510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k050283

B. Purpose for Submission:
Notification of intent to introduce into interstate commerce, for commercial distribution, Creatinine LiquiColor® an in vitro diagnostic test for professional use.

C. Measurand:
Creatinine

D. Type of Test:
Enzymatic Method

E. Applicant:
Stanbio Laboratory

F. Proprietary and Established Names:
Classification name – Creatinine Test
Proprietary name – Creatinine LiquiColor®

G. Regulatory Information:
1. Regulation section:
   21 CFR 862.1225 Creatinine test system.

2. Classification:
   Class II

3. Product code:
   JFY

4. Panel:
   75, Chemistry

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

2. Indication(s) for use:
   The Stanbio Creatinine LiquiColor® test system is a device intended for to measure creatinine levels in serum and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine

analytes.

3. Special conditions for use statement(s):
   This is an in vitro diagnostic test for professional use only.

4. Special instrument requirements:
   A minimum of a spectrophotometer capable of absorbance readings at 540nm is required.

I. Device Description:
The Stanbio Creatinine LiquiColor® test system is comprised of two reagents, Reagent 1 (R1) and Reagent 2. To calibrate the test kit, a calibrator is used that has values determined by a similar method.

J. Substantial Equivalence Information:
1. Predicate device name(s):
   Roche Diagnostics Creatinine Reagent

2. Predicate 510(k) number(s):
   k941837

3. Comparison with predicate:

	Stanbio Creatinine LiquiColor	Roche Creatinine
Test Methodology	Enzymatic	Modified Jaffe
Intended Use	For the quantitative determination of Creatinine in serum and urine.	For the quantitative determination of Creatinine in serum, plasma, and urine.
Linearity	Serum : 0.04 to 5.1 mg/dL Urine: 0.04 to 200 mg/dL	Serum/Plasma: 0.7-30 mg/dL Urine: 18 – 200 mg/dL
Wavelength	546 nm	500 nm
Interferences	Ascorbic Acid – up to 2000 mg/dL Hemoglobin – up to 500 mg/dL	Hemoglobin – less than 0.1 mg/dL interference up to 10 g/L Lipemia – a decrease of 0.2 mg/dL was found in serum with 1.5 mg/dL Creatinine when 1000 mg/dL added of Intralipid
Accuracy/Correlation (Serum)	$y = 1.4815x - 0.5831$; $r = 0.9991$	$y = 1.06x + 0.14$; $r = 0.99$
Accuracy/Correlation (Urine)	$y = 1.0545x + 0.3607$; $r = 0.9854$	$y = 0.94x - 0.694$; $r = 0.998$
Storage	2 – 8 °C	15 – 25 °C

K. Standard/Guidance Document Referenced (if applicable):
Linearity was performed based upon the NCCLS guideline EP6-P2:
Evaluation of the Linearity of Quantitative Analytical Methods. Precision was performed based on NCCLS EP5-A2: *Evaluation of Precision Performance of Clinical Chemistry Devices.*

L. Test Principle:
The Stanbio method for Creatinine LiquiColor® employs an enzymatic - colorimetric method.

M. Performance Characteristics (if/when applicable):
1. <u>Analytical performance:</u>
   a. *Precision/Reproducibility:*
   Intra-assay Precision was performed with 20 replicates in a single run on a Hitachi 717 analyzer.

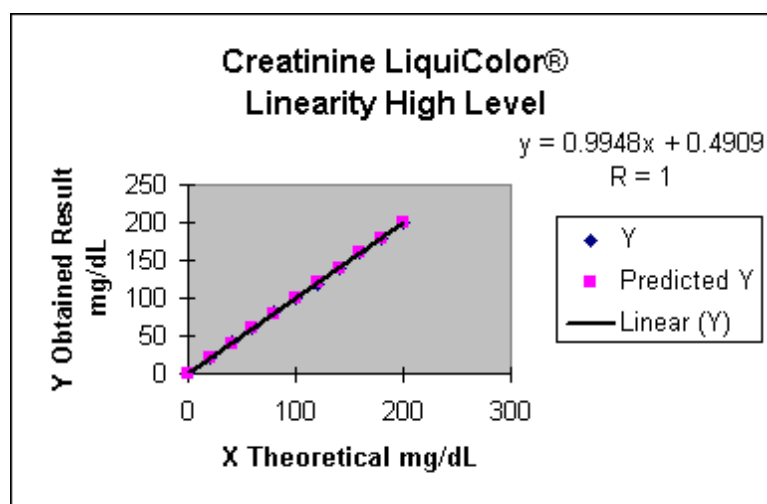| Mean (mg/dL)	SD	CV%
0.610	0.007	1.14
1.107	0.009	0.84
5.733	0.2	0.41

   Inter-assay Precision was performed with duplicate samples in two runs per day for five days on a Hitachi 717 analyzer.

Mean (mg/dL)	SD	CV%
0.629	0.008	1.98
1.134	0.011	0.98
5.814	0.022	0.38

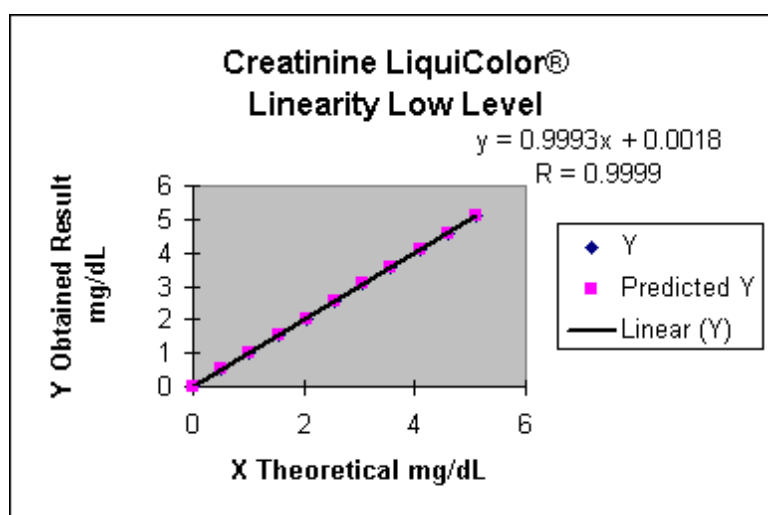   No precision data was submitted for samples with concentrations above 6 mg/dL.

   b. *Linearity/assay reportable range:*
   Linearity studies were performed based upon the guidelines set forth in NCCLS EP6-P2: *Evaluation of the Linearity of Quantitative Analytical Methods.* A high Urine sample was diluted to obtain 10 equally spaced concentrations.

Creatinine LiquiColor®
Linearity High Level

$y = 0.9948x + 0.4909$
$R = 1$

Dilution Step	X Theoretical mg/dL	Y Result mg/dL
0/10	0	0
1/10	20	20.5
2/10	40	40.8
3/10	60	60.5
4/10	80	80.3
5/10	100	99.5
6/10	120	119.5
7/10	140	139.4
8/10	160	160.1
9/10	180	179.8
10/10	200	199.3

A high serum sample was diluted to obtain 10 equally spaced concentrations.

Creatinine LiquiColor®
Linearity Low Level

$y = 0.9993x + 0.0018$
$R = 0.9999$

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Dilution Step	X Theoretical mg/dL	Y Result mg/dL
0/10	0	0.01
1/10	0.51	0.51
2/10	1.02	1.02
3/10	1.53	1.53
4/10	2.04	2.02
5/10	2.55	2.54
6/10	3.06	3.09
7/10	3.57	3.57
8/10	4.08	4.07
9/10	4.59	4.6
10/10	5.1	5.09

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

The stability performance was determined by performing analysis on controls (normal and abnormal levels) over real time for 13 months. (Assigned expiry date of 13 months.)

The control recovery shall be within +/- 10% of the established mean value.

	0 Months mg/dL	3 Months mg/dL	7 Months mg/dL	13 Months mg/dL
Serum Level 1	1.14	1.12	1.10	1.07
Serum Level 2	5.84	5.82	5.87	5.84
Urine Level 1	9.65	9.75	9.94	9.98
Urine Level 2	19.32	19.50	19.85	19.93

Reagent is stabile for 13 months when stored at 2-8 $^{\circ}$C.

Open vial stability was established at two levels (1 and 7 mg/dL), and supports a 30 day open vial stability claim at 2-8 $^{\circ}$C.

d. *Detection limit:*

Deionized water was injected 10 times. Samples were run on a Roche Hitachi 717. A mean was determined and the standard deviation (SD) was calculated. From this determination, a 3 SD was calculated and then this value was added to the mean value. The final calculated value was defined as the lower limit of detection.

The upper range cut off value was determined by looking at the graphical representation of the analyte concentration versus its dilution level. Looking at the graph and observing where the "line" breaks (is non-linear) is the point at which the cut-off is determined.

e. *Analytical specificity:*
Specification – Within ± 10% from the Creatinine result recovered at 0 mg/dL.
Bilirubin Conjugate – no effect up to 32 mg/dL
Bilirubin Free – no effect up to 40 mg/dL
Hemoglobin – No effect up to 500 mg/dL
Ascorbic Acid – no effect up to 200 mg/dL

e. *Assay cut-off:*
Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*
   Serum Creatinine correlation determination of the Stanbio Inc Creatinine(y) and the predicate device (x) was performed by using a combination of 25 clinical samples and 5 spiked samples on a Hitachi 717 analyzer, to obtain the following results y=1.4815x-0.5831 mg/dL, r=0.9991.

   Urine Creatinine correlation determination of the Stanbio Inc Creatinine(y) and the predicate device (x) was performed by using 37 clinical samples on a Hitachi 717 analyzer, to obtain the following results y=1.0545x+0.3607-0.5831 mg/dL, r=0.9854.

   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:
   The normal ranges supplied are derived from Larsen K. *Clin Chem Acta* 41:209, 1972.

   Normal Range: Male (serum): 0.9-1.5 mg/dL
                                    Male Urine: 1000 – 2000 mg/24 hours
                                    Female (serum) 0.7 – 1.4 mg/dL
                                    Female (urine): 600 – 1500 mg/24 hours

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.