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

A. 510(k) Number:
k113131

B. Purpose for Submission:
New analyzer for use with previously cleared glucose reagent k080468 and ISE module k080468/k063376

C. Measurand:
Glucose, Potassium, Chloride and Sodium

D. Type of Test:
Quantitative photometric and ion selective electrodes

E. Applicant:
AMS

F. Proprietary and Established Names:
LIASYS 450 SAT 450

G. Regulatory Information:
1. Regulation section:
   21CFR Sec.-862.1345 - Glucose Test System.
   21CFR Sec.-862.1600 - Potassium Test System.
   21CFR Sec.-862.1170 - Chloride Test System.
   21CFR Sec.-862.1665 - Sodium Test System.
   21CFR Sec.-862.2160 - Discrete Photometric Chemistry Analyzer For Clinical Use.
2. Classification:
   Class II and Class I (Analyzer)

3. Product code:
   CFR - Hexokinase, Glucose
   CEM - Electrode, Ion Specific, Potassium
   CGZ - Electrode, Ion-Specific, Chloride
   JGS - Electrode, Ion Specific, Sodium
   JJE - Analyzer, Chemistry (Photometric, Discrete), For Clinical Use

4. Panel:
   Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See indication(s) for use below

2. Indication(s) for use:
The "LIASYS 450 SAT 450" is a random access, computer controlled, counter top, clinical analyzer for clinical chemistry. The instrument provides in vitro quantitative measurements for glucose, sodium, potassium and chloride in serum. Other various chemistry assays are adaptable to this instrument.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia and of pancreatic islet cell carcinoma. Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus and other diseases involving electrolyte imbalance. Measurements of potassium are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

3. Special conditions for use statement(s):
Prescription Use
4. Special instrument requirements:
LIASYS 450 SAT 450

I. **Device Description:**
The LIASYS 450 SAT 450 is a benchtop, fully automatic, random access, open analyzer for clinical and immunoturbidimetric assays.
It communicates with a computer through a USB and/or RS 232 port.
The LIASYS 450 SAT 450 instrument is composed of the following main parts:
- Sampling Arm;
- Diluter;
- Reactions Plate;
- Samples Plate;
- Reagents Plate;
- Photometer;
- Washing Station;
- Electronic Boards.

J. **Substantial Equivalence Information:**
1. Predicate device name(s):

LIASYS Chemistry Analyzer, AMS Glucose Hexokinase and ISE Module

2. Predicate 510(k) number(s):
k080468
3. Comparison with predicate:

Description	Liasys 450/SAT 450	Predicate (k080468)
Indications for Use	The "LIASYS 450 SAT 450" is a random access, computer controlled, counter top, clinical analyzer for clinical chemistry. The instrument provides in vitro quantitative measurements for various chemistry assays.	Same
Analytes	Glucose, Potassium, Chloride and Sodium	Glucose, Urea Nitrogen, Creatinine, Aspartate Amino Transferase, Potassium, Chloride and Sodium
System Principle	Automatic, random access, computer controlled, counter top, non-stop loading clinical chemistry and immunoturbidimetric analysis instrument.	Same
Throughput	450 tests per hour	300 test per hour
Configuration	Analytical Unit & CPU	Same
Optical Measurement		
Measurement Modes	Absorbance	Same
Detector	Photometer: double ray	Same
Optical System	Wavelength range: 340 nm to 680 nm	Wavelength range: 340 nm to 620 nm
Filters	Interferential filters	Same
Linear Absorbance Range	0.0001/4.200 Abs	0.0001/2.500 Abs
Light Source	6V/10W halogen bulb	Same
Data Processing		
Calibration Curve	End point, Fixed Time, Kinetic, Bi-chromatic, Differential and Immunoturbidimetric	Same
Cuvettes	Washable/reusable Reaction Cuvettes	Same
Number of cuvettes	20 cuvettes per segment, four segment total (80 cuvettes)	60 Individually replaceable cuvettes
Cuvette Washing	Consists of 5 probes, which empty, wash and dry the reaction cuvette	Consists of 5 probes, which empty, wash and dry the reaction cuvette
Path Length	6mm	10mm
Cuvette volume	200-450uL	300-670uL
Diluent Volume	3-99 uL	Same

Reagent volume	2-350 uL	3-500 uL
Sample/Reagent Delivery		
Pipetting System	Single probe equipped with: Volume level sensor, pre-heating (37˚C) and automatic probe washing	Same
Sample Dispense	2-99 uL	Same
Reagent Dispense	2-350 uL	181-499 uL
ISE Module	Medica ISE (k063376)	Same

K. Standard/Guidance Document Referenced (if applicable):
   None were referenced.

L. Test Principle:
   The AMS Diagnostics glucose hexokinase method is based on a modification of Slein, using hexokinase and glucose-6-phosphate-dehydrogenase to catalyze the reaction. Glucose is phosphorylated with adenosine triphosphate (ATP) in the reaction catalyzed by hexokinase (HK). The product, glucose-6-phosphate (G6P) is then oxidized with the concomitant reduction of nicotinamide adenine dinucleotide (NAD) to NADH in the reaction catalyzed by glucose-6-phosphate-dehygrogenase (G6PDH). The formation of NADH causes an increase in absorbance at 340 nm. The increase is directly proportional to the amount of glucose in the sample.

   ISE module measures the potentials developed when the sample is positioned in the electrodes. Next, Calibrant A is positioned in the electrodes. The difference in the two potentials is related logarithmically to the concentration of the measured ions in the sample divided by their respective concentrations in the Calibrant solution.

M. Performance Characteristics (if/when applicable):
   1. Analytical performance:
       a. *Precision/Reproducibility:*
          Three levels of serum based chemistry controls were evaluated; the value of one level is in the normal range, the other two levels above or below the normal range. Within Run Precision was performed by running each precision sample twenty times in a single run. Total Run Precision is performed for a minimum of 20 days.

	Level 1	Level 2	Level 3
Glucose Precision:			
Within Run			
Mean (mg/dL)	49.5	91.3	305.1
S.D. (mg/dL)	0.7	1.3	3.4
C.V. (%)	1.4	1.4	1.1
Total			
S.D. (mg/dL)	2.0	2.5	8.1

C.V. (%)	4.1	2.7	2.7

Precision: Na (Sodium)

Within Run	Level 1	Level 2	Level 3
Mean (mmol/L)	112.7	137.9	161.5
S.D.(mmol/L)	1.6	0.4	0.5
C.V. (%)	1.4	0.3	0.3
Total			
S.D.(mmol/L)	1.9	1.2	1.5
C.V. (%)	1.7	0.8	1.0

Precision: K (Potassium)

Within Run	Level 1	Level 2	Level 3
Mean (mmol/L)	2.44	4.31	6.25
S.D.(mmol/L)	0.04	0.02	0.05
C.V. (%)	1.5	0.5	0.9
Total			
S.D.(mmol/L)	0.05	0.05	0.09
C.V. (%)	2.0	1.2	1.5

Precision: CL (Chloride)

Within Run	Level 1	Level 2	Level 3
Mean (mmol/L)	87.9	103.4	161.5
S.D.(mmol/L)	0.2	0.3	0.6
C.V. (%)	0.3	0.3	0.3
Total			
S.D.(mmol/L)	1.0	1.3	1.4
C.V. (%)	1.2	1.3	1.1

b. *Linearity/assay reportable range:*
The assays were evaluated for the result variation difference between test method measurements and that of a known standard over the full range of expected values. The studies were performed using multilevel linearity material run in duplicate with freshly prepared reagents. The linearity sample concentrations included values at the high and low end of reagents' linear ranges. The run included normal, and abnormal control material to evaluate validity of the assay.

Linear Range claimed	Slope	intercept
Glucose 13 to 500 mg/dL	1.023	0.4
Na (Sodium) 24 – 200 mmol/L	1.003	0.1
K (Potassium) 1.1 – 10.0 mmol/L	1.000	0.14
CL (Chloride) 28 – 150 mmol/L	1.006	-0.5

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

Not Applicable

d. *Detection limit:*
The limit of detection for Glucose was determined, first by determining the Level of Blank (LOB) using analyte free samples run 30 times over three days; then the Limit of Detection (LOD) using low analyte samples run 30 times over three days; and then qualifying the LOD to be less then a CV of 20% (4.63) to establish the Level of Quantitation (LOQ)=LOD.

Glucose - Level of Quantitation (LOQ) 12.77 mg/dL
ISE -   Not Applicable using linearity as lower limit of detection

e. *Analytical specificity:*
Studies to determine the level of interference for hemoglobin, bilirubin, and lipemia were carried out, the following results were obtained:
Glucose
*   Hemoglobin: Use fresh unhemolyzed serum removed from the clot as soon as possible. No significant interference (± 10%) from hemoglobin up to 1000 mg/dL.
*   Bilirubin: No significant interference (± 10%) from bilirubin up to 21.7 mg/dL.
*   Lipemia: No significant interference (± 10%) from lipemia up to 407 mg/dL measured as triglycerides.

ISE

No significant interference (± 10% / ± 3 mmol/L) up to the below levels

	Hemolysis	Lipemia	Bilirubin
Na (Sodium)	1000 mg/dL	1084.5 mg/dL	19.3 mg/dL
K (Potassium)	1000 mg/dL	1084.5 mg/dL	21.7 mg/dL
CL (Chloride)	900 mg/dL	1084.5 mg/dL	21.7 mg/dL

A number of drugs and substances may affect the accuracy of these methods. See Young, D.S. et al, Clin. Chem. 21:1D (1975)

f. *Assay cut-off:*
Not Applicable

2. Comparison studies:
a. *Method comparison with predicate device:*
Studies using serum samples were performed between the candidate device and the predicate device yielded the following results:
Glucose
Number of samples pairs: 64
Range Tested: 18-490 (mg/dL)

Correlation Coefficient: 0.9984
Slope: 0.987
Intercept: -0.8 (mg/dL)

Serum Sodium
Number of samples pairs: 63
Range of samples: 35 - ≈ 200(mmol/L)
Correlation Coefficient: 0.9994
Slope: 1.000
Intercept: -1.3 (mmol/L)

Serum Potassium
Number of samples pairs: 62
Range of samples: 1.3 – 9.7 (mmol/L)
Correlation Coefficient: 0.9997
Slope: 1.017
Intercept: -0.11(mmol/L)

Serum Chloride
Number of samples pairs: 63
Range of samples: ≈ 28- 144 (mmol/L)
Correlation Coefficient: 0.9976
Slope: 0.926
Intercept: 6.0 (mmol/L)

    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:
    Glucose   70-105 mg/dL
    Tietz, N.W., Fundamentals of Clinical Chemistry, 2nd ed., W.B. Saunders Co., Philadelphia, p.243, (1976)
    Na (Sodium)   136 – 145 mmol/L
    K (Potassium)   3.5 – 5.1 mmol/L
    CL (Chloride)   98 – 107 mmol/L

Tietz, textbook of Clinical Chemistry 2nd ed, Philadelphia, W.B. Saunders, (1994) pg: 1357, 1360 and 1370

N. Instrument Name:

LIASYS 450 SAT 450 Analyzer

O. System Descriptions:

1. <u>Modes of Operation</u>:

   Random access analyzer

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

   Yes __X__ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

   Yes _____ or No __X__

2. <u>Software</u>:

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

   Yes __X__ or No _____

3. <u>Specimen Identification</u>:

   Worklist and barcode for positive sample identification

4. <u>Specimen Sampling and Handling</u>:

   Four rotating racks with up to 15 sample positions each and four satellite stationary racks with up to 2 sample positions each.

5. <u>Calibration</u>:

   The user can define the mathematical calculation for the test in execution (Factor, Standard, Point-to-Point, Quadratic, Cubic, Quadratic Five Point, Inverse Cubic, Log Logit, Cubic Log Logit)

6. <u>Quality Control</u>:

The analyzer has a built in quality control program. The labeling recommends the use of two external quality control materials to be assayed according to government 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.