K033105

JUL 1 3 2004

Summary of Safety and Effectiveness Information
Captia™ HSV 1 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 1 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 1 antigen. The Captia™ HSV 1 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 1 IgG Type Specific test is an Enzyme-Linked Immunosorbent assay to detect IgG antibodies to Herpes simplex 1 antigen. Purified recombinant HSV gG1 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 1 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 1 Western Blot (WB) from a Pacific Northwest university. Of 155 WB positives, Trinity ELISA was 136 positive, 18 negative and 1 equivocal. Of 55 WB negatives, Trinity ELISA was 54 negative and 1 positive.

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

Characteristic	*% (EL/WB)**	*95% Confidence Interval (CI)*
% agreement positive to WB	87.74% (136/155)	82.6-92.9%‡
% agreement negative to WB	98.18% (54/55)	90.3-100.0%

† 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.
‡ 95% CI calculated using the normal approximate method.

% 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 1 Western Blot (WB) from a Pacific Northwest university. Of 116 WB positives, Trinity ELISA was 102 positive and 14 negative. Of 80 WB negatives, Trinity ELISA was 80 negative.

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

Characteristic	*% (EL/WB)**	*95% Confidence Interval (CI)*
% agreement positive to WB	87.93% (102/116)	82.0-93.9%‡
% agreement negative to WB	100.00% (80/80)	95.5-100.0%

* Excludes two atypical Western Blots.
† 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.
‡ 95% CI calculated using the normal approximate method.

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

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 1 Western Blot (WB) from a Pacific Northwest university. Of 131 WB negatives, Trinity ELISA was 128 negative, 1 positive and 2 equivocal. Of 53 WB positives, Trinity ELISA was 42 positive, 8 negative and 3 equivocal.

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

Characteristic	*% (EL/WB)**	*95% Confidence Interval (CI)*
% agreement positive to WB	79.25% (42/53)	65.9-89.2%
% agreement negative to WB	97.71% (128/131)	93.5-99.5%

†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 1 positive (n = 53). Reference methods included culture (infection) and an HSV 1 Western Blot (WB) (antibody) from a Pacific Northwest university. Of 53 culture positives: 1) Trinity ELISA was 37 positive, 12 negative and 4 equivocal and, 2) WB was 44 positive and 9 negative. Of 44 WB positives: Trinity ELISA was 36 positive, 6 negative, and 2 equivocal.

% Agreement Positive with Culture Positives (n = 53)†

Characteristic	*% (EL/WB or Culture)*	*95% Confidence Interval (CI)*
% agreement positive to culture	69.81% (37/53)	55.7-81.7%
% agreement positive to WB	81.82% (36/44)	67.3-91.8%
† 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 to Alternate HSV 1 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 1 Type Specific IgG kit and an alternate HSV 1 type specific IgG ELISA test with 200 prospective, unselected, sequentially submitted specimens.

Prospectively Collected, Sequential Sera		**Alternate HSV 1 Type Specific IgG**		
		+	-	E
Trinity Biotech Captia HSV 1 Type Specific	+	**92**	**3**	**0**
	-	**6**	**99**	**0**
	E	**0**	**0**	**0**

Characteristic	**% (TBU ELISA / Alt. ELISA)**	**95% Confidence Interval (CI)**
Percent Positive Agreement	93.88 % (92 / 98)	87.2 – 97.7%
Percent Negative Agreement	97.06 % (99 / 102)	91.6 – 99.4 %
Percent Agreement	95.50 % (191 / 200)	91.6 – 97.9 %

Type Specificity with HSV 2 Western Blot Positives

An outside investigator at a Pacific Northwest University assessed the type specificity using HSV 2 Western Blot positive and HSV 1 Western Blot negative sera from the above described populations (n = 56): expectant mothers, sexually active adults, low prevalence persons, and HSV 2 culture positives. Of 56 HSV 2 Western Blot positive and HSV 1 Western Blot negative samples, Trinity ELISA was 54 negative and 2 positive.

Type Specificity with HSV 2 Western Blot Positives (n = 56)

Characteristic	*% (EL/WB)*	*95% Confidence Interval (CI)*
Type-specificity relative to WB	96.4% (54/56)	87.7-99.6%
Type cross-reactivity relative to WB	3.6% (2/56)	0.43-12.3%

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: k033105
Trade/Device Name: Captia™ HSV 1 IgG Type Specific ELISA
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes Simplex Virus Serological Reagents
Regulatory Class: Class III
Product Code: MXJ
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.

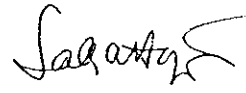
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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: K033105
Device Name: Captia™ HSV1 IgG Type Specific ELISA

Indications for Use:
The Trinity Biotech Captia™ Herpes Simplex Virus (HSV) 1 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-1 in human serum. In conjunction with the Trinity Biotech Captia™ Herpes Simplex Virus (HSV) 2 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 performanace 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)

Reddy Tu. Poole
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033105/S1