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

A. 510(k) Number:

k072143

B. Purpose for Submission:

New device

C. Measurand:

Albumin (ALB)

D. Type of Test:

Quantitative

E. Applicant:

Alfa Wassermann Diagnostic Technology, Inc.

F. Proprietary and Established Names:

S Test Albumin (ALB) Reagent cartridge

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CIX – Albumin	Class II	21 CFR§ 862.1035	75 Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:

   The S-Test Albumin Reagent is intended for the quantitative determination of albumin concentration in serum or heparin plasma using the S40 Clinical Analyzer. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys. 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 S-Test albumin (ALB) reagent cartridge used with the S40 Clinical Analyzer is intended for quantitative in vitro diagnostic determination of ALB in serum or heparin plasma based on a photometric test measuring the formation of a bluish-green complex from ALB and bromcresol green. It is composed of a bi-reagent cartridge, and is intended for use in clinical laboratories or physician office laboratories.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACE plus ISE/Clinical Chemistry System, Alfa Wassermann
   Olympus AU640 Clinical Chemistry Analyzer, Olympus
   Piccolo xpress Chemistry Analyzer, Abaxis Inc.

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

   Albumin: k930104 (ACE), k924368 (AU640), k942782 (Piccolo)

3. Comparison with predicate:

   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 ALP Reagent	ACE plus ISE Clinical Chemistry System
Sample Volume	5 µL	3 µL
Measuring Range	0.4-7.1 g/dL	0.1-7.0 g/dL
Detection Limit	0.4 g/dL	0.1 g/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 Laboratory; Approved Guideline-Second Edition (2000), Section 8.2: Transference and Validation

L. Test Principle:

S Test ALB – Bromcresol green (BCG) in solution binds specifically to albumin to form a green colored complex which is measured bichromatically at 660 nm/ 700 nm. The rate of increase in absorbance is directly proportional to the albumin activity in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Three serum samples (with normal, intermediate and elevated levels) were tested for albumin on two S40 Clinical Analyzers two times per run, two runs per day, for a total of 22 days. The mean, standard deviations, and % coefficients of variation (CV) were calculated for each sample.

Sample 1 Mean = 2.3 g/dL ALB	Within Run	Between Run	Between Day	Total
Coefficient of Variation	1.8%	4.7%	2.5%	5.6%

Sample 2 Mean = 3.3 g/dL ALB	Within Run	Between Run	Between Day	Total
Coefficient of Variation	2.0%	4.1%	1.0%	4.7%

Sample 3 Mean = 3.9 g/dL ALB	Within Run	Between Run	Between Day	Total
Coefficient of Variation	1.9%	3.2%	3.6%	5.2%

In-house precision studies were conducted by testing human serum pools at three levels. The samples were run three times a day for five days using one instrument. 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	%CV Total
In-House	1	2	2.5%	2.8%
POL 1	1	2.2	1.8%	2.1%
POL 2	1	2.2	2.3%	2.3%
POL 3	1	2.4	2.2%	2.2%
In-House	2	4	1.5%	2.0%
POL 1	2	4.3	1.4%	1.5%
POL 2	2	4.4	1.4%	1.3%
POL 3	2	4.6	0.9%	1.0%
In-House	3	6.1	1.8%	1.8%
POL 1	3	6.6	1.1%	1.1%
POL 2	3	6.7	1.1%	1.0%
POL 3	3	6.9	1.0%	1.1%

b. *Linearity/assay reportable range:*

The reportable range is 0.4 to 7.1 g/dL for albumin. 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 study shown below.

Linearity across the assay range was confirmed by testing commercial linearity standards, 7 levels each with known commercial concentrations of

albumin. Each level was tested in replicates of four. Results are presented below:

Albumin			
Sample	Assigned Value g/dL	Measured Value g/dL	% Recovery
1	0.89	1.00	112%
2	1.78	1.80	101%
3	2.85	3.18	112%
4	3.92	4.28	109%
5	4.99	5.30	106%
6	6.06	6.10	101%
7	7.13	7.13	100%
Linear Regression: $y = 0.989x + 0.210$, $r^2 = 0.9950$			

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

The S Test ALB cartridges are factory calibrated and traceable to the NIST standard reference material SRM927d. 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 ºC the assay reagent is good until the expiration date.

d. *Detection limit:*

The Limit of Detection was determined 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 limit of detection for albumin is 0.4 g/dL.

e. *Analytical specificity:*

Interference studies to determine the effects of Unconjugated Bilirubin, Hemolysis and Lipemia were performed. Seven serum pool containing approximately 4.0 g/dl albumin were spiked with varies concentrations of unconjugated bilirubin (1.6-50 mg/dL), hemoglobin (31-1000 mg/dL) and Intralipids (63-2000 mg/dl). Sponsor states that interference is considered to be significant if the analyte recovery changes by more than 10%.

There was no significant interference (no change greater than 10%) from bilirubin or lipemia at the tested concentrations. Hemolysis showed a positive interference (~11%) at 1000 mg/dL.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Clinical correlation studies were performed comparing the S-Test ALB generated on the S40 Clinical analyzer against the results from the ACE Clinical analyzer.

A series of 92 serum specimens with albumin values ranging from 0.7 to 6.8 g/dL were assayed on the S40 Clinical Analyzer using S-Test ALB Reagent and the ACE Clinical Chemistry System as the reference method. Least-squares regression analysis (Deming) yielded the following results:

Regression Equation	y = 0.927x + 0.28
Correlation Coefficient	0.9605
Std. Error Est.	0.24
Confidence Interval Slope	0.873 to 0.982
Confidence Interval Intercept	0.05 to 0.51

Point of Care

Performance for the S Test ALB was evaluated at four Physician Office Laboratories and with a total of four operators. Operators ran unaltered clinical serum samples obtained from each site. The S Test ALB test results were compared to the ACE results. All operators had experience running chemistry instruments. The correlation study between the device and the predicate for serum yielded the following results.

		n	Slope	Intercept	Correlation	Range
	Lab A	56	0.998	-0.08	0.9927	0.5-6.8 mg/dL
ALB	Lab B	56	1.01	-0.07	0.9943	0.5-6.8 mg/dL
	Lab C	55	1	–0.10	0.9899	0.5-6.8 mg/dL
	Lab D	56	0.985	-0.09	0.9874	0.5-6.8 mg/dL

b. *Matrix comparison:*

A study was performed on the S40 by running 33 albumin determinations on paired samples drawn from the same patients in serum and heparin plasma tubes. Albumin was added to six of these samples immediately after they were drawn. Three paired serum/plasma samples were also diluted with saline. The

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serum results ranged from 0.8 to 6.4 g/dL. Least-squares regression analysis (Deming) yielded the following results (serum - x, plasma - y):

Regression Equation	y = 0.981x + 0.06
Correlation Coefficient	0.9944
Std. Error Est.	0.12
Confidence Interval Slope	0.942 to 1.019
Confidence Interval Intercept	-0.09 to 0.21

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:

   Albumin: 3.5 – 5.0 g/dL
   Referenced from: Tietz, N.W. (Ed.), Clinical Guide to Laboratory Tests, 3rd Edition, W.B. Saunders Co., Philadelphia, PA (1995). This range was confirmed with 82 normal serum samples.

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.