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

A. 510(k) Number:
K042189

B. Purpose for Submission:
New Device

C. Analyte:
Sodium
Quality Control Material

D. Type of Test:
Quantitative

E. Applicant:
Diazyme Laboratories

F. Proprietary and Established Names:
Diazyme Sodium Enzymatic Assay and Calibrators
Diazyme Enzymatic Sodium Serum Controls

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1665 Sodium Test System
   21 CFR 862.1150 Calibrators
   21 CFR 862.1660 Quality Control Material
2. Classification:
   Class II
   Class II
   Class I
3. Product Code:
   Diazyme Sodium Enzymatic Assay and Calibrators – MZU and JIT
   Diazyme Enzymatic Sodium Serum Controls - JJX
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   Diazyme Sodium Enzymatic Assay Kit in conjunction with Diazyme Sodium Low and High Calibrators, are intended for the quantitative determination of sodium (NA) in serum.
   Diazyme Sodium Enzymatic Assay Kit contains a low level standard and a high level standard. The standards are used to generate a linear graph that will be used in the calculation of sodium concentrations in unknown serum samples.
   Diazyme Sodium Enzymatic Assay has controls for normal serum sodium level and abnormal serum sodium level. The controls are used as reference samples for checking the functionality of the Diazyme Sodium Enzymatic Assay.

2. Indication(s) for use:
   Diazyme Sodium Enzymatic Assay Kit in conjunction with Diazyme Sodium Low and High Calibrators, are intended for the quantitative determination of sodium (NA) in serum.
   Diazyme Sodium Enzymatic Assay Kit contains a low level standard and a high level standard. The standards are used to generate a linear graph that will be used in the calculation of sodium concentrations in unknown serum samples.
   Diazyme Sodium Enzymatic Assay has controls for normal serum sodium level and abnormal serum sodium level. The controls are used as reference samples for checking the functionality of the Diazyme Sodium Enzymatic Assay.
3. Special condition for use statement(s):
   For Prescription Use Only
4. Special instrument Requirements:
   None Reported

I. Device Description:

The Diazyme Sodium Enzymatic Assay is a spectrophotometric assay intended for the quantitative determination of sodium ion in human serum. The assay includes a high and low calibrator. The assay controls are sold separately. The Diazyme Sodium Enzymatic Assay consists of 4 components that are used in 2 stages (diluent 1 and enzyme 1 form reagent 1 and diluent 2 and substrate 2 form reagent 2). Reagent 1 is first mixed with the serum sample and incubated at 37° for 5 minutes and then reagent 2 is added. Absorbance is read at 405 nm after 3 minutes and again after 2 more additional minutes.

The Diazyme Sodium Enzyme Calibrator set is a bi-level serum calibrator with high (170 mM) and low (120mM) sodium levels. The calibrator is prepared with Tris buffer, pH 7.5 and sodium chloride equivalent to the high or low level calibrator.

The Diazyme Enzymatic Sodium Serum Control kit is sold as a lyophilized bi-level serum control with normal (144 mM) and abnormal (155 mM) sodium levels. The controls are pooled sodium free human serum that were tested and found negative for HIV-1 p24 Ag, HIV 1/11 Ab, HBsAg and HCV using FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Synchron LX I 725 Clinical System
2. Predicate K number(s):
   K023049

3. Comparison with predicate:

Diazyme Sodium Enzyme Calibrator Set

Similarities		
Item	**Device**	**Predicate**
Indications for Use	Diazyme Sodium Enzymatic Assay Kit is for quantitative *in vitro* determination of sodium in human serum.	Synchron LX Systems is used for quantitative *in vitro* determination of sodium in human serum, plasma and urine
Sample	Serum	Serum, Plasma and Urine
Analyte	Sodium	Sodium
Differences		
Item	**Device**	**Predicate**
Test Principle	Sodium is determined enzymatically via sodium dependent b-galactosidase activity with ONPG as a substrate. The absorbance at 405 nm of the product O-nitrophenyl is proportional to the sodium concentration.	Sodium is determined through a microprocessor-based instrument using ion-selective electrodes.
Assay Range	117-200 mmol/L	100 – 200 mmol/L

Diazyme Sodium Enzymatic Calibrators

Similarities		
Item	**Device**	**Predicate**
Indications for Use	The Diazyme Sodium Enzymatic Calibrators is a bi-level calibrator set and is used to used to generate a linear graph that will be used in the calculation of sodium concentrations in unknown serum samples.	Synchron LX Systems is a tri-level calibrator set that is used to used to generate a linear graph that will be used in the calculation of sodium concentrations in unknown serum samples.
Differences		
Item	**Device**	**Predicate**
Stability	Reconstituted stable for 14 days.	Open-Vial for 30 days.

Diazyme Enzymatic Sodium Serum Controls

Similarities		
Item	**Device**	**Predicate**
Indications for Use	Diazyme Sodium Enzymatic Assay has controls for normal serum sodium level and abnormal serum sodium level. The controls are used as reference samples for checking the functionality of the Diazyme Sodium Enzymatic Assay.	Synchron LX Systems is has controls for 2 serum sodium levels. The Controls are used as a reference for checking the functionality of the Synchron LX System.
Analyte	Sodium	Sodium

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

None Referenced

L. Test Principle:

Sodium is measured spectrophotometrically and is determined enzymatically using sodium dependent b-galactosidase activity with ONPG as a substrate. The absorbance at 405 nm of the product O-nitrophenyl is proportional to the sodium concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Two levels of sodium specimens (145 mM and 164 mM) were tested within 20 runs to obtain a %CV of 0.98 and 1.09 respectively. The same levels were tested for precision to obtain a %CV of 1.54 for 145 mM and 1.42 for 164 mM.

The Diazyme Enzymatic Sodium Controls were tested for reproducibility on the Hitachi 917 and Hitachi 717 at two laboratories with serum specimens, 144 mM (low) and 155 mM (high). Site 1 obtained with an average of 146.1 mM and 157.6 mM sodium for the low and high controls respectively. Site 2 obtained an average of 149.1 mM and 161.6 mM for the low and high controls respectively.

b. Linearity/assay reportable range:

Linearity was tested on serum samples spiked with sodium that ranged from 117 to 200 mmol/L. Samples were diluted with distilled water or spiked with sodium chloride to achieve 4 concentration levels. For levels 1 to 3, the equation was $Y = 1.1543x - 20.541$ with a R^2 of 0.9915. For levels 2 to 4, the equation was $Y = 1.0357x - 3.6477$ with a R^2 of 0.9915.

The assay has a linear range from 117 to 200 mM sodium.

c. *Traceability (controls, calibrators, or method):*
The Diazyme Sodium controls are sold separately and are prepared with purchased pooled human sera. The Diazyme Sodium calibrators are included with the Diazyme Sodium Assay and are prepared gravimetrically using commercially available solutions.

Stability
Real time stability was conducted on the Diazyme Enzymatic Sodium Assay kit. The studies conducted support a 7 month stability claim in the lyophilized form and a 21 day stability claim in the reconstitiuted form.
The Diazyme Sodium Enzymatic Calibrators were studied in real time at 4° C and support a 5 months stability claim. There is an ongoing real time study.
The Diazyme Sodium Serum Controls were studied using an accelerated protocol to support a shelf life of 4 months in the lyophilized form and 21 days when reconstituted at 2-8° C.

d. *Detection limit:*
See Linearity Above.

e. *Analytical specificity:*
Interference was tested on cations and substances normally present in serum with the Diazyme Enzymatic Sodium Assay by spiking 140 mM sodium serum samples. The study found less than 10% deviations at the following levels and substances:
1 mM NH_4Cl, 1.5 mM NaPi, 5 mM $CaCl_2$, 200 mM NaCl, 0.25 mM $CuCl_2$, 0.25 $ZnCl_2$, 0.025 mM $FeCl_3$, 5 mM Ascorbic Acid, 5 mM Glucose, and 10 mg/ dl Bilirubin.

f. *Assay cut-off:*
See Linearity Above

2. Comparison studies:
   a. *Method comparison with predicate device:*
   A mixture of clinical serum samples and spiked with sodium to obtain a good distribution across the reportable range were used. Sixty-Six serum samples were tested with both the Diazyme Enzymatic Sodium Assay and the Synchron LX I 725 Clinical System. An equation of $Y = 0.9736X + 4.3832$ was obtained with an R^2 of .9965.
   b. *Matrix comparison:*
   N/A
3. Clinical studies:
   a. *Clinical sensitivity:*
   N/A
   b. *Clinical specificity:*
   N/A
   c. *Other clinical supportive data (when a and b are not applicable):*
   N/A

4. Clinical cut-off:
   N/A
5. Expected values/Reference range:
   Normal sodium serum values range from 136- 146 mmol/l (313-336 mg/dL), as described Tietz 1983 “Clinical Guide to Laboratory Tests”.

N. Conclusion:

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