K033106

JUL 1 3 2004

Summary of Safety and Effectiveness Information
Captia™ HSV 2 IgG Type Specific ELISA Test Kit

I. Trinity Biotech USA
2823 Girts Rd.
Jamestown, NY 14701
Contact Person: Bonnie B. DeJoy
Telephone: 716-483-3851
Date of Preparation: July 9, 2004

II. Description of Device

The Captia™ HSV 2 IgG Type Specific kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative determination of IgG antibodies in human serum to Herpes simplex Type 2 antigen. The Captia™ HSV 2 IgG Type Specific assay may be used as an aid in the diagnoses of Herpes infection

For *In Vitro* Diagnostic Use Only.

The Captia™ HSV 2 IgG Type Specific test is an Enzyme-Linked Immunosorbent assay to detect IgG antibodies to Herpes simplex 2 antigen. Purified recombinant HSV gG2 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 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 an indirect measurement of specific antibody in the patient specimen.

III. Predicate Device

The Captia™ HSV 2 IgG Type Specific test is substantially equivalent to Western Blot. Equivalence is demonstrated by the following comparative results:

Perfomance Characteristics

% Agreement Positive and % Agreement Negative with Expectant Mothers†

An outside investigator assessed the % agreement positive and % agreement negative with consented, coded, unselected, banked and masked sera from expectant mothers (n = 210). The reference method was an HSV 2 Western Blot (WB) from a Pacific Northwest university. Of 43 WB positives: Trinity ELISA was 43 positive. Of 165 WB negatives: Trinity ELISA was 151 negative, 13 positive and 1 equivocal.

% Agreement Positive and % Agreement Negative with Expectant Mothers (n = 210)†

Characteristic	*% (EL/WB)**	*95% Confidence Interval (CI)*
% agreement positive to WB	100.00% (43/43)	91.8-100.0%
% agreement negative to WB	91.52% (151/165)	86.2-95.3%
+		

* Excludes one atypical Western Blot and one sample that was both atypical Western Blot and ELISA equivocal.

† The word "% agreement" refers to comparing this assay's results with those of a similar assay. No attempt was made to correlate the assay results to disease presence or absence. No judgment can be made on the similar assay's accuracy in predicting disease.

% Agreement Positive and % Agreement Negative with Sexually Active Adults†

An outside investigator assessed the % agreement positive and % agreement negative with consented, unselected and masked sera from sexually active adults over the age of 14 (n = 198). The reference method was an HSV 2 Western Blot (WB) from a Pacific Northwest university. Of 61 WB positives: Trinity ELISA was 59 positive and 2 negative. Of 134 WB negatives: Trinity ELISA was 121 negative and 13 positive.

% Agreement Positive and % Agreement Negative with Sexually Active Adults (n = 198)†

Characteristic	*% (EL/WB)**	*95% Confidence Interval (CI)*
% agreement positive to WB	96.72% (59/61)	88.7-99.6%
% agreement negative to WB	90.30% (121/134)	84.0-94.7%

* Excludes three atypical Western Blot.

† The word "% agreement" refers to comparing this assay's results with those of a similar assay. No attempt was made to correlate the assay results to disease presence or absence. No judgment can be made on the similar assay's accuracy in predicting disease.

% Agreement Positive and % Agreement Negative with a Low Prevalence Population†

An outside investigator assessed the % agreement positive and % agreement negative with unselected, banked and masked sera from a low prevalence population (n = 184). The reference method was an HSV 2 Western Blot (WB) from a Pacific Northwest university. Of 179 WB negatives: Trinity ELISA was 163 negative, 14 positive and 2 equivocal. Of 4 WB positives: Trinity ELISA was 4 positive.

% Agreement Positive and % Agreement Negative with a Low Prevalence Population (n = 184)†

Characteristic	*% (EL/WB)**	*95% Confidence Interval (CI)*
% agreement positive to WB	100.00% (4/4)	39.8-100.0%
% agreement negative to WB	91.06% (163/179)	85.9-94.8%

* Excludes one atypical Western Blot.

† The word "% agreement" refers to comparing this assay's results with those of a similar assay. No attempt was made to correlate the assay results to disease presence or absence. No judgment can be made on the similar assay's accuracy in predicting disease.

% Agreement Positive with Culture Positives†

An outside investigator assessed the % agreement positive using unselected, retrospective and masked sera from patients that were at least six weeks but not more than one year post clinical presentation and culture HSV 2 positive (n = 56). Reference methods included culture (infection) and an HSV 2 Western Blot (WB) (antibody) from a Pacific Northwest university. Of 56 culture positives: 1) Trinity ELISA was 56 positive and, 2) WB was 55 positive and 1 negative.

% Agreement Positive with Culture Positives (n = 56)†

Characteristic	*% (EL/WB or Culture)*	*95% Confidence Interval (CI)*
% agreement positive to culture	100.00% (56/56)	93.6-100.0%
% agreement positive to WB	100.00% (55/55)	93.5-100.0%
† The word "% agreement" refers to comparing this assay's results with those of a similar assay. No attempt was made to correlate the assay results to disease presence or absence. No judgment can be made on the similar assay's accuracy in predicting disease.		

% Agreement Positive and % Agreement Negative with Alternate HSV 2 Type Specific IgG ELISA

An outside investigator at a Pacific Northwest University assessed the % agreement positive and % agreement negative of the Trinity Biotech Captia™ HSV 2 Type Specific IgG kit and alternate HSV 2 type specific IgG ELISA test with 200 prospective, unselected, sequentially submitted specimens.

Prospectively Collected, Sequential Sera		**Alternate HSV 2 Type Specific IgG**		
		+	-	E
Trinity Biotech Captia™ HSV 2 Type Specific	+	**68**	**10**	**2**
	-	**2**	**117**	**0**
	E	**0**	**1**	**0**

Characteristic	**% (TBU ELISA / Alt. ELISA)**	**95% Confidence Interval (CI)**
Percent Positive Agreement	97.14 % (68 / 70)	90.1 – 99.7 %
Percent Negative Agreement	92.13 % (117 / 127)	86.0 – 96.2 %
Percent Agreement	92.50 % (185 / 200)	87.9 – 95.7 %

Type Specificity with HSV 1 Western Blot Positives

An outside investigator at a Pacific Northwest University assessed the type specificity using HSV 1 Western Blot positive and HSV 2 Western Blot negative sera from the above described populations (n = 292): expectant mothers, sexually active adults, low prevalence persons, and HSV 1 culture positives. Of 292 HSV 1 Western Blot positive and HSV 2 Western Blot negative samples: ELISA was 265 negative, 23 positive and 4 equivocal.

Type Specificity with HSV 2 Western Blot Positives (n = 292)

Characteristic	*% (EL/WB)*	*95% Confidence Interval (CI)*
Type-specificity relative to WB	90.75% (265/292)	86.8-93.8%
Type cross-reactivity relative to WB	8.0% (23/292)	5.06-11.6%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 1 3 2004

Ms. Bonnie B. DeJoy
Director of Quality Systems
Trinity Biotech USA
2823 Girts Road
Jamestown, NY 14701

Re: k033106
Trade/Device Name: Captia™ HSV2 IgG Type Specific ELISA
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes Simplex Virus Serological Reagents
Regulatory Class: Class III
Product Code: MYF
Dated: April 20, 2004
Received: April 21, 2004

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.

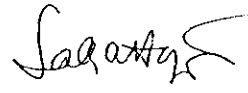
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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,



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

510(k) Number: K033106
Device Name: Captia™ HSV2 IgG Type Specific ELISA

Indications for Use:
The Trinity Biotech Captia™ Herpes Simplex Virus (HSV) 2 Type Specific IgG kit is an Enzyme-linked Immunosorbent Assay (ELISA) intended for qualitatively detecting the presence or absence of human IgG class antibodies to HSV-2 in human serum. In conjunction with the Trinity Biotech Captia™ Herpes Simplex Virus (HSV) 1 Type Specific IgG kit, the test is indicated for testing sexually active adults or expectant mothers for aiding in the presumptive diagnosis of HSV infection. Due to the implications of positive results, it is recommended they be confirmed in a low prevalence population with Western blot. The performance of this assay has not been established for use in a pediatric population, for neonatal screening, for testing of immunocompromised patients, or for use with automated equipment. The user is responsible for establishing assay performance in these populations and with automated equipment.

Prescription Use ✓ AND/OR Over-The Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033106