

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k070207

B. Purpose for Submission:

New device

C. Measurand:

None - Submission is for calibrators

D. Type of Test:

Calibrators

E. Applicant:

Pointe Scientific Inc.

F. Proprietary and Established Names:

Multi-Analyte Chemistry Calibrator

G. Regulatory Information:

1. Regulation section:

21 CFR§ 862.1150 – Calibrator

2. Classification:

Class II

3. Product code:

JIX – Calibrator, Multi-analyte mixture

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Chemistry calibrator is for use as a calibrator of Pointe Scientific, Inc. clinical chemistry assays. The analyte constituents, set-point values and instruments are provided in the product labeling.

3. Special conditions for use statement(s):

For prescription use.

4. Special instrument requirements:

Use with automated and semi-automated chemistry analyzers

I. Device Description:

The Multi-analyte Chemistry calibrator is a product consists of lyophilized human serum and a diluent for reconstitution. The human serum contains calibrator constituents added to provide the defined assay values for Albumin, Total Bilirubin, Direct Bilirubin, BUN, Calcium, CO₂, Chloride, Cholesterol, Creatinine, Glucose Hx, Glucose Ox, Iron, Magnesium, Phosphorus, Total Protein, Trig-GPO, and Uric Acid. The concentration of the calibrator components are lot specific and the values of the analytes are provided in the product labeling.

All human materials were tested by FDA approved methods and found to be negative for the presence of antibodies to HIV-1, HIV-2, HBsAg, and HCV.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Calibrator for Automated Systems

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

k990460

3. Comparison with predicates:

Similarities		
Characteristics	Multi-Analyte Chemistry Calibrator (Proposed Device)	Roche Calibrator (C.f.a.s.) (Predicate Device)
Intended Use	The Chemistry calibrator is for use as a calibrator of Pointe Scientific, Inc. clinical chemistry assays. The analyte constituents, set-point values and instruments are provided in the product labeling	For use as a calibrator of clinical chemistry assays. This calibrator material is well suited for automated and semi-automated analytical procedures.
Composition	Lyophilized pooled serum with constituents added to obtain desired values	Lyophilized pooled serum with constituents added to obtain desired values
Stability	<ul style="list-style-type: none"> ●Unreconstituted chemistry calibrator is stable until the expiration date when stored at 2-8°C. ●Reconstituted chemistry calibrator is stable for seven days when stored at 2-8°C with the exception of Bilirubin, which is stable five days at 2-8°C. ●Store calibrator tightly capped and protected from light when not in use. 	<ul style="list-style-type: none"> ●Stability of the lyophilized calibrator at 2-8°C: up to stated expiration date. ●Stability of the components in the reconstituted calibrator: at 2-8°C, 2 days. Exceptions: see below. Total Bilirubin: at 2-8°C: 1 day. Direct Bilirubin: at 2-8°C: 8 hours. ●Store calibrator tightly capped and protected from light when not in use.

Levels	Single Level	Single Level
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Differences		
Item	Device	Predicate
Constituents	Albumin, Total Bilirubin, Direct Bilirubin, BUN, Calcium, CO2, Chloride, Cholesterol, Creatinine, Glucose Hx, Glucose Ox, Iron, Magnesium, Phosphorus, Total Protein, Trig-GPO, Uric Acid	Acid Phosphatase, Alkaline Phosphatase, Alanine Aminotransferase, Alpha-Amylase, Aspartate Aminotransferase, Cholinesterase, creatine kinase, Gamma-Glutamyl transferase, Lactate Dehydrogenase, Lipase, Albumin, Total Bilirubin, Direct Bilirubin, Urea (BUN), Calcium, CO2, Chloride, Cholesterol, Creatinine, Glucose, Iron, Magnesium, Phosphorus, Total Protein, Triglyceride, Uric Acid, Sodium, Potassium, Bicarbonate, UIBC, LDI

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

Not Applicable

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable): 3

1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable

b. Linearity/assay reportable range:

Not Applicable

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

Traceability

The sponsor provided the available NIST traceability information for constituents in the calibrator mixture. It is also available to the user upon request from the sponsor.

Value Assignment

The calibrator values are determined using Pointe Scientific, Inc. reagent methods and the analyzers listed in the value assignment table on the reverse side of the package insert. Determinations are performed under standardized conditions, utilizing known NIST standard materials. The commercial calibrator lot value is assigned with 3 runs, 10 values per run and using different lot numbers of the reagent. The final established value is obtained after calibrating against the previous calibrator lot, which is traceable to NIST

material at $100 \pm 10\%$. The sponsor's final acceptance criterion is that the newly manufactured calibrator values must recover within $100 \pm 10\%$ of a previous lot of calibrator.

Stability

The sponsor conducted long-term storage stability and open-vial stability using 3 lots and 3 replicates per lot. Data analysis demonstrated the products stored at +2 to +8°C are stable for at least 36 months. Testing cycles are, 0 and 36 months. Open-vial testing of reconstituted calibrator demonstrated 7-day stability for all the constituents with the exception of Bilirubin for which the data indicate stability of 5 days at +2 to +8°C storage.

d. Detection limit:

Not Applicable

e. Analytical specificity:

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable

b. Matrix comparison:

Not Applicable

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:

Not Applicable

N. Proposed Labeling:

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

O. Conclusion:

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