

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

**A. 510(k) Number:**

k072140

**B. Purpose for Submission:**

New device

**C. Measurand:**

Urea Nitrogen (BUN), Bilirubin (BIL), and Glucose (GLU)

**D. Type of Test:**

Quantitative

**E. Applicant:**

Alfa Wassermann Diagnostic Technology, Inc.

**F. Proprietary and Established Names:**

S Test Urea Nitrogen (BUN)  
S Test Total Bilirubin (BIL)  
S Test Glucose (GLU)  
S40 Clinical Analyzer

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
CDN - BUN	Class II	21 CFR§ 862.1770	75 Chemistry
JFM - Bilirubin	Class II	21 CFR§ 862.1110	75 Chemistry
CFR - Glucose	Class II	21 CFR§ 862.1345	75 Chemistry
JJE – Discrete photometric chemistry analyzer for clinical use	Class I	21 CFR§ 862.2160	75 Chemistry

**H. Intended Use:**

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The S40 Clinical Analyzer is an automatic wet chemistry system intended for use in clinical laboratories or physician office laboratories that consists of a desktop analyzer, an operation screen that prompts the user for operation input and displays data, a unit cover, and disposable reagent cartridges. The desktop analyzer includes a single pipettor, an incubation rotor, and a multi-wavelength photometer.

The S-Test Blood Urea Nitrogen Reagent is intended for the quantitative determination of urea nitrogen in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of Urea Nitrogen are used in the diagnosis and treatment of certain renal and metabolic diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

The S-Test Total Bilirubin Reagent is intended for the quantitative determination of bilirubin in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

The S-Test Glucose Reagent is intended for the quantitative determination of glucose in serum or heparin plasma using the S40 Clinical Analyzer. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

S40 Clinical Analyzer

## **I. Device Description:**

The S40 Clinical Analyzer is an automatic wet chemistry system intended for use in clinical laboratories or physician office laboratories that consists of a desktop analyzer, an operation screen that prompts the user for operation input and displays data, a unit cover, and disposable reagent cartridges. The desktop analyzer includes a single pipettor, an incubation, and a multi-wavelength photometer.

The S-Test Total Bilirubin Reagent measures bilirubin, a product of hemoglobin degradation in the cells of the reticuloendothelial system. The bilirubin formed is transported to the liver where it is conjugated with glucuronic acid and secreted in the bile. Total serum bilirubin is the sum of unconjugated (free or indirect) and conjugated (direct) bilirubin. Total bilirubin levels are measured using the enzyme bilirubin oxidase.

The S-Test BUN Reagent measures urea, the most common nitrogen containing end-product of protein catabolism, normally excreted rapidly by the kidneys. The test uses the enzyme urease (urea amidohydrolase) to break down urea into ammonia and carbon dioxide, followed by analysis for NADPH.

The S-Test Glucose Reagent measures glucose. Glucose is the transport form of carbohydrate in the body and is used by all cells as a source of energy. The S40 Assay is an enzymatic method analyzing the resulting level of NADPH.

## **J. Substantial Equivalence Information:**

1. Predicate device name(s):

ACE plus ISE/Clinical Chemistry System, Alfa Wassermann

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

k930104

3. Comparison with predicate:

BUN (BUN):

The device and the predicate devices share a similar intended use, analytes measured, test principle, reaction type and sample type.

Differences		
Item	S40 Clinical Analyzer S Test BUN Reagent	ACE plus ISE Clinical Chemistry System
Sample Volume	12 µL	3 µL
Measuring Range	4.9-75 mg/dL	0-100 mg/dL
Detection Limit	4.9 mg/dL	0 mg/dL

Bilirubin (BIL):

The device and the predicate devices share a similar intended use, analytes measured, test principle, reaction type and sample type.

Differences		
Item	S40 Clinical Analyzer S Test CRP Reagent	ACE plus ISE Clinical Chemistry System
Sample Volume	12 µL	20 µL
Measuring Range	0.2-33.6 mg/dL	0-40.0 mg/dL
Detection Limit	0.2 mg/dL	0 mg/dL

Glucose (GLU):

The device and the predicate devices share a similar intended use, analytes measured, test principle, reaction type and sample type.

Differences		
Item	S40 Clinical Analyzer S Test CRP Reagent	ACE plus ISE Clinical Chemistry System
Sample Volume	5 µL	3 µL
Measuring Range	18-463 mg/dL	1-750 mg/dL
Detection Limit	18 mg/dL	1 mg/dL

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

CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition (2004)

CLSI EP10-A: Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline –Second Edition (2002)

CLSI EP6-A: Evaluation of Linearity of Quantitative Measurement Procedures, A Statistical Approach: Approved Guideline (2003)

CLSI EP7-A: Interference Testing in Clinical Chemistry; Approved Guideline (2002)

CLSI EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline (2004)

LSI EP9-A2: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (2002)

CLSI C28-A2: How to Define and Determine Reference Intervals in the Clinical

#### **L. Test Principle:**

S Test BUN - In the presence of urease, urea in serum is hydrolyzed to yield ammonia (NH<sub>3</sub>) and carbon dioxide (CO<sub>2</sub>). The ammonia formed then reacts with  $\alpha$ -ketoglutaric acid and NADPH in the presence of glutamate dehydrogenase (GLDH) to yield glutamic acid and NADP. The rate of decrease in absorbance of NADPH, monitored bichromatically at 340 nm/405 nm, is directly proportional to the concentration of urea in the sample.

S Test BIL - Total bilirubin in the sample is oxidized into biliverdine by the action of bilirubin oxidase (BOD) at pH 7-8, which causes the absorbance at 450 nm to decrease. The total bilirubin concentration in the sample is determined by measuring this absorbance decrease. The rate of decrease in absorbance, monitored bichromatically at 450 nm/546 nm, is directly proportional to the amount of bilirubin in the sample.

S Test GLU - Glucose in serum reacts with adenosine triphosphate (ATP) in the presence of hexokinase (HK) and magnesium with the formation of glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) catalyzes the oxidation of glucose-6-phosphate with NADP to form 6-phosphogluconate and NADPH. NADPH absorbs strongly at 340 nm, whereas NADP does not. The total amount of NADPH formed is proportional to the initial amount of glucose present. The rate of increase in absorbance, monitored bichromatically at 340 nm/450 nm, is directly proportional to the glucose concentration in the sample.

#### **M. Performance Characteristics (if/when applicable):**

##### **1. Analytical performance:**

###### ***a. Precision/Reproducibility:***

###### **BUN**

In-house precision studies were conducted by testing human serum pools at three levels. The samples were run three times a day five days using one instrument. The three levels were assayed 2 times per run, 2 runs per day, for a total of 22 days. Results are summarized below.

<u>Sample 1</u> Mean = 14.0 mg/dL BUN	Within Run	Between Run	Between Day	Total
Coefficient of Variation	2.3%	5.9%	0.0%	6.4%

<u>Sample 2</u> Mean = 39.1 mg/dL BUN	Within Run	Between Run	Between Day	Total
Coefficient of Variation	2.2%	5.9%	2.1%	6.6%

<u>Sample 3</u> Mean = 67.4 mg/dL BUN	Within Run	Between Run	Between Day	Total
Coefficient of Variation	1.2%	5.6%	2.4%	6.2%

Precision studies were also conducted at three Physician Office Laboratories (POL) with four trained operators typically found in these settings. Human serum pools at three concentrations were tested three times a day for five days on four instruments (one at each lab). The results are presented below:

Lab	Sample	Mean	%CV	
			Within-Run	Total
In-House	1	13.6	2.5%	2.5%
POL 1	1	13.9	1.9%	1.8%
POL 2	1	14.5	0.7%	0.9%
POL 3	1	14.4	2.1%	2.4%
In-House	2	39.3	2.0%	2.3%
POL 1	2	40.9	1.4%	1.4%
POL 2	2	42.3	0.7%	1.0%
POL 3	2	41.8	1.2%	1.4%
In-House	3	64.2	1.2%	1.5%
POL 1	3	66.4	0.8%	1.1%
POL 2	3	68.3	1.1%	1.3%
POL 3	3	67.9	1.1%	1.3%

#### BIL

In-house precision studies were conducted by testing human serum pools at three levels. The samples were run three times a day five days using one instrument. The three levels were assayed 2 times per run, 2 runs per day, for a total of 22 days. Results are summarized below.

<u>Sample 1</u> Mean = 0.5 mg/dL Bilirubin	Within Run	Between Run	Between Day	Total
Coefficient of Variation	10.7%	7.9%	1.0%	13.3%

<u>Sample 2</u> Mean = 2.6 mg/dL Bilirubin	Within Run	Between Run	Between Day	Total
Coefficient of Variation	2.0%	3.8%	3.0%	5.2%

<u>Sample 3</u> Mean = 6.3 mg/dL Bilirubin	Within Run	Between Run	Between Day	Total
Coefficient of Variation	0.9%	3.6%	3.6%	5.2%

Precision studies were also conducted at three Physician Office Laboratories (POL) with four trained operators typically found in these settings. Human serum pools at three concentrations were tested three times a day for five days on four instruments (one at each lab). The results are presented below:

Lab	Sample	Mean	%CV	
			Within-Run	Total
In-House	1	0.6	10.4%	10.4%
POL 1	1	0.6	6.2%	6.2%
POL 2	1	0.6	7.0%	8.0%
POL 3	1	0.6	0.0%	0.0%
In-House	2	3.3	1.8%	1.7%
POL 1	2	3.4	0.9%	0.8%
POL 2	2	3.3	1.8%	1.9%
POL 3	2	3.4	1.5%	2.0%
In-House	3	23.9	1.1%	1.1%
POL 1	3	24.2	0.9%	1.1%
POL 2	3	24.1	1.2%	1.9%
POL 3	3	24.2	1.1%	2.5%



### GLU

In-house precision studies were conducted by testing human serum pools at three levels. The samples were run three times a day five days using one instrument. The three levels were assayed 2 times per run, 2 runs per day, for a total of 22 days. Results are summarized below.

<u>Sample 1</u> Mean = 62 mg/dL Glucose	Within Run	Between Run	Between Day	Total
Coefficient of Variation	1.6%	6.4%	0.0%	6.6%

<u>Sample 2</u> Mean = 122 mg/dL Glucose	Within Run	Between Run	Between Day	Total
Coefficient of Variation	1.8%	5.0%	2.5%	5.8%

<u>Sample 3</u> Mean = 372 mg/dL Glucose	Within Run	Between Run	Between Day	Total
Coefficient of Variation	1.4%	5.5%	1.2%	5.8%

Precision studies were also conducted at three Physician Office Laboratories (POL) with four trained operators typically found in these settings. Human serum pools at three concentrations were tested three times a day for five days on four instruments (one at each lab). The results are presented below:

Lab	Sample	Mean	%CV	
			Within-Run	Total
In-House	1	84	2.3%	3.0%
POL 1	1	86	2.9%	3.4%
POL 2	1	83	1.5%	1.5%
POL 3	1	88	1.3%	1.4%
In-House	2	231	1.6%	2.4%
POL 1	2	239	1.4%	2.2%
POL 2	2	232	2.0%	2.0%
POL 3	2	241	1.1%	1.3%
In-House	3	419	1.5%	1.7%
POL 1	3	436	1.3%	1.3%
POL 2	3	428	1.5%	1.5%
POL 3	3	444	1.3%	1.5%

*b. Linearity/assay reportable range:*

BUN

The reportable ranges are 4.9 to 75.7 mg/dL for BUN, 0.2 to 26.6 mg/dL for BIL, and 18 to 472 mg/dL for GLU. This range is supported by the limit of detection study (section M.1.d below), the method comparison (section M.2.a below), and the linearity shown below.

Linearity across the assay range was confirmed by testing commercial linearity standards, 6-8 levels each with known commercial concentrations of BUN, BIL, GLU. The assigned value of the highest sample was set to its mean value. The assigned values of the other levels were calculated by multiplying the mean value by the ratios obtained from the manufacturer. Each level was tested in replicates of four. Results are presented below:

<b>BUN</b>			
Sample	Assigned Value mg/dL	Measured Value mg/dL	% Recovery
1	5.00	5.00	100%
2	25.20	24.75	98%
3	50.50	47.83	95%
4	75.70	75.70	100%
Linear Regression: $y = 0.9914x - 0.446$ , $r^2 = 0.9974$			

<b>BIL</b>			
Sample	Assigned Value mg/dL	Measured Value mg/dL	% Recovery
1	0.3	0.3	100%
2	1.2	1.3	108%
3	2.2	2.2	100%
4	4.5	4.5	100%
5	6.6	6.7	102%
6	11.1	11.4	103%
7	17.7	18.2	103%
8	26.6	26.6	100%
Linear Regression: $y = 1.006x + 0.054$ , $r^2 = 0.9994$			

<b>GLU</b>			
Sample	Assigned Value mg/dL	Measured Value mg/dL	% Recovery
1	26	26	100%
2	66	67	102%
3	105	108	103%
4	184	183	99%
5	262	266	102%
6	451	442	98%
7	472	472	100%
Linear Regression: $y = 0.988x + 2.3$ , $r^2 = 0.9992$			

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

The S Test BUN cartridges are factory calibrated and traceable to the NIST standard reference material SRM912a.

The S Test BIL cartridges are factory calibrated and traceable to the NIST standard reference material SRM916a.

The S Test GLU cartridges are factory calibrated and traceable to the NIST standard reference material SRM917a.

The 2-D barcode printed on each cartridge provides the analyzer with lot-specific calibration data.

Real time stability studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. When stored at 2-8 °C the assay reagent is stable until the expiration date.

*d. Detection limit:*

The Limit of Blank and Limit of Detection was determined for each analyte by running a low sample and true blank sample for 3 days, 20 replicates/day for a total of 60 results. The testing was split between two instruments. The limits of detection are 4.9 mg/dL BUN, 0.2 mg/dL BIL, and 18 mg/dL GLU.

*e. Analytical specificity:*

Interference studies to determine the effects of Unconjugated Bilirubin, Hemolysis and Lipemia were performed. The sponsor states that interference is considered to be significant if the analyte recovery changes by more than 10%.

BUN

Assay performance claims have been established on the S40 Clinical Analyzer by testing a serum pool containing approximately 19 mg/dL BUN to the following concentrations of each interferent: Unconjugated Bilirubin - 50 mg/dL; Hemolysis - 1000 mg/dL; Lipemia (Intralipid) - 2000 mg/dL.

Bilirubin: No significant interference to 25 mg/dL. Positive interference (>75 mg/dL BUN result) at 50 mg/dL.

Hemolysis: Positive interference (~11-13%) at 31, 63, 125 and 250 mg/dL. Any level of hemolysis may cause interference. Do not use hemolyzed specimens.

Lipemia (Intralipid): No significant interference was observed.

BIL

Assay performance claims have been established on the S40 Clinical Analyzer by testing a serum pool containing approximately 0.6 mg/dL bilirubin to the following concentrations of each interferent: Hemolysis - 1000 mg/dL; Triglycerides (Intralipid) - 2000 mg/dL.

Hemolysis: Positive interference ( $\geq 50\%$ ) occurred at 125 mg/dL and above.

Lipemia (Intralipid): Positive interference (>58%) occurred at 500 mg/dL and above.

GLU

Assay performance claims have been established on the S40 Clinical Analyzer by testing a serum pool containing approximately 85 mg/dL glucose to the

following concentrations of each interferent: Bilirubin - 50 mg/dL; Hemolysis - 1000 mg/dL; Triglycerides (Intralipid) - 2000 mg/dL.

Bilirubin: No significant interference was observed.

Hemolysis: No significant interference at 125, 250, 500 and 1000 mg/dL. Positive interference (~22%) at 31 mg/dL and (~12%) at 63 mg/dL. Any level of hemolysis may cause interference. Do not use hemolyzed specimens.

Lipemia (Intralipid): No significant interference up to 1000 mg/dL. Negative interference (~16%) at 2000 mg/dL.

*f. Assay cut-off:*

Not applicable

## 2. Comparison studies:

*a. Method comparison with predicate device:*

### BUN

A series of 94 serum specimens with BUN values ranging from 6 to 70 mg/dL were assayed on the S40 Clinical Analyzer using S-Test BUN Reagent and the ACE Clinical Chemistry System as the reference method. Least-squares regression analysis (Deming) yielded the following results:

Regression Equation	$y = 1.009x + 0.91$
Correlation Coefficient	0.9973
Std. Error Est.	0.9
Confidence Interval Slope	0.979 to 1.040
Confidence Interval Intercept	0.34 to 1.47

Further studies were done in four separate POL sites. These studies were conducted by personnel without formal medical technology education. The studies consisted of running 50 or more serum samples with varying levels of BUN in singlicate on the S40 Clinical Analyzer and the ACE Clinical Chemistry System, with the following linear regression data:

Lab	n	Range	Regression Equation	Correlation Coefficient	Standard Error	Confidence Interval Slope	Confidence Interval Intercept
A	54	6-72	$y = 0.989x - 1.47$	0.9965	1.30	0.996 to 1.012	-2.11 to -0.83
B	50	6-74	$y = 0.948x + 0.32$	0.9955	1.83	0.922 to 0.974	-0.66 to 1.30
C	54	6-73	$y = 0.964x - 0.18$	0.9961	1.36	0.940 to 0.987	-0.88 to 0.51
D	54	6-73	$y = 0.965x + 0.29$	0.9973	1.11	0.945 to 0.985	-0.22 to 0.80

### BIL

A series of 91 heparin plasma specimens with bilirubin values ranging from 0.2 to 23.9 mg/dL were assayed on the S40 Clinical Analyzer using S-Test BIL Reagent and the Olympus AU640 as the reference method. Least-squares regression analysis (Deming) yielded the following results:

Regression Equation	$y = 1.044x + 0.07$
Correlation Coefficient	0.9955
Std. Error Est.	0.5
Confidence Interval Slope	0.963 to 1.125
Confidence Interval Intercept	0.00 to 0.15

Further studies were done in three separate POL sites. These studies were conducted by personnel without formal medical technology education. The studies consisted of running 83 or more samples (the same samples were run at all sites) with varying levels of bilirubin in singlicate on the S40 Clinical Analyzer and a comparison method, with the following linear regression data:

Lab	n	Range	Regression Equation	Correlation Coefficient	Standard Error	Confidence Interval Slope	Confidence Interval Intercept
A	87	0.2-27.4	$y = 0.940x + 0.14$	0.9976	0.48	0.926 to 0.954	0.02 to 0.26
B	87	0.2-27.4	$y = 0.956x + 0.17$	0.9972	0.53	0.941 to 0.972	0.03 to 0.30
C	83	0.2-26.7	$y = 0.965x + 0.15$	0.9974	0.49	0.950 to 0.981	0.02 to 0.27

### GLU

A series of 97 serum specimens with GLU values ranging from 26 to 454 mg/dL were assayed in singlicate on the S40 Clinical Analyzer using S-Test GLU Reagent and the ACE Clinical Chemistry System as the reference method. Least-squares regression analysis (Deming) yielded the following results:

Regression Equation	$y = 1.033x - 6.11$
Correlation Coefficient	0.9964
Std. Error Est.	7.4
Confidence Interval Slope	0.994 to 1.073
Confidence Interval Intercept	-10.3 to -1.87

Further studies were done in four separate POL sites. These studies were conducted by personnel without formal medical technology education. The studies consisted of running 56 or more serum samples with varying levels of glucose in singlicate on the S40 Clinical Analyzer and the ACE Clinical Chemistry System, with the following linear regression data:

Lab	n	Range	Regression Equation	Correlation Coefficient	Standard Error	Confidence Interval Slope	Confidence Interval Intercept
A	54	19-413	$y = 1.082x - 11.6$	0.9951	11.4	1.052 to 1.111	-16.9 to -6.3
B	55	19-413	$y = 1.078x - 11.0$	0.9975	7.7	1.058 to 1.099	-14.9 to -7.1
C	54	19-413	$y = 1.100x - 12.8$	0.9962	9.4	1.073 to 1.126	-17.1 to -8.4
D	55	19-413	$y = 1.089x - 10.0$	0.9891	16.0	1.044 to 1.133	-17.5 to -2.6

*b. Matrix comparison:*

BUN

A study was performed on the S40 by running 25 BUN determinations in singlicate on paired samples drawn from the same patients in serum and heparin plasma tubes. The serum results ranged from 9.5 to 71.5 mg/dL. Least-squares regression analysis (Deming) yielded the following results:

Regression Equation	$y = 1.003x + 0.15$
Correlation Coefficient	0.9972
Std. Error Est.	1.54
Confidence Interval Slope	0.970 to 1.035
Confidence Interval Intercept	-1.06 to 1.36

BIL

A study was performed on the S40 by running 34 bilirubin determinations in singlicate on paired samples drawn from the same patients in serum and heparin plasma tubes. Bilirubin was added to eleven of these samples immediately after they were drawn. The serum results ranged from 0.3 to 24.5 mg/dL. Least-squares regression analysis (Deming) yielded the following results:



Regression Equation	$y = 0.995x - 0.02$
Correlation Coefficient	0.9992
Std. Error Est.	0.30
Confidence Interval Slope	0.980 to 1.009
Confidence Interval Intercept	-0.15 to 0.10

### GLU

A study was performed on the S40 by running 29 glucose determinations in singlicate on paired samples drawn from the same patients in serum and heparin plasma tubes. Glucose was added to five of these samples immediately after they were drawn. The serum results ranged from 25 to 417 mg/dL. Least-squares regression analysis (Deming) yielded the following results:

Regression Equation	$y = 0.995x - 0.2$
Correlation Coefficient	0.9967
Std. Error Est.	7.1
Confidence Interval Slope	0.963 to 1.027
Confidence Interval Intercept	-6.5 to 6.0

### 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:

BUN: 7-25 mg/dL at 37°C<sup>1</sup>

BIL: 0.2 – 1.0 mg/dL at 37°C<sup>2</sup>

GLU: 70 – 105 mg/dL for fasting patients<sup>2</sup>

<sup>1</sup>Determined by transferred ranges in accordance with How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline-Second Edition (2000), CLSI/NCCLS, C28-A2, Section 8.2: Transference and Validation. Ranges transferred from the predicate device (k930104).

<sup>2</sup>Above referenced from: Tietz, N.W. (Ed.), *Clinical Guide to Laboratory Tests*, 3rd Edition, W.B. Saunders Co., Philadelphia, PA (1995).

**N. Instrument Name:**

S40 Clinical Analyzer

**O. System Descriptions:**

1. Modes of Operation:

This instrument is capable of testing several assays via self-contained reagent cartridges. The instrument identifies the assay through reading a 2D bar code on the cartridges.

2. Software:

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

Yes   X   or No           

3. Specimen Identification:

Samples are identified as serum, plasma, and urine based on their location in the instrument.

4. Specimen Sampling and Handling:

This instrument is capable of testing serum, plasma, and urine samples. The type of sample that can be used for each assay is indicated in the assay's product labeling.

5. Calibration:

Each lot of S Test cartridges is calibrated by the manufacturer prior to shipment using traceable material (see section M.1.c above). A 2-D barcode printed on each cartridge provides the analyzer with lot-specific calibration data.

6. Quality Control:

The sponsor recommends the use of two levels of controls (one normal and one abnormal) be tested in accordance with federal, state and local regulatory requirements for quality control practices.

**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.