510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k052794

B. Purpose for Submission:
New Device

C. Manufacturer and Instrument Name:
DiaSorin Inc.
DiaSorin ETI-MAX 3000™

D. Type of Test or Tests Performed:
For qualitative and semi-quantitative assays. The instrument performance was validated using three 510(k) cleared devices (ENA Screen, ANA Screen and Anti-SS-A (Ro) from Euro-Diagnostica).

E. System Descriptions:

1. Device Description:
   The ETI-MAX 3000™ is a fully automated, EIA microtiter plate laboratory analyzer performing the complete sample processing (barcode scanner, predilution station, pipetting station, plate transport, wash station, incubators and photometric measurement). The instrument is controlled by the Windows PC software ETI-MAX 3000™. This software allows the user to process the pre-defined assays of DiaSorin.

   The ETI-MAX 3000™ consists of 3 main components; sample processing, management system and software.

   The sample processing system automates the steps required to process microplate assays from barcode reading, sample distribution, sample dilution, incubation, washing, reagent addition and detection using absorbance technology. The plate loading is managed with time scheduling, the plate capacity is 4, but can be up to 7 in continuous loading mode. There is also the capability to run multiple assays per plate.

   The management system (computer) is a Pentium III, 500MHz, 64 Mbytes RAM or equivalent with a 3.5" Floppy drive, a 6.4 Gbyte Hard Disk, an Alphanumeric keyboard, standard Mouse, 15" color monitor, and Standard Inkjet printer.

   The software (Operating system) uses Microsoft Windows® 95, 98 or 2000 32-bit application, for all operations, including assay creation and worklist generation, time scheduling, data reduction and reporting of results, and has multi-language capabilities. The software also provides in-process control, validation and verification.

2. Principles of Operation:
   The ETI MAX and its predicate devices share the same principle of operation. The device consists of pipetting, washing and incubation station and uses the same basic technology to provide specimen pipetting and dilution, reagent pipetting, microplate washing and incubation.

The instrument is programmed to mimic the steps of the manual assay procedures for EIA/ELISA microtiter plate assays.

3. Modes of Operation:
    The ETI-MAX 3000™ Analyzer is an open tube, batch mode analyzer with a continuous load option. The reagent bottles used from the test kit are placed on the instrument with the caps removed. The sample tubes can be the primary tubes with stoppers removed or the serum/plasma can be poured off into identified test tubes.

4. Specimen Identification:
    There are multiple ways to identify the patient. Each ETI-MAX 3000™ sample rack holds 20 patient specimens. The sample rack has a barcode label at each position which identifies the rack and the unique sample position (1-20). There are 12 spaces (channels) numbered 1-12 which holds 1 sample rack each. The samples are placed in the rack and then put onto the instrument where the barcode scanner reads the barcodes on the rack.
    1. The customer can use patient barcode identifiers if so desired. Patients are placed into samples racks, put on the instrument and the barcode scanner scans the rack, the rack barcode identifiers and the patient sample barcode identifier in each position.
    2. LIS system – patient ID's and test requests can be sent to the instrument through the lab LIS.
    3. Manual identification
        Patient names/ID's can be entered via Patient Editor

    The ETI-MAX 3000™ Analyzer can be set to pipette the samples in ascending order, descending order or None (no order).
    -Ascending order – the samples will be pipetted in ascending order whether they are in the same rack or spread throughout several racks.
    -Descending order – the samples will be pipetted in descending order whether they are the same rack or spread throughout several racks.
    -None – if this option is selected, the instrument will pipette the all the samples in positions 1-20, starting in channel 12 (which is always the 1st position loaded) then once all the samples are pipetted in that rack, it will move to the next rack (channel 11) and pipette those samples (1-20).

5. Specimen Sampling and Handling:
    The DiaSorin assays programmed on the ETI-MAX 3000™ do not use whole blood. All the DiaSorin assays use either serum or plasma as the sample type. Samples can be loaded onto the instrument in their primary tubes, or they can be poured off into test tubes ranging in size from 10 -16 mm in diameter.

    If a dilution step is required, the instrument dispenses sample into the specimen diluent. Once this is completed the samples is then aspirated and dispensed into

the dilution tube a couple of times to ensure a good mixing of the sample and diluent.

The ETI-MAX 3000™ also performs a shaking of the microtiter plate once the specimens and reagents are added to the wells.

The operator is responsible for placing samples in the sample racks and loading or unloading the racks from the ETI-MAX 3000™ analyzer.

6. Calibration:
Each of the instrument modules require calibration. The calibration procedure is described in the Service manual of the instrument. The calibration procedures do not use whole blood or commercial calibration materials.

The calibration procedures use a Dye Test that is performed by the Service Engineers at the time of Installation, whenever service to one of the modules is performed and at the 6 month PM intervals.

Each assay also has its own calibration (assay verification) to ensure the assay is valid. Each of these verification specifications that are used for the manual assay are programmed into the ETI-MAX™ 3000 protocol and are used to ensure the Validity of the assay on the ETI-MAX 3000™.

7. Quality Control:
The ETI-MAX 3000™ Analyzer in and of itself does not require quality control procedures or commercial quality control materials. Each individual assay that is programmed on the ETI-MAX 3000™ follows the quality control information as recommended in the Instructions for Use for that assay. The quality control used on the ETI-MAX 3000™ would be the same as required for running the assay by the manual method.

Additional commercial quality control materials are used by the operator for the assay as required by their laboratory or regulating agency.

A quality control analysis report (Levy-Jennings plot), are available for tracking the results of a selected quality control material over a period of time. The QA Analysis report has to be activated on the ETI-MAX 3000™ by defining QA Labels in the Lot specific Values dialogue box, while preparing a worklist.

The QA-Label must match the label which is used in the assay layout definition.

8. Software:
FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:
Yes__√_____ or No_____

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.2170 (Micro chemistry analyzer for clinical use)
2. Classification:
   Class I
3 Product code:
   JJF
4. Panel:
   Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:
   The ETI-MAX 3000™ is a fully automated EIA microtiter plate analyzer designed to perform the complete sample processing of qualitative and semi-quantitative assays with respect to (sample dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation. The qualitative and semi-quantitative performance of the ETI-MAX™ instrument were assessed using the DiaSorin ANAScreen ELISA kit, the DiaSorin Anti-SS-A(Ro)ELISA kit and the EuroDiagnostica AB ENA Single Well Screen kit.

2. Special Conditions for Use Statement(s):
   For Prescription Use only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
   Labotech (a.k.a ETI-LAB) (K922081)
   Mago™ Automated EIA Processor (K973177)
2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate (Labotech)
Intended Use/Indications for Use	The DiaSorin ETI-MAX 3000™ is a fully automated microtiter plate analyzer designed to perform the complete sample processing (sample dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation.	The Labotech is a fully automated microtiter plate analyzer designed to perform the complete sample processing (sample dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation.
Barcode Reading	Yes	Yes
Internal	X	X
External Hand Held *Optional	X	X
Sample Identification	X	X
Batch Loading	X	X
Sample / Reagent Dispensing Unit	Yes	Yes

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Similarities		
Item	Device	Predicate (Labotech)
Disposable Tips	X	X
Metal Needle * optional		X
Pipetting area capacity (# of plates)	4	3
Mixing	X	X
Multi-Dispensing	X	X
Liquid Level Detection	Yes	Yes
Clot Detection	Yes	Yes
Incubation Assembly	Yes	Yes
Temperature controlled chambers	X	X
Reading Assembly	Yes	Yes
# of Chambers	1	3
# of Channels (per chamber)	8	8
Vertical with Photodiodes	X	X
Absorbance Reading Method	X	X
Single or Double Beam w/over range filter	X	X
Spectrum (400nm to 700 nm)	X	X
Filters (404, 450, 492, 550, 620)	X	X
Washer Assembly	Yes	Yes
Buffer Capacity	4	2
Wash Head (8 channel, dual needle)	X	X
Buffer Level Sensing	X	X
Waste Tank Level Sensing	X	X
Standards Met	IEC 61010 1:90+A1:92+A2:95 EN 61326 - 1:97 + A1:98 IEC 60027 ASTM E 1381 – 91 ASTM E 1394 - 91	IEC 1010-1/1990 IEC 801/1988 IEC 825 EN 55011

Differences		
Item	Device	Predicate (Labotech)
Barcode Reading Reagent Identification	X	
Loading Random Access	X	
Liquid Level Detection	Electronic	Pneumatic
Clot Detection	Electronic	Pneumatic
(Incubation) # of Chambers	4	3
Shaking (longitudinal)	X	
(Reading) # of Chambers	1	3
Kinetic Reading	X	

Similarities		
Item	Device	Predicate (Mago)
Description/ Intended Use/ Indications for Use	The DiaSorin ETI-MAX 3000™ is a fully automated microtiter plate analyzer designed to perform the complete sample processing (sample dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation.	The Diamedix Mago™ Automated EIA Processor is indicated for use as a general purpose automated EIA processor for use in clinical laboratories.

I. Special Control/Guidance Document Referenced (if applicable):
NCCLS EP5-A2
NCCLS EP17-A

J. Performance Characteristics*:*
1. Analytical Performance:
    a. Accuracy:
    The clinical studies were conducted at DiaSorin Inc. and at two external US laboratories. Testing was performed on 159 repository samples in each of the three assays. The breakdown for the 159 ANA repository samples is as follows:
    - 88 negative samples (negative result using manual assay)
    - 64 positive samples (positive result using manual assay)
    - 7 equivocal samples (equivocal result using manual assay)

    The breakdown for the 159 ENA repository samples is as follows:
    - 92 negative samples (negative result using manual assay)
    - 63 positive samples (positive result using manual assay)
    - 4 equivocal samples (equivocal result using manual assay)

    The breakdown for the 159 Anti-SS-A (Ro) repository samples is as follows:
    - 104 negative samples (negative result using manual assay)
    - 55 positive samples (positive result using manual assay)
    - 0 equivocal samples (equivocal result using manual assay)

    Study Analysis
    All assay results were expressed in OD and S/CO. In addition, the Anti-SS-A (Ro) included U/mL. A sample was considered negative, equivocal, or positive based on the criteria as specified in the currently released assay package inserts.
    ANA Screen:
    - negative <0.7 S/CO.
    - equivocal ≥0.7 and <1.0 S/CO.
    - positive ≥1.0 S/CO.

ENA Screen:
- negative <0.95 S/CO.
- equivocal ≥0.95 and ≤1.0 S/CO.
- positive >1.0 S/CO.

Anti-SS-A (Ro) Qualitative:
- negative <0.95 S/CO.
- equivocal ≥0.95 and ≤1.0 S/CO.
- positive >1.0 S/CO.

Anti-SS-A (Ro) Quantitative:
- negative ≤2.0 U/mL.
- positive >2.0 U/mL.

The performance of the ETI-Max was determined by calculating the percent agreement among negative samples, percent agreement among positive samples, and overall percent agreement with the reference (manual) method for each assay. The relevant 95% confidence limits were computed by applying the exact method.

Results:
The tables below show the comparison of the ETI-Max and Manual assay results for the retrospective samples population. The results are summarized below as positive, negative, and overall percent agreement with the Manual assay results with 95% exact confidence intervals.

ANA Screen	Manual Method			
ETI-MAX 3000™	Positive	Negative	Equivocal	Total
Positive ≥1.0 S/CO	62	0	0	62
Negative <0.7 S/CO	0	88	3	91
Equivocal ≥0.7 and <1.0 S/CO	2	0	4	6
Total	64	88	7	159

Positive agreement = 96.9% (62/64) (Exact 95% CI: 89.2 – 99.6%)
Negative agreement = 100.0% (88/88) (Exact 95% CI: 95.9 – 100.0%)
Overall agreement = 96.9% (154/159) (Exact 95% CI: 92.8 – 99.0%)

ENA Screen	Manual Method			
ETI-MAX 3000™	Positive	Negative	Equivocal	Total
Positive >1.0 S/CO	59	0	0	59

Negative <0.95 S/CO	4	92	4	100
Equivocal ≥0.95 and ≤1.0 S/CO	0	0	0	0
Total	63	92	4	159

Positive agreement = 93.7% (59/63) (Exact 95% CI: 87.6 – 99.7%)
Negative agreement = 100.0% (92/92) (Exact 95% CI: 96.1 – 100.0%)
Overall agreement = 95.0% (151/159) (Exact 95% CI: 90.3 – 97.8%)

Anti-SS-A (Ro) Qualitative	Manual Method			
ETI-MAX 3000™	Positive	Negative	Equivocal	Total
Positive >1.0 S/CO	55	0	0	55
Negative <0.95 S/CO	0	104	0	104
Equivocal ≥0.95 and ≤1.0 S/CO	0	0	0	0
Total	55	104	0	159

Positive agreement = 100.0% (55/55) (Exact 95% CI: 93.5 – 100.0%)
Negative agreement = 100.0% (104/104) (Exact 95% CI: 96.5 – 100.0%)
Overall agreement = 100.0% (159/159) (Exact 95% CI: 97.7 – 100.0%)

Anti-SS-A (Ro) Quantitative	Manual Method		
ETI-MAX 3000™	Positive	Negative	Total
Positive >2.0 U/mL	54	1	55
Negative ≤2.0 U/mL	0	104	104
Total	54	105	159

Positive agreement = 100.0% (54/54) (Exact 95% CI: 93.4 – 100.0%)
Negative agreement = 99.0% (104/105) (Exact 95% CI: 94.8 – 100.0%)
Overall agreement = 99.4% (158/159) (Exact 95% CI: 96.6 – 100.0%)

		Intercept		X Variable 1	
	R Square	Lower 95.0%	Upper 95.0%	Lower 95.0%	Upper 95.0%
ANA Screen	0.974	-0.007	0.056	0.779	0.82
ENA Screen	0.979	0.039	0.122	0.754	0.79
SSA (Semi-quantitative)	0.953	-0.544	0.345	0.816	0.876
SSA (Qualitative)	0.983	-0.125	-0.046	0.955	0.996

ANAScreen Method Comparison S/CO

y = 0.8034x + 0.0226
R^2 = 0.9734

ENAScreen Method Comparison S/CO

y = 0.7722x + 0.0802
R^2 = 0.9786

SSA qual method comparison

y = 1.0068x + 0.1096
$R^2 = 0.9826$

SSA semi quant Method comparison

y = 1.143x + 0.3888
$R^2 = 0.9545$
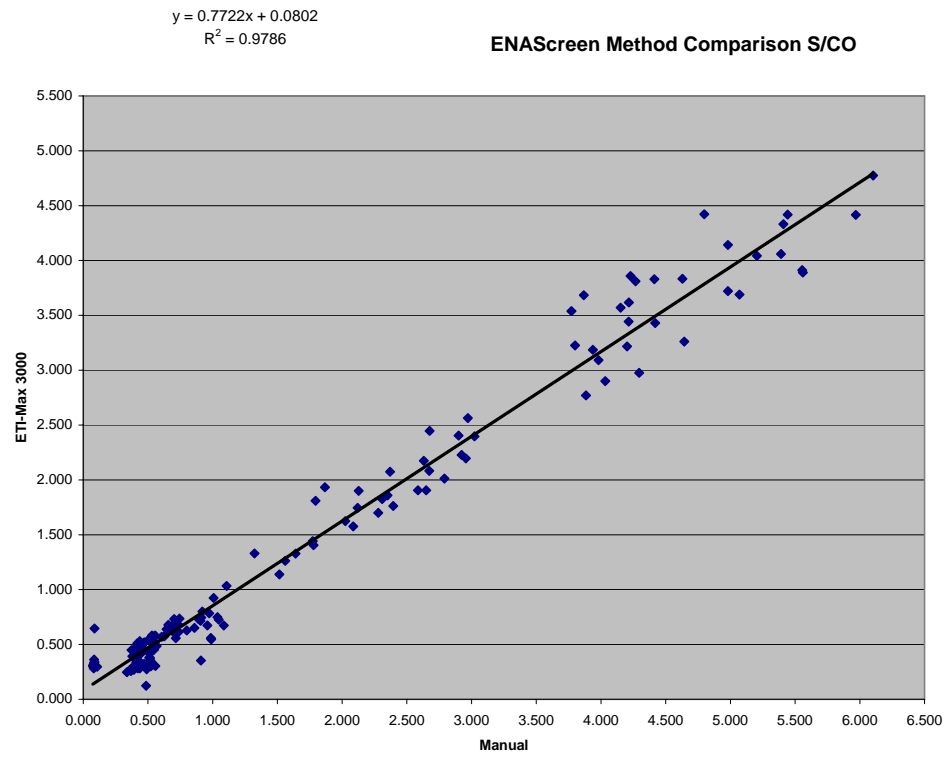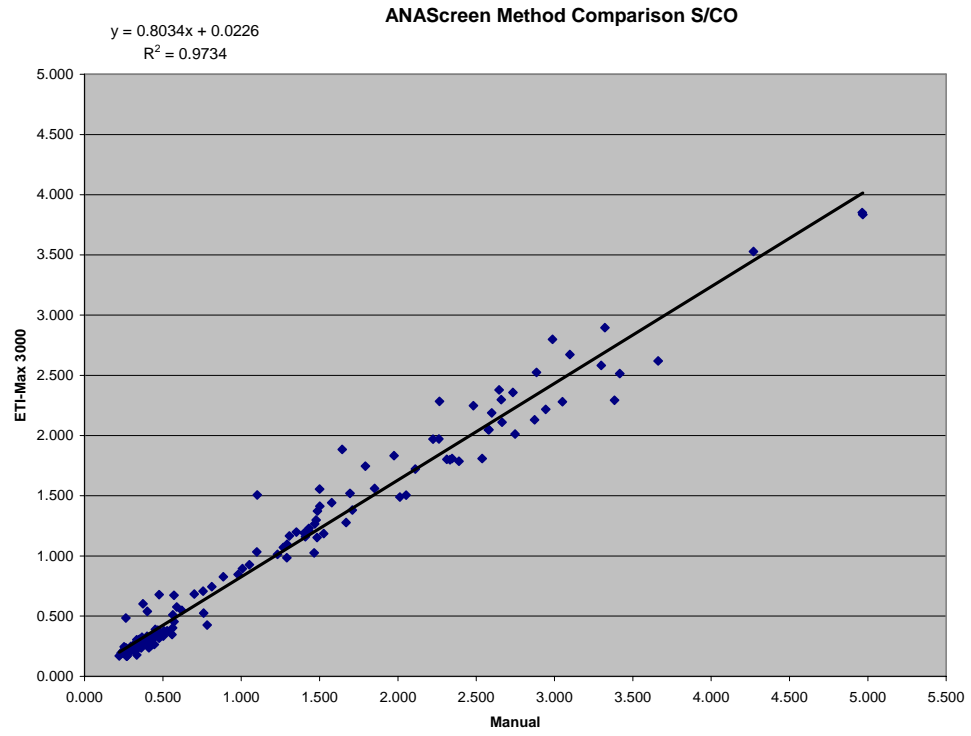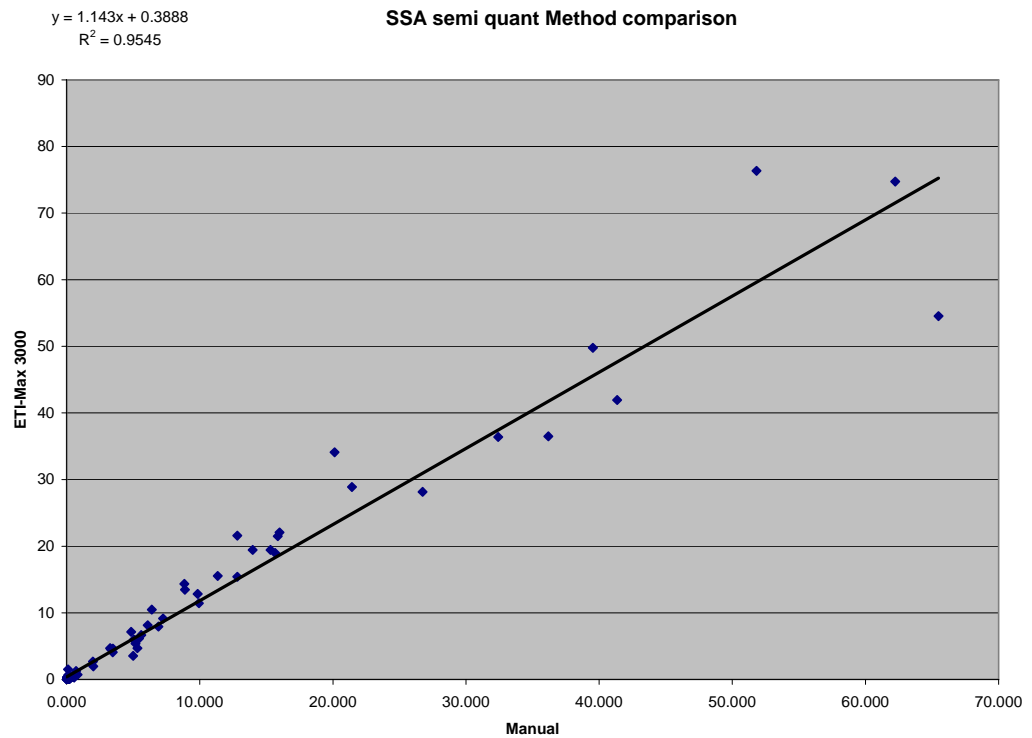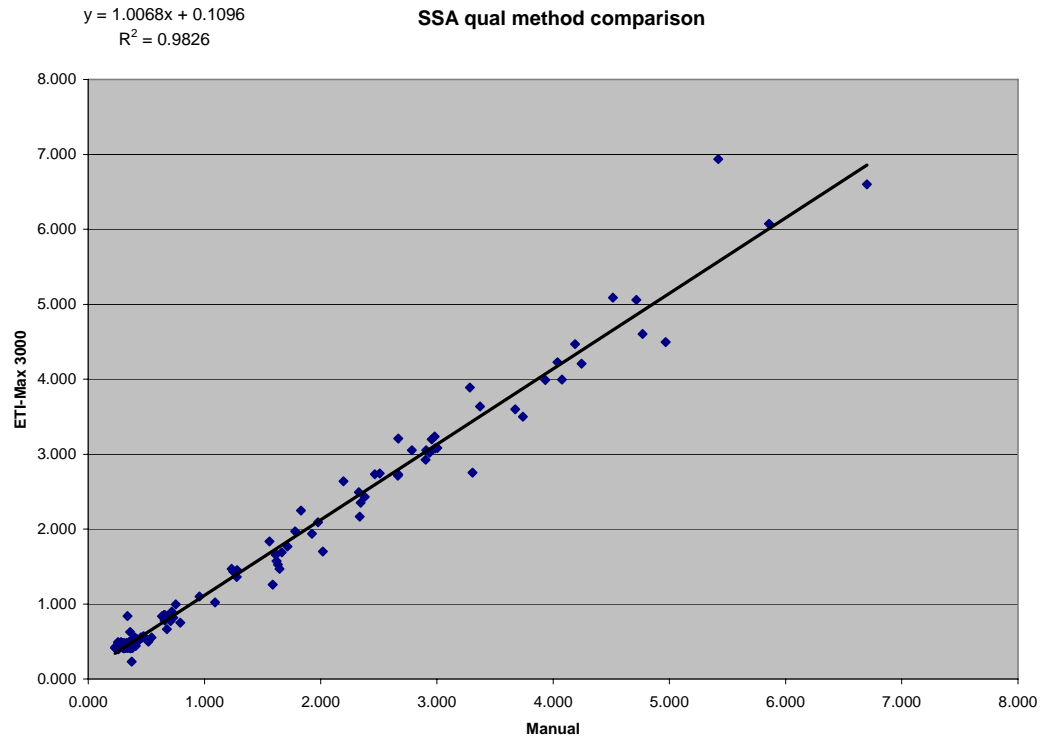
b. *Precision/Reproducibility*:
    The instrument reproducibility/precision study was conducted at two external
    US laboratories and at DiaSorin Inc A coded panel comprised of 8 frozen

repository serum samples was prepared at DiaSorin and provided to each site for testing by the DiaSorin ETI-MAX 3000™ instrument and the three autoimmune assays. The samples were at or near the cut-off. All panel members were divided into aliquots and stored frozen prior to testing. The same coded panel was tested at all three sites, using four replicates per run in one run per day during five operating days at each trial site on the ETI-MAX 3000™ and manually.

Table of Precision for **ANA Screen** ETI-MAX 3000™ Method:

ID#	Site	N	mean (S/CO)	within run %CV	between run %CV	total %CV	instrument to instrument %CV
#1	1	20	0.98	6.6	0	6.3	
	2	20	0.86	8.5	25.7	27.1	6.8
	3	20	0.93	20.6	0	20.4	
#2	1	20	1.05	3.1	2.6	4.0	
	2	20	1.12	1.9	1.1	2.2	3.2
	3	20	1.09	2.0	0.5	2.0	
#3	1	20	0.73	4.0	2.6	4.8	
	2	20	0.51	4.2	50.4	50.6	18.6
	3	20	0.71	4.3	3.2	5.4	
#4	1	20	1.21	2.3	3.3	4.1	
	2	20	1.29	1.5	3.3	3.6	3.1
	3	20	1.25	4.3	0	4.2	
#5	1	20	1.17	4.0	2.6	4.8	
	2	20	1.22	2.4	4.0	4.6	2.7
	3	20	1.23	2.7	2.0	3.4	
#6	1	20	1.26	3.0	3.0	4.3	
	2	20	1.08	10.9	36.4	37.9	8.4
	3	19	1.23	22.0	0	21.8	
#7	1	20	1.33	2.0	3.6	4.2	
	2	20	1.34	2.7	7.0	7.5	2.8
	3	20	1.40	3.0	0	2.9	
#8	1	20	1.29	3.0	0.3	3.0	
	2	20	1.28	2.2	16.0	16.1	3.2
	3	20	1.36	2.9	4.2	5.1	

Table of Precision for **ENA 6 Screen** ETI-MAX 3000™ Method:

			mean	within run	between run	total	instrument to instrument
ID#	Site	N	(S/CO)	%CV	%CV	%CV	%CV
#1	1	20	0.52	7.1	5.1	8.7	
	2	20	0.48	3.0	8.9	9.4	4.5
	3	20	0.50	6.0	5.7	8.3	
#2	1	20	1.61	4.5	4.3	6.2	
	2	20	1.82	3.5	2.4	4.2	6.2
	3	20	1.70	2.8	4.4	5.2	
#3	1	20	1.60	3.4	6.4	7.3	
	2	20	1.63	6.8	5.9	8.9	1.6
	3	20	1.66	4.0	3.0	5.0	
#4	1	20	1.81	5.3	7.5	9.1	
	2	20	1.76	5.3	19.6	20.3	3.0
	3	20	1.87	2.8	4.2	5.0	
#5	1	20	1.25	5.0	4.9	7.0	
	2	20	1.20	10.9	20.8	23.4	3.1
	3	20	1.27	5.4	3.2	6.3	
#6	1	20	1.45	4.2	3.7	5.6	
	2	20	1.51	6.0	8.8	10.7	2.0
	3	20	1.50	4.4	4.6	6.3	
#7	1	20	1.30	3.2	2.9	4.3	
	2	20	1.50	13.7	10.2	17.1	8.3
	3	20	1.30	9.9	5.1	11.1	
#8	1	20	1.47	5.8	3.9	7.0	
	2	20	1.59	7.9	10.2	12.9	5.0
	3	20	1.45	3.4	6.5	7.4	

Table of Precision for **Anti-SS-A (Ro)** ETI-MAX 3000™ Method:

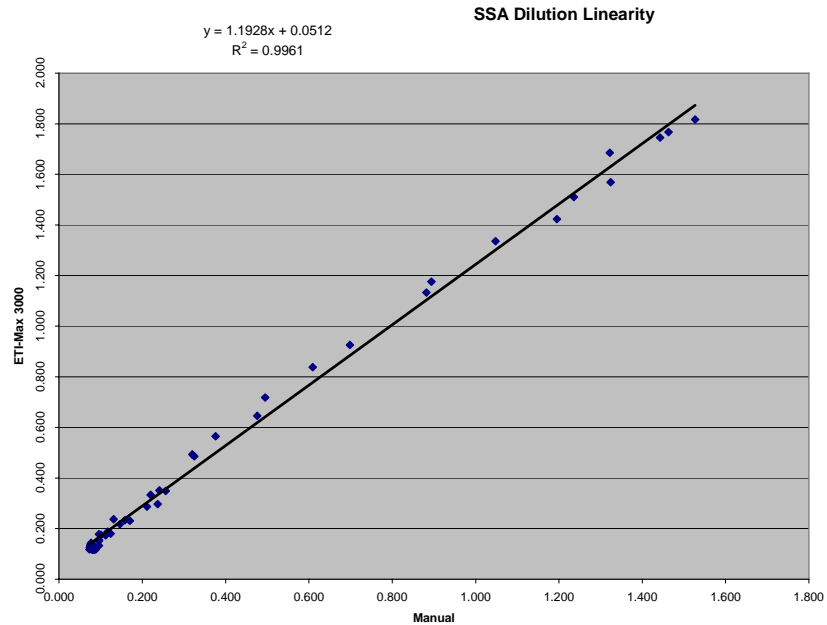| ID#	Site	N	mean (S/CO)	within run %CV	between run %CV	total %CV	instrument to instrument %CV
#1	1	20	0.81	4.2	6.1	7.4	
	2	20	0.80	8.1	5.9	10.0	3.7
	3	20	0.86	7.1	0	7.1	
#2	1	20	0.93	3.1	4.8	5.7	
	2	20	0.88	4.7	2.8	5.5	2.9
	3	20	0.91	2.6	3.1	4.1	
#3	1	20	1.00	3.1	5.0	5.9	
	2	20	0.84	8.4	42.6	43.4	12.1
	3	20	1.07	5.1	0	4.9	
#4	1	20	1.00	4.3	3.0	5.2	
	2	20	0.80	4.8	42.0	42.3	12.2
	3	20	1.00	3.6	4.7	5.9	
#5	1	20	0.99	4.3	3.7	5.6	
	2	20	1.04	4.3	2.7	5.1	4.7
	3	20	1.08	7.0	7.7	10.4	
#6	1	20	1.01	3.4	3.9	5.2	
	2	20	0.99	3.7	3.8	5.3	2.5
	3	20	1.04	3.8	2.6	4.6	
#7	1	20	1.10	4.2	3.7	5.5	
	2	20	1.05	12.7	6.5	14.3	8.3
	3	20	1.23	6.6	3.9	7.6	
#8	1	20	1.00	3.9	3.4	5.2	
	2	20	1.03	4.3	1.4	4.5	4.7
	3	20	1.09	4.6	7.4	8.7	

    c. *Linearity*:
    Four samples were serially diluted across the assay range to study the
    linearity of the ANA Screen, ENA 6 Screen and Anti-SS-A (Ro) semi-
    quantitative assays using the manual and ETI-MAX methods. Samples
    were tested in singlicate. Acceptance Criteria: The ETI-MAX 3000™
    result within +/- 1 dilution of the manual result.

Results:

	R Square	Intercept		X Variable 1	
		Lower 95.0%	Upper 95.0%	Lower 95.0%	Upper 95.0%
ANA Screen	0.982	-0.112	-0.067	1.196	1.307
ENA Screen	0.983	-0.037	0.059	1.197	1.324
Anti-SS-A (Ro)	0.996	0.036	0.066	1.169	1.216

$y = 1.2415x - 0.0871$
$R^2 = 0.9825$

ANAScreen Dilution Linearity

$y = 1.2606x + 0.0105$
$R^2 = 0.9834$

ENAScreen Dilution Linearity

SSA Dilution Linearity

$$y = 1.1928x + 0.0512$$
$$R^2 = 0.9961$$
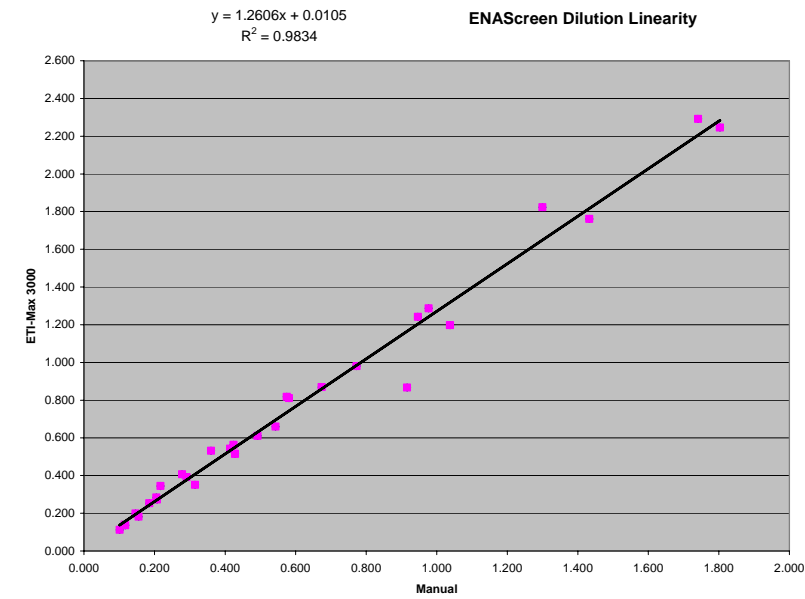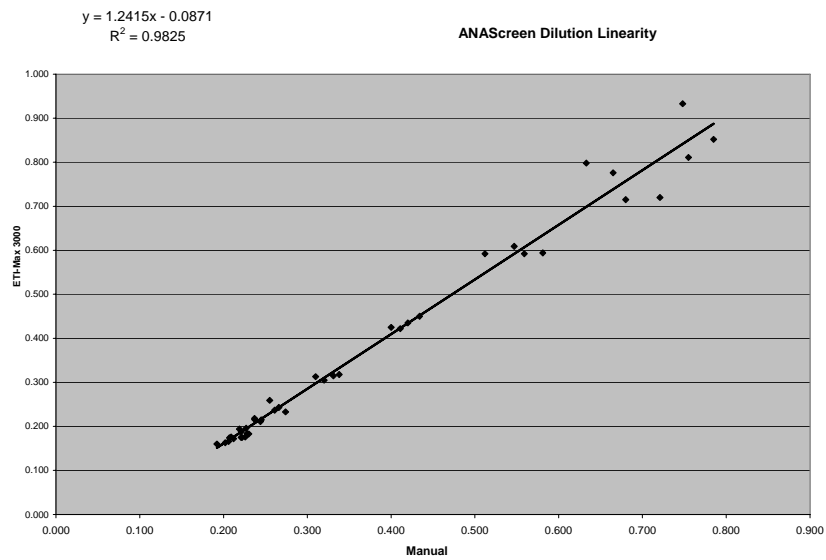
d. *Carryover*:
   Study Design
   A Reference Plate consisting of 5 strips of Negative samples (n=40) was
   tested in each assay (ANA Screen, ENA 6 Screen, and Anti-SS-A (Ro) to
   establish the baseline for comparison during the carry over tests. The mean,
   SD and +/- 3SD range of the negative sample on the reference plate were
   calculated.

   Pipettor and Washer Carryover Tests
   One high dose sample was tested in replicates of four, followed by a negative
   sample tested in replicates of eight (in 3 separate sequences) to evaluate
   Pipettor carryover.
   Two high dose sample strips (n=16) followed by 2 negative sample strips
   (n=16) were tested to evaluate washer carryover.
   Acceptance Criteria: The mean of the negative samples on the Pipettor and
   Washer Carry Over Test plates within the 3SD range of the Negative Sample
   on the Reference Plate.

   Results
   ANA Screen

	Reference Plate Negative Sample	Pipettor Carry Over Negative Sample	Washer Carry Over Negative Sample
Mean OD	0.141	0.143	0.141
SD	0.014		
+/- 3SD Range	0.099 – 0.183	Pass	Pass

   ENA 6 Screen

	Reference Plate Negative Sample	Pipettor Carry Over Negative Sample	Washer Carry Over Negative Sample
Mean OD	0.160	0.141	0.128
SD	0.009		
+/- 3SD Range	0.133 – 0.187	Pass	Pass

Anti-SS-A (Ro)

	Reference Plate Negative Sample	Pipettor Carry Over Negative Sample	Washer Carry Over Negative Sample
Mean OD	0.105	0.098	0.093
SD	0.012		
+/- 3SD Range	0.069 – 0.141	Pass	Pass

e. *Interfering Substances*:
   Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:
   Analytical Sensitivity:
   Analytical sensitivity was established using parametric methods for the determination of Limit of Detection (LOD) according to NCCLS EP17-A. Limit of Blank (LOB) was estimated from a minimum of 60 measurements of multiple blank (analyte-free) samples. The Blank standard deviation was multiplied by 1.645 (95th percent of the standard Gaussian distribution) and added to the Blank average. In order to establish LOD, a sample standard deviation was obtained from repeated measurement of several low-concentration samples; a minimum of 60 results were then used to calculate a pooled standard deviation. The pooled standard deviation was multiplied by a term C_β, representing the 95th percentile of the standard Gaussian distribution and a correction factor, and then added to LOB to establish LOD.

Assay	Manual				ETI-MAX 3000™			
	n	LOB	n	LOD	n	LOB	n	LOD
ANAScreen	68	0.087	70	0.144	68	0.116	71	0.133
ENAScreen	90	0.070	88	0.122	90	0.106	88	0.136
Anti-SSA(Ro)	82	0.084	80	0.133	74	0.109	104	0.138

Assay Drift:
Eight replicates of a low positive sample were tested at the beginning of the plate in strip 2 (just after the reference sample and assay controls) and again at the end of the plate in strip 12 to evaluate assay drift. The mean, SD and +/-2SD range for S/CO and OD were calculated. OD and U/mL were calculated for the Quantitative Anti-SSA assay.

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Acceptance Criteria: The low positive S/CO, U/mL and OD results from strip 12 must fall within the 2 SD range (S/CO, U/mL and OD) calculated for strip 2. If the results from strip 12 do not fall within the 2SD ranges the assay will need to be repeated.

Results
ANA Screen

	Strip 2 Low Positive Sample		Strip 12 Low Positive Sample	
	OD	S/CO	OD	S/CO
Mean	0.315	0.757	0.303	0.728
SD	0.010	0.023		
+/- 2SD Range	0.295-0.335	0.711-0.803	Pass	Pass

ENA 6 Screen

	Strip 2 Low Positive Sample		Strip 12 Low Positive Sample	
	OD	S/CO	OD	S/CO
Mean	0.418	1.502	0.379	1.363
SD	0.024	0.085		
+/- 2SD Range	0.370-0.466	1.332-1.672	Pass	Pass

Anti-SS-A (Ro) Semi-quantitative

	Strip 2 Low Positive Sample		Strip 12 Low Positive Sample	
	OD	U/mL	OD	U/mL
Mean	0.796	7.31	0.773	7.04
SD	0.023	0.27		
+/- 2SD Range	0.751-0.841	6.77-7.86	Pass	Pass

Dye test data to determine the accuracy of pipettor and washer:
Upon request, the sponsor provided the dye tests data which is used to determine the accuracy of the pipettor and washer. A summary of the results of the pipettor and washer dye test along with the Acceptance/Validation Criteria is listed below. These tests were performed on the ETI-MAX 3000™ Analyzer asset number 10142 at the DiaSorin site. A printout from the instrument for each test is attached for your review.

Verification of Residual Volume (Washer)

Assay Name	Criteria	Result
Val-Wash.Asy	Max(W1) < 1.2%	0.675 < 1.2
	W1 < 0.4%	0.310313 < 0.4

Verification of Dilution 1:100 and 10μL+200μL

Assay Name	Criteria	Result
Dilution.asy	CV(W1) <= 10%	1.66693 <= 10
	CV(D) <= 5%	2.56137 <= 5

Verification of Multi-Dispensing 8x100μL

Assay Name	Criteria	Result
8x100.asy	CV(W1) <= 2.5%	1.47316 <= 2.5

Verification of Single Pipette 100μL and 50μL

Assay Name	Criteria	Result
100x50.asy	CV(W1) <= 2.5%	0.784174 <= 2.5
	CV(W2) <= 5%	3.30849 <=5

These tests are performed at the time of installation of the instrument, every 6 months for Preventative Maintenance and whenever service on the pipettor is performed.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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