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

A. 510(k) Number:
k062118

B. Purpose for Submission:
Clearance of a new device

C. Measurand:
Glucose

D. Type of Test:
Quantitative

E. Applicant:
Pointe Scientific, Inc.

F. Proprietary and Established Names:
Glucose Hexokinase Liquid Reagent set for the Pointe 360 Analyzer

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1345
2. Classification:
   Class II
3. Product code:
   CFR, Glucose test system
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   The Glucose Hexokinase reagent set is intended to be used in a diagnostic laboratory setting by qualified laboratory technologists for the quantitative determination of glucose in human serum and plasma on the Pointe 360 Analyzer. It is for in vitro diagnostic use only. The determination of glucose in serum and plasma is for use in the diagnosis and treatment of diabetes mellitus.
2. Indication(s) for use:
   See Intended Use above.
3. Special conditions for use statement(s):
   For Prescription Use Only
4. Special instrument requirements:
   Pointe 360

I. Device Description:

The Pointe 360 is a computerized bench top laboratory instrument. It is capable of automating all stages of assay processing that involve incubation, reagent delivery, mixing, optical reading, calculating, data storage and reporting within specified limits. The glucose reagent set for the Pointe 360 is an assay for the determination of glucose in plasma or serum.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Roche Diagnostics Glucose/HK on the Hitachi 917
2. Predicate 510(k) number(s):
   k953847
3. Comparison with predicate:

Characteristics	Liquid Glucose (Proposed Device) and Pointe 360 analyzer	Roche Diagnostics Glucose/HK (Predicate Device) and Hitachi 917
Intended Use	The Glucose reagent set is intended to be used in a diagnostic laboratory setting by qualified laboratory technologists for the quantitative determination of glucose in human serum.	Enzymatic in vitro test for the quantitative determination of glucose in human serum, plasma, urine and CSF.
Linearity / Assay range	1.0 – 500.0 mg/dl	2.0 – 750 mg/dl
Low Limit of Detection	1.0 mg/dl	2.0 mg/dl
Interference	No interference was observed from bilirubin up to 16.0 mg/dl, hemoglobin up to 300 mg/dl and lipemia (intralipid) up to 1000 mg/dl. (using a criteria of >10% variance from control) This data was generated using the Pointe 360 analyzer.	No significant (> 10.0%) lipemic interference found at Intralipid levels from 1-1000 mg/dl (0-3000 mg/dl Triglyceride). No significant (> 10.0%) icteric interference at Bilirubin levels of 60 mg/dl. No significant (> 10.0%) Hemoglobin levels of 1000 mg/dl.
Precision (Within Day)	Mean SD CV N Sample 1 81 0.6 0.7 % 20 Sample 2 276 1.1 0.4 % 20 Sample 3 468 4.9 1.0 % 20	Mean CV N Sample 1 127 1.0 % 63 Sample 2 66 1.1 % 63 Sample 3 274 0.8 % 63
Precision (Day to Day)	Mean SD CV N Sample 1 81 1.3 1.6 % 20 Sample 2 261 3.2 1.2 % 20 Sample 3 451 7.5 1.7 % 20	Mean CV N Sample 1 126 1.7 % 63 Sample 2 118 1.9 % 63 Sample 3 253 1.9 % 63
Correlation	Corr. Coefficient : Reg. Equation	Corr. Coefficient : Reg. Equation
Serum	0.996 y = 0.960x + 3.1	0.999 y = 1.02x -2.72
Plasma	0.997 y = 0.977x + 0.6	Not listed

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

1. CLSI Guideline, EP5-A2 Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline Second edition
2. CLSI Guideline, EP6-A Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline
3. CLSI Guideline, EP9-A2 Method Comparison and Bias Estimation Using Patient

Samples; Approved Guideline Second edition
4. CLSI Guideline, EP17-A Protocols for Determination of Limits of Detection and Limits of Quantitation
5. Pointe Scientific, Inc. application development protocols were also referenced during the evaluation and development phases.
6. IEEE Std 1016-1987 IEEE Recommended Practices for Software Design.
7. J-Std 016/IEEE Std 1498 Software Development and Documentation, with appropriate tailoring.
8. IEEE Std 610.12-1990, IEEE Standard Glossary of Software Engineering Terminology.
9. Software Requirements Specifications of the Pointe 360 Device, revision 01.

L. Test Principle:

Glucose is phosphorylated with adenosine triphosphate (ATP) in the reaction catalyzed by hexokinase (HK). The product, glucose-6-phosphate (G_6P) is then oxidized with the concomitant reduction of NAD to NADH in the reaction catalyzed by glucose-6-phosphate-dehydrogenase (G_6PDH). The formation of NADH causes an increase in absorbance at 340nm. The increase is directly proportional to the amount of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Pooled serum and known control materials were analyzed once a day for 20 days. The repeatability and within-lab precision coefficients of variation (%CV) were calculated.

Results are summarized below.

Precision (Within Day)				
	Mean (mg/mL)	SD	CV	N
Sample 1	81	0.6	0.7%	20
Sample 2	276	1.1	0.4%	20
Sample 3	468	4.9	1.0%	20

Precision (Day to Day)				
	Mean (mg/mL)	SD	CV	N
Sample 1	81	1.3	1.6%	20
Sample 2	261	3.2	1.2%	20
Sample 3	451	7.5	1.7%	20

b. Linearity/assay reportable range:

Linearity was assessed by analyzing dilutions of calibrators. The linearity of glucose on the Pointe 360 was evaluated by comparing observed versus expected values across the expected range. The sponsors acceptance criteria was ±10% compared to the expected value. Results are summarized below.

Sample	N	Expected Value, mg/dL	Observed Value, mg/dL	Percent Recovery
1	4	0	-1.5	-
2	4	55	55.5	101%
3	4	110	110.5	100%
4	4	165	166.5	101%
5	4	220	219.8	100%
6	4	275	272.5	99%
7	4	330	324.5	98%
8	4	385	377.8	98%
9	4	440	429.3	98%
10	4	495	481.5	97%
11	4	550	558.0	101%

Least squares regression analysis gave the following linear equation: Observed = 1.001(Expected) -1.5.

A low end linearity study was also performed to determine the linearity at concentrations from 0 to 45 mg/dL. A linear regression analysis was performed on the data and plotted. The sponsors acceptance criteria was ±10% compared to the expected value. Results are summarized below.

Sample	N	Expected Value, mg/dL	Observed Value, mg/dL
1	3	0	0.7
2	3	5	5.3
3	3	10	10.7
4	3	15	15.3
5	3	20	20.0
6	3	25	25.0
7	3	30	30.3
8	3	35	36.0
9	3	40	41.0
10	3	45	46.7

Least squares regression analysis gave the following linear equation: Observed = 0.981(Expected) -0.6.

The sponsor will claim the assay range to be 1 mg/dL to 500 mg/dL. The lower value being determined from the detection limit (below).

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The calibrator used with this assay (Pointe Scientific, Inc. Multi-Analyte Chemistry Calibrator) was cleared under k070207, and the control used with this assay was cleared under k981339 (Consolidated Technologies, Inc. Quickcheck Lyophilized Chemistry Control Conforma).

d. Detection limit:
The lower limit of detection (LoD) was determined using CLSI EP17-A by running replicates of 20 for a zero and low level (5 mg/dL) sample. The LoD was found to be 0.5 mg/dL for the glucose assay when used on the Pointe 360. The sponsor will claim a lower limit of detection of 1.0 mg/mL.

e. Analytical specificity:
Interference was evaluated. Bias is the difference in the results between the control sample (without the interferant) and the test sample's (contains the interferant) 95% confidence interval. The sponsor's acceptance criteria is a bias not exceeding 16 mg/dL for bilirubin, 16.3 mg/dL for hemoglobin, and 13 mg/dL for intralipid being considered interference (which equate to 10% change in the glucose concentration tested). Results are summarized below.

Interferant	# of Replicates	Highest Non-interfering Concentration	Glucose Concentration Tested
Bilirubin	3	14.6 mg/dL	157.0 mg/dL
Hemoglobin	3	305 mg/dL	163.3 mg/dL
Intralipid	3	1000 mg/dL	133.7 mg/dL

f. Assay cut-off:
Not applicable.

2. Comparison studies:
   a. Method comparison with predicate device:
   The sponsor performed a method comparison study with the predicate device using clinical samples. The study was performed using 100 samples ranging from 53 to 370 mg/dL for serum and 99 samples from 64 to 546 mg/dL for plasma. Results are summarized below.

Matrix	Deming Regression Equation	Correlation Coefficient
Serum	$y = 0.960x + 3.1$	0.996
Plasma	$y = 0.977x + 0.6$	0.997

3. Clinical studies:
   a. Clinical Sensitivity:
   Not applicable.

b. Clinical specificity:
Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):
Not applicable.

4. Clinical cut-off:
   Not applicable.
5. Expected values/Reference range:
   The reference range for the assay is indicated to be:

   Normal range is reported to be 74-106 mg/dL.

   These values were quoted from the following reference:
   Tietz, N.W., Text Book of Clinical Chemistry, Philadelphia, W.B. Saunders, p.782 (1999).

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.