510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k183555

B. Purpose for Submission:

New device

C. Measurand:

Creatinine, blood urea nitrogen (BUN), and total carbon dioxide (tCO_2)

D. Type of Test:

Quantitative; enzymatic amperometry (creatinine)
Quantitative; enzymatic potentiometry (BUN)
Quantitative; potentiometry (tCO_2)

E. Applicant:

Instrumentation Laboratory Co.

F. Proprietary and Established Names:

GEM Premier ChemSTAT

G. Regulatory Information:

Analyte	Product Code	Classification	Regulation Section	Panel
Creatinine	JFY	Class II	21 CFR 862.1225 Creatinine test system	Chemistry (75)
BUN	CDQ	Class II	21 CFR 862.1770 Urea nitrogen test system	
tCO_2	KHS	Class II	21 CFR 862.1160 Bicarbonate/carbon dioxide test system	

H. Intended Use:

1. Intended use(s):

   See indications for use.

2. Indication(s) for use:

   The GEM Premier ChemSTAT analyzer is a portable system used by health care professionals to analyze arterial and venous lithium heparinized whole blood samples for creatinine, blood urea nitrogen (BUN), and total carbon dioxide (tCO_2) at point of care in a clinical setting or at a central laboratory. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status and metabolite balance.

   Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis.

   Blood Urea Nitrogen (BUN) or urea measurements are used for the diagnosis, monitoring and treatment of certain renal and metabolic diseases.

   Total carbon dioxide/tCO_2 (also referred to as bicarbonate/HCO3-) is used in the diagnosis, monitoring and treatment of patients' acid/base status and metabolite balance.

3. Special conditions for use statement(s):

   For prescription use only at point-of-care and central laboratory settings

4. Special instrument requirements:

   GEM Premier ChemSTAT analyzer

I. Device Description:

The GEM Premier ChemSTAT system is a prescription-use-only, portable system used by health care professionals to analyze arterial and venous lithium heparinized whole blood samples at point-of-care or a central laboratory. The system has two primary components: the GEM Premier ChemSTAT analyzer and a disposable, multiuse GEM Premier ChemSTAT Cartridge/PAK (GEM PAK).

The GEM Premier ChemSTAT analyzer has the internal logic and processing power necessary to perform analysis. It employs a touch-sensitive color screen and a set of menus and buttons for user interaction.

The GEM Premier ChemSTAT PAK (or GEM PAK) is a disposable, multi-use PAK that houses all components necessary to operate the instrument. These components include the sensors, solutions, sampler, and waste bag. The GEM PAK enables analysis of 75 to 450 samples.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Cobas Integra Creatinine Plus Ver.2 assay
   Cobas Integra Urea/BUN
   Cobas Integra Bicarbonate Liquid

2. Predicate 510(k) number(s):

   k024098 - Cobas Integra Creatinine Plus Ver. 2
   k954000 - Cobas Integra Urea/BUN
   k031879 - Cobas Integra Bicarbonate Liquid

3. Comparison with predicate:

Creatinine

Similarities and Differences		
Device Characteristic	**Candidate Device** GEM Premier ChemSTAT	**Predicate Device** Cobas Integra Creatinine Plus Ver. 2.
Intended Use	Quantitative measurement of creatinine	Same
Intended User	Central Laboratory and Point-of-Care	Central Laboratory
Measurement Principle	Enzymatic Amperometry	Enzymatic Colorimetry
Sample Volume	150 µL	2-5 µL
Sample Type	Lithium heparinized whole blood (arterial and venous)	Serum, plasma, and urine
Reportable Range	0.20-15 mg/dL	0.06-30.5 mg/dL
Calibration	3-point	2-Point

BUN

Similarities and Differences		
Device Characteristic	**Candidate Device** GEM Premier ChemSTAT	**Predicate Device** Cobas Integra Urea/BUN
Intended Use	Quantitative measurement of BUN	Same
Intended User	Central Laboratory and Point-of-Care	Central Laboratory
Measurement Principle	Enzymatic Potentiometry	Enzymatic Colorimetry
Sample Volume	150 µL	2 µL
Sample Type	Lithium heparinized whole blood (arterial and venous)	Serum, plasma, and urine
Reportable Range	3.0-112.0 mg/dL	1.4-112 mg/dL
Calibration	2-point	Same

tCO_2

Similarities and Differences		
Device Characteristic	**Candidate Device** GEM Premier ChemSTAT	**Predicate Device** Cobas Integra Bicarbonate Liquid
Intended Use	Quantitative measurement of tCO_2	Same
Intended User	Central Laboratory and Point-of-Care	Central Laboratory
Measurement Principle	Potentiometry	Enzymatic Colorimetry
Sample Volume	150 µL	2 µL
Sample Type	Lithium heparinized whole blood (arterial and venous)	Serum and plasma
Reportable Range	5-50 mmol/L	2-50 mmol/L
Calibration	2-point	Same

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

Clinical and Laboratory Standards Institute (CLSI). EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition.

Clinical and Laboratory Standards Institute (CLSI). EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

Clinical and Laboratory Standards Institute (CLSI). EP07: Interference Testing in Clinical Chemistry, 3rd Edition.

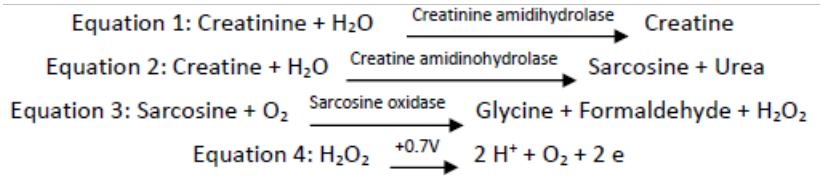
Clinical and Laboratory Standards Institute (CLSI). EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guidelines – Second edition.

Clinical and Laboratory Standards Institute (CLSI). EP25-A: Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

Clinical and Laboratory Standards Institute (CLSI). C46-A2: Blood Gas and pH Analysis and Related Measurements; Approved Guideline – Second Edition.

L. Test Principle:

Creatinine
The creatinine electrode measures a series of coupled enzymatic reactions involved in the conversion of creatinine to hydrogen peroxide (shown below in equations 1-3). The creatine electrode measures a series of coupled enzymatic reactions involved in the conversion of creatine to hydrogen peroxide (shown below in Equations 2-3).



The hydrogen peroxide resulting from these reactions is oxidized at the platinum electrode operated at a positive potential (shown above in Equation 4), with respect to the card reference electrode. The oxidation current is proportional to the concentration of creatinine and creatine in the sample.

BUN

The urea sensor consists of immobilized urease enzyme on a PVC-based ion selective electrode, consisting of an internal Ag/AgCl reference electrode and an internal electrolyte layer. The urease catalyzes the hydrolysis of urea to ammonium ion. It is detected by an ammonium-ion selective electrode. The sensor potential is measured against the card reference electrode (Ag/Ag+) and is proportional to logarithm of urea concentration.

$$CO(NH_2)_2 + 2\ H_2O \xrightarrow{Urease} CO_2 + 2\ NH_4OH$$

tCO_2

The sensor for HCO_3^- relies on a pH selective polymer as a gas permeable outer membrane and an internal bicarbonate buffer. The generated potential against the reference electrode is related to the logarithm of bicarbonate in the sample, as described per the following formula:

$$tCO_2 = HCO_3^-(m) + 0.03 * pCO_2$$

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Precision studies were conducted following the CLSI EP05-A3 guideline.

   Internal Precision Study – Whole Blood

   An internal precision study was performed by testing samples of whole blood for creatinine, blood urea nitrogen, and total carbon dioxide. Samples were analyzed by 2 operators using 3 different GEM Premier ChemSTAT analyzers over 5 days. A single run evaluating 8 replicates of 5 predetermined quantities per analyte (n=120 per level of analyte) was completed per day. The results of the precision study are present in the table below:

Analyte	Level	Mean	Within run		Between Instruments		Within Lab (Total)	
			SD	%CV	SD	%CV	SD	%CV
Creatinine (mg/dL)	1	0.48	0.014	2.9	0.010	2.1	0.017	3.6
	2	1.53	0.016	1.0	0.028	1.8	0.032	2.1
	3	2.83	0.019	0.7	0.064	2.3	0.067	2.4
	4	5.67	0.028	0.5	0.118	2.1	0.121	2.1
	5	9.36	0.056	0.6	0.228	2.4	0.235	2.5
Blood Urea Nitrogen (mg/dL)	1	6.5	0.06	1.0	0.04	0.6	0.08	1.1
	2	25.7	0.24	0.9	0.12	0.5	0.27	1.1
	3	50.0	0.88	1.8	0.00	0.0	0.88	1.8
	4	81.9	1.37	1.7	0.00	0.0	1.37	1.7
	5	102.4	1.44	1.4	0.63	0.6	1.57	1.5
tCO_2 (mmol/L)	1	8.0	0.11	1.3	0.06	0.7	0.12	1.5
	2	14.8	0.22	1.5	0.00	0.0	0.22	1.5
	3	21.2	0.23	1.1	0.20	0.9	0.30	1.4
	4	32.8	0.23	0.7	0.49	1.5	0.54	1.7
	5	43.5	0.30	0.7	0.83	1.9	0.88	2.0

External Reproducibility Study with Aqueous Controls – Point-of-Care Setting

A reproducibility study was performed at 3 external clinical point-of-care (POC) sites by 9 different operators using a single lot of cartridges on 6 different analyzers. Each site used the same lots of aqueous control materials. Each aqueous control level was run in triplicate twice a day for 5 days, for a total of 30 replicates per level (N= 3 sites x 5 days x 2 runs x 3 replicates = 90 per analyte/ per control level). Individual POC site statistics were analyzed by two-way nested ANOVA with factors day and run nested within day. Multisite statistics were determined via three-way nested ANOVA with the factors being site, day and nested within site and run nested within site and day. The pooled results of the study are present in the tables below:

Creatinine (mg/dL)											
Control	Mean	Repeatability		Between Run		Between Day		Within Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CVP 1	0.96	0.016	1.6	0.025	2.7	0.020	2.1	0.054	5.7	0.065	6.8
CVP 2	5.17	0.105	2.0	0.116	2.2	0.000	0.0	0.048	0.9	0.164	3.2
CVP 3	0.98	0.015	1.6	0.023	2.3	0.000	0.0	0.014	1.4	0.031	3.1
CVP 4	0.62	0.011	1.8	0.32	5.2	0.000	0.0	0.052	8.4	0.063	10.1
PVP 1	0.46	0.011	2.3	0.011	2.3	0.010	2.1	0.037	7.9	0.041	8.8
PVP 2	1.03	0.017	1.7	0.015	1.5	0.029	2.8	0.068	6.6	0.077	7.5
PVP 3	3.02	0.036	1.2	0.041	1.4	0.000	0.0	0.102	3.4	0.116	3.8
PVP 4	5.37	0.093	1.7	0.054	1.0	0.000	0.0	0.073	1.4	0.13	2.4
PVP 5	8.31	0.083	1.0	0.094	1.1	0.039	0.5	0.045	0.5	0.139	1.7

BUN (mg/dL)											
Control	Mean	Repeatability		Between Run		Between Day		Within Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CVP 1	15.5	0.26	1.7	0.14	0.9	0.00	0.0	0.08	0.5	0.31	2.0
CVP 2	57.2	0.44	0.8	0.18	0.3	1.14	2.0	1.31	2.3	1.80	3.1
PVP 1	5.7	0.10	1.9	0.00	0.0	0.01	0.1	0.08	1.5	0.13	2.4
PVP 2	15.5	0.24	1.6	0.05	0.3	0.00	0.0	0.09	0.6	0.26	1.7
PVP 3	38.2	0.33	0.9	0.19	0.5	0.67	1.8	0.68	1.8	1.03	2.7
PVP 4	56.5	0.61	1.1	0.00	0.0	1.08	1.9	1.21	2.1	1.73	3.1
PVP 5	96.2	1.26	1.3	0.00	0.0	1.78	1.9	1.93	2.0	2.91	3.0

tCO_2 (mmol/L)											
Control	Mean	Repeatability		Between Run		Between Day		Within Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CVP 1	25.4	0.15	0.6	0.10	0.4	0.25	1.0	0.55	2.2	0.63	2.5
CVP 2	13.0	0.13	1.0	0.00	0.0	0.21	1.6	0.53	4.0	0.58	4.5
PVP 1	41.1	0.42	1.0	0.00	0.0	0.50	1.2	1.05	2.6	1.23	3.0
PVP 2	25.7	0.25	1.0	0.00	0.0	0.14	0.5	0.52	2.0	0.60	2.3
PVP 3	18.7	0.18	1.0	0.00	0.0	0.04	0.2	0.08	0.4	0.20	1.1
PVP 4	13.0	0.12	0.9	0.00	0.0	0.18	1.4	0.53	4.1	0.57	4.4
PVP 5	8.0	0.10	1.2	0.00	0.0	0.15	1.9	0.40	5.0	0.44	5.5

External Precision - Whole Blood

A precision study was performed at 3 external clinical POC sites by 6 different operators using a single lot of cartridges on 3 different analyzers. Reproducibility was not assessed for whole blood samples as the whole blood samples at each clinical site are unique.

Analyte	**Site**	**N**		**Mean**		**Within Sample Precision**	
		SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Creatinine (mg/dL)	1	33	36	0.91	3.50	0.011	1.4
	2	60	6	0.88	5.13	0.014	1.4
	3	54	12	0.72	3.52	0.013	0.6
	Pooled	147	54	0.83	3.69	0.013	1.2
BUN (mg/dL)	1	36	33	15.2	45.6	0.18	2.8
	2	54	12	12.4	36.4	0.18	0.7
	3	42	21	11.8	52.1	0.12	0.9
	Pooled	132	66	13.0	46.0	0.16	1.9
tCO_2 (mmol/L)	1	33	39	14.8	24.6	0.11	1.1
	2	30	36	17.4	22.9	0.12	0.9
	3	18	45	15.4	23.2	0.12	0.5
	Pooled	81	120	15.9	23.6	0.12	0.9

b. Linearity/assay reportable range:

A linearity study was performed following the CLSI EP06-A guideline. 9 levels per analyte were prepared by spiking or diluting whole blood from healthy volunteers to challenge the claimed measurement range for each analyte. At least 2 levels exceeded the claimed measurement range at the low and high ends. Each blood level was analyzed in triplicate on 6 different analyzers using cartridges from 3 different production lots (N=18 per level). The observed values were plotted against the expected values and linear regression analysis was performed. The results from a representative lot for each analyte are present below. The results of the linear regression analysis support the following claimed measuring ranges for the creatinine, BUN, and tCO_2 assays:

Analyte	Claimed Measuring Range	Tested Range	Slope	Intercept	R^2
Creatinine (mg/dL)	0.20-15	0.10-16.40	0.986	-0.039	0.9963
BUN (mg/dL)	3.0-112	2.4-122.0	1.016	-0.323	0.9997
tCO_2 (mmol/L)	5-50	3.6-51.3	1.015	-1.346	0.9997

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

Traceability

The traceability of the parameters measured by GEM Premier ChemSTAT are listed below:

Creatinine: Traceable to NIST Standard 967a

BUN: Traceable to NIST SRM 912

tCO_2: Per CLSI guideline C46-A2, calculated from pH and pCO2 concentrations of aqueous secondary standard.

d. Detection limit:

The limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) were determined according to CLSI EP17-A2 guideline.

For LoB studies, 60 blank samples per cartridge lot were tested on 3 days with 3 different cartridge lots (N=60/analyte/lot). After recording 60 blank sample measurements, the results were ranked from lowest to highest. The LoB was determined as the maximal LoB value for each of the three cartridge lots per analyte.

The LoD was determined using a "low" sample with a target analyte concentration 1-5x greater than the estimated LoB.

$$LoD = LoB + \frac{1.645}{1-\left(\frac{1}{4(L-J)}\right)} * SD_L$$

Where:
L = total number of all low level sample results across all cartridge lots
J= number of low level samples (number of days)

The LoQ was assessed by testing low-level whole blood samples. 60 replicates of the low-level samples were measured per day by 3 analyzers (N=60/analyte/day). LoQ was defined as the lowest concentration that met the total error goal of 0.3 mg/dL or 15% for creatinine, 2.0 mg/dL or 9% for BUN and 2.0 mmol/L or 10% for tCO2.

The overall results of LoB, LoD, and LoQ are summarized below:

Analyte	LoB	LoD	LoQ	Claimed Measuring Range
Creatinine (mg/dL)	0.04	0.07	0.10	0.20-15
BUN (mg/dL)	0.3	0.3	1.2	3.0-112
tCO_2 (mmol/L)	0.0	0.2	2.0	5-50

e. *Analytical specificity:*

To determine the effects of potential endogenous and exogenous interference, the sponsor conducted an analytical specificity study according to the CLSI EP07 guideline. Testing was conducted using whole blood samples at two different analyte concentrations. Substances were considered not interfering if the difference between the test and control samples was less than or equal to the following clinically significant interference limits set for each analyte:

Analyte	Clinically significant interference
Creatinine (mg/dL)	$\leq$ 0.20 mg/dL
BUN (mg/dL)	$\leq \pm$10%
tCO_2 (mmol/L)	$\leq \pm$10%

Substances identified as interfering substances were further characterized to determine the concentration that produces a clinically significant interference.

Summary of interference studies for creatinine:
The interferences tested and found to be clinically non-significant are summarized below:

Substance tested	Highest concentration tested showing no significant interference
Acetaminophen	1,030 µmol/L
Acetoacetate	2 mmol/L
L-Ascorbic acid	298 µmol/L
Atracurium	50 mg/L
Bilirubin	40 mg/dL
Ceftriaxone	1,510 µmol/L
Chlorpromazine	10.3 µmol/L

Substance tested	Highest concentration tested showing no significant interference
Diatrizoate sodium	301 µmol/L
Dobutamine	0.121 mg/dL
Dopamine	4.06 µmol/L
Epinephrine	0.5 µmol/L
Ethanol	130 mmol/L
Ethylene Glycol	8.8 mmol/L
Etomidate	50 mg/L
Fentanyl	0.03 µg/mL
Furosemide	48.1 µmol/L
Gadodiamide	1.4 mmol/L
Glycolic acid	1.0 mmol/L
Hct	25%
Hct	60%
Hemoglobin	1,000 mg/dL
Heparin	100,000 U/L
β-Hydroxybutyrate	2 mmol/L
Ibuprofen	1,060 µmol/L
Icodextrin	20 mg/dL
Isoniazid	438 µmol/L
Methadone	10.3 µmol/L
Midazolam	0.376 mg/mL
Morphine	27.3 µmol/L
N-Acetyl-L-cysteine	920 µmol/L
Phenobarbital	2,970 µmol/L
Piperacillin	110 mg/mL
pO2	30 mmHg
Pralidoxime Iodide	4 mg/mL
Propofol	4.8 mg/mL
Suxamethonium	68 µmol/L
Tazobactam	3.05 mg/mL
Thiocyanate	898 µmol/L
Intralipid	2,000 mg/dL
Uric acid	1.4 mmol/L
Vancomycin	82.8 µmol/L

Clinically significant interfering substances for creatinine measurements are itemized below:

- Creatinine concentrations are increased by 0.20 mg/L when 0.77 mg/dL hydroxyurea is present in the sample.
- Creatinine concentrations are increased by 0.20 mg/dL when 0.382 mmol/L creatine is present in the sample.

Summary of interference studies for BUN

The interferences tested and found to be clinically non-significant are summarized below:

Substance tested	Highest concentration tested showing no significant interference
Ammonium	151 µmol/L
Atracurium	50 mg/L
Benzalkonium	5 mg/L
Bilirubin	40 mg/dL
Ceftriaxone	1,510 µmol/L
Diatrizoate sodium	301 µmol/L
Epinephrine	0.5 µmol/L
Etomidate	50 mg/L
Fentanyl	0.03 µg/mL
Furosemide	48.1 µmol/L
Gadodiamide	1.4 mmol/L
Hemoglobin	1,000 mg/dL
Heparin	100,000 U/L
Hydroxyurea	3.08 mg/dL
Ibuprofen	1,060 µmol/L
Leflunomide	100 µg/mL
Methadone	10.3 µmol/L
Midazolam	0.376 mg/mL
Morphine	27.3 µmol/L
N-Acetyl-L-cysteine	920 µmol/L
Perchlorate	20 mg/dL
Phenobarbital	2,970 µmol/L
Piperacillin	110 mg/mL
Propofol	4.8 mg/mL
Salicylic acid	0.207 mmol/L
Suxamethonium	68 µmol/L
Tazobactam	3.05 mg/mL
Teriflunomide	100 µg/mL
Thiocyanate	898 µmol/L
Thiopental	1,660 µmol/L
Triglycerides	2,000 mg/dL
Vancomycin	82.8 µmol/L

Summary of interference studies for tCO_2:
The interferences tested and found to be clinically non-significant are summarized below:

Substance tested	Highest concentration tested showing no significant interference
Atracurium	50 mg/L
Bilirubin	40 mg/dL
Ceftriaxone	1,510 µmol/L
Epinephrine	0.5 µmol/L
Etomidate	50 mg/L
Fentanyl	0.03 µg/mL
Furosemide	48.1 µmol/L
Gadodiamide	1.4 mmol/L
Hemoglobin	1,000 mg/dL
Ibuprofen	1,060 µmol/L
Methadone	10.3 µmol/L
Midazolam	0.376 mg/mL
Morphine	27.3 µmol/L
N-Acetyl-L-cysteine	920 µmol/L
Phenobarbital	2,970 µmol/L
Piperacillin	110 mg/mL
Propofol	4.8 mg/mL
Suxamethonium	68 µmol/L
Tazobactam	3.05 mg/mL
Thiopental	1,660 µmol/L
Triglycerides	2,000 mg/dL
Vancomycin	82.8 µmol/L

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were performed at 3 external POC sites by 2 POC operators at each site. Lithium heparinized whole blood samples were tested in singlicate on a single GEM Premier ChemSTAT Analyzer. The same samples were then centrifuged, and the plasma portions were tested in singlicate on 2 Roche Cobas analyzers for creatinine, BUN, and tCO_2. The results for each sample measured by the Roche Cobas analyzers were averaged. Additional contrived samples (<10%) were prepared and tested when necessary to span the reportable range for each analyte.

Regression Analysis Summary for GEM Premier ChemSTAT Analyzer vs. Roche Cobas Analyzer:

Analyte	Sample Range	N	Slope	Intercept	R
Creatinine (mg/dL)	0.20-14.18	405	1.009	-0.027	0.997
BUN (mg/dL)	3.0-109.7	405	0.965	0.441	0.997
tCO_2 (mmol/L)	5.5-47.2	416	0.979	0.535	0.986

b. Matrix comparison:

Not applicable. The creatinine, BUN and tCO2 assays are for use with lithium heparinized whole blood only.

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 following expected values are provided in the product inert for arterial blood (unless otherwise noted) based on the literature:

Analyte	**Reference Range**
Creatinine	0.04-0.33 (0-1 yr) mg/dL 0.04-0.45 (2-5 yr) mg/dL 0.20-0.52 (6-9 yr) mg/dL 0.22-0.59 (10 yr) mg/dL 0.62-1.10 (male adult) mg/dL 0.45-0.75 (female adult) mg/dL

Analyte	Reference Range
BUN	3-25 (1 wk) mg/dL 4-19 (< 1 yr) mg/dL 5-18 (infant/child) mg/dL 6-20 (18-60 yr) mg/dL 8-23 (60-90 yr) mg/dL 10-31 (> 90 yr) mg/dL
tCO_2	19.0-24.0 mmol/L 22.0-26.0 (venous) mmol/L

- Burtis, Carl and David Bruns, Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, Elsevier Saunders, 7th Edition, 2015, pp 952-982.
- Wu, A., Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Co., St. Louis MO, 4th Edition, 2006, page 316 and 1096.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

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