagent Configuration	Liquid single reagent, ready for use	Same
Measurement Range	3-45 mmol/L	1.5-50 mmol/L

<b>Comparison Table: EON Uric Acid Reagent</b>		
Item	New Device (k100060)	Predicate (k873363)
Intended Use	Intended to measure uric acid in serum and plasma	Same
Reagent Configuration	Liquid single reagent, ready for use	Same
Measurement Range	1.0-20 mg/dL	0.2-25.0 mg/dL

<b>Comparison Table: EON Carbon Dioxide Calibrator</b>		
Item	New Device (k100060)	Predicate (k031880)
Intended Use	Intended for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.	same
Format	Liquid, ready for use	same
Stability	Stable until expiration date printed on label when stored at 2-8°C	same

<b>Comparison Table: EON Calibrator kit</b>		
Item	New Device (k100060)	Predicate (k030621)
Intended Use	Intended for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.	same
Analytes	Albumin, total protein, and uric acid	Albumin, calcium, cholesterol, creatinine, glucose, magnesium, phosphorus, total bilirubin, total protein, and urea
Format	Lyophilized	same
Stability	Stable until expiration date printed on label when stored at 2-8°C	same

#### **K. Standard/Guidance Document Referenced (if applicable):**

1. ISO 14971. Medical Devices - Application of Risk Management to Medical Devices.
2. CLSI EP5-A2. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline.
3. CLSI EP9-A2. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.
4. CLSI EP17-A. Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.

#### **L. Test Principle:**

##### Photometric Chemistries

The EON 100 analyzer utilizes up to eight wavelengths in conjunction with reagents, which are mixed with samples by a dispensing arm assembly, to perform the following tests: Amylase, Albumin, Bicarbonate, and Uric Acid. The analyzer is adaptable to test methods based on kinetic and end-point monitoring using monochromatic or bi-chromatic measurements. The EON 100 contains a carousel system for both reagents and samples including a reagent tray with 28 refrigerated, numbered positions. The sample and reagent are aspirated and dispensed into a reaction cuvette or the ISE inlet port by the dispensing arm assembly. A washing cycle follows each dispensing operation. The photometric reaction is read in front of the optical group using the appropriate wavelength after designated incubation times for each cuvette. The optical group is composed of a spectrophotometer with a ten-position filter tray that allows for the selection of the particular wavelength required by the method. The photometer measures optical density for each test in mono or bi-chromatic mode. Readings are based on the Lambert-Beer's law.

##### Potentiometric Chemistries - Sodium, Potassium, and Chloride

The EON 100 analyzer also includes an integrated ISE module that measures Sodium, Potassium, and Chloride. The sodium, potassium, and chloride electrodes employ selective membrane materials. The potential of each electrode is measured relative to a fixed, stable voltage established by the double-junction silver/silver chloride reference electrode. An ion-selective electrode develops a voltage that varies with the concentration of the ion to which it responds. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic (Nernst equation). Three solutions contained in the ISE Reagent Pack are necessary to operate the ISE module. Calibrant A is used for one and two-point calibrations as well as pump and bubble calibration. Calibrant B is used for two-point calibrations. The Daily Cleaning Solution is sold separately and is used to prevent protein buildup in the fluid path and on the electrodes. The ISE Reagent Pack has been previously reviewed and cleared under 510(k) submission k070057.

##### Amylase Reagent

Amylase cleaves 2-chloro-4-nitrophenyl- $\alpha$ -D-maltotriose (CNP-  $\alpha$  -G<sub>3</sub>) to produce 2-chloro-4-nitrophenol (CNP), a yellow dye which absorbs at 405 nm. The EON 100 Analyzer determines the activity of amylase in the original sample by monitoring the rate of absorbance increase at 405 nm.

#### Albumin Reagent

The EON Albumin Reagent is a dye-binding reagent. Albumin can bind bromocresol green as well as other dyes to produce complexes with different optical properties. When albumin in the sample binds with the bromocresol green in the reagent, the resulting increase in absorbance at 630 nm is directly proportional to the amount of albumin in the sample.

#### Bicarbonate Reagent

The EON Bicarbonate Reagent is an enzymatic rate method that uses PEP = phosphoenolpyruvate, PEPC = phosphoenolpyruvate carboxylase, and MDH = malate dehydrogenase. The rate of production of NAD<sup>+</sup> analog produces a decrease in absorbance at 405 nm, which is directly proportional to the concentration of bicarbonate present in the sample or control material being assayed.

#### Uric Acid Reagent

The EON Uric Acid Reagent is an enzymatic method that utilizes uricase to oxidize uric acid. The EON Uric Acid method uses the hydrogen peroxide produced in the oxidation step to drive a Trinder indicator reaction producing an intensely colored red dye. Uric acid is oxidized in the presence of oxygen and uricase. The resulting hydrogen peroxide reacts with 4-aminoantipyrine (4-AAP) and N-ethyl-N-(hydroxyl-3-sulfopropyl)-toluidine (TOOS) to form an indamine dye that absorbs strongly at 546 nm. The increase in absorbance is proportional to the concentration of uric acid in the sample. Potassium ferrocyanide and ascorbic oxidase are added to the reagent to reduce interference from bilirubin and ascorbic acid.

#### Eon Calibrator Kit

The EON Calibrator Kit contains albumin, protein, and uric acid in a human serum matrix at specified set points indicated in the calibrator labeling. The sponsor states that the source materials in this product have been tested for human immunodeficiency virus (HIV1, HIV2) antibody, hepatitis B surface antigen (HBsAg), and hepatitis C (HCD) antibody and found to be non-reactive. The Eon Calibrator has been previously reviewed and cleared under 510(k) submission k030621.

#### Carbon Dioxide Calibrator

The EON Carbon Dioxide Calibrator is an aqueous solution containing sodium carbonate and sodium bicarbonate in equimolar amounts to produce total carbon dioxide concentration of 25 mmol/L.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision studies were performed based on the Clinical and Laboratory Standards Institute (CLSI) guideline EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods using three levels of serum based control. Studies were carried out over a period of 20 to 22 days, two runs per day, by one operator using one lot of reagent on one EON 100 instrument for each assay. The mean, standard deviation (SD), and coefficients of variation (CV) were determined for each control level and each assay as summarized below:

<b>Precision Data Summary</b>						
<b>Amylase</b>						
<b>Sample</b>	<b>N</b>	<b>Within Run</b>			<b>Total</b>	
		<b>Mean (U/L)</b>	<b>SD (U/L)</b>	<b>CV (%)</b>	<b>SD (U/L)</b>	<b>CV (%)</b>
1	88	85	3.2	3.8	5.2	6.1
2	88	533	15.4	2.9	27.5	5.1
3	88	959	33.1	3.5	48.9	5.1
<b>Albumin</b>						
<b>Sample</b>	<b>N</b>	<b>Within Run</b>			<b>Total</b>	
		<b>Mean (g/dL)</b>	<b>SD (g/dL)</b>	<b>CV (%)</b>	<b>SD (g/dL)</b>	<b>CV (%)</b>
1	80	2.5	0.05	1.8	0.07	2.7
2	80	3.9	0.07	1.7	0.11	2.8
3	80	5.1	0.07	1.4	0.13	2.5
<b>Bicarbonate</b>						
<b>Sample</b>	<b>N</b>	<b>Within Run</b>			<b>Total</b>	
		<b>Mean (mmol/L)</b>	<b>SD (mmol/L)</b>	<b>CV (%)</b>	<b>SD (mmol/L)</b>	<b>CV (%)</b>
1	80	12	0.7	6.0	1.2	10.3
2	80	21	0.7	3.5	1.6	7.5
3	80	31	1.1	3.5	2.0	6.5
<b>Sodium</b>						
<b>Sample</b>	<b>N</b>	<b>Within Run</b>			<b>Total</b>	
		<b>Mean (mmol/L)</b>	<b>SD (mmol/L)</b>	<b>CV (%)</b>	<b>SD (mmol/L)</b>	<b>CV (%)</b>
1	84	135	1.4	1.0	1.7	1.3
2	84	154	1.4	0.9	1.9	1.2
3	84	112	0.8	0.7	1.4	1.3
<b>Potassium</b>						
<b>Sample</b>	<b>N</b>	<b>Within Run</b>			<b>Total</b>	
		<b>Mean (mmol/L)</b>	<b>SD (mmol/L)</b>	<b>CV (%)</b>	<b>SD (mmol/L)</b>	<b>CV (%)</b>
1	80	3.6	0.03	0.8	0.04	1.1

2	80	5.6	0.05	0.9	0.08	1.4
3	80	2.7	0.02	0.9	0.04	1.3
Chloride						
Sample	N	Within Run			Total	
		Mean (mmol/L)	SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
1	84	99	1.05	1.1	1.41	1.4
2	84	119	0.94	0.8	1.70	1.4
3	84	78	0.68	0.9	1.08	1.4
Uric Acid						
Sample	N	Within Run			Total	
		Mean (mg/dL)	SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)
1	84	2.8	0.10	3.4	0.11	4.1
2	84	7.2	0.21	2.9	0.27	3.7
3	84	11.6	0.30	2.6	0.43	3.7

*b. Linearity/assay reportable range:*

Linearity studies were carried out following an internal protocol using no less than six different levels of commercially available standards or in-house prepared aqueous-based linearity standards. Linear regression analyses results and claimed reportable ranges are shown below. Results of the study support the sponsor's measuring range claims.

Linearity Data Summary					
Measurand	Slope	CI (95%)	Intercept	CI (95%)	Range
Amylase	1.015	0.994 to 1.035	0.73	-0.20 to 1.66	6-1715 U/L
Albumin	0.994	0.975 to 1.014	0.15	0.07 to 0.24	0.5-7.1 g/dL
Bicarbonate	0.964	0.923 to 1.005	0.10	-1.0 to 1.3	3-45 mmol/L
Sodium	0.966	0.943 to 0.989	0.3	-3.4 to 4.1	79-243 mmol/L
Potassium	0.929	0.921 to 0.937	-0.01	-0.07 to 0.06	0.9-13.9 mmol/L
Chloride	1.047	1.028 to 1.066	-12.9	-15.3 to -10.4	49-197 mmol/L
Uric Acid	0.993	0.983 to 1.004	0.23	0.12 to 0.33	0.4-21 mg/dL

Claimed Measuring Ranges	
Measurand	Measuring Range
Amylase	10-1600 U/L
Albumin	1.0-7.0 g/dL
Bicarbonate	3-45 mmol/L
Sodium	100-200 mmol/L
Potassium	1.0-8.0 mmol/L
Chloride	75-150 mmol/L
Uric Acid	1.0-20 mg/dL

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability

Calibrators are traceable to NIST reference material or in-house solutions using high purity, commercially available material. For Amylase, there is no calibration required as the analyzer automatically calculates activity based on the absorptivity of 2-chloro-4-nitrophenol. A summary of traceability is shown in the table below.

<b>Traceability Summary</b>		
Device	Reference Material	Method
Albumin	NIST SRM 927	Bromocresol Green, 650 nm, End-point
Bicarbonate	NIST SRM 351a	PEP Carboxylase/MDH, 340 nm, End-point
Sodium	in-house solutions using high purity chemicals	Manufacturers standing measurement procedures on ISE module.
Potassium		
Chloride		
Uric Acid	NIST SRM 909b	Enzymatic Uricase, End-point (uricase/peroxidase) at 500 nm

Reagent Stability

On board stability of each reagent was established by real-time studies on the EON 100 Analyzer. Study results support the following storage conditions:

<b>On Board Reagent Stability Summary</b>		
Reagent	Storage Period	Storage Temperature
Albumin	21 days	10°C
Amylase	14 days	10°C
Bicarbonate	14 days	10°C
Uric Acid	21 days	10°C

The ISE Reagent Pack can be stored between 5-25°C. The reagent pack is stable until the expiration date shown in the label.

Calibrators: Value Assignment and Stability

Expected values for the EON Calibrator kit are determined by duplicate analyses of at least six vials of each new calibrator lot using  $N \geq 2$  EON 100 analyzers and at least two lots of reagents. Pre-determined acceptance criteria for analyte recovery must be met for each control lot. The target value for each calibrator is the mean of the observed values. The EON CO<sub>2</sub> Standard and EON ISE Reagent Pack calibrators are commercially available standards that are verified on the EON 100 chemistry

analyzer for each lot preparation by evaluating the recoveries of quality control material and secondary linearity set materials. Calibrator assigned values are lot dependent and are listed in the labeling.

Accelerated and real-time stability studies have been completed by the manufacturer in order to support the stability claims for the EON Calibrator Kit and the EON CO<sub>2</sub> Calibrator. The manufacturer has an on-going real-time stability study protocol to support the recommended storage conditions for the life of the product. The calibrators' stability claims are summarized below:

<b>Calibrator Stability Summary</b>				
Calibrator	Shelf-Life (Unopened Vial)		Open Vial (Reconstituted)	
	Storage Period	Storage Temperature	Storage Period	Storage Temperature
EON Calibrator Kit (Albumin, total protein, uric acid)	Expiration date on label	2-8°C	7 days (Reconstituted)	2-8°C
EON CO <sub>2</sub> Calibrator	Expiration date on label	2-8°C	Expiration date on label	2-8°C

The sponsor recommends that calibration should be carried out after loading new reagent, after maintenance, and whenever quality control results fall outside established limits.

*d. Detection limit:*

Limits of Blank (LoB) and Limits of Detection (LoD) for each assay were evaluated using CLSI EP17-A guideline: Protocol for Determination of Limits of Detection and Limits of Quantitation. Sixty (60) blank samples consisting of saline (9% NaCl) and sixty (60) low standard samples were used in the LoB and LoD studies. Analytical sensitivity for each reagent was determined in calibrated assays using the mean calibrator factor obtained over a minimum of 10 runs (1/factor = change in absorbance per analyte concentration). Studies were performed using a minimum of two lots of reagent at least two EON 100 analyzers for each assay.

<b>Detection Limits Data Summary</b>		
<b>Analyte</b>	<b>LoB</b>	<b>LoD</b>
Amylase	4 U/L	10 U/L
Albumin	0.2 g/dL	1.0 g/dL
Bicarbonate	1 mmol/L	3 mmol/L
Uric Acid	0.7 mg/dL	1.0 mg/dL

See linearity study in section M.1.b of this 510(k) decision summary for ISE methods.

*e. Analytical specificity:*

Interferences Studies were performed by spiking normal sera at clinically significant medical decision points for each measurand at various concentrations of interfering compounds normally found in serum or plasma. Measurements ( $N \geq 3$ ) obtained from sera containing each potential interfering substance was evaluated and compared against measurements with a control group. Both groups were assayed on the EON 100 analyzer. No significant interference (recovery within  $\pm 10\%$ ) was observed for hemoglobin, bilirubin (unconjugated), lipemia (Intralipid measured as triglycerides), triglycerides, or ascorbic acid up to the levels shown in the table below:

<b>Interferences Data Summary</b>					
<b>Measur- and (Conc.)</b>	<b>Hemoglobin (mg/dL)</b>	<b>Bilirubin (mg/dL)</b>	<b>Lipemia (mg/dL)</b>	<b>Triglycerides (mg/dL)</b>	<b>Ascorbic Acid (mg/dL)</b>
Amylase	do not use hemolyzed samples	60	450	2000	-
Albumin	1000	60	2000	2000	-
Bicarbonate	1000	60	1000	500	-
Sodium	1000	60	500	2000	-
Potassium	do not use hemolyzed samples	60	500	2000	-
Chloride	1000	60	500	2000	-
Uric Acid	750	30	500	2000	20

The following limitation is included in the package insert for each device: Many other substances can affect results. For additional information, refer to Effects of Drugs on Clinical Laboratory Tests (Young D.S. AACC Press, 2000) and Effects of Pre-Analytical Variables on Clinical Laboratory Tests (Young D.S. AACC Press, 1997). The results of this assay should only be interpreted in conjunction with other diagnostic test results, clinical findings, and the patient's medical history.

*f. Assay cut-off:*

Not applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Comparison studies were performed using CLSI EP9-A2 guideline: Method Comparison and Bias Estimation Using Patient Samples. Measurements from serum samples assayed on the EON 100 Analyzer using  $\leq 20\%$  altered samples (i.e. diluted or spiked) were compared to those obtained with each predicate device. Regression analyses results are summarized below.

<b>Method Comparison Data Summary</b>							
Measurand	Range	N	Slope	CI (95%)	Intercept	CI (95%)	r
Amylase	14-1457 U/L	197	0.957	0.952 to 0.961	-4.4	-5.8 to -2.9	0.9995
Albumin	1.1-7.0 g/dL	106	0.930	0.904 to 0.956	0.16	0.05 to 0.28	0.9900
Bicarbonate	3-45 mmol/L	202	0.990	0.962 to 1.019	-0.651	-1.296 to -0.006	0.9795
Sodium	106-197 mmol/L	190	1.004	0.989 to 1.020	-2.07	-4.28 to 0.15	0.9943
Potassium	1.6-7.9 mmol/L	153	0.953	0.943 to 0.963	0.066	0.022 to 0.111	0.9978
Chloride	81-144 mmol/L	186	0.985	0.970 to 1.000	0.051	-1.535 to 1.638	0.9945
Uric Acid	1.2-17.3 mg/dL	171	1.043	1.026 to 1.060	0.015	-0.098 to 0.128	0.9942

*b. Matrix comparison:*

Matrix comparison studies were performed by assaying fresh serum/lithium heparin matched pairs on the EON 100 analyzer for each assay. Results were compared by linear regression analysis. Study results are summarized below:

<b>Matrix Comparison Data Summary</b>							
Measurand	Range	N	Slope	CI (95%)	Intercept	CI (95%)	r
Amylase	19-1595 U/L	44	0.943	0.979 to 0.989	1.69	-0.333 to 3.712	0.9997
Albumin	1.0-6.5 g/dL	45	0.999	0.981 to 1.017	0.003	-0.067 to 0.074	0.9966
Bicarbonate	3-42 mmol/L	43	0.943	0.902 to 0.984	0.818	-0.259 to 1.896	0.9806
Sodium	100-181 mmol/L	43	1.017	1.001 to 1.034	-2.649	-4.921 to -0.377	0.9973
Potassium	1.1-7.0 mmol/L	46	0.996	0.976 to 1.017	-0.025	-0.106 to 0.056	0.9953
Chloride	80.7-147 mmol/L	40	0.990	0.982 to 0.998	0.945	0.091 to 1.798	0.9994
Uric Acid	1.0-19.9 mg/dL	45	1.008	0.989 to 1.027	-0.085	-0.200 to 0.030	0.9960

The recommended specimen type is serum or lithium heparin plasma.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable

*b. Clinical specificity:*

Not applicable

*c. Other clinical supportive data (when a. and b. are not applicable):*

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The reference ranges for each reagent shown below were taken from the literature and verified by assaying a minimum of 20 normal samples per specimen matrix type (i.e. serum and plasma). The manufacturer indicates in the labeling that cited reference ranges should be used as “guide only”. The manufacturer recommends each laboratory to verify the cited range or to establish a reference range for the population that it serves.

Expected Values <sup>1</sup>	
Reagent	Range
Amylase	22-80 U/L
Albumin	3.5-5.2 g/dL
Bicarbonate	23-29 mmol/L
Sodium <sup>2</sup>	136-146 mmol/L
Potassium <sup>2</sup>	3.5-5.0 mmol/L
Chloride <sup>2</sup>	98-106 mmol/L
Uric Acid (Male)	3.5-7.2 mg/dL
Uric Acid (Female)	2.6-6.0 mg/dL

References:

1. Burtis C.A., Ashwood E.R., Eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, Fourth Ed. W.B. Saunders Co.: Philadelphia, PA, 2006.
2. Zilva J.F, Pannall P.R. Clinical Chemistry in Diagnosis and Treatment, Third Ed. Lloyd-Luke: London, 1979.

**N. Instrument Name:**

Vital Diagnostics, EON 100 Chemistry Analyzer with Ion Selective Electrode Module

**O. System Descriptions:**

1. Modes of Operation:

Random access routine and STAT mode. For every sample, the following photometric method types can be selected: end-point, bi-chromatic end-point, kinetics, fixed time (two-point kinetics), differential two reagents, and differential sample blank. The ISE module includes ion selective electrodes and three peristaltic pumps mounted within the analyzer. Upon warm up, the ISE module performs a pump calibration, bubble calibration, and two-point calibration. The EON 100 software includes firmware, controlling software, user interface, and laboratory information system communications interface module.

Does the applicant’s device contain the ability to transmit data to a computer, webserver,

or mobile device?:

Yes  or No

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

Yes  or No

2. Software:

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

Yes  or No

3. Specimen Identification:

The EON 100 Analyzer is equipped with a sample tray that contains labeled positions identified by numbers. Primary tubes for samples can also be labeled with barcodes for the positive identification of the patients and the automatic association with a work list. The barcode reader is a laser device able to perform 600-650 nm scans per second with an integrated decoder that works with different types of barcodes (length  $\geq 0.3$  mm). The system features LIS bidirectional data exchange connection.

4. Specimen Sampling and Handling:

The user should follow specifications in each reagent kit for specimen sampling and storage. Samples are loaded into the EON 100 Analyzer using a sample tray that contains labeled positions which can be assigned to a patient, calibrator/standard, and/or control samples. A sample and reagent dispensing assembly arm is used to draw and dispense liquid from the sample tray into a reaction cuvette or the ISE inlet port. An automatic wash cycle of the probe is performed after each dispensing operation. The system is equipped with a diluter. Incubation and reading cycles are performed in a rotating cuvette tray that maintains samples at a constant temperature of  $37\pm 2^{\circ}\text{C}$ .

5. Calibration:

For photometric chemistries, multi-standard methods make use of a calibration curve for extrapolation of results at different standard concentrations. The following algorithms are included: linear regression, cubic spline, point-to-point, and Logit/Log4 parameters. A two-point calibration of the ISE module occurs automatically after system warm up and every eight hours when in use.

6. Quality Control:

The EON 100 system has a quality control menu that allows the management of quality control serum values and parameters. The sponsor recommends that for each assay, at

least two levels of control be tested daily in accordance with an accepted quality control program using commercially available control material. Quality control material tested during analytical performance evaluation is recommended by the manufacturer in the labeling.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

Not applicable

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.