

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

A. 510(k) Number:

k102647

B. Purpose for Submission:

New Device: Analyzer, Assay, Control material and Calibrator Material

C. Measurand:

Aspartate Aminotransferase, Sodium, Potassium, and Chloride

D. Type of Test:

Quantitative enzymatic and indirect potentiometric measurement with Ion-Selective Electrodes

E. Applicant:

Seppim S.A.S.

F. Proprietary and Established Names:

ELITech Clinical Systems AST/GOT 4+1 SL

ELITech Clinical Systems ISE Na, K, Cl Electrodes

ELITech Clinical Systems Elical 2

ELITech Clinical Systems Elitrol I and II

ELITech Clinical Systems Selectra ProM

ELITech Clinical Systems ISE Calibrators

G. Regulatory Information:

1. Regulation section:

21CFR 862.1100: Aspartate aminotransferase (AST/GOT) Test System

21CFR 862.1665: Sodium test system

21CFR 862.1600: Potassium test system

21CFR 862.1170: Chloride test system

21CFR 862.1660: Quality Control material (assayed and unassayed)

21CFR 862.1150: Calibrator

21CFR 862.2160: Discrete Photometric Chemistry Analyzer for Clinical Use

2. Classification:

Class II, Class II, Class II, Class II, Class I, reserved, Class II, and Class I, respectively

3. Product code:

CIT, JGS, CEM, CGZ, JJY, JIX, and JJE respectively

4. Panel:

75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See indication(s) for use below

2. Indication(s) for use:

ELITech Clinical Systems Selectra ProM

The ELITech Clinical Systems Selectra ProM is an automated clinical chemistry system intended for use in clinical laboratories. It is intended to be used for a variety of assay methods that have been applied to spectrophotometric and electrochemical techniques. The system has two core modules: one consisting of a spectrophotometric system for measurement of analytes using spectrophotometric techniques, such as end point, rate and turbidometric assays. The second module is an electrometer used for measurement of electrolytes.

ELITech Clinical Systems AST/GOT 4+1 SL

The ELITech Clinical Systems AST/GOT 4+1 SL is a reagent is for the quantitative *in vitro* diagnostic determination of the activity of the enzyme Aspartate amino transferase

(AST) in human serum and plasma on the ELITech Clinical Systems Selectra ProM analyzer. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart diseases.

ISE Sodium Electrode

The sodium electrode for the ELITech Clinical Systems Selectra ProM is intended for the quantitative determination of sodium in serum and plasma. Sodium measurements are used in the diagnosis and treatment of adrenalism (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.

ISE Potassium Electrode

The potassium electrode for the ELITech Clinical Systems Selectra ProM is intended for the quantitative determination of potassium in serum and plasma. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

ISE Chloride Electrode

The chloride electrode for the ELITech clinical Systems Selectra ProM is intended for the quantitative determination of chloride in serum and plasma. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

ELITech Clinical Systems ISE Calibrators

ELITech Clinical Systems ISE Calibrators are used for the calibration of sodium (Na^+), potassium (K^+) and chloride (Cl^-) on ELITech Clinical Systems Selectra ProM analyzer equipped with ISE module.

ELITech Clinical Systems ELITROL I & II

ELITech Clinical Systems ELITROL I & II are multi-parametric control sera for *in vitro* diagnostic use in accuracy and precision of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra ProM analyzer equipped with ISE module.

ELITech Clinical Systems ELICAL 2

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 ELITech Clinical Systems Selectra ProM analyzers.

3. Special conditions for use statement(s):

Prescription Use Only. This device is for central laboratory use and has not been evaluated for Point of Care Use

4. Special instrument requirements:

Performance was provided for the ELITech Clinical Systems Selectra ProM.

I. Device Description:

AST/GOT 4+1 SL is available as a kit only. It consists of 2 reagents: Reagent 1 contains Tris buffer, L-Aspartate; Lactate dehydrogenase (LDH), Malate dehydrogenase (MDH) and sodium azide. Reagent 2 contains α -Ketoglutarate, NADH and sodium azide.

The Sodium, Potassium, and Chloride ISE Electrodes are comprised of the electrodes plus ISE Reference Solution, ISE Diluent, and ISE Calibrators.

The ELITech Clinical Systems ISE Na, K, Cl system is composed of three (3) different kits:

ISE Diluent: **DIL** is supplied in liquid ready-to-use form and consists of a buffered solution and surfactant.

ISE Reference Solution: **SOLN A** is supplied in liquid ready-to-use form and consists of a buffered solution with sodium, potassium and chloride surfactant.

ISE Calibrators: consists of 2 levels: **CAL L** (Low level) and **CAL H** (High level). Calibrators are supplied in liquid ready-to-use form and are aqueous solutions containing sodium, potassium and chloride.

ELITech Clinical Systems ELICAL2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration. ELICAL 2 is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to the antibodies to HCV and HIV according to FDA-approved methods.

ELITROL I and ELITROL II are two level quality control products consisting of a lyophilized human serum containing constituents at desired levels. ELITROL I and ELITROL II are prepared exclusively from the blood of donors tested individually and found to be negative for HBsAG and to antibodies to HCV and HIV according to FDA-approved methods.

The ELITech Selectra ProM is an automated, in-vitro analyzer capable of performing clinical chemistry, specific protein and electrolyte tests. Analytes are measured photometrically. The analyzer also has an ISE module for measuring sodium, potassium, and chloride electrometrically. The Selectra ProM instrument is a random access analyzer designed to be operated on a bench top in the professional environment using a combination of a

photometric analysis unit and an ion selective electrode (ISE). The ISE unit is an integrated module of the analyzer. The Dry ISE unit measures sodium (Na⁺), potassium (K⁺) and chloride (Cl⁻) using a dry electrode technology.

J. Substantial Equivalence Information:

1. Predicate device name(s):

HORIBA ABX Pentra 400
 Roche cobas C111
 ABX PENTRA AST CP
 Roche Diagnostics Calibrator for Automated Systems (C.f.a.s)
 Roche Diagnostics Precinorm U and Precipath U
 Roche Standards for the Cobas ISE Module

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

k052007
 k071211
 k060318
 k041227
 k033501
 k897071

3. Comparison with predicate:

Similarities and Differences		
Item	Candidate Device (Selectra ProM)	Predicate (Horiba ABX Pentra 400 k052007)
Intended use/Indications for Use	Automated clinical chemistry system intended for use in centralized laboratories. It is intended to be used for a variety of assay methods that have been applied to spectrophotometric and electrochemical techniques	Same
Technology	spectrophotometric and electrochemical tests	Same
Operators	Clinical laboratory setting	Same

Similarities and Differences		
Item	Candidate Device (Selectra ProM ISE Module)	Predicate (Roche Cobas C111 ISE Module k071211)
Intended use/Indications	The Selectra ProM ISE module is an electrometer used for measurement of sodium,	Same

Similarities and Differences		
Item	Candidate Device (Selectra ProM ISE Module)	Predicate (Roche Cobas C111 ISE Module k071211)
for Use	potassium and chloride for determining electrolyte imbalance	
Technology	Indirect potentiometry measurement with Ion-Selective Electrode	Same
Sample type	Serum and plasma	Same
Calibration frequency	Calibration is recommended for every 4 hours or as needed.	Every 24 hours or as needed

Similarities and Differences		
Item	Candidate Device (ELITech Clinical Systems AST/GOT 4+1 SL Reagent)	Predicate Device (ABX Pentra AST CP k060318)
Intended Use/Indications for use	The quantitative in vitro diagnostic determination of the activity of the enzyme Aspartate amino transferase in human serum and plasma. Aspartate Aminotransferase (AST) measurements are used in the diagnosis and treatment of certain types of liver and heart disease.	Same
Test Method	Modified IFCC method without pyridoxal- phosphate	Same.
Reagents	Liquid form, ready to use	Same
Sample type	Serum, Plasma in lithium heparin	Same
Calibration frequency	28 days	8 days
On board stability	28 days (refrigerated)	55 days (refrigerated)

Similarities and Differences		
Item	Candidate Device (ELITech Clinical Systems ELITROL I and ELITROLII)	Predicate (Roche Diagnostics Precinorm U and Precipath U k041227)
Intended Use/Indications for Use	For <i>in vitro</i> diagnostic use in accuracy and precision of quantitative methods	Same
Format	Lyophilized human sera with constituents added as required to obtain defined component levels	Same
Levels	Two Levels (Level I and Level II)	Same
Stability	Lyophilized: Store at 2-8°C and protected from light until the expiry date. After Reconstitution: 12 hours between 15-25°C, 5 days between 2-8°C, 4 weeks between -25 and -15°C (when frozen once)	Same

Similarities and Differences		
Item	Candidate Device (ELITech Clinical Systems ELICAL 2)	Predicate Roche Calibrator for Automated Systems (C.f.a.s.) k033501
Intended Use/Indications for Use	For <i>in vitro</i> diagnostic use in the calibration of quantitative methods	Same
Format	Lyophilized calibrator based on human serum with constituents added as requires to obtain desired component levels	Same
Level	Single Level	Same
Stability	Lyophilized: store at 2-8°C and protect from light until the expiry date. After reconstitution: 8 hours between 15-25°C, 2 days between 2-8°C, 4 weeks between -25 and -15°C (when frozen once)	Same

Similarities and Differences		
Item	Device ELITech Clinical Systems ISE Calibrators	Predicate Roche standards for ISE Module (k897071)
Intended Use/ Indications for Use/	ELITech Clinical Systems ISE Calibrators are used for the calibration of sodium (Na ⁺), potassium (K ⁺) and chloride (Cl ⁻) on ELITech Clinical Systems Selectra ProM analyzer equipped with ISE module.	For use with the Cobas ISE module for standardization of sodium, potassium and chloride levels in human serum.
Format	Aqueous solutions containing sodium, potassium and chloride with 2 different levels of concentrations	Same
Storage	Store at 2-30°C. Do not freeze.	Store at 2-8°C.
Stability	Calibrators are stable until the expiry date stated on the label. After opening, calibrators are stable 30 days when stored at 2-30°C	Calibrators are stable until the expiry date stated on the label. After opening, calibrator is stable 4 weeks when stored at 2-8°C

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

CLSI-Interference Testing in Clinical Chemistry-EP07-A2

CLSI-Method Comparison and Bias estimation using patient samples-EP-09-A2

CLSI-Evaluation of the linearity of Quantitative Analytical Methods- EP06-A

CLSI-Evaluation of precision performance of quantitative measurement methods EP05-A2

L. Test Principle:

AST catalyzes the transfer of amino group from aspartate to oxoglutarate during the formation of glutamate and oxaloacetate. Oxaloacetate is reduced to malate by malate dehydrogenase (MHD). During this conversion, an equivalent amount of NADH is oxidized to NAD. The resulting decrease in absorbance at 340 nm is directly proportional to the activity of AST in serum.

ISE measurements are based on the potentiometric Nernst Equation principle. Sample is

diluted with a diluent and aspirated into ion-selective electrodes. The measured potential difference between the reference electrode and the ion specific electrodes is proportional to the logarithm of the concentration of the measured ions.

The ELITech Selectra ProM is based on the colorimetric principle and Lambert Beer’s law which relates the absorption of light to the properties of the material through which light is traveling. Sample that contains the analyte being measured is accurately dispensed into an optical clear cuvette and mixed with accurately dispensed reagent. The analyte in the sample will react with the reagent and a change in color will occur. The change in color is directly proportional to the concentration of the analyte in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

ELITECH Clinical Systems AST/GOT 4+1 SL

Precision was evaluated with one quality control material and three human pool samples. A natural human pool serum (low), two spiked human serum pools (medium and high) and a control sample were run on the Selectra Pro M Analyzer following CLSI-EP5-A2 guideline. Samples were analyzed in duplicate, twice a day for 10 days. Results are summarized in the table below:

Material	n	Mean (U/L)	Within-run		Total	
			SD	CV(%)	SD	CV(%)
Human Serum pool (low)	40	21.0	0.3	1.6	0.4	2.1
Spiked Serum Pool (medium)	40	54.1	0.3	0.6	0.8	1.5
Spiked Serum Pool (high)	40	201.0	0.3	0.2	2.8	1.4
Control Serum	40	135.3	0.3	0.5	2.1	1.5

Elitech SODIUM System

Precision was evaluated with one quality control material and three human serum pool samples. A human serum pool diluted with distilled water (low), a natural human sera pool (medium), a spiked human serum pool (high) and a control serum were analyzed on the Selectra Pro M Analyzer following CLSI EP5-A2 guideline. Samples were analyzed in duplicate for, twice a day for 10 days. Results are summarized in the table below:

Material	n	Mean mEq/L	Within-run		Total	
			SD	CV(%)	SD	CV(%)
Diluted Serum pool (low)	40	121.7	1.0	0.8	1.6	1.3

Natural Serum Pool (medium)	40	142.4	1.0	0.7	1.9	1.3
Spiked Serum Pool (high)	40	161.1	1.2	0.8	1.7	1.1
Control Serum	40	152.0	1.1	0.7	1.6	1.1

Elitech POTASSIUM System

Precision was evaluated with one quality control material and two human sera pool samples. A human serum pool diluted with saline (low), a natural human serum pool (medium) and a control serum (high) were analyzed on the Selectra Pro M Analyzer following CLSI EP5-A2 guideline. Samples were analyzed in duplicate for twice a day for 10 days. Results are summarized in the table below:

Material	n	Mean mEq/L	Within-run		Total	
			SD	CV(%)	SD	CV(%)
Diluted Serum Pool (low)	40	2.02	0.03	1.7	0.05	2.3
Natural Serum Pool (medium)	40	4.01	0.06	1.5	0.07	1.8
Control Serum (high)	40	6.44	0.06	1.0	0.12	1.9

Elitech CHLORIDE System

Precision was evaluated with one quality control material and three human serum pool samples. A human serum pool diluted with distilled water (low), a natural human sera pool (medium), a spiked human serum pool (high) and a control serum were analyzed on the Selectra Pro M Analyzer following CLSI EP5-A2 guideline. Samples were analyzed in duplicate for, twice a day for 10 days. Results are summarized in the table below:

Material	n	Mean mEq/L	Within-run		Total	
			SD	CV(%)	SD	CV(%)
Diluted Serum pool (low)	40	81.7	1.2	1.5	1.5	1.9
Natural Serum Pool (medium)	40	109.4	0.6	0.6	1.4	1.3
Spiked Serum Pool (high)	40	124.1	1.8	1.5	2.2	1.8
Control Serum	40	116.3	1.1	1.0	1.8	1.6

b. *Linearity/assay reportable range:*

ELITECH Clinical Systems AST/GOT 4+1 SL

Linearity across the assay range was determined by testing two pools of patient serum, one at a low concentration (9.9 U/L) and one at a high concentration (247.9

U/L). The low sample was prepared by diluting the serum sample pool with saline and the high sample was prepared by spiking the serum sample pool. The high and low samples were mixed to produce 9 intermediate samples. All samples were assayed in triplicate. Data was analyzed using 1st, 2nd, and 3rd order least square regressions according to CLSI Protocol EP6-A. The difference in predicted values between the first, second and third order models are as follows:

1st order $y=23.53x-13.08$

2nd order $y=0.05x^2 + 22.90x-11.71$

3rd order $y=0.03x^3-0.57x^2+26.00x-15.46$

The sponsor chose the third 3rd order regression because it is significant and the results are shown in the table below:

Levels	Mean	Predicted 1 st order	Predicted 3 rd order	Difference 3 rd -1 st	% Difference
1	9.9	10.5	10.0	-0.5	▲
2	35.1	34.0	34.5	0.6	1.6%
3	57.8	57.5	58.4	0.9	1.5%
4	81.7	81.0	81.7	0.6	0.8%
5	104.8	104.6	104.7	0.1	0.1%
6	127.3	128.1	127.6	-0.5	-0.4%
7	151.2	151.6	150.6	-1.1	-0.7%
8	173.4	175.2	173.9	-1.3	-0.7%
9	197.9	198.7	197.7	-1.0	-0.5%
10	222.1	222.2	222.3	0.1	0.0%
11	247.9	245.8	247.8	2.0	0.8%

Based on the data, the sponsor claimed the assay's linearity range is 10 to 250 U/L

Elitech Sodium System

Linearity across the assay range was determined by testing two pools of patient serum, one at a low concentration (79.9 mEq/L) and one at a high concentration (205.1 mEq/L). The low sample was prepared by diluting the serum sample pool with saline and the high sample was prepared by spiking the serum sample pool. The low and high samples were mixed to produce 9 intermediate samples. All samples were assayed in triplicate. Data was analyzed using 1st, 2nd and 3rd order least square regressions according to CLSI protocol EP6-A. The difference in predicted values between the first and second order model are as follows:

$$1^{\text{st}} \text{ order } y=1.005x-0.6465$$

$$R^2=0.9992$$

The sponsor chose the 1st order regression because it is significant and the results are shown in the table below:

Level	Mean	Predicted 1st order	Difference: Observed - 1st Order	% Difference
1	79.9	79.3	0.6	0.7%
2	91.9	91.7	0.2	0.3%
3	104.2	104.2	0.0	0.0%
4	115.4	116.6	-1.2	-1.0%
5	129.1	129.1	0.0	0.0%
6	140.0	141.5	-1.5	-1.0%
7	153.9	153.9	0.0	0.0%
8	166.5	166.4	0.1	0.1%
9	181.2	178.8	2.4	1.4%
10	189.8	191.3	-1.5	-0.8%
11	205.1	203.7	1.4	0.7%

Based on the data, the sponsor claimed the assay's linearity range is 80.0 to 200 mEq/L.

Elitech Potassium System

Linearity across the assay range was determined by testing two pools of patient serum, one at a low concentration (2.06 m Eq/L) and one at a high concentration (12.28 mEq/L). The low sample was prepared by diluting the serum sample pool with saline and the high sample was prepared by spiking the serum sample pool. The low and high samples were mixed to produce 9 intermediate samples. All samples were assayed in triplicate. Data was analyzed using 1st, 2nd, and 3rd order least square regressions according to CLSI EP6-A. The difference in predicted values between the first and second order model are as follows:

$$1^{\text{st}} \text{ order } y=1.02x + 0.99$$

$$2^{\text{nd}} \text{ order } y=0.01x^2 + 0.95x + 1.13$$

The sponsor chose the 2nd order regression because it is significant and the results are shown in the table below:

Levels	Mean	Predicted 1 st order	Predicted 2 nd order	Difference 2 nd -1 st	% Difference
1	2.06	2.01	2.09	0.08	3.8%
2	3.08	3.03	3.06	0.03	1.0%
3	4.06	4.04	4.04	-0.01	-0.2%
4	5.02	5.06	5.03	-0.03	-0.6%
5	6.04	6.08	6.03	-0.05	-0.8%
6	6.99	7.09	7.04	-0.05	-0.7%
7	8.03	8.11	8.06	-0.05	-0.6%
8	9.15	9.13	9.09	-0.03	-0.3%
9	10.17	10.14	10.14	-0.01	-0.1%
10	11.13	11.16	11.19	0.03	0.3%
11	12.28	12.18	12.25	0.08	0.7%

Based on the data, the sponsor claimed the assay's linearity range is 2.0 to 12.0 mEq/L.

Elitech Chloride System

Linearity across the assay range was determined by testing two pools of patient serum, one at a low concentration (69.7 U/L) and one at a high concentration (161.2 U/L). The low sample was prepared by diluting the sample pool with saline and the high sample was prepared by spiking the serum sample pool. The low and high samples were mixed to produce 9 intermediate samples. All samples were assayed in triplicate. Data was analyzed using 1st, 2nd and 3rd order least square regressions according to CLSI EP6-A. The difference in predicted values between the first and third order model are as follows:

$$1^{\text{st}} \text{ order } y=9.44x+58.72$$

$$2^{\text{nd}} \text{ order } y=0.05x^2 + 8.88x + 59.94$$

$$3^{\text{rd}} \text{ order } y= -0.03x^3+0.58x^2+6.18x + 63.20$$

The sponsor chose the 3rd order regression because it is significant and the results are shown in the table below:

Levels	Mean	Predicted 1 st order	Predicted 3 rd order	Difference 3 rd -1 st	% Difference
1	69.7	68.2	69.9	1.8	2.5%
2	77.8	77.6	77.7	0.1	0.1%
3	86.6	87.0	86.2	-0.8	-1.0%
4	95.3	96.5	95.4	-1.1	-1.2%
5	105.2	105.9	105.0	-0.9	-0.9%
6	115.1	115.3	114.9	-0.5	-0.4%
7	123.8	124.8	124.9	0.1	0.1%
8	134.4	134.2	134.8	0.5	0.4%
9	144.5	143.7	144.4	0.7	0.5%
10	155.2	153.1	153.6	0.5	0.3%
11	161.2	162.5	162.2	-0.4	-0.2%

Based on the data, the sponsor claimed that the assay's linearity range is 70 to 160 mEq/L

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

Device	Traceability
Sodium	NIST SRM 918b/919b
Potassium	NIST SRM 918b
Chloride	NIST SRM 919b
AST	IFCC formulation (Schulman, 2002)

Stability

AST/GOT 4+1 SL

On board stability for the ELITech Clinical Systems AST/GOT was established by real time studies on the ELITech Clinical Systems Selectra ProM. The on-board stability of the reagent is 28 days. The ELITech Clinical Systems AST/GOT is stable until the expiration date printed on the label when stored at 2-8°C.

ELITech Clinical systems ISE Reference Solution, ISE Diluent and ISE Calibrators are purchased from a commercial vendor (previously cleared under k945271). ISE Reference Solution and ISE Diluent should be stored at 10-30°C and ISE Calibrators should be stored at 2-30°C and should not be frozen. ISE reference solutions and calibrators are stable until the expiration date stated on the label (reference solution is stable for 18 months, diluent is stable for 24 months). Shelf Life of the ISE calibrators is 24 months at 2-30°C. ISE calibrators are stable for 30 days when stored at 2-30°C

after opening. On-board stability of the ISE Reference Solution is 30 days. On-board stability of the ISE Diluent is 3 days.

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.

Calibrator material is purchased from a commercial vendor (previously cleared under k033501). The sponsor claimed the following for stability: Elical 2 is stable until the expiration date printed on the label when stored at 2-8°C prior to reconstitution. After reconstitution the stability is 8 hours when stored at 15-25°C, 2 days at 2-8°C or 4 weeks (when frozen once) at -25° and -15°C. The labeling stated that the Elical 2 should be stored tightly capped and protected from light when not in use.

Value Assignment

Elitrol I and II are value assigned using multiple Vital Scientific PRO M 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 then calculated.

Elical 2 is tested against predetermined values on multiple Vital Scientific PRO M using the AST reagent and 2 levels of quality control material. The mean analyte value is calculated and a target value is assigned.

The expected values for the ISE calibrators are determined by analyzing the calibrator in triplicate on multiple ELITech Clinical System Selectra ProM analyzers over several days. The target value of the low and high calibrator is the median of the observed values.

d. Detection limit:

ELITech Clinical Systems AST/GOT 4+1 SL

A detection limit study was evaluated according to CLSI EP-7A. The Limit of Blank (LoB) was determined by assaying a blank sample 60 times on the Selectra ProM analyzer. The LoB was determined using the 95% value. The limit of detection (LoD) was determined by assaying 4 low (1.7 U/L) diluted sample pools 60 times on the Selectra Pro M analyzer in one day. The LoD was determining using the median minus the 5th percentile plus the LoB value. The Limit of Quantitation (LoQ) was determined by assaying 4 low (5 U/L) diluted sample pools 15 times on the Selectra Pro M analyzer.

LoB, LoD and LoQ were established using the guideline CSLI. *Protocols for*

Determination of Limits of Detection and Limits of Quantitation; Approved Guideline, CSLI document CSLI document EP17-A.

	LoB	LoD	LoQ
Limits	0.4 U/L	0.8 U/L	5.0 U/L

The claimed measuring range is 10-250 U/L based on linearity.

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

e. Analytical specificity:

Study Design

Testing for interfering substances was based on CSLI EP-7A. Testing was performed on a minimum of five concentrations for each interfering substance. Samples with increasing amounts of triglycerides (Intralipid®, Bilirubin, Diatobilirubin, Sodium, Pyruvate (AST/GOT 4+1SL) Acetylsalicylate (Na⁺, K⁺, Cl⁻), and Ascorbic Acid were tested in triplicate and compared to the same sample without the interferent.

The sponsor defined non-significant interference as the highest level tested that does not cause >10% change between the tested samples and the control sample for AST/GOT 4+1 SL.

The sponsor defined non-significant interference as the highest level tested that does not cause >2.6% change between the tested sample and the control sample for Na⁺.

The sponsor defined non-significant interference as the highest level tested that does not cause >6.2% change between the tested sample and the control sample for K⁺.

The sponsor defined non-significant interference as the highest level tested that does not cause >3.9% change between the tested sample and the control sample for Cl⁻.

AST/GOT 4+1 SL

	Highest concentration tested that showed no significant interference
Triglyceride	614
Unconjugated Bilirubin	30
Conjugated Bilirubin	29.5
Sodium Pyruvate	3.0
Ascorbic Acid	20.0

The labeling states that hemolyzed samples should not be used since significant hemolysis may increase AST concentration because of high levels of AST in erythrocytes.

ISE (Na⁺, K⁺, Cl⁻)

	Highest concentration tested that showed no significant interference
Triglyceride	614
Unconjugated Bilirubin	36
Conjugated Bilirubin	25
Acetylsalicylic Acid	50.0
Ascorbic Acid	20.0

The labeling states that hemolysis may increase the potassium concentration of 0.5mmol/L because of high concentration in erythrocytes. The labeling also states that hyperlipidemia or hyperproteinemia lead to negative bias in the measurement of electrolytes because of dilution effect.

f. Assay cut-off:

Not Applicable

2. Comparison studies:*a. Method comparison with predicate device:*

All method comparison studies were performed at the manufacturer's site. No studies were performed at point of care sites.

AST/GOT 4+1 SL

A method comparison study was performed using the HORIBA ABX AST CP reagent on a PENTRA 400 chemistry analyzer and the ELITech AST/GOT 4+1 SL reagent on the Selectra ProM analyzer according to CLSI protocol EP9-A2. A total of 100 serum samples covering the linearity of the AST/GOT 4+1 SL assay were assayed. Of these 100 samples, 94 were native samples, 2 were diluted, and 4 were spiked samples. The results are presented in the table below.

ISE (Na⁺, K⁺, Cl⁻)

Method comparison study was performed using the Roche ISE calibrator on the Roche ISE Unit of the Cobas C111 analyzer and the Elitech ISE calibrator on the Selectra Pro M analyzer according to CLSI protocol EP9-A2. A total of 100 serum samples covering the linearity of the Na, K, Cl assays were evaluated. Of these 100 samples that were analyzed for Na⁺, 81 were natural samples, 13 were diluted and 6 were spiked. Of the 100 samples that were run for K⁺, 81 were natural samples, 12 were diluted and 7 were spiked. Of the 100 samples that were run for Cl⁻, 85 were natural samples, 11 were diluted and 4 were spiked. The results are presented in the table below.

Parameter	Units	Range	Total n	Slope	Intercept	R ²	Sy.x
AST/GOT	U/L	10.0-248.1	100	1.028	-0.16	0.998	1.8
Na ⁺	m/Eq/L	83.0-196.2	100	1.042	-6.9	0.996	1.6
K ⁺	m/Eq/L	2.06-11.75	100	1.008	-0.08	0.997	0.08
Cl ⁻	m/Eq/L	70.2-154.5	100	0.952	3.4	0.988	2.3

b. *Matrix comparison:*

AST/GOT 4+1 SL

Forty paired serum and plasma (lithium heparin samples) ranging from 10.2 to 248.7 U/L were analyzed on the Selectra Pro M analyzer. 36 were native patient samples, 1 was diluted and 3 were spiked samples. The results are presented in the table below.

ISE (Na⁺, K⁺, Cl⁻)

Forty paired serum and plasma samples were run on the Selectra Pro M. Of these 40 samples that were analyzed for Na⁺ 32 were native patient samples, 4 were diluted samples and 4 were spiked samples. There were 32 native samples, 2 diluted samples and 6 spiked samples analyzed for K⁺. There were 33 native samples, 3 diluted and 4 spiked for Cl⁻. The results are presented in the table below.

Parameter	Units	Range	Total n	Slope	Intercept	R ²	Sy.x
AST/GOT	U/L	10.2-248.7	40	0.993	1.07	0.999	3.1
Na ⁺	m/Eq/L	80.5-199.3	40	1.067	-9.5	0.997	2.5
K ⁺	m/Eq/L	2.22-11.61	40	1.076	-0.18	0.996	0.19
Cl ⁻	m/Eq/L	72.6-155.1	40	0.977	3.0	0.994	1.4

Based on the data, the sponsor claims lithium heparin is an acceptable anticoagulant for these assays.

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:

Reference Values are provided in the labeling according to literature as follows:

Analyte	Serum	Plasma
AST ¹	<40 U/L	<40 U/L
Sodium ² (Na ⁺)	136-145 mmol/L	136-145 mmol/L
Potassium ² (K ⁺)	3.5 – 4.5 mmol/L	3.4-4.5 mmol/L
Chloride ² (Cl ⁻)	98-107 mmol/L	98-107 mmol/L

1: Tietz:N.W.Clinical Guide to Laboratory tests 3rd Ed., (WB Saunders eds. Philadelphia USA), (1995), 76.

2: Tietz: N.W. Clinical Guide to Laboratory tests 4th Ed. (WB Saunders eds. Philadelphia, USA (2006) 234, 880, 992.

In the labeling, the sponsor also recommends that each laboratory should establish and maintain its own reference values.

N. Instrument Name:

Vital Scientific Selectra ProM also trademarked as the Flexor EL 200.

O. System Descriptions:

1. Modes of Operation:

Automated continuous random access analyzer.

2. Software:

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

Yes ___ X ___ or No _____

3. Specimen Identification:

Barcoding or manual entry

4. Specimen Sampling and Handling:

Samples in sample tubes or sample cups with a tube adaptor are placed into sample tray. Specimens, calibrators and controls are pipetted by a sample arm into a cuvette rotor. ISE samples are diluted in a cuvette and aspirated via a dedicated ISE probe. A pump located on the ISE module pumps the diluted sample from the cuvette into electrodes. A cuvette blank must be conducted every 24 hours. The cuvette rotor must be replaced every 10,000 tests or when the cuvette blank produces a high standard deviation.

5. Calibration:

On demand calibration. It is recommended to perform a calibration and a quality control measurement after installing a new or fresh bottle of reagent. It is recommended to recalibrate ISEs after installing a new vial of ISE reference solution and/or ISE diluent. ISE calibration is required every 4 hours or when quality control results fall outside the established range after replacing electrode, and after ISE cleaning maintenance. ISE calibrators must not be placed on the rotor more than 10 minutes before they are used.

6. Quality Control:

The software contains a quality control program that evaluates control results and determines if they are within specified acceptable limits.

In the labeling the sponsor recommends that control measurements be assayed daily and the frequency depends on the test method, quality control materials should be used in accordance with local, state and/ or federal guidelines.

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

None

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.