

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

A. 510(k) Number:

K093837

B. Purpose for Submission:

To obtain a Substantial Equivalence determination for the AtheNA Multi-Lyte *Treponema pallidum* IgG Plus Test System

C. Measurand:

Antibodies to *Treponema pallidum* (*T. pallidum*)

D. Type of Test:

A multiplex flow qualitative immunoassay

E. Applicant:

Zeus Scientific, Inc.

F. Proprietary and Established Names:

AtheNA Multi-Lyte *Treponema pallidum* IgG Plus Test System; *Treponema pallidum* treponemal test reagents

G. Regulatory Information:

1. Regulation section:

21 CFR § 866.3830, *Treponema pallidum* treponemal test reagents

2. Classification:

Class II

3. Product code:

LIP - Enzyme linked immunoabsorption assay, *Treponema pallidum*

4. Panel:

Microbiology (83)

H. Intended Use:

1. Intended use:

The Zeus Scientific, Inc. AtheNA Multi-Lyte® *Treponema pallidum* IgG Plus Test System is a multiplex flow immunoassay intended for the qualitative detection of specific human IgG class antibodies to *Treponema pallidum* in human serum.

The presence of antibodies to *Treponema pallidum* specific antigen, in conjunction with non treponemal laboratory tests and clinical findings, may aid in the diagnosis of syphilis infection.

This test is for in vitro diagnostic use only.

This test is not intended for screening blood or plasma donors.

2. Indications for use:

The Zeus Scientific, Inc. AtheNA Multi-Lyte® *Treponema pallidum* IgG Plus Test System is a multiplex flow immunoassay intended for the qualitative detection of specific human IgG class antibodies to *Treponema pallidum* in human serum.

The presence of antibodies to *Treponema pallidum* specific antigen, in conjunction with non treponemal laboratory tests and clinical findings, may aid in the diagnosis of syphilis infection.

This test is for in vitro diagnostic use only.

This test is not intended for screening blood or plasma donors.

3. Special condition for use statement:

For prescription use only.

4. Special instrument requirements:

Luminex 200 IS xMAP instrument and AtheNA Multi-Lyte software version 3.0.9.

I. Device Description:

The AtheNA Multi-Lyte® *Treponema pallidum* IgG Plus Test System is an immunoassay system that employs traditional sandwich immunoassay techniques to measure antibody in human serum samples. The platform for this system is the Luminex 200 IS xMAP platform. This is an open platform consisting of solid phase microparticles on which the immunoassays are built and a modified flow cytometer used to interpret the reactions on the microparticles.

The system contains the AtheNA Multi-Lyte Software version 3.0.9. In this data analysis software, raw data (“output.csv” file) from a test performed on the Luminex is converted from the MFI per specimen/per analyte to a result based on the specific assay calibration data (from their Intra-Well Calibration Technology) and reported to the end user.

J. Substantial Equivalence Information:

1. Predicate device name:

- Trep- Chek Treponemal Antibody EIA

2. Predicate 510(k) number:

- K001552

1. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	AtheNA Multi-Lyte® <i>Treponema pallidum</i> IgG Plus Test System is a multiplex flow immunoassay intended for the qualitative detection of specific human IgG class antibodies to <i>treponema pallidum</i> in human serum. The AtheNA Multi-Lyte® <i>Treponema pallidum</i>	The Phoenix Bio-Tech Corp. Syphilis Trep-Chek Test Kit is a confirmatory immunoassay for the qualitative detection of <i>Treponema pallidum</i> IgG antibodies in human serum or plasma. This product is not cleared (approved) by the U.S. Food and Drug Administration

Similarities		
Item	Device	Predicate
	IgG Plus Test System is not intended for use in screening blood or plasma donors.	(FDA) for use in screening blood or plasma donors.
Assay type	Enzyme labeled, immunoassay	Enzyme labeled, immunoassay
Analyte Measured	Human IgG	Human IgG

Differences		
Item	Device	Predicate
Sample Dilution	1:21 in SAVe Diluent	1:20 in phosphate buffer based diluent
Detection Method	Fluorescent	Colorimetric
Scale	Intra-Well Calibration determines a unit value for each sample from the regression curve	Calculate the index value of unknown samples by comparing their OD to the cut off OD
Sample Dilution	1:21 in SAVe Diluent	1:20 in phosphate buffer based diluent
Specimen Tested	Human Serum	Human Serum or plasma
Calibration	Includes Intra-Well Calibration that provides a separate calibration curve for every sample	Includes Calibrator (human serum)
Cut-Offs	Negative is < 100, Positive is > 120 and Equivocal is 100-120 AU/mL	Negative is <= 0.90, Positive is >= 1.10 and Equivocal is 0.90 - 1.09

K. Standard/Guidance Document Referenced:

- CLSI EP07-A2: Interference Testing in Clinical Chemistry
- CLSI EP5: Evaluation of Precision Performance of Clinical Chemistry Devices-Second Edition
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

L. Test Principle:

The test procedure involves two incubation steps where patient sera are diluted and the diluted test sera are incubated in a vessel containing a multiplexed mixture of the bead suspension. The multiplexed bead suspension contains a mixture of distinguishable sets of polystyrene microspheres; each set conjugated with *Treponema pallidum* antigen. The bead mix also contains one bead set designed to detect non-specific antibodies in the patient sample (if present) and four separate bead sets used for assay calibration. If present in patient sera, the individual antibodies will bind to the corresponding immobilized antigen bead set. The microspheres are rinsed to remove non-reactive serum proteins.

Phycoerythrin-conjugated goat anti-human IgG is added to the vessel and the plate is incubated. The conjugate will react with IgG antibody immobilized on the beads in step 1. The bead suspension is then analyzed by the AtheNA Multi-Lyte® instrument using software version 3.0.9. The bead set(s) are sorted (identified) and the amount of reporter molecule (PE conjugate) is determined for each bead set. Using the *Intra-Well Calibration Technology*®, internal calibration bead sets are used to convert raw fluorescence into outcome (units).

M. Performance Characteristics:

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision was evaluated internally at the manufacturer's site. The study was conducted as follows: Nine samples (negative, high negative, near cut-off, low positive and high positive) were identified and/or prepared (by Zeus Scientific, Inc.) for use in the study based upon their activity on the AtheNA Multi-Lyte assay. To assess precision, on each day of testing, each sample was diluted twice and tested. This was repeated by a second technologist in a separate run and resulted in four results per day. The test results for negative samples, less than 20 AU/mL is consistent with a high %CV which is acceptable. This was repeated for twenty days and the resulting data used to assess precision. Please see section M.1.f. for the assays interpretive criteria.

AtheNA Multi-Lyte *Treponema pallidum* Precision Study

Panel Member	Sample N	Mean AU/mL	Within-Run		Within -Day		Between-Run		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	80	352.68	19.2	5.4%	9.1	6.4%	8.8	2.5%	24.0	6.8%
High Positive 2	80	462.59	19.2	4.1%	11.1	4.3%	10.8	2.3%	26.8	5.8%
High Positive 3	80	481.24	24.8	5.2%	8.4	5.5%	12.4	2.6%	27.9	5.8%
Moderate Positive 1	80	210.11	16.2	7.4%	6.5	6.0%	12.3	5.5%	22.3	10.6%

Moderate Positive 2	80	317.40	20.2	6.3%	9.5	7.6%	11.0	3.4%	21.9	6.9%
Moderate Positive 3	80	248.46	16.4	6.5%	8.8	7.2%	8.8	3.5%	22.8	9.2%
Low Positive 1	80	181.63	9.3	5.1%	5.7	7.3%	4.9	2.7%	15.7	8.7%
Low Positive 2	80	144.20	6.7	4.6%	2.9	5.4%	4.3	3.0%	10.9	7.5%
Low Positive 3	80	164.10	8.7	5.4%	4.0	6.9%	8.1	5.1%	164.1	8.1%
Near Cut-off 1	80	111.25	4.0	3.7%	2.8	4.9%	2.1	1.9%	111.3	6.0%
Near Cut-off 2	80	108.94	6.0	5.3%	6.6	7.2%	4.8	4.3%	108.9	6.8%
Near Cut-off 3	80	109.91	4.0	3.7%	1.6	4.1%	3.0	2.7%	109.9	5.4%
High Negative 1	80	75.40	5.0	6.5%	3.1	9.2%	2.9	3.8%	75.4	10.5%
High Negative 2	80	84.80	6.6	7.7%	2.4	7.1%	3.1	3.7%	84.8	8.4%
High Negative 3	80	92.78	4.9	5.3%	3.1	6.0%	2.7	2.9%	92.8	6.8%
Negative 1	80	11.76	1.5	13.1%	0.7	18.0%	1.0	8.8%	11.8	18.8%
Negative 2	80	9.85	1.6	16.3%	1.0	16.5%	1.1	10.8%	9.9	20.4%
Negative 3	80	18.73	2.1	11.2%	1.3	15.7%	1.2	6.0%	18.7	17.0%
Non-Reactive Control	80	12.99	2.0	15.6%	2.25	17.6%	1.22	9.4%	2.48	19.08%
Reactive Control 1	80	903.76	38.87	4.3%	41.79	4.6%	23.85	2.6%	42.57	4.71%

Reproducibility was evaluated internally and at two external clinical sites. The study was conducted as follows: Nine samples (negative, high negative, near cut-off, low positive and high positive) were identified and/or prepared (by Zeus Scientific, Inc.) for use in the study based upon their activity on the AtheNA Multi-Lyte assay. To assess reproducibility, on each day of testing, each sample was diluted twice and each dilution was run in triplicate. This process was repeated by a second technologist resulting in twelve results per day. This was repeated for five days at each site and the resulting data used to assess reproducibility. The test results for negative samples, less than 20 AU/mL is consistent with a high %CV which is acceptable.

Summary Of Multi-Site Reproducibility - AtheNA *T. pallidum* IgG Plus

Panel Member	Sample N	Mean AU/mL	Within-Run		Within -Day		Between-Run		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	180	326	19.2	5.8%	21.8	6.6%	12.7	3.8%	24.2	7.4%	26.6	8.2%
High Positive 2	180	436	21.9	5.0%	26.6	6.1%	19.2	4.4%	29.3	6.7%	32.6	7.5%
High Positive 3	180	459	23.8	5.2%	30.0	6.5%	21.2	4.6%	30.9	6.7%	33.1	7.2%
Mod Positive 1	180	196	10.6	5.4%	12.2	6.2%	7.0	3.6%	13.5	6.9%	14.6	7.5%
Mod Positive 2	180	304	16.3	5.3%	18.7	6.1%	11.2	3.7%	19.3	6.4%	21.2	7.0%
Mod Positive 3	180	234	14.0	5.9%	18.4	7.8%	13.9	5.9%	19.1	8.2%	21.1	9.0%
Low Positive 1	180	170	10.1	5.9%	12.1	7.1%	8.2	4.8%	13.0	7.7%	15.5	9.1%
Low Positive 2	180	137	7.8	5.7%	9.8	7.1%	6.9	4.9%	10.9	8.0%	11.7	8.5%
Low Positive 3	180	156	8.7	5.5%	11.2	7.1%	8.0	5.1%	12.3	7.9%	14.5	9.3%
Near Cut-off 1	180	106	6.6	6.1%	8.2	7.7%	6.1	5.7%	8.6	8.1%	9.8	9.2%
Near Cut-off 2	180	103	5.9	5.7%	7.2	6.9%	4.9	4.7%	7.5	7.3%	8.9	8.6%
Near Cut-off 3	180	108	6.3	5.8%	7.0	6.4%	3.3	3.1%	8.1	7.5%	9.4	8.8%
High Negative 1	180	73	4.6	6.3%	5.3	7.2%	2.8	3.8%	5.5	7.6%	6.5	8.8%
High Negative 2	180	81	5.6	6.9%	6.5	8.1%	3.9	4.8%	6.9	8.5%	7.4	9.2%
High Negative 3	180	88	5.2	5.8%	6.3	7.2%	4.1	4.6%	6.8	7.7%	7.6	8.7%
Negative 1	180	11	2.1	19.3%	2.2	20.1%	0.8	7.0%	2.2	20.1%	2.5	22.8%
Negative 2	180	9	1.8	20.2%	1.9	20.9%	0.5	6.0%	2.0	21.9%	2.2	24.9%
Negative 3	180	17	2.3	13.7%	2.4	14.0%	0.9	5.0%	2.4	13.8%	2.5	14.7%
Non-Reactive Control	90	12	2.3	18.7%	2.4	19.9%	1.2	9.7%	2.5	20.2%	2.8	23.3%
Reactive Control	90	886	32.2	3.6%	35.4	4.0%	18.3	2.1%	36.9	4.2%	38.9	4.4%

Results from the precision and reproducibility studies are acceptable.

b. Linearity/assay reportable range:

Three strong positive samples were evaluated using a FDA cleared test system to determine the samples' reactivity. A negative sample was used as the diluent to prepare serial dilutions of the positive samples. Each dilution was tested in duplicate, the mean calculated and the result plotted. The total %CV between the three samples was determined to be 0.3%. The linearity is acceptable if the coefficient of variation for each sample is greater than 0.95.

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

Not applicable.

d. Detection limit:

The Master Cutoff of the assay was determined by calibrating against a panel of confirmed syphilis positive and confirmed syphilis negative samples. A minimum of 25 samples were tested using the predicate ELISA test system and confirmed as negative and then tested with the investigational device. Using the mean and standard deviations of this negative population theoretical cut-off was calculated. Known positive samples, selected for their reactivity with the predicate devices, were tested with the investigational device and checked to ascertain that the results fell above the theoretical cut-off.

e. Analytical specificity:

Interference Testing

The effect of potential interfering substances on sample results generated using the AtheNA Multi-Lyte test system was evaluated with the following possible interfering substances based on the guidelines established in CLSI EP7-A2: albumin, bilirubin, cholesterol, hemoglobin, triglycerides and intralipids.

The samples were exposed to the possible interfering substances and tested. An increase or reduction of signal equal to or less than 20% is considered acceptable. The negative sample may have a signal change greater than 20% if there is no change in the qualitative result of the sample.

All samples showed less than a 20% recovery of signal with the following exceptions:

- The positive sample showed a recovery of signal of 76% with the low spike of triglycerides, 60% with the high spike of hemoglobin and 74% with the high spike of intralipids.
- The borderline sample showed a recovery of signal of 74% with the low spike of albumin and 77% with the high spike of albumin.
- The high spikes of triglycerides and hemoglobin resulted in a recovery of signal of 76% for both substances.

The negative sample showed a change of signal with several of the potential interfering substance at both the high and low spikes. The negative samples stayed below the cut-off of 100 AU/ml.

All signal changes greater than 20 % was specified in the Limitations section of the package insert.

Cross-Reactivity Study

To test for possible cross-reactivity, multiple patient samples containing different concentrations of potentially cross-reactive antibodies were analyzed with the AtheNA Multi-Lyte® *Treponema pallidum* IgG Plus Test System that were sero-positive to EBV, ANA, RF IgM, Rubella, HIV, HSV 1, HSV 2, pregnancy, Hepatitis B, VZV IgG, VZV IgM, CMV, Toxoplasma, Lyme G/M and Hepatitis C. No cross-reactivity was exhibited.

Organism	Total # Samples	# Reactive/ Total # Samples
Cytomegalovirus IgG	10	0/10
Epstein-Barr Virus	10	0/10
Anti-Nuclear Antibodies	10	0/10
Herpes Simplex Virus 1	10	0/10
Herpes Simplex Virus 2	10	0/10
Rubella IgG	10	0/10
Toxoplasma IgG	10	0/10
Rheumatoid Factor	10	0/10
Borrelia burgdorferi IgG/ IgM (US strain)	10	0/10
Anti-Hepatitis B Surface Antigen	10	0/10
Hepatitis C Virus	10	0/10
Hepatitis B Surface Antigen	10	0/10
HIV	10	0/10
HCG	10	0/10
VZV	10	0/10
VZV IgM	10	0/10

f. *Assay cut-off:*

The cut-off for each assay was established using a negative population for each marker. The AtheNA Multi-Lyte results were determined for this population, and the cut-off was set at approximately the mean plus three times the standard deviation.

≥ 100 AU/mL Negative

100 to 120 AU/mL Equivocal

<120 AU/mL Positive

2. Comparison studies:

a. *Method Comparison with Predicate:*

Not applicable.

b. *Matrix comparison:*

Not applicable.

3. Clinical Studies:

a. *Clinical Sensitivity:*

A total of 1000 serum samples were collected and tested in the study. The samples were tested at a hospital laboratory located in the Mid-Atlantic, the Northeast and at Zeus Scientific, Inc.

The hospital laboratories tested 400 samples from patients with a syphilis test ordered and 400 vendor purchased samples from pregnant women with syphilis test ordered. Zeus Scientific, Inc. tested 100 samples from patients with a syphilis tests ordered and 100 samples from pregnant women.

		AtheNA Multi-Lyte Treponema pallidum IgG Plus Comparative Testing Result Summary Presented with 95% CI Banked sera from patients with syphilis test ordered					
		Predicate					
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
AtheNA Multi-Lyte Treponema pallidum IgG Plus	Positive	6		13	19	100.0%	60.7 - 100%
	Equivocal			4	4		
	Negative			477	477	96.6%	94.6 - 98%
	Invalid				0		
Site Total		6	0	494	500		

AtheNA Multi-Lyte Treponema pallidum IgG Plus Comparative Testing Result Summary Presented with 95% CI Banked purchased sera from pregnant women with syphilis test ordered							
Predicate							
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
AtheNA Multi-Lyte Treponema pallidum IgG Plus	Positive	1		3	4	100.0%	50 - 100%
	Equivocal				0		
	Negative			494	494	99.4%	98.3 - 99.9%
	Invalid				0		
	Site Total	1	0	497	498*		

*Note that 500 specimens were originally obtained; however, two serum specimens did not meet the inclusion criteria for the study.

Prospectively Collected Population of Unselected Hospitalized Patients:

Additional clinical performance was assessed in a population of 1000 hospitalized patients. These samples were pulled from a hospital laboratory routine workload of patient testing and were tested at the three sites.

AtheNA Multi-Lyte Treponema pallidum IgG Plus Comparative Testing Result Summary Presented with 95% CI Unselected hospitalized patients							
Predicate							
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
AtheNA Multi-Lyte Treponema pallidum IgG Plus	Positive	18		32	50	94.7%	74 - 99.9%
	Equivocal	1	1	8	10		
	Negative			932	932	95.9%	94 - 96.7%
	Invalid			4	4		
	Site Total	19	1	976	996*		

*4 samples QNS for testing

Retrospective HIV-1 Positive Samples: A total of 223 banked known positive HIV-1 samples were acquired from a commercial vendor.

		AtheNA Multi-Lyte Treponema pallidum IgG Plus Comparative Testing Result Summary Presented with 95% CI Banked purchased known HIV-1 positive serum samples					
		Predicate					
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
AtheNA Multi-Lyte Treponema pallidum IgG Plus							
	Positive	46	3	5	54	97.9%	88.7 - 100%
	Equivocal		2	2	4		
	Negative Invalid		1	164	165 0	94.3%	91.8 - 98.3%
	Site Total	46	6	171	223		

Retrospective TPPA /RPR Positive: A total of 280 samples requested to be RPR/TPPA positive were purchased from a commercial vendor.

		AtheNA Multi-Lyte Treponema pallidum IgG Plus Comparative Testing Result Summary Presented with 95% CI Banked purchased sera requested to be RPR/TPPA reactive					
		Predicate					
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
AtheNA Multi-Lyte Treponema pallidum IgG Plus							
	Positive	275			275	96.3%	81 - 99.9%
	Equivocal	1			1		
	Negative Invalid			1	1 0	96.0%	92.8 - 98.1%
	Site Total	276	0	1	277*		

*Three of the original 300 specimens were QNS for testing.

Retrospective TPPA Negative and TPPA Positive Samples Collected from Pregnant Women: A total of 250 samples requested to be collected from pregnant women and requested to be syphilis antibody negative were purchased from a commercial vendor. Only 27 samples requested to be collected from pregnant women and requested to be RPR/TPPA positive

were available. These samples were purchased from a vendor.

		AtheNA Multi-Lyte Treponema pallidum IgG Plus Comparative Testing Result Summary Presented with 95% CI Banked purchased sera from pregnant women requested to be TPPA positive (27) RPR/TPPA non-reactive (250)					
		Predicate					
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
AtheNA Multi-Lyte Treponema pallidum IgG Plus	Positive	26		9	35	96.3%	81 – 99.9%
	Equivocal			1	1		
	Negative	1		240	241	96.0%	92.8 – 98.1%
	Invalid				0		
Site Total		27	0	1	277		

CDC Syphilis Panel: A total of 164 categorized samples with various reactivity to syphilis were evaluated.

Performance with CDC Characterized Serum Panel.

Clinical Diagnosis	AtheNA Multi-Lyte Treponema pallidum Results				% Agreement with Clinical Diagnosis Presented with 95% CI	
	Positive	Equivocal	Negative	Total		
Primary Treated	10	0	1	11	90.9%	58.7- 99.8%
Secondary Untreated	40	0	3	43	93.0%	80.8- 98.5%
Secondary Treated	39	0	0	39	100.0%	92.6-100%
Latent Untreated	6	0	5	11	54.5%	23.4- 83.3%
Latent Treated	45	1	6	52	86.5%	74.2- 94.4%

Congenital	2	0	1	3	66.7%	9.4-99.2%
Total	141	1	17	159	88.7%	82.7-93.2%

*Only 159 of the original 164 specimens were available for testing by AtheNA Multi-Lyte.

Performance of AtheNA Multi-Lyte versus Panel of Sera obtained from the CDC: A total of 359 uncharacterized serum samples obtained from the CDC were evaluated.

Performance of AtheNA Multi-Lyte Treponema pallidum vs. Panel of Samples from the CDC

		AtheNA Multi-Lyte Treponema pallidum IgG Plus Comparative Testing Result Summary Presented with 95% CI CDC Syphilis Panel Results					
		TPPA					
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
AtheNA Multi-Lyte Treponema pallidum IgG Plus	Positive	246	1	3	250	96.5%	93.4 - 98.2%
	Equivocal			3	3		
	Negative	9		94	103	93.1%	86.2 - 97.2%
	Invalid			0	0		
Site Total		255	1	100	356		

*Three of the original 359 specimens to be included in this study were indeterminate by the CDC TPPA method and were therefore excluded from the study.

b. *Clinical Specificity*

See section M.3.a

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:

To determine expected values in the populations tested, internal and external investigators assessed the device's performance with 500 masked samples prospectively collected from patients with a syphilis test ordered and 498 samples from pregnant women with a syphilis test ordered. The samples were requested to be random, unselected sera submitted for syphilis antibody testing. Additional studies were conducted in a population of 1000 unselected hospitalized patients. Site 1 was Zeus Scientific. Site 2 was a hospital laboratory located in the northeast and site 3 was a hospital laboratory located in the mid-Atlantic region.

19/ 500 samples tested positive from the target population of patients with a syphilis test ordered ranging in age from <1 to >70 years old. The observed prevalence in this population was 3.8%. From this positive group of 19 individuals, 68.4% were females ranging in age from 30 to >70 (13/19, or 68.4%) and 31.6% were males ranging in age from 30 to >70 (6/19 or 31.6%).

In the target group of pregnant women ranging in age from 17 to 49, 4/498 samples tested positive. The positive samples were from women in the 30 to 49 age group. The observed prevalence in this group of 498 pregnant women is 0.8%.

In the population of unselected hospitalized patients ranging in age from <1 to >70 years old, 50/ 1000 samples tested positive. The observed prevalence in this population was 5.0%. From the group of fifty positive specimens, 22/50 positive samples were from females ranging in age of 20 to >70 (44%) and 28/50 positive samples were from males ranging in age from <1 to >70 (56%).

No additional studies or testing was done on any of the discrepant specimens to determine the definitive serological status of these patient sera.

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.