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

A. 510(k) Number:

k100263

B. Purpose for Submission:

New devices and the addition of phosphorus, uric acid and urea assays with calibrator and control materials to a previously cleared device in k093883

C. Measurand:

Phosphorus, Uric Acid and Urea in human serum or lithium heparin plasma

D. Type of Test:

Quantitative spectrophotometry

E. Applicant:

SEPPIM S.A.S.

F. Proprietary and Established Names:

ELITech Clinical Systems Phosphorus, ELITech Clinical Systems Uric Acid Mono SL, ELITech Clinical Systems Urea UV SL, ELITech Clinical Systems ELICAL 2, ELITech Clinical Systems ELITROL 1 & 2

G. Regulatory Information:

1. Regulation section:

Device	Regulation	Classification	Pro code
ELITech Clinical Systems Urea UV SL	21 CFR § 862.1770, Urea nitrogen test system	II	CDQ
ELITech Clinical Systems ELICAL 2	21 CFR § 862.1150, Calibrator	II	JIX
ELITech Clinical Systems Phosphorus	21 CFR § 862.1580, Phosphorus (inorganic) test system	I (reserved)	CEO
ELITech Clinical Systems Uric Acid	21 CFR § 862.1775, Uric acid test system	I (reserved)	KNK

Mono SL			
ELITech Clinical Systems ELITROL 1 & 2	21 CFR § 862.1660, Quality Control material	I (reserved)	JJY

2. Panel:

   75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use

2. Indication(s) for use:

   ELITech Clinical Systems PHOSPHORUS reagent is for the quantitative *in vitro* diagnostic determination of inorganic phosphorus in human serum and plasma on the Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

   ELITech Clinical Systems URIC ACID MONO SL reagent is for the quantitative *in vitro* diagnostic determination of uric acid in human serum and plasma on the Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings. 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.

   ELITech Clinical Systems UREA UV SL reagent is for the quantitative *in vitro* diagnostic determination of urea nitrogen in human serum and plasma on the Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

   ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

   ELITech Clinical Systems ELITROL I is a multi-parametric control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

ELITech Clinical Systems ELITROL II is a multi-parametric control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior analyzer and the Vital Scientific Flexor Junior analyzers.

3. Special conditions for use statement(s):

   Serum and lithium heparin plasma only

   Prescription use

4. Special instrument requirements:

   For use on the Vital Scientific Selectra Junior (also trademarked as the Vital Scientific Flexor Junior) Analyzer

   All studies were performed on the Vital Scientific Selectra Junior.

I. Device Description:

The ELITech Clinical Systems PHSOPHORUS kit reagent is a one (1) reagent system with reagent R. Reagent R is supplied in liquid ready-to-use form and contains sulfuric acid and ammonium molybdate.

The ELITech Clinical Systems URIC ACID MONO SL kit reagent is a one (1) reagent system. Reagent R is supplied in liquid ready-to-use form and contains Phosphate buffer, N-Ethyl-N-(2-Hydroxy-3-Sulfopropyl) *m*-Toluidine (EHSPT), Ferrocyanide, Amino-4-antipyrine (4-AAP), Uricase (microorganisms), Peroxidase (horseradish) and sodium azide. The measuring range can be extended by making manual dilutions with 0.9% saline.

The ELITech Clinical Systems UREA UV SL kit reagent is a two (2) reagents system with reagent R1 and reagent R2. Reagents R1 and R2 are supplied in liquid ready-to-use form. Reagent R1 contains Tris buffer (pH 7.60), Adenosine diphosphate potassium salt (ADP), α-Ketoglutarate, Urease (jack bean), Glutamate dehydrogenase (GlDH) (bovine liver) and sodium azide. Reagent R2 contains NADH and sodium azide. The measuring range can be extended by making manual dilutions with 0.9% saline.

ELITech Clinical Systems Elical 2 is a lyophilized calibrator based on human serum containing added constituents.

ELITech Clinical Systems Elitrol I and II is a two level quality control product consisting of lyophilized human serum containing constituents at desired levels.

All human source materials were tested with FDA-approved methods and found to be negative for HbsAG and to antibodies to HCV and HIV 1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s) and 2. Predicate 510(k) number(s):

Device	Predicate Device Name	Predicate 510(k) number
The ELITech Clinical Systems PHOSPHORUS	ABX Pentra Phosphorus CP	k060205
The ELITech Clinical Systems URIC ACID MONO SL	ABX Pentra Uric Acid CP	k060205
The ELITech Clinical Systems UREA UV SL	ABX Pentra Urea CP	k060205
ELITech Clinical Systems Elical 2	Roche Diagnostics Calibrator for Automated Systems (C.f.a.s)	k033501
ELITech Clinical Systems Elitrol I and II	Roche Diagnostics Precinorm U and Precipath U	k041227

3. Comparison with predicate:

Similarities		
Item	The ELITech Clinical Systems PHOSPHORUS	ABX Pentra Phosphorus CP k060205
Intended use	For in vitro diagnostic use in the quantitative determination of inorganic phosphorus.	Same
Assay Principle	UV method using phosphomolybdate	Same
Appearance of reagents	Liquid form, ready to use	Same
Composition	Reagent R: Sulfuric acid, Ammonium molybdate	Same
Expected values	Serum, plasma : 2.7 – 4.5 mg/dL	Same

Differences		
Item	The ELITech Clinical Systems PHOSPHORUS	ABX Pentra Phosphorus CP k060205
Sample type	Serum Plasma in lithium heparin	Serum Plasma in lithium heparin Urine
Reagent storage	Store at 2-25 °C and protect from light.	Store at 2-8 °C.

Differences		
Item	The ELITech Clinical Systems PHOSPHORUS	ABX Pentra Phosphorus CP k060205
Measuring range	2.0 to 20.0 mg/dL	0.30 to 24.18 mg/dL Automatic post-dilution: 96.72 mg/dL
LoD LoQ	0.02 mg/dL 1.00 mg/dL	0.28 mg/dL
Calibration Frequency	28 days	34 days
On board stability	refrigerated area : 28 days	refrigerated area: 70 days
Precision	Within run Level 2.37 mg/dL, CV=1.1% Level 4.80 mg/dL, CV=1.5% Level 9.55 mg/dL, CV=1.7% Total Level 2.37 mg/dL, CV=1.9% Level 4.80 mg/dL, CV=1.7% Level 9.55 mg/dL, CV=2.2%	Within run Level 4.08 mg/dL, CV=1.25% Level 6.34 mg/dL, CV=0.77% Level 2.39 mg/dL, CV=2.48% Level 3.48 mg/dL, CV=1.61% Level 9.19 mg/dL, CV=1.38% Total Level 4.01 mg/dL, CV=2.50% Level 6.35 mg/dL, CV=1.82% Level 2.50 mg/dL, CV=3.56% Level 11.44 mg/dL, V=1.38%
Method comparison	y=0.999x - 0.09 mg/dL r2= 0.994 range: 2.02 to 20.08 mg/dL	y=1.04x + 0.15 mg/dL r2= 0.998 range: 0.30 to 24.08 mg/dL
Limitations	Hemoglobin: No significant interference up to 50 mg/dL. Triglycerides: No significant interference up to 732 mg/dL, Unconjugated bilirubin: No significant interference up to 15 mg/dL Conjugated bilirubin: No significant interference up to 1.5 mg/dL Glucose: No significant interference up to 500 mg/dL.	Hemoglobin: No significant interference up to 125 mg/dL. Triglycerides: No significant interference up to 262.5 mg/dL. Total bilirubin: No significant interference up to 6 mg/dL. Direct bilirubin: No significant interference up to 25 mg/dL.

Similarities		
Item	The ELITech Clinical Systems URIC ACID MONO SL	ABX Pentra Uric Acid CP k060205
Intended use	For in vitro diagnostic use in the quantitative determination of uric acid.	Same
Assay protocol	Enzymatic determination using a chromogenic system in the presence of peroxidase and uricase (Trinder method).	Same
Appearance of reagents	Liquid form, ready to use	Same
Reagent storage	Store at 2-8 °C and protected from light.	Same
Expected values	Serum, plasma Women: 2.6 – 6.0 mg/dL Men: 3.5 – 7.2 mg/dL	Same

Differences		
Item	The ELITech Clinical Systems URIC ACID MONO SL	ABX Pentra Uric Acid CP k060205
Composition	Reagent R: Phosphate buffer, pH 7.0 EHSPT Ferrocyanide Amino-4-antipyrine Uricase Peroxidase Sodium azide	Reagent 1: Phosphate buffer, pH 7.0 EHSPT Ascorbate oxidase Bovine albumin Sodium azide Reagent 2: 4-Aminoantipyrine Uricase Peroxidase Ferrocyanide Bovine albumin Sodium azide
Sample type	Serum Lithium heparin plasma	Serum Lithium heparin plasma Urine
Measuring range	1.5 to 25.0 mg/dL Extended measuring range: 25.0-78.0 mg/dL	0.18 to 25.00 mg/dL Automatic post-dilution: 75.00 mg/dL
LoD LoQ	0.02 mg/dL 0.50 mg/dL	0.19 mg/dL

Differences		
Item	The ELITech Clinical Systems URIC ACID MONO SL	ABX Pentra Uric Acid CP k060205
Precision	Within run Level 2.49 mg/dL, CV=0.8% Level 5.19 mg/dL, CV=1.3% Level 7.63 mg/dL, CV=1.1% Total Level 2.49 mg/dL, CV=2.6% Level 5.19 mg/dL, CV=2.0% Level 7.63 mg/dL, CV=2.1%	Within run Level 4.62 mg/dL, CV=0.45% Level 11.63 mg/dL,CV=0.34% Level 2.53 mg/dL, CV=1.24% Level 4.58 mg/dL, CV=0.91% Level 7.19 mg/dL, CV=1.02% Total Level 4.64 mg/dL, CV=2.81% Level 11.73 mg/dL, CV=1.39% Level 4.67 mg/dL, CV=2.64% Level 6.74 mg/dL, CV=2.51%
Method comparison	y=1.015 x + 0.03 mg/dL r2= 0.999 range: 1.49 to 24.40 mg/dL	y=0.95 x + 0.09 mg/dL r2= 0.996 range: 0.18 to 23.59 mg/dL
Limitations	Hemoglobin: No significant interference up to 50 mg/dL Triglycerides: No significant interference up to 1070 mg/dL. Unconjugated bilirubin: No significant interference up to 30 mg/dL. Conjugated bilirubin: No significant interference up to 14.8 mg/dL Glucose: No significant interference up to 500 mg/dL. Ascorbic acid: Significant interference at all levels of ascorbic acid. Methyldopa: No significant interference up to 1 mg/dL. Calcium dobesilate: Induces falsely low results at therapeutic concentrations.	Hemoglobin: No significant interference up to 500 mg/dL. Triglycerides: No significant interference up to 612.5 mg/dL. Total bilirubin: No interference up to 36 mg/dL. Direct bilirubin: No interference up to 30 mg/dL.
Calibration Frequency	28 days	15 days
On board stability	refrigerated area : 28 days	refrigerated area: 41 days
Measuring range	1.5 to 25.0 mg/dL Extended measuring range: 25.0-78.0 mg/dL	0.18 to 25.00 mg/dL Automatic post-dilution: 75.00 mg/dL

Similarities		
Item	The ELITech Clinical Systems UREA UV SL	ABX Pentra Urea CP k060205
Intended use	For in vitro diagnostic use in the quantitative determination of urea nitrogen in serum and plasma.	Same
Assay protocol	Enzymatic UV method using Urease and Glutamate dehydrogenase	Same
Appearance of reagents	Liquid form, ready to use	Same
Reagent storage	Store at 2-8 °C and protected from light.	Same

Differences		
Item	The ELITech Clinical Systems UREA UV SL	ABX Pentra Urea CP k060205
Expected values	Serum, plasma: *Urea nitrogen (BUN)* Adults (18-60 years)6-20 mg/dL Adults (60-90 years)8-23 mg/dL Adults (> 90 years)10-31 mg/dL	Serum, plasma: *Urea nitrogen (BUN)* **Adults:** Global : 7.9-20.2 mg/dL Women < 50 years 7.3-18.8 mg/dL Women > 50 years 9.8-20.2 mg/dL Men < 50 years 9.0-20.5 mg/dL Men > 50 years 8.4-25.8 mg/dL **Children:** 1-3 years 5.1-16.8 mg/dL 4-13 years 7.0-16.8 mg/dL 14-19 years 8.1-21.1 mg/dL
Measuring range	4.7 to 140.0 mg/dL Extended measuring range: 140.0-670.0 mg/dL	1.03 to 140.3 mg/dL Automatic post-dilution: 701.5 mg/dL
LoD LoQ	0.3 mg/dL 2.3 mg/dL	0.9 mg/dL
Precision	**Within run**	**Within run**

Differences		
Item	The ELITech Clinical Systems UREA UV SL	ABX Pentra Urea CP k060205
	Level 7.3 mg/dL CV=2.1% Level 29.2 mg/dLCV=0.8% Level 72.4 mg/dLCV=0.7% **Total** Level 7.3 mg/dL CV=2.8% Level 29.2 mg/dLCV=1.3% Level 72.4 mg/dLCV=1.6%	Level 18.7 mg/dL, CV=2.27% Level 72.8 mg/dL, CV=1.66% Level 6.0 mg/dL, CV=2.76% Level 20.9 mg/dL, CV=1.58% Level 85.5 mg/dL, CV=1.80% Total Level 18.5 mg/dL, CV=2.14% Level 71.7 mg/dL, CV=1.93% Level 19.2 mg/dL, CV=2.14% Level 70.1 mg/dL, CV=1.97%
Method comparison	y=0.991 x + 0.6 mg/dL r^2= 0.999 range: 4.4 to 139.8 mg/dL	y=0.99 x - 0.06 mg/dL r^2= 0.996 range: 1.03 to 138.89 mg/dL
Limitations	Hemoglobin: No significant interference up to 500 mg/dL. Turbidity: No significant interference up to 614 mg/dL triglyceride equivalent. Unconjugated bilirubin: No significant interference up to 36 mg/dL. Conjugated bilirubin: No significant interference up to 25 mg/dL. Ascorbic acid: No significant interference up to 20 mg/dL. Methyl-dopa: No significant interference up to 1 mg/dL.	Hemoglobin: No interference up to 460 mg/dL Triglycerides: No interference up to 612.5 mg/dL Total bilirubin: No interference up to 22.23 mg/dL Direct bilirubin: No interference up to 23.4 mg/dL
Calibration Frequency	7 days	8 days
On board stability	14 days	70 days

Similarities and Differences		
Item	ELITech Clinical Systems Elical 2	Roche Calibrator (C.f.a.s) k033501
Intended Use/Indications for Use	For in vitro diagnostic use in the calibration of quantitative methods	Same
Format	Lyophilized calibrator based on human serum with constituents added as required	Same

	to obtain desired component levels	
Level	Single level	Same
Stability	Lyophilized: store at 2-8° C and protect from light until the expiry date. After reconstitution: < 8 hrs between 15-25° C, 2 days between 2-8° C, 4 weeks between -25° to -15° C (when frozen once).	Same
Instrument	Vital Scientific Selectra Junior Analyzer (also trademarked as the Vital Scientific Flexor Junior Analyzer)	Roche Analyzers

Similarities and Differences		
Item	ELITech Clinical Systems Elitrol I/Elitrol II	Roche Diagnostics Precinorm U and Precipath U k041227
Intended Use/Indications for Use	For in vitro diagnostic use in accuracy control of quantitative methods	Same
Format	Lyophilized calibrator based on human serum with constituents added as required to obtain desired component levels	Same
Level	Two levels	Same
Stability	Lyophilized: store at 2-8° C and protect from light until the expiry date. After reconstitution: < 12 hrs between 15-25° C, 5 days between 2-8° C, 4 weeks between -25° to -15° C (when frozen once).	Same
Instrument	Vital Scientific Selectra Junior Analyzer (also trademarked as the Vital Scientific Flexor Junior Analyzer)	Roche Analyzers

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

CLSI EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline—2nd edition, Vol. 25, No. 27, Nov 2005.

CLSI EP9-A2: Method comparison and bias estimation using patient samples; Approved Guideline—2nd edition, Vol. 22, No. 19, Sept 2002.

CLSI EP6A: Evaluation of the linearity of the measurement of quantitative procedures: a statistical approach. Vol 23, No. 16, Apr 2003

CLSI EP5-A2: Evaluation of precision performance of quantitative measurement methods; Approved guideline—2nd edition, Vol. 24, No.25, Aug. 2004

Use of Symbols on Labels and in Labeling of in Vitro Diagnostic Devices Intended for Professional Use: Guidance for Industry and FDA Staff, Nov 2004.

Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission, Nov 2003

Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, Aug. 2005.

L. Test Principle:

1. The ELITech Clinical Systems PHOSPHORUS:
   In the presence of sulfuric acid (acid medium), inorganic phosphate forms with ammonium molybdate an ammonium phosphomolybdate complex.

$$\text{Ammonium molybdate} + \text{Sulfuric acid} \xrightarrow{\textit{Phosphorus}} \text{Phosphomolybdate complex}$$

   The concentration of phosphomolybdate formed is directly proportional to the inorganic phosphate concentration in the sample and is measured at 340 nm.

2. The ELITech Clinical Systems URIC ACID MONO SL:
   Uric acid is cleaved by uricase to form allantoine, CO_2 and hydrogen peroxide (H_2O_2). H_2O_2 reacts with 4-amino-antipyrine (4-AAP) and N-Ethyl-N-(2-Hydroxy-3-Sulfopropyl) *m*-Toluidine (EHSPT) under the catalytic action of peroxidase to form a colored quinoneimine. The absorbance of the quinoneimine at 546 nm is proportional to the concentration of uric acid in the sample.

$$\text{Uric acid} + 2H_2O + O_2 \xrightarrow{\textit{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

$$2H_2O_2 + \text{4-AAP} + \text{EHSPT} \xrightarrow{\textit{Peroxidase}} \text{Quinoneimine} + 4H_2O$$

3. The ELITech Clinical Systems UREA UV SL

Urea is hydrolyzed by urease to form ammonium and carbonate. The ammonium produce reacts with α-Ketoglutarate and NADH under the catalytic action of Glutamate Dehydrogenase (GlDH) to form L-Glutamate and NAD^+. The decrease in absorbance of NADH at 340 nm is proportional to the concentration of urea in the sample.

$$\text{Urea} + 2H_2O \xrightarrow{\textit{Urease}} 2NH_4^+ + CO_3^{2-}$$

$$NH_4^+ + \alpha\text{-Ketoglutarate} + \text{NADH} \xrightarrow{\textit{GlDH}} \text{L-Glutamate} + NAD^+ + H_2O$$

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-run and Total precision results for the ELITech Clinical Systems Phosphorus, Uric Acid Mono SL, and Urea UV SL were obtained by spiking 3 serum pools to concentrations below, within, and above the expected value ranges for each analyte. The sponsor performed two runs per day, two measures per run, for twenty days according to CLSI protocol EP5-A2 using one Selectra Junior and one lot of reagent. The results are presented in the tables below:

1). The ELITech Clinical Systems PHOSPHORUS:

	n	Mean (mg/dL)	Within-run SD	Total SD	Within-run CV%	Total CV%
Low level	80	2.37	0.03	0.04	1.1	1.9
Medium level	80	4.80	0.07	0.08	1.5	1.7
High level	80	9.55	0.16	0.21	1.7	2.2

The ELITech Clinical Systems URIC ACID MONO SL:

	n	Mean (mg/dL)	Within-run SD	Total SD	Within-run CV%	Total CV%
Low level	80	2.49	0.02	0.06	0.8	2.6
Medium level	80	5.19	0.07	0.11	1.3	2.0
High level	80	7.63	0.08	0.16	1.1	2.1

The ELITech Clinical Systems UREA UV SL:

	n	Mean (mg/dL)	Within-run SD	Total SD	Within-run CV%	Total CV%
Low level	80	7.3	0.16	0.20	2.1	2.8
Medium level	80	29.2	0.23	0.39	0.8	1.3
High level	80	72.4	0.53	1.12	0.7	1.6

b. Linearity/assay reportable range:

The linearity of the Phosphorus, Uric Acid Mono SL and Urea UV SL was determined using the same protocol. Stock solutions for each device were gravimetrically prepared from commercially available material to make a high and low serum pools. High and low serum pools were mixed for each of the measurands to obtain 11 samples covering the proposed measuring range of each device. One Selectra Junior and one lot of reagent were used. Samples were tested in triplicate. The data analysis was performed and evaluated according to CLSI EP6-A using linear regression as well as second and third order non-linear fitted polynomial regressions. Linearity met the 1st order polynomial for the three devices. The results are summarized below:

Device	Linear Regression	R^2	Measuring Range
Phosphorus	y = 1.011x – 0.0947	0.9998	2.0-20.0 mg/dL
Uric Acid Mono SL	y = 0.9972x +0.1347	0.9994	1.5-25 mg/dL
Urea UV SL	y = 1.0177x – 0.8375	0.9985	4.7-140 mg/dL

Recovery studies were performed for Uric Acid Mono SL and Urea to demonstrate that the analyzer can accurately measure manually or automated diluted samples. The study protocols for both measurands were the same. Stock spiking solutions were prepared for each analyte using commercially available dry reagents. 10 natural samples for each test, with known concentrations of uric acid or urea, were spiked with the stock solutions to obtain expected concentrations of 25.62-78.16 mg/dL of uric acid or 139.7-690.2 mg/dL of urea. All samples were then diluted 1:5 with 9 gm/L saline. Samples were analyzed in duplicate on one Spectra Junior using one lot of reagents and one calibration. The means were calculated for each sample, and multiplied by the dilution factor. The observed values were compared to the expected values to determine % recovery. The pre-determined acceptance criterion for recovery was within 10% of the expected value. Results are summarized below.

Uric Acid Mono SL

Expected Concentrations	Observed Results	Recovery %
25.62	23.49	-8.3%
29.91	28.02	-6.3%
36.39	33.35	-8.4%
42.51	40.69	-4.3%
47.03	44.21	-6.0%
54.29	53.05	-2.3%
59.95	59.31	-1.1%
65.46	64.67	-1.2%
70.62	69.27	-1.9%
78.16	77.41	-1.0%

Urea Nitrogen Mono SL

Expected Concentrations	Observed Results	Recovery %
139.7	137.5	-1.6%
199.3	200.8	0.8%
258.8	277.4	7.2%
320.3	325.1	1.5%
382.9	393.9	2.9%
438.8	442.4	0.8%
497.1	490.5	-1.3%
565.5	558.6	-1.2%
623.9	614.4	-1.5%
690.2	668.2	-3.2%

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

ELICal 2 Calibrator for Phosphorus, Uric Acid Mono SL, and Urea UV SL are purchased from a commercially available source and are traceable to: a NIST traceable material, ID-MS, and SRM 909b, respectively.

Calibrator material is purchased from commercially available sources (previously cleared under k033501). Elical 2 calibrator is value assigned using multiple runs on two Vital Scientific Flexor Junior Analyzers. The target value of Elical 2 calibrator is the mean of the observed values range. After validation of the target value, a confidence range (high and low values) is calculated. Unreconstituted calibrators are stable for 11 months at 2-8° C. Reconstituted calibrator stability for all three analytes has been verified for the following temperatures and time limits: 12 hrs. at 15-25° C, 5 days at 2-8° C, 4 weeks at -15° C and -25° C.

Protocols and acceptance criteria were provided to support on-board calibration stability for 28 days for phosphorus and uric acid and 7 days for urea at 15-25° C.

Control material is purchased from a commercial vendor (previously cleared under k041227). The sponsor claimed the following for stability: before reconstitution, the shelf-life of the ELITech Clinical Systems Elitrol 1 and Elitrol II is 30 months at 2-8˚C. After reconstitution the stability is 12 hours when stored at 15-25˚C, 5 days when stored at 2-8˚C or 4 weeks (when frozen once) at -25˚ and -15˚ C. Elitrol I and II control solutions are value assigned using two Vital Scientific Flexor Junior Analyzers. Each sample is tested in triplicate over several days. The target value of Level I and II are the median of the observed values range. After validation of the target value, a confidence range (high and low values) is calculated.

Reagent stability for the Phosphorus, Uric Acid Mono SL, and Urea UV SL were evaluated on one Selectra Junior with one lot of reagent using three samples with low, medium and high concentrations of each measurand. These samples were aliquoted

and analyzed. On board stability are 28 days for phosphorus and uric acid and 14 days for urea.

d. Detection limit:

The Limits of Blank (LoB), Detection (LoD) and Quantitation (LoQ) studies were conducted following CLSI EP17-A for Phosphorus, Uric Acid Mono SL, and Urea UV SL. One Selectra Junior and one lot of the respective reagents were used. The LoBs were determined by analyzing 60 blank samples. The LoD and LoQ studies each used 4 serum pools for the individual assays. The serum pools for the LoD had concentrations of the individual measurands approximately 4 times the LoB. LoQs were determined by analyzing 4 serum pools near the expected LoQ and evaluating the Total Error. Results are summarized below:

Device	LoB	LoD	LoQ	Total Error
Phosphorus	0.01 mg/dL	0.02 mg/dL	1.00 mg/dL	11.0%
Uric Acid Mono SL	0.01 mg/dL	0.02 mg/dL	0.50 mg/dL	4.8%
Urea UV SL	0.1 mg/dL	0.3 mg/dL	2.3 mg/dL	12.4%

e. Analytical specificity:

i. **Endogenous interferences** of turbidity (20% Intralipid solution), triglycerides, unconjugated bilirubin, conjugated bilirubin, hemoglobin and glucose were investigated for the ELITech Clinical Systems PHOSPHORUS, URIC ACID MONO SL, and UREA UV SL. Each device was tested in triplicate at two concentrations for each of the individual measurands. Recovery was compared to a sample with no interfering substance and significant interference was defined as recoveries ≥ 10%. Urea was not tested for native triglycerides or glucose. The concentrations of interferents tested for the three devices are in the table below:

Interferent	Range of interferent tested
Turbidity (Intralipid®)	up to 614 mg/dL
Triglycerides	up to 1000 mg/dL
Unconjugated Bilirubin	up to 30.0 mg/dL
Conjugated Bilirubin	up to 29.5 mg/dL
Hemoglobin	up to 500 mg/dL
Glucose	up to 550 mg/dL

The concentrations of endogenous substances that demonstrated no significant interference for each device are below:

	Phosphorus	Uric Acid Mono UV	Urea UV
Turbidity (Intralipid®)	See below*	See below*	up to 614 mg/dL
Triglycerides	up to 732 mg/dL	up to 1070 mg/dL	Not tested
Unconjugated Bilirubin	up to 15 mg/dL	up to 30 mg/dL	up to 30 mg/dL

Conjugated Bilirubin	up to 1.5 mg/dL	up to 14.8 mg/dL	up to 29.5 mg/dL
Hemoglobin	up to 50 mg/dL	up to 50 mg/dL	up to 500 mg/dL
Glucose	up to 500 mg/dL	up to 500 mg/dL	Not tested

* Interference from turbidity was observed at both phosphorus concentrations and uric acid concentrations tested across all concentrations of Intralipid® (turbidity). Therefore, the sponsor recommends in the labeling that only clear (non-turbid) samples should analyzed for phosphorus and uric acid.

Hemoglobin concentrations of 50 mg/dL also demonstrate interference for both phosphorus and uric acid. Therefore, the sponsor recommends in the labeling that no visibly hemolyzed samples should be analyzed for phosphorus and uric acid.

Conjugated bilirubin concentration of >1.5 mg/dL also demonstrated interference for phosphorus ≥10%, therefore, the sponsor put a limitation that icteric samples should not be used with the phosphorus assay.

Exogenous interferences were evaluated for PHOSPHORUS, URIC ACID MONO SL and UREA UV using the same concentrations of measurands as the endogenous interference studies. The substances were tested up to 1 mg/dL of methyl dopa, up to 20 mg/dL of ascorbic acid, and up to 50 mg/dL of calcium dobesilate. The concentrations of exogenous substances that demonstrated no significant interference for each device are below:

	Phosphorus	**Uric Acid Mono UV**	**Urea UV**
Methyl dopa	Up to 1 mg/dL	up to 1 mg/dL	up to 1 mg/dL
Ascorbic Acid	Up to 20 mg/dL	See below**	up to 20 mg/dL
Calcium dobesilate	Not tested	See below**	Not tested

**Ascorbic acid and calcium dobesilate demonstrated interference at all uric acid concentrations tested. Therefore, the sponsor has the following statement of limitation in their labeling:

Samples with any amount of ascorbic acid or Calcium dobesilate will have significant interference and should not be used for uric acid measurement."

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

1). ELITech Clinical Systems PHOSPHORUS: A combination of 100 human serum

and plasma samples were analyzed on the predicate and the Selectra Junior according to CLSI EP9-A2. Twenty samples were tested each day for 5 days. Phosphorus concentrations ranged from 2.0 mg/dL to 20.0 mg/dL.

Slope (95%CI)	Intercept (95%CI)	r	Sy.x
0.999 (0.994 to 1.004)	– 0.09 (-0.12 to -0.06)	0.999	0.12

2). ELITech Clinical Systems URIC ACID MONO SL: A combination of 100 human serum and plasma samples were analyzed on the predicate and the Selectra Junior according to CLSI EP9-A2. Twenty samples were tested each day for 5 days. Uric Acid concentrations ranged from 1.5 mg/dL to 24.0 mg/dL.

Slope (95%CI)	Intercept (95%CI)	r	Sy.x
1.015 (1.010 to 1.020)	0.03 (-0.01 to 0.07)	0.999	0.18

3). ELITech Clinical Systems UREA UV SL: ELITech Clinical Systems UREA UV SL: A combination of 100 human serum samples were analyzed on the predicate and the Selectra Junior according to CLSI EP9-A2 over 7 days. Urea concentrations ranged from 4.7 mg/dL to 140.0 mg/dL.

Slope (95%CI)	Intercept (95%CI)	r	Sy.x
0.991 (0.985 to 0.997)	0.6 (0.4 to 0.9)	0.999	1.3 mg/dL

b. Matrix comparison:

Paired serum and lithium heparin samples were collected for each of the three devices. Analysis was performed on one Select Junior over a period of several days using one lot of reagents.

1). ELITech Clinical Systems PHOSPHORUS:

52 paired serum and lithium heparin samples were analyzed ranging from 2.0 mg/dL to 20.0 mg/dL on the Selectra Junior. The linear regression is :

Slope (95%CI)	Intercept (95%CI)	r	Sy.x
1.010 (1.003 to 1.016)	-0.2 (-0.27 to -0.14)	0.999	0.21

2). ELITech Clinical Systems URIC ACID MONO SL:

50 paired serum and lithium heparin samples were analyzed ranging from 1.5 mg/dL to 25.0 mg/dL on the Selectra Junior. The linear regression is :

Slope (95%CI)	Intercept (95%CI)	r	Sy.x
0.996 (0.986 to 1.006)	-0.06 (-0.21 to 0.08)	0.999	0.39

3). ELITech Clinical Systems UREA UV SL:

40 paired serum and lithium heparin samples were analyzed ranging from 4.7 mg/dL to 140.0 mg/dL on the Selectra Junior. The linear regression is :

Slope (95%CI)	Intercept (95%CI)	r	Sy.x
0.984 (0.970 to 0.999)	0.5 (-0.5 to 1.6)	0.998	2.6

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:

[1]Phosphorus: Serum, plasma: 2.7-4.5 mg/dL, 0.87-1.45 mmol/L
[2]Uric Acid: Serum, plasma: Women: 2.6 – 6.0 mg/dL, Men: 3.5 – 7.2 mg/dL
[3]Urea: Serum, plasma: Adults (18-60 years) 6-20 mg/dL, Adults (60-90 years) 8-23 mg/dL, Adults (> 90 years) 10-31 mg/dL

[1] Endres, D.B., Rude, R.K., *Mineral and bone metabolism.* Tietz Fundamentals of Clinical Chemistry, Burtis, C.A. and Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 795.
[2] Newman, D. J., Price, C. P., *Non protein Nitrogen Metabolite*. Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burtis, C.A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 414.
[3] Tietz, N.W., Clinical guide to laboratory tests, 3rd Ed., (W.B. Saunders eds. Philadelphia USA), (1995), 622.

N. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

None

O. Proposed Labeling:

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

P. Conclusion:

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