



Food and Drug Administration
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July 22, 2015

ELITECH GROUP
DEBRA HUTSON
VP RA/QA
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BOTHELL WA 98021

Re: K151113

Trade/Device Name: ELITech Clinical Systems CALCIUM ARSENAZO
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: II
Product Code: CJY
Dated: April 23, 2015
Received: April 27, 2015

Dear Debra Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

k151113

Device Name

ELITech Clinical Systems CALCIUM ARSENAZO

Indications for Use (Describe)

ELITech Clinical Systems CALCIUM ARSENAZO is intended for the quantitative in vitro diagnostic determination of total calcium in human serum, plasma and urine using ELITech Clinical Systems Selectra Pro Series Analyzers.

It is not intended for use in Point of Care settings.

Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

ELITech Clinical Systems CALCIUM ARSENAZO

1. Date: April 23, 2015
2. Submitter: ELITech Clinical Systems SAS
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3. Contact Person: Debra K. Hutson
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Email: d.hutson@elitechgroup.com
4. Device Name: ELITech Clinical Systems CALCIUM ARSENAZO
Classification: Class II
CJY
Clinical Chemistry
21 CFR 862.1145
5. Predicate Device: k123171
HORIBA ABX
ABX PENTRA CALCIUM AS CP

6. Intended Use:

ELITech Clinical Systems CALCIUM ARSENAZO is intended for the quantitative *in vitro* diagnostic determination of total calcium in human serum, plasma and urine using ELITech Clinical Systems Selectra Pro Series Analyzers.

It is not intended for use in Point of Care settings. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Special conditions for use statement(s):

Rx only.

This device is intended for professional use and in vitro diagnostic use only.

CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Special instrument requirements:

For use with ELITech Clinical Systems Selectra Pro Series Analyzers. Performance data was obtained on the Selectra ProM Analyzer.

7. **Device Descriptions**

ELITech Clinical Systems CALCIUM ARSENAZO is available as a kit only. It consists of a mono-reagent R whose composition is: 100 mmol/L MES buffer (pH 6.50), 200 µmol/L Arsenazo III.

8. **Substantial Equivalence Information**
Assay (reagent)

1. Predicate Device Name
ABX PENTRA CALCIUM AS CP
2. K123171
3. Comparison with predicate

Similarities

Parameter	<u>New Device</u> ELITech Clinical Systems CALCIUM ARSENAZO	<u>Predicate Device</u> ABX PENTRA CALCIUM AS CP, k123171
Intended Use	ELITech Clinical Systems CALCIUM ARSENAZO is intended for the quantitative <i>in vitro</i> diagnostic determination of total calcium in human serum, plasma and urine using ELITech Clinical Systems Selectra Pro Series Analyzers. It is not intended for use in Point of Care settings.	ABX Pentra Calcium AS CP reagent, with associated calibrator and controls, is a diagnostic reagent for quantitative in vitro determination of calcium in human serum, plasma and urine based on a colourimetric method, using the ABX Pentra 400 Clinical Chemistry analyzer.

Parameter	<u>New Device</u> ELITech Clinical Systems CALCIUM ARSENAZO	<u>Predicate Device</u> ABX PENTRA CALCIUM AS CP, k123171
Indication for Use	Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).	Measurements of calcium is used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
Sample Type	Serum, Plasma, Urine	Same
Assay Technology	Colorimetric test	Same
Composition	Reagent R: MES Buffer, pH 6.50 100 mmol/L Arsenazo III 200 µmol/L	Same
Appearance of reagents	Liquid form, ready to use	Same

Differences

Parameter	<u>New Device</u> ELITech Clinical Systems CALCIUM ARSENAZO	<u>Predicate Device</u> ABX PENTRA CALCIUM AS CP, K123171
Assay Format	12 x 20 mL	1 x 79 mL
Storage & Expiry	Store at 2-8°C and protect from light. The reagent is stable until the expiry date stated on the label.	Reagents, in unopened cassettes, are stable up to the expiry date on the label if stored at 2-8°C and contamination is avoided.
Assay Range	Serum, Plasma : 5.00 – 15.00 mg/dL Urine: 1.50 – 18.00 mg/dL	Serum, Plasma : 4.00 – 18.05 mg/dL Urine: 0.64 – 18.05 mg/dL
Instrument	Selectra Pro M	ABX Pentra 400
Reference Values	Serum/ Plasma : 8.6 - 10.3 mg/dL 2.15 - 2.57 mmol/L Urine (for a urinary volume of 1.5 L per day) : 100 – 300 mg/24h 2.50 – 7.50 mmol/24h Calcemia is always interpreted according to the plasmatic protein rates.	Serum / Plasma : 8.6 - 10.3 mg/dL (2.15 - 2.57 mmol/L) Urine : Women: < 250 mg/24h (6.24 mmol/24h) Men: < 300 mg/24h (7.49 mmol/24h)

Parameter	<u>New Device</u> ELITech Clinical Systems CALCIUM ARSENAZO	<u>Predicate Device</u> ABX PENTRA CALCIUM AS CP, K123171
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) (cleared in k110830) ELITech Clinical Systems ELITROL II (Pathologic control) (cleared in k110830)	Recommended quality control material (not included): ABX Pentra N Control ABX Pentra P Control ABX Pentra Urine Control
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2 (cleared in k110830)	Recommended calibration material (not included): ABX Pentra MultiCal
Limit of Detection	Serum/Plasma: 0.04 mg/dL Urine: 0.15 mg/dL	Serum/Plasma: 0.28 mg/dL Urine: 0.23 mg/dL
Limit of Quantitation	Serum/Plasma: 5.00 mg/dL Urine: 1.50 mg/dL	Serum/Plasma: 1.54 mg/dL Urine: 0.64 mg/dL
Interferences- Serum/Plasma	<p><u>Unconjugated bilirubin:</u> No significant interference up to 30.0 mg/dL (513 µmol/L).</p> <p><u>Conjugated bilirubin:</u> No significant interference up to 29.5 mg/dL (504 µmol/L).</p> <p><u>Hemoglobin:</u> No significant interference up to 500 mg/dL.</p> <p><u>Triglycerides:</u> No significant interference up to 1726 mg/dL.</p> <p><u>Magnesium:</u> No significant interference up to 12.0 mg/dL.</p> <p><u>Ascorbic acid:</u> No significant interference up to 20.0 mg/dL.</p> <p><u>Acetylsalicylic Acid:</u> No significant interference up to 200 mg/dL.</p> <p><u>Acetaminophen:</u> No significant interference up to 30 mg/dL.</p>	<p><u>Total Bilirubin:</u> No significant influence is observed up to 788 µmol/L (46.1 mg/dL).</p> <p><u>Direct Bilirubin:</u> No significant influence is observed up to 445 µmol/L (26.0 mg/dL).</p> <p><u>Haemoglobin:</u> No significant influence is observed up to 290 µmol/L (500 mg/dL).</p> <p><u>Lipemia:</u> No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 500 mg/dL.</p> <p><u>Magnesium:</u> No significant influence is observed up to 4.42 mmol/L (10.7 mg/dL).</p> <p><u>Ascorbic Acid:</u> No significant influence is observed up to 3.40 mmol/L (60 mg/dL).</p> <p><u>Acetylsalicylic Acid:</u> No significant influence is observed up to 3.62 mmol/L (65.2 mg/dL).</p> <p><u>Acetaminophen:</u> No significant influence is observed up to 1324 µmol/L (20 mg/dL).</p> <p><u>Ibuprofen:</u> No significant influence is observed up to 2.42 mmol/L (50.1 mg/dL).</p>

Parameter	<u>New Device</u> ELITech Clinical Systems CALCIUM ARSENAZO	<u>Predicate Device</u> ABX PENTRA CALCIUM AS CP, K123171
Interferences - Urine	<p>Conjugated bilirubin: No significant interference up to 29.5 mg/dL (504 µmol/L).</p> <p>Hemoglobin: No significant interference up to 500 mg/dL</p> <p>Ascorbic acid: No significant interference up to 20.0 mg/dL.</p> <p>Urea: No significant interference up to 5000 mg/dL.</p> <p>Uric Acid: No significant interference up to 100 mg/dL.</p> <p>Magnesium: No significant interference up to 10.0 mg/dL</p> <p>pH: No significant interference for pH values ranging between 2.5 and 6.0.</p>	<p>Direct Bilirubin: No significant influence is observed up to 432 µmol/L (25.3 mg/dL).</p> <p>Haemoglobin: No significant influence is observed up to 290 µmol/L (500 mg/dL).</p> <p>Ascorbic Acid: No significant influence is observed up to 3.40 mmol/L (60 mg/dL).</p> <p>Lipemia: No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 200 mg/dL.</p> <p>Magnesium: No significant influence is observed up to 5.34 mmol/L (13.0 mg/dL).</p> <p>pH: The urine should not be alkalinized.</p>
On-board stability	28 days	60 days
Calibration frequency	Calibration frequency: 28 days Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.	The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens. The calibration stability is 10 days. <i>Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.</i>

9. **Standard/Guidance Document Reference**

No applicable mandatory performance standards or special controls exist for this device

10. **Test Principle:**

Arsenazo III [2,7-(bis(2-aronophenylazo))-1,8-dihydroxynaphtalene-3,6-disulphonic acid], forms in neutral medium a blue complex with calcium. The color intensity is directly proportional to the total calcium concentration.

11. **Performance Characteristics – Analytical Performance**

a. **Precision/Reproducibility**

Precision

The precision of the device was determined in accordance with CLSI EP05-A2 protocol (Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition).

Within-run and total precision results were obtained by performing two runs per day, two measures per run, for 3 levels of samples on 2 instruments during twenty operating days

according to CLSI EP05-A2 protocol. The results are presented in the table below:

Serum

Level	n	Mean (mg/dL)	Precision %	
			Within-run CV%	Total CV%
Level 1	80	8.28	1.1	1.7
Level 2	80	10.32	0.5	1.4
Level 3	80	12.96	0.5	1.0

Urine

Level	n	Mean (mg/dL)	Precision %	
			Within-run CV%	Total CV%
Level 1	80	4.53	1.3	1.8
Level 2	80	10.89	0.5	1.2
Level 3	80	17.51	0.3	0.8

b. Linearity/assay reportable range

The linearity study of ELITech Clinical Systems CALCIUM ARSENAZO was performed according to CLSI protocol EP06-A (Evaluation of the Linearity of the Measurement of Quantitative Procedures: a Statistical Approach; Approved Guideline).

Serum:

The linearity of ELITech Clinical Systems CALCIUM ARSENAZO was studied by mixing a sample with high value (15.35 mg/dL) and a sample with low value (4.94 mg/dL) to obtain 11 levels with equidistant concentrations and then measuring the Calcium concentration of each of the 11 levels using ECS Calcium Arsenazo reagent. From this study, a measuring range from 5.00 – 15.00 mg/dL has been determined.

Urine:

The linearity of ELITech Clinical Systems CALCIUM ARSENAZO was studied by mixing a sample with high value (18.60 mg/dL) and a sample with low value (1.45 mg/dL) to obtain 11 levels with equidistant concentrations and then measuring the Calcium concentration of each of the 11 levels using ECS Calcium Arsenazo reagent. From this study, a measuring range from 1.50 – 18.00 mg/dL has been determined.

Auto-dilution 1 to 5 allows the use of the ELITech Clinical Systems CALCIUM ARSENAZO with analyte activities up to 90.00 mg/dL.

c. Traceability

For calibration, a multi-parametric calibrator, most recently cleared under k132399, named ELITech Clinical Systems ELICAL 2 (manufactured by ELITech Clinical Systems SAS under product code CALI-0580) must be used. Traceability of the assigned value for all constituents in this calibrator, including the calcium value assigned to calibrate ELITech Clinical Systems CALCIUM ARSENAZO, is included in its labeling. Traceability for calcium is to NIST SRM 956c Quality Control Materials.

d. Stability

On board stability:

This evaluates the period of time during which correct measurements are obtained after installation of a new vial on board.

At least 3 levels of sample (high/medium/low) are tested in duplicate at Day 0 (D0).

At regular intervals, the three (3) concentration levels are analyzed in duplicate, until the deviations from the results at D0 are higher than acceptance criteria or for at least 30 days. During this period, the reagents are stored on the analyzer (vial open).

This study was performed on one (1) lot of ELITech Clinical Systems CALCIUM ARSENAZO reagent on ELITech Clinical Systems Selectra Pro M Analyzer. Results indicate the on-board stability of the reagent is 28 days.

Real-time stability:

The shelf-life of ELITech Clinical Systems CALCIUM ARSENAZO reagent has been followed in real time for 24 months at 2-8°C on 3 different batches.

e. Detection limit

Determined according to CLSI protocol EP17-A (Protocols for Determination of Limits of Detection and Limits of Quantification; Approved Guideline).

Serum

Limit of Detection:

The limit of Detection was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems CALCIUM ARSENAZO and diluted with NaCl 0.9% to obtain a concentration of approximately 5 mg/dL.

The data are not Gaussian, so $LoD = LoB + D_{S,\beta}$ (where $D_{S,\beta}$ is determined by calculating the median minus the 5th percentile of the low concentration sample distribution).

Limit of Detection = 0.04 mg/dL.

Limit of Quantification:

The limit of Quantification was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems CALCIUM ARSENAZO and diluted with NaCl 0.9% to obtain a concentration of 5.0 mg/dL.

Acceptance criteria: The acceptable Total Error for the determination Limit of Quantification is ≤ 0.32 mg/dL. If the confidence Interval is within the acceptable total error limits, then the Limit of Quantification is acceptable. The value must be equal or higher than the Limit of Detection.

Limit of Quantification = 5.00 mg/dL.

Urine

Limit of Detection:

The limit of Detection was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems CALCIUM ARSENAZO and diluted with NaCl 0.9% to obtain a concentration of 0.40 mg/dL.

The data are not Gaussian, so $LoD = LoB + D_{S,\beta}$ (where $D_{S,\beta}$ is determined by calculating the median minus the 5th percentile of the low concentration sample distribution).

Limit of Detection = 0.15 mg/dL.

Limit of Quantification

The limit of Quantification was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems CALCIUM ARSENAZO and diluted with NaCl 0.9% to obtain a concentration of 1.50 mg/dL.

Limit of Quantification = 1.50 mg/dL.

f. Interference/analytical specificity

Serum

Interferences due to unconjugated bilirubin, conjugated bilirubin, hemoglobin, triglycerides, magnesium, ascorbic acid, acetylsalicylic acid and acetaminophen were investigated following the recommended sample levels in CLSI EP07-A2 protocol (Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition).

For each potential interferent tested, 2 serum sample pools at two calcium levels close to those specified in Appendix B of EP7-A2 were prepared:

-1st pool: low concentration at nominal 8.00 mg/dL

-2nd pool: high concentration at nominal 12.00 mg/dL

Aliquots of each of the serum sample pools were spiked with increasing interferent concentration. Test ranges covered at least the interferent level specified in Appendix D of EP7-A2. Thus, there were two series of interferent spike for each potential interferent tested. A control sample was prepared from the sample pool diluted in the appropriate diluent.

Interferent	Test range	Number of different concentrations tested
Unconjugated bilirubin	up to 30.0 mg/dL	7
Conjugated bilirubin	up to 29.5 mg/dL	7
Hemoglobin	up to 500 mg/dL	9
Triglycerides	up to 3172 mg/dL	8
Magnesium	up to 12.2 mg/dL	8
Ascorbic acid	up to 20 mg/dL	7
Acetylsalicylic Acid	up to 200 mg/dL	7
Acetaminophen	up to 30 mg/dL	7

Two (2) levels of control (Serum control Level 1 (ELITROL I) and Serum control Level 2 (ELITROL II)) were tested to check the calibration.

For both sample pools for each interferent, each point was measured in triplicate per run.

Acceptance criteria: an accepted bias of $\pm 10\%$ in sample pools with low (8.00 mg/dL) or high (12.00 mg/dL) nominal concentration.

The results of testing interferences are the following:

- Concentration up to 30.0 mg/dL unconjugated bilirubin, 29.5 mg/dL conjugated bilirubin, 500 mg/dL hemoglobin, 1726 mg/dL triglycerides, 12.0 mg/dL magnesium, 20.0 mg/dL ascorbic acid, 200 mg/dL acetylsalicylic acid and 30 mg/dL acetaminophen do not show any significant interference for each substance.
- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM

type (Waldenstrom's macroglobulinemia) can cause unreliable results.

The following statement will also be included in the labeling:

Other compounds may interfere. Users should refer to the three following literature references:

-Young, D. S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).

-Young, D. S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

-Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.

Urine

Interferences due to Conjugated bilirubin, Hemoglobin, Ascorbic acid, Urea, Uric Acid, Magnesium, and pH were investigated following the recommended sample levels in CLSI EP07-A2 protocol (Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition).

For each potential interferent tested, 2 urine sample pools at two calcium levels close to those specified in Appendix B of EP7-A2 were prepared:

-1st pool: low concentration at nominal 4.00 mg/dL

-2nd pool: high concentration at nominal 16.00 mg/dL

Aliquots of each of the serum sample pools were spiked with increasing interferent concentration. Test ranges covered at least the interferent level specified in Appendix D of EP7-A2. Thus, there were two series of interferent spike for each potential interferent tested. A control sample was prepared from the sample pool diluted in the appropriate diluent.

Interferent	Test range	Number of different concentrations tested
Conjugated bilirubin	up to 29.5 mg/dL	7
Hemoglobin	up to 500 mg/dL	9
Ascorbic acid	up to 20 mg/dL	7
Urea	up to 5000 mg/dL	6
Uric Acid	up to 100 mg/dL	6
Magnesium	up to 10 mg/dL	8
pH	2.5 to 12.0	7

Two (2) levels of control (Serum control Level 1 (ELITROL I) and Serum control Level 2 (ELITROL II)) were tested to check the calibration.

For both sample pools for each interferent, each point was measured in triplicate per run.

Acceptance criteria: an accepted bias of $\pm 10\%$ in sample pools with low (4.00 mg/dL) or high (16.00 mg/dL) nominal concentration.

The results of testing interferences are the following:

- Concentration up to 29.5 mg/dL conjugated bilirubin, 500 mg/dL hemoglobin, 10.0 mg/dL magnesium, 20.0 mg/dL ascorbic acid, 5000 mg/dL urea, 100 mg/dL uric acid, and pH values ranging between 2.5 and 6.0 do not show any significant interference for each substance.

The following statement will also be included in the labeling:

Other compounds may interfere. Users should refer to the two following literature references:

-Young, D. S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).

-Young, D. S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

11. Performance Characteristics – Comparison Studies

a. Method comparison

Serum

A correlation study was performed between ELITech Clinical Systems CALCIUM ARSENAZO reagent on a Selectra ProM Analyzer and ABX Pentra Calcium AS CP reagent on a ABX Pentra analyzer according to CLSI EP09-A2 protocol (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition).

This study was performed using 106 serum patient samples from 5.07 to 14.79 mg/dL over a span of 5 days.

Regression analysis of the results yielded the following:

$$y = 0.949x + 0.41 \text{ mg/dL.}$$

$$r = 0.993$$

$$r^2 = 0.986$$

Standard error of the estimate $S_{y.x} = 0.29 \text{ mg/dL.}$

Urine

A correlation study was performed between ELITech Clinical Systems CALCIUM ARSENAZO reagent on a Selectra ProM Analyzer and ABX Pentra Calcium AS CP reagent on a ABX Pentra analyzer according to CLSI EP09-A2 protocol (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition)

This study was performed using 52 urine patient samples from 1.50 to 17.14 mg/dL over a span of 5 days.

Regression analysis of the results yielded the following:

$$y = 0.936x + 0.20 \text{ mg/dL}$$

$$r = 0.995$$

$$r^2 = 0.990$$

Standard error of the estimate $S_{y.x} = 0.39 \text{ mg/dL}$

b. Evaluation of Accuracy: Matrix Effect

63 paired serum and plasma patient specimens (in lithium heparin samples, ranging from 5.19 to 14.38 mg/dL), were tested on ELITech Clinical Systems Selectra ProM Analyzer according to CLSI protocol EP09-A2 (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition).

Regression analysis of the results yielded the following:

$$y = 0.976x + 0.26 \text{ mg/dL}$$

$$r = 1.000$$

$$r^2 = 0.993$$

Standard error of the estimate $S_{y.x} = 0.19 \text{ mg/dL}$

c. Expected values/Reference Range

As indicated in the instructions for use for ELITech Clinical Systems CALCIUM ARSENAZO, each laboratory should establish and maintain its own reference values. The values given are used as guidelines only.

Serum/ Plasma²:

8.6 - 10.3 mg/dL

2.15 - 2.57 mmol/L

Urine (for a urinary volume of 1.5 L per day)¹:

100 – 300 mg/24h

2.50 – 7.50 mmol/24h

Calcemia is always interpreted according to the plasmatic protein rates.

These reference values are from:

¹Wu, A.H.B., Tietz Clinical guide to laboratory tests, 4 th Ed., (W.B. Saunders), (2006), 684.

²Endres D.B., Rude R.K., *Disorders of Bone*, Tietz Fundamentals of Clinical Chemistry, 6th ED., Burtis, C.A. & Ashwood, E.R., Bruns.D.E., (Saunders), (2008), 711.

d. Clinical Studies:

Not applicable

e. Clinical Cut-off:

Not applicable

12. Conclusion

The information on the principle and performance of our device that is contained in this premarket notification is complete and supports a decision that our device is substantially equivalent to the predicate device.