K033083

NOV 2 6 2003

Summary of Safety and Effectiveness Information
Borrelia burgdorferi IgG/IgM ELISA Test Kit

I. Trinity Biotech
2823 Girts Road
Jamestown, NY 14701
Contact person: Bonnie B. DeJoy
Telephone: 716-483-3851
Date of preparation: Nov. 20, 2003

II. Description of Device

The *Borrelia burgdorferi* IgG/IgM ELISA kit is an Enzyme-Linked ImmunosorbentAssay (ELISA) for the qualitative presumptive detection of total (IgG/IgM) antibodies to *Borrelia burgdorferi* in human serum. This ELISA should only be used for patients with signs and patients with symptoms that are consistent with Lyme disease. Equivocal or positive results should be supplemented by testing with a standardized Western blot procedure. Positive supplemental results are supportive evidence of exposure to *B. burgdorferi* and can be used to support a clinical diagnosis of Lyme disease.

The *Borrelia burgdorferi* IgG/IgM ELISA test is an enzyme linked immunosorbent assay to detect IgG/IgM antibodies to *Borrelia burgdorferi*. Purified *Borrelia burgdorferi* antigen is attached to a solid phase microtiter well. Diluted test sera is added to each well. If the antibodies are present that recognize the antigen, they will bind to the antigen in the well. After incubation, the wells are washed to remove unbound antibody. An enzyme labeled anti-human IgG/IgM is added to each well. If antibody is present, it will bind to the antibody attached to the antigen on the well. After incubation the wells are washed to remove unbound conjugate. A substrate solution is added to each well. If enzyme is present, the substrate will undergo a color change. After an incubation period the reaction is stopped and the color intensity is measured photometrically, producing and indirect measurement of specific antibody in the patient specimen.

III. Predicate Device

The *Borrelia burgdorferi* IgG/IgM ELISA test is substantially equivalent to BioWhittaker's Lyme STAT test. Equivalence is demonstrated by the following comparative results:

Performance Characteristics

The CDC Lyme Disease Serum Panel Stratified by Time After Onset

The following information is from a serum panel obtained from the CDC and tested by Trinity Biotech. The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement of the assay by the CDC.

Table 1
Trinity Biotech *B. burgdorferi* IgG/IgM ELISA Results

Time From Onset	positive	equivocal	negative	Total	% Agreement with Clinical Diagnosis
normals	0	0	5	5	100%
< 1 month	2	0	3	5	40.0%
1-2 months	6	2	2	10	80.0%
3-12 months	9	3	7	19	63.3%
> 1yr	8	0	0	8	100.0%
Total	25	5	17	47	

Because the equivocals would have been tested by immunoblotting in a 2-step test system, they were considered 1-step positive for purposes of calculating % agreement. The Trinity Bitoech *Borrelia burgdorferi* IgG/IgM ELISA demonstrated 71% (30/42) agreement with clinical diagnosis of Lyme disease.

Study 2

One hundred seventy-six fresh sera from patients of various ages and genders that were submitted to a large clinical lab for *B. burgdorferi* antibody testing were tested on the Trinity Biotech *B. burgdorferi* IgG/IgM ELISA and BioWhittaker Lyme Stat. Any serum found positive or equivocal was tested by Mardx Diagnostics Western Blot on both IgG and IgM. The results are illustrated in Table 2.

Table 2

		Western-blot +		-	
Trinity *B. burgdorferi* IgG/IgM	+	6		3	
	eq	1		6	
Lyme Stat	+	5		3	
	eq	0		5	

Type of Result (95%CI)	Trinity (95%CI)	Lyme Stat (95%CI)
1-step (ELISA) Pos. or Eq.	9.1% (4.8% - 13.4%) (16/176)	7.4% (3.4% - 11.3%) (13/176)
1-step Pos. or Eq. & 2-step (WB) Pos.	4% (1.0% - 6.9%) (7/176)	2.8% (0.3% - 5.3%) (5/176)
2-step Pos. among 1-step Pos. or Eq.	44% (18.9% - 68.6%) (7/16)	39% (11.5% - 65.4%) (5/13)

CI = Confidence Interval

Precision

Seven sera were assayed ten times each on three different plates at three different sites. An additional three sera were assayed ten times each on three different plates at two different sites. The intersite precision is shown in Table 3. With appropriate technique the user should obtain precision of <15% CV.

Table 3
Trinity Biotech *Borrelia burgdorferi* IgG/IgM ELISA
Inter-Assay Precision Between Sites

	Inter-Assay (n=90)			
Serum #	**X**	**SD**	**CV**	**n**
1	1.18	0.113	9.58%	90
2	2.26	0.226	10.02%	90
3	3.85	0.278	7.21%	90
4	5.36	0.402	7.50%	90
5	2.04	0.186	9.11%	90
6	0.33	0.132	40.57%	90
7	0.34	0.234	68.93%	90
8	1.47	0.152	10.34%	60
9	1.47	0.104	7.10%	60
10	1.65	0.131	7.95%	60
HPC	5.31	0.314	5.91%	15
LPC	2.70	0.107	3.96%	15
NC	0.20	0.043	21.97%	15
CAL	3.34	0.103	3.08%	45

A total of 810 determinations were made at the three sites. In all 810 determinations there was
not one case of a positive result for a negative serum or a negative result for a positive serum.

X=Mean ISR
SD=Standard Deviation
CV=Coefficient of Variation=SD/X x 100
The methods in NCCLS EP5 were utilized for precision parameters.

Cross-Reactivity

The following potentially cross-reactive sera were run on the Trinity Biotech *Borrelia burgdorferi* IgG/IgM ELISA assay to assess cross-reactivity with the assay: lipemic, bilirubinemic, RPR+, dsDNA+, RF+, EBV+, CMV+, RMS+, elevated ESR, and CRP. The data in Table 4 illustrate the amount of reactivity with the sera.

Table 4
Cross-Reactivity

Laboratory result (Titer)	**# of samples**	**# of positives**
Lipemic (+ + +)	5	0
Bilirubinemic (1.9-16.9)	5	1
RPR + (1:2-1:64)	10	0
Rheumatoid Factor + (1:40-1:320)	3	0
Epstein Barr Virus Antibody + (1:40-1:2560)	7	0
Cytomegalovirus Antibody + (O.D. 0.718-2.308)	6	1
Rocky Mt Spotted Fever Antibody + (1:256-1:16,384)	4	0
CRP + (2.79-8.61 mg/dl)	5	0
Elevated ESR (40-115)	10	0
dsDNA + (52.3-1072 IU)	16	0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 26 2003

Ms. Bonnie B. DeJoy
Director, Quality Systems
Trinity Biotech USA
P.O. Box 1059
Jamestown, NY 14702-1059

Re: k033083
Trade/Device Name: Captia *Borrelia burgdorferi* IgG/IgM ELISA
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: Class II
Product Code: LSR
Dated: September 17, 2003
Received: September 29, 2003

Dear Ms. DeJoy:

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 either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K033083

Device Name: Trinity Biotech Captia™ *Borrelia burgdorferi* IgG/IgM ELISA

Indications For Use: The Trinity Biotech Captia™ *Borrelia burgdorferi* IgG/IgM ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative presumptive detection of total (IgG/IgM) antibodies to *Borrelia burgdorferi* in human serum. This ELISA should only be used for patients with signs and symptoms that are consistent with Lyme disease. Equivocal or positive results must be supplemented by testing with a standardized Western blot procedure. Positive supplemental results are supportive evidence of exposure to *B. burgdorferi* and can be used to support a clinical diagnosis of Lyme disease.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 XFR 801.109) (Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033083