Zeus Scientific Inc. 510(k) Summary ZEUS ELISA Treponema pallidum IgG Test System K102283

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Measurand: Treponema pallidum IgG antibodies.
Type of Test: ELISA.
Proprietary Name: ZEUS ELISA Treponema pallidum IgG Test System.

Section 1: Regulatory Information

1. Device Classification: Enzyme Linked Immunoabsorbent Assay, Treponema pallidum
2. Regulation Description: Treponema pallidum treponemal test reagents
3. Class: 2
4. Product Code: LIP
5. Panel: Microbiology
6. Regulation Number: 866.3830

Section 2: Intended Use

The ZEUS ELISA *Treponema pallidum* IgG Test System is intended for the qualitative detection of specific IgG class antibodies to *T. pallidum* in human serum. The test may be used in conjunction with non treponemal testing and clinical findings to provide serological evidence of infection with *T. pallidum.*
This test is for *in vitro* diagnostic use only.
This test is not intended for screening blood or plasma donors.

Section 3: Indications for Use

Indications for Use: This test system when used in conjunction with non-treponemal based assays provides serological evidence of infection with Treponema pallidum.

Special Conditions for Use Statements:

This test is for *in vitro* diagnostic use only.
This test is for prescription use only.
This test is not intended for screening blood or plasma donors.

Section 4: Substantial Equivalence

Examination of enclosed data indicates that the ZEUS ELISA Treponema pallidum IgG Test System for the qualitative detection of specific human IgG class antibodies to treponema pallidum in human serum is substantially equivalent to a commercially marketed test system which has been previously cleared by the FDA for *in vitro diagnostic use*.

Section 5: Interpretation of Results

***T. pallidum* IgG Result Interpretation:**

OD Value	Result	Interpretation
≤ 0.90	Negative	A result of ≤0.90 indicates no detectable IgG antibodies to *T. pallidum* and should be reported as non-reactive for IgG antibody to *T. pallidum*.
0.91 – 1.1	Equivocal	Specimens with results in the equivocal range (0.91 – 1.1) should be retested in duplicate. Any two of the three results which agree should be reported. Specimens that remain equivocal after repeat testing may be tested by an alternate serologic procedure and/or re-evaluated by drawing another sample one to three weeks later.
>1.1	Positive	A result of > 1.1 indicates that the specimen is positive for IgG antibody to T. pallidum, the causative agent for syphilis. A positive test result presumes a current or past infection with *T. pallidum*, and should be reported as reactive for IgG antibody to *T. pallidum*. Other *T. pallidum* serology assays should be performed to confirm or rule out a current case of active syphilis.

Section 5A: Comparison of Investigational Device to Predicate Device

The comparisons of the ZEUS ELISA T.pallidum IgG Test System to the predicate device follow, including intended use and various aspects of the procedure.

Characteristic	ZEUS ELISA T.pallidum IgG		Pheonix Bio-Tech Trep-Chek
Use	For in vitro diagnostic use only		For in vitro diagnostic use only
Intended Use	Intended Use: The ZEUS ELISA *Treponema pallidum* ELISA Test System is intended for the qualitative detection of specific IgG class antibodies to *T. pallidum* in human serum. The test system is intended to be used as an aid in the laboratory diagnosis of Syphilis disease caused by *T. pallidum* spirochete.		The Phoenix Bio-Tech Corp. Syphilis Trep-Chek Test Kit is a confirmatory immunoassay for the qualitative detection of Treponema pallidum IgG antibodies in human serum.
Assay	Immunoassay		Immunoassay
Detection Method	Colormetric		Colormetric
Solid Phase	Polystyrene 96 well plate		Polystyrene 96 well plate
Antigen Used	recombinant p 17 Treponema pallidum antigen		Recombinant Treponema pallidum antigen
Specimen Tested	Human Serum		Human Serum
Controls	One Positive Control, one Negative Control		One Positive Control, one Negative Control
Calibration	Includes Calibrator (human serum)		Includes Calibrator (human serum)
Analyte Measured	Human IgG		Human IgG
Sample Dilution	1:21 in SAVe Diluent		1:20 in phosphate buffer based diluent
Sample Incubation	25 +/- 5 minutes at room temperature		30 +/- 2 minutes at room temperature
Post Sample Wash	5x wash (dispense/aspirate)		4x wash (dispense/aspirate)
Conjugate	Goat anti-human IgG; Fc chain specific		Goat anti-human IgG; *y* chain specific
Conjugate Label	Horse radish peroxidase		Horse radish peroxidase
Conjugate Incubation	25 +/- 5 minutes at room temperature		30 +/- 2 minutes at room temperature
Post Conjugate Wash	5x wash (dispense/aspirate)		4x wash (dispense/aspirate)
Substrate	TMB		TMB
Reading	Read the color change (optical density) of the wells		Read the color change (optical density) of the wells
Data Points	Read one OD value for each control and sample		Read one OD value for each control and sample
Math	Single point curve		Single point curve
Scale	Calculate the index value of unknown samples by comparing their OD to the cut off OD		Calculate the index value of unknown samples by comparing their OD to the cut off OD
Interpretation Criteria	Negative is <= 0.90, Positive is >= 1.10 and Equivocal is 0.90 - 1.09		Negative is <= 0.90, Positive is >= 1.10 and Equivocal is 0.90 - 1.09

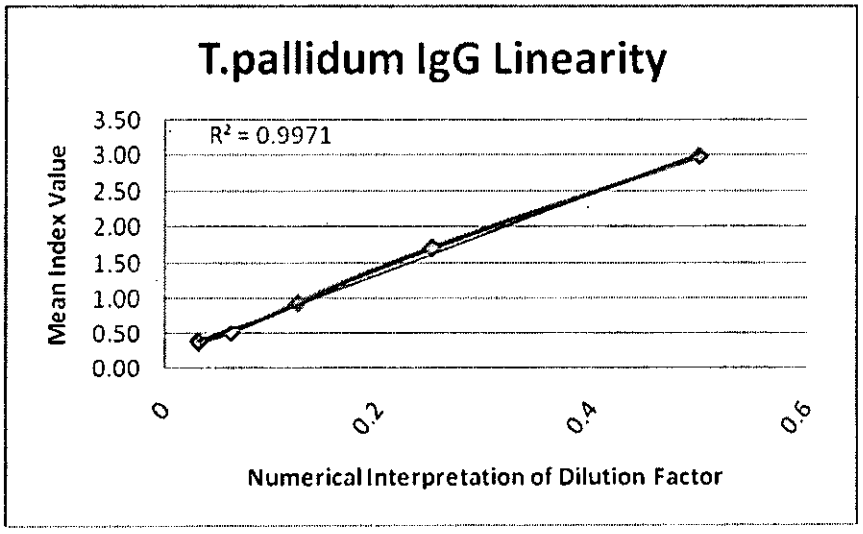
Section 6: Test Principle

The ZEUS ELISA Treponema pallidum IgG Test System is designed to detect IgG class antibodies in human sera to Treponema pallidum. Wells of plastic microwell strips are sensitized by passive absorption with *T. pallidum* antigen. The test procedure involves three incubation steps:

1. Test sera are diluted with SAVE Diluent. During sample incubation, any antigen specific IgG antibody in the sample will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components.
2. Peroxidase conjugated goat anti-human IgG is added to the wells and the plate is incubated. The conjugate will react with IgG antibody immobilized on the solid phase in step 1. The wells are washed to remove unbound conjugate.
3. The microwells containing immobilized peroxidase conjugate are incubated with peroxidase substrate solution. Hydrolysis of the substrate by peroxidase produces a color change. After ten minutes have elapsed, the reaction is stopped and the color intensity of the solution is measured photometrically. The color intensity of the solution depends on upon the antibody concentration in the original test sample.

Section 7: Linearity

The WHO International Standard was diluted serially. Each dilution was tested in duplicate, the mean calculated and the result plotted.



Section 8: Analytical Specificity

Interfering Substances

The effect of potential interfering substances on sample results generated using the test system was evaluated with the following possible interfering substances: albumin, bilirubin, cholesterol, hemoglobin, triglycerides and intralipids.

The quantity of analyte in each interfering substance is as follows:

Bilirubin: 1mg/dL (low), 15 mg/dL (high)
Albumin: 3.5 g/dL (low), 5 g/dL (high)
Cholesterol: 150 mg/dL (low), 250 mg/dL (high)
Triglycerides: 150 mg/dL (low), 500 mg/dL (high)
Hemoglobin: 20 g/dL (low), 20 g/dL (high)
Intralipid: 300 mg/dL (low), 750 mg/dL (high)

Three samples for Treponema pallidum IgG were chosen based on their performance on the Treponema pallidum IgG ELISA test system: positive, borderline and negative. 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 signal changes greater than 20 % must be specified in the package insert.

All positive samples showed less than a 20% recovery of signal.
The borderline samples showed a recovery of signal <20% of with the exception of the high spike of hemoglobin (25.2%).
The negative sample showed a change of signal (>20%) with the high and low spikes of albumin, hemoglobin, intralipid, bilirubin, cholesterol and triglycerides. The negative sample results in each instance stayed below the cut-off and the change in signal did not affect the qualitative result.

Cross Reactivity
Ten samples minimally for each cross-reactant were tested. The results presented were obtained by testing the analytes against high concentrations of possible cross reactants. The results of this study are summarized in the following table.

Treponema pallidum IgG Cross reactivity Study	
Analyte	positive/tested
EBV	0/10
ANA	0/10
RF IgM	0/10
Rubella	0/10
HIV	0/10
HSV 1	0/10
HSV 2	0/10
Sera from Pregnant Patients	0/10
Hepatitis B	0/10
VZV	0/10
VZV IgM	0/10
CMV	0/10
Toxoplasma	0/10
Lyme G/M	0/10
Hepatitis C	0/10

Detection Limits
This is a qualitative assay (Positive, Negative or Equivocal results) so there is no limit of detection study.

Section 9: Clinical Performance

Clinical Data Generated for Submission: Method Comparison with Predicate Device

1. **Prospectively Collected Intended Use Populations:**
   - 500 unselected samples from patients with a syphilis test ordered. The samples were submitted for syphilis antibody testing, sequentially numbered, de-identified and archived.
   - 500 unselected samples from pregnant women with a syphilis test ordered. The samples were submitted for syphilis antibody testing, sequentially numbered, de-identified and archived.

   After procurement, the samples were tested at a hospital laboratory located in the Mid-Atlantic, the Northeast and at Zeus. The hospital laboratories tested 200 samples from patients with a syphilis test ordered and 200 samples from pregnant women. Zeus tested 100 samples from patients with a syphilis tests ordered and 100 samples from pregnant women.

2. **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.

3. **Prospective HIV-1 Positive Samples:** 223 banked known positive HIV-1 samples were acquired from a New York vendor.

4. **Retrospective TPPA /RPR Positive:** 280 samples requested to be RPR/TPPA positive were purchased from a New York vendor.

5. **Retrospective TPPA Negative Collected from Pregnant Women:** 250 samples requested to be collected from pregnant women and requested to be syphilis antibody negative were purchased from a New York vendor.

6. **Retrospective TPPA Positive Collected from Pregnant Women:** 27 samples requested to be collected from pregnant women and requested to be RPR/TPPA positive were purchased from a New York vendor.

7. **CDC Syphilis Panel:** 157 samples of various reactivity to syphilis were evaluated.

8. **Precision and Reproducibility:** Precision of the device was assessed using fifteen samples. These repeatability studies were performed internally at the manufacturing site's laboratory. Reproducibility was assessed using fifteen samples tested at two external sites and internally at Zeus.

Prevalence and Expected Values

To determine expected values in the populations tested, internal and external investigators assessed the device's performance with 500 masked samples prospectively collected from individuals and 500 samples from pregnant women. 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.

In the 500 prospectively collected samples from patients ranging in age from <1 to >70 years of age, 7 tested positive. The overall observed prevalence in this group was 1.4% (7/500 samples).

In the 500 samples collected from pregnant women ranging in age from 15 to 48, 3/498 samples tested positive. The observed prevalence in this group was 0.6%. Two samples were excluded due to questionable age.

In the group of 1000 samples from unselected hospitalized patients ranging in age from <1 to >70 years of age, 32 tested positive. The overall observed prevalence in this group was 3.2% (32/999 samples). One sample was QNS for testing.

Clinical Performance and Comparative Testing for Intended Use Populations in a Prospective Study

The comparative study for the Intended Use Populations consisted of 500 unselected serum samples from patients with a syphilis test ordered. 500 purchased serum samples from pregnant women were also tested.

PERFORMANCE CHARACTERISTICS

The clinical study consisted of 2,937 serum samples evaluated at three sites located in the United States. All serum samples evaluated for concordance were tested with the treponemal (TPPA) reference assay. Samples that were positive by TPPA were reference assay positive. Samples that were negative by TPPA were reference assay negative. The testing sites, samples and sample volumes are presented in the following table:

Sites, Populations and Amounts of Samples Tested							
	Prospective Samples			Rerospective Samples			
	patients with syphilis test	pregnant women with syphilis test	sera from unselected hospitalized	purchased sera from HIV positive	purchased sera from pregnant	purchased sera requested to be	CDC Syphilis characterized

Sites	ordered	ordered	patients	patients	women	RPR/TPPA +	samples
Zeus	100	100	350	223	0	0	0
Monmouth	200	200	350	0	277	280	0
Mainline	200	200	300	0	0	0	0
CDC	0	0	0	0	0	0	157
Total	500	500	1000	223	277	280	157

Prospectively Collected Intended Use Populations:

500 unselected samples from patients with a syphilis test ordered. The samples were submitted for syphilis antibody testing, sequentially numbered, de-identified and archived.

		Banked sera from patients with syphilis test ordered					
		Predicate					
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
T.pallidum IgG ELISA	Positive	4	0	3	7	80.0%	28.4-99.5%
	Equivocal	1	0	1	2		
	Negative	0	0	491	491	99.2%	97.9-99.8%
	Site Total	5	0	495	500		

500 unselected samples from pregnant women with a syphilis test ordered. The samples were submitted for syphilis antibody testing, sequentially numbered, de-identified and archived.

		Banked purchased sera from pregnant women with syphilis test ordered					
		Predicate					
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
T.pallidum IgG ELISA	Positive	3	0	0	3	75.0%	19.4-99.4%
	Equivocal	0	0	0	0		
	Negative	1	0	494	495	100.0%	99.4-100%
	Site Total	4	0	494	498		

*2 samples excluded due to unverifiable age

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 clinical sites.

Unselected hospitalized patients					
Predicate					
				PPA	

		Positive	Equivocal	Negative	Site Total	NPA	95% CI
T.pallidum IgG ELISA							
	Positive	13	1	18	32	61.9%	38.4-81.9%
	Equivocal	1	0	9	10		
	Negative	7	0	950	957	97.1%	95.9-98.1%
	QNS	0	0	1	1		
	Site Total	21	1	978	1000		

Retrospective HIV-1 Positive Samples: 223 banked known positive HIV-1 samples were acquired from a New York vendor.

		Banked purchased known HIV-1 positive serum samples					
		Predicate					
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
T.pallidum IgG ELISA							
	Positive	41	0	1	42	85.4%	72.2-93.9%
	Equivocal	1	0	0	1		
	Negative	4	2	174	180	99.4%	96.9-100%
	Site Total	46	2	175	223		

Retrospective TPPA /RPR Positive: 280 samples requested to be RPR/TPPA positive were purchased from a New York vendor.

		Banked purchased sera requested to be RPR/TPPA reactive					
		Predicate					
		Positive	Equivocal	Negative	Site Total	PPA NPA	95% CI
T.pallidum IgG ELISA							
	Positive	259	1	4	264	98.5%	96.2-99.6%
	Equivocal	1			1		
	Negative	3		12	15	70.6%	46.9-98.7%
	Site Total	263	1	16	280		

Retrospective TPPA Negative and TPPA Positive Samples Collected from Pregnant Women: 250 samples requested to be collected from pregnant women and requested to be syphilis antibody negative were purchased from a New York 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 New York vendor.

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
T.pallidum IgG ELISA	Positive	26	1	0	27	92.9%	76.5-99.1%
	Equivocal	0	0	0	0		
	Negative	2	0	248	250	99.6%	97.8-100%
	Site Total	28	1	248	277		

CDC Syphilis Panel: 157 samples from patients with various clinical diagnoses with syphilis disease were evaluated. The % agreement of the Treponema pallidum IgG ELISA kit with the clinical diagnosis is presented in the following table.

	T. pallidum IgG ELISA Results				% Agreement with Clinical Diagnosis	
Clinical Diagnosis	Positive	Equivocal	Negative	Total	Presented with 95% CI	
Primary Treated	11	0	0	11	100% (11/11)	76.2-100%
Secondary Untreated	41	0	2	43	95.3% (41/43)	84.2-99.4%
Secondary Treated	39	0	0	39	100% (39/39)	92.6-100%
Latent Untreated	6	0	5	11	54.5% (6/11)	23.4-83.3%
Latent Treated	48	0	2	50	96.0% (48/50)	86.3-99.5%
Congenital	1	1	1	3	33.3% (1/3)	0.84-90.6%
Total	146	1	10	157	93.0% (146/157)	87.8-96.5%

PRECISION and REPRODUCIBILITY

Precision

Precision was evaluated at the manufacturer site. The study was conducted as follows: fifteen samples were identified and/or prepared (by Zeus Scientific, Inc.) for use in the study based upon their activity on the **ZEUS ELISA Treponema pallidum IgG** assay. Three samples each were selected that were negative, high negative, near cut-off, low positive and high positive. On each day of testing, the samples were diluted twice and tested. This was repeated in a second run on the same day by a different technologist for a total of twelve days. Precision is considered acceptable for the reactive samples if the Total CV is <15%. The reproducibility for the negative samples is considered acceptable if the Total CV is <25%. This study is summarized below:

Summary Of In-House Repeatability										
Panel	Sample	Mean	Within-Run		Within -Day		Between-Run		Total	
Member	N	AU/mL	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative 1	48	0.08	0.003	3.8%	0.006	8.0%	0.006	6.8%	0.011	13.1%
Negative 2	48	0.12	0.005	4.0%	0.003	6.5%	0.009	7.0%	0.013	10.5%
Negative 3	48	0.50	0.017	3.6%	0.034	9.5%	0.020	3.9%	0.045	9.0%
High Negative 1	48	0.75	0.057	7.6%	0.030	8.6%	0.019	2.5%	0.058	7.7%
High Negative 2	48	0.72	0.046	6.4%	0.014	7.1%	0.015	2.0%	0.052	7.2%

High Negative 3	48	0.74	0.015	2.0%	0.018	4.7%	0.011	1.4%	0.034	4.5%
Near Cut-off 1	48	0.92	0.028	3.0%	0.025	5.0%	0.036	3.9%	0.056	6.1%
Near Cut-off 2	48	1.04	0.022	2.1%	0.014	3.9%	0.033	3.1%	0.045	4.3%
Near Cut-off 3	48	0.95	0.037	3.9%	0.025	6.4%	0.036	3.8%	0.061	6.4%
Low Positive 1	48	1.48	0.029	2.0%	0.029	3.9%	0.014	0.9%	0.058	3.9%
Low Positive 2	48	1.43	0.026	1.8%	0.020	2.5%	0.017	1.2%	0.050	3.5%
Low Positive 3	48	1.65	0.027	1.6%	0.037	4.2%	0.018	1.1%	0.078	4.7%
High Positive 1	48	5.43	0.131	2.4%	0.154	3.8%	0.27	5.0%	0.38	7.0%
High Positive 2	48	4.85	0.110	2.3%	0.176	3.6%	0.17	3.6%	0.29	6.0%
High Positive 3	48	4.74	0.136	2.8%	0.189	4.9%	0.17	3.5%	4.74	5.2%
Non-Reactive Control	48	0.13	0.004	3.3%	0.008	6.23%	0.007	5.39%	0.010	8.2%
Reactive Control 1	48	5.63	0.049	7.5%	5.5	5.15%	0.29	5.11%	0.42	7.51%

Reproducibility

Reproducibility was evaluated internally and at two external clinical sites. The study was conducted as follows: fifteen samples were identified and/or prepared (by Zeus Scientific, Inc.) for use in the study based upon their activity on the assay. Three samples each were selected that were negative, high negative, near cut-off, low positive and high positive. To assess reproducibility, on each day of testing, each sample was diluted twice and each dilution was run in triplicate. This was repeated in a second run by a second technologist resulting in twelve results per day. This was repeated for five days at each site and the resulting data used. Reproducibility is considered acceptable for the reactive samples if the Total CV is <15% and if the Total CV for the borderline and positive samples do not congregate at the high end of acceptability but show a spread of results of at least 3%. The reproducibility for the negative sample is considered acceptable if the Total CV is <50% and shows no change in the qualitative outcome.

Summary Of Multi-Site Reproducibility												
Panel	Sample	Mean	Within-Run		Within -Day		Between-Run		Between-Site		Total	
Member	N	Index value	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative 1	180	0.06	0.01	14.7%	0.01	19.3%	0.01	10.7%	0.02	29.1%	0.02	36.6%
Negative 2	180	0.08	0.01	9.7%	0.01	12.2%	0.01	8.3%	0.01	14.6%	0.01	15.5%
Negative 3	180	0.31	0.03	8.6%	0.03	10.7%	0.02	6.6%	0.04	12.7%	0.04	13.3%
High Negative 1	180	0.80	0.04	5.1%	0.05	6.3%	0.03	4.2%	0.06	7.3%	0.06	7.3%
High Negative 2	180	0.74	0.04	5.1%	0.04	5.8%	0.02	3.0%	0.05	7.0%	0.05	7.4%
High Negative 3	180	0.76	0.04	5.0%	0.04	5.6%	0.21	2.7%	0.05	6.5%	0.05	7.2%
Near Cut-off 1	180	1.05	0.07	6.3%	0.07	7.3%	0.03	3.6%	0.09	9.0%	0.11	10.3%
Near Cut-off 2	180	1.13	0.05	4.7%	0.06	5.4%	0.04	3.1%	0.07	6.0%	0.08	6.7%
Near Cut-off 3	180	0.95	0.05	5.6%	0.07	6.7%	0.04	4.0%	0.08	8.5%	0.09	9.9%
Low Positive 1	180	1.45	0.09	6.2%	0.11	7.6%	0.06	4.4%	0.13	8.9%	0.14	9.6%
Low Positive 2	180	1.77	0.11	5.9%	0.14	7.8%	0.10	5.8%	0.15	8.3%	0.16	9.2%
Low Positive 3	180	1.93	0.14	7.1%	0.17	8.9%	0.12	5.9%	0.19	9.7%	0.21	10.7%
Positive	180	3.6	0.20	5.7%	0.22	6.2%	0.10	2.8%	0.30	8.4%	0.37	10.2%
Positive 2	180	3.1	0.20	6.2%	0.22	7.3%	0.13	4.4%	0.28	9.0%	0.34	10.9%
Positive 3	180	3.1	0.18	5.7%	0.22	6.9%	0.16	4.9%	0.26	8.4%	0.31	10.2%
Non-Reactive Control	180	0.09	0.01	10.6	0.01	12.8	0.01	6.2	0.01	15.9	0.02	21.0%
Reactive Control	180	3.9	0.16	4.1	0.12	5.1	0.14	3.5	0.22	5.7	0.02	5.9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Zeus Scientific Inc.
c/o Ms. Ewa Nadolczak
Manager Clinical Affairs
200 Evans Way
Branchburg, NJ 08876

FEB 10 2011

Re: k102283

Trade/Device Name:	*Treponema pallidum* IgG ELISA Test System
Regulation Number:	21CFR §866.3830
Regulation Name:	*Treponema pallidum* treponemal test reagents.
Regulatory Class:	Class II
Product Code:	LIP
Dated:	January 25, 2011
Received:	January 26, 2011

Dear Ms. Nadolczak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section

510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K102283

Device Name: ZEUS ELISA *Treponema pallidum* IgG Test System

Indications for Use:

The ZEUS ELISA *Treponema pallidum* IgG Test System is intended for the qualitative detection of specific IgG class antibodies to *T. pallidum* in human serum. The test may be used in conjunction with non treponemal testing and clinical findings to provide serological evidence of infection with *T. pallidum*.
This test is for *in vitro* diagnostic use only.
This test is not intended for screening blood or plasma donors.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K102283