

2/26/99

K983541

**510(k) SUMMARY
FOR
HSV 1+2 IgG ELISA TEST**

SUBMITTER: Gull Laboratories, Inc.
1011 Murray Holladay Road
Salt Lake City, UT 84117
(801) 263-3524

CONTACT PERSON: Fred W. Rachford

DATE: December 17, 1998

DEVICE NAME:

Trade/Proprietary Name: HSV 1+2 IgG ELISA Test
Common/Usual Name: Anti-HSV IgG Antibody Test
Classification Name: Herpes Simplex Virus Serological Reagent

PREDICATE DEVICE: HSV 1+2 IgG ELISA Test / Gull Laboratories, Inc.

DEVICE DESCRIPTION:

The HSV 1+2 IgG ELISA Test is an *in vitro* diagnostic medical device intended for the qualitative detection of IgG antibody to the herpes simplex virus (HSV) in human serum by the enzyme-linked immunosorbent assay (ELISA) method.

The HSV 1+2 IgG ELISA Test is comprised of the following items:

1. **Antigen-Coated ELISA Plate:** One 96-well plate comprised of twelve 8-well strips with breakaway wells, each well coated with partially purified HSV antigen.
2. **IgG Specimen Diluent:** One bottle containing 30 ml of a lavender colored dilution buffer with sodium azide.
3. **Conjugate:** One bottle containing 15 ml of a pink colored solution of alkaline phosphatase-labeled antihuman IgG (Caprine) with sodium azide.
4. **Substrate Buffer:** One bottle containing 30 ml of a blue colored buffer solution with sodium azide.
5. **p-NPP Tablets:** One foil pack containing 6 tablets of p-nitrophenyl phosphate (p-NPP).
6. **Stopping Reagent:** One bottle containing 30 ml of a colorless solution of 1.5 N sodium hydroxide (NaOH).
7. **Positive Control and Negative Control:** One vial of each containing 200 μ l of serum (human) with sodium azide.
8. **Reference Serum:** One vial containing 400 μ l of serum (human) with sodium azide.
9. **20X Wash Solution:** One bottle containing 60 ml of a green colored solution with detergent and sodium azide.
10. **ELISA Plate Sealer:** One acetate sheet with contact adhesive.
11. **Resealable Storage Bag:** One plastic sealable bag.
12. **ELISA Worksheet:** One worksheet for recording data.

When the HSV 1+2 IgG ELISA Test is employed, diluted patient serum is incubated with partially purified HSV antigen bound to the ELISA plate wells. If antibodies to herpes simplex virus are present, they bind to the antigen and do not rinse off. Subsequently when enzyme-labeled antihuman IgG is added to the reaction site it binds to the immobilized IgG antibodies. After washing and the addition of a chromogenic substrate and stopping reagent, specimens containing antibodies to herpes simplex virus produce a color endpoint reaction which can be read with a standard ELISA plate reader.

INTENDED USE:

The HSV-1 Specific IgG ELISA Test is intended for use manually or in conjunction with the DUET™ Instrument in the qualitative detection of IgG antibody to herpes simplex virus type 1 and type 2 in human serum by the enzyme-linked immunosorbent assay (ELISA) method. When performed according to instructions, the HSV 1+2 IgG ELISA Test is of value in the determination of immunological experience pertaining to infection with herpes simplex virus type 1 and type 2 and as an aid in the diagnosis of herpes simplex virus type 1 and type 2 associated disease.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICE:

The HSV 1+2 IgG ELISA Test and the HERPELISA II Test kit both are technologically based on the enzyme-linked immunosorbent assay (ELISA) method.

SUBSTANTIAL EQUIVALENCE PERFORMANCE DATA:

Blood samples from 154 donors were evaluated for the presence of IgG antibody to herpes simplex virus type 1 and type 2 at Gull Laboratories, Inc. with the HSV 1+2 IgG ELISA Test and the HERPELISA II Test Kit. The relative agreement between the two test systems was 96.7% (148/153) with a 95% confidence interval of 92.5% to 98.9%. The relative sensitivity and relative specificity of the HSV 1+2 IgG ELISA Test were 99.1% (112/113) with a 95% confidence interval of 95.2% to 100.0% and 90.0% (36/40) with a 95% confidence interval of 75.3% to 97.2% respectively when compared to the HERPELISA II Test Kit. Equivocal results were not included in the calculations. The calculations for the 95% confidence interval made by the Exact Method.

The following relates to the evaluation of the HSV 1+2 IgG ELISA Test with a serum panel obtained from the Centers for Disease Control (CDC). This serum panel was comprised of one hundred frozen clinical specimens (50 paired sera) which were characterized at the CDC using both an enzyme immunoassay (EIA) and an in-house Western Blot method for HSV type specific antibody detection (9). The serum panel consisted of 72% positive and 28% negative samples. The results of this evaluation are presented below as a means to convey further information regarding the performance of this assay with a masked, characterized serum panel. There should be no other inferences drawn from the panel results presented herein. This does not imply an endorsement of the assay by the CDC.

This serum panel was tested at a hospital in the Northeastern region of the U.S. (Site 1), a clinical laboratory in the Northwestern region of the U.S. (Site 2), and Gull Laboratories, Inc. (Site 3) for IgG antibody to HSV-1 and/or HSV-2 using the HSV 1+2 IgG ELISA Test. All three sites produced the same qualitative results for all but one sample which gave negative results at the hospital laboratory in the Northeastern region of the U.S. and the clinical laboratory in the Northwestern region of the U.S. but equivocal results at Gull Laboratories, Inc. The test results were sent to the CDC for analysis and decoding of the specimens.

Based on the CDC's analysis, when the serum panel samples were tested at the hospital laboratory in the Northeastern region of the U.S. and the clinical laboratory in the Northwestern region of the U.S. the HSV 1+2 IgG ELISA Test demonstrated 96.0% (96/100) total agreement with the CDC results at each site. Of the results obtained by the HSV 1+2 IgG ELISA Test, there was 100% (72/72) agreement for the positive specimens and 85.7% (24/28) agreement for negative specimens.

When the serum samples were tested at Gull Laboratories, Inc. the HSV 1+2 IgG ELISA Test demonstrated 95% (95/100) total agreement with the CDC results. Of the results obtained by the HSV 1+2 IgG ELISA Test, there was 100% (72/72) agreement for the positive specimens and 82.1% (23/28) agreement for negative specimens. One equivocal test result was included in these calculations.

CONCLUSIONS:

The HSV 1+2 IgG ELISA Test is believed to be substantially equivalent to the HERPELISA II Test Kit. This assessment is based on (1) the two tests are technologically equivalent, both being based on the enzyme-linked immunosorbent assay method, (2) the data from clinical studies conducted at Gull Laboratories, Inc. and two outside clinical institutions demonstrated acceptable agreement and the relative sensitivity and relative specificity when compared with the expected specimen reactivity for patient specimens characterized for IgG antibodies to herpes simplex virus type 1 and type 2.



FEB 26 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fred W. Rachford, Ph.D.
Senior Vice President
Gull Laboratories, Inc.
1011 Murray Holladay Road
Salt Lake City, Utah 84117-4999

Re: K983541
Trade Name: HSV 1+2 IgG ELISA Test
Regulatory Class: III
Product Code: LGC
Dated: December 17, 1998
Received: December 22, 1998

Dear Dr. Rachford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

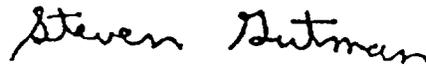
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

EXHIBIT G - REVISED 12/17/98

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): New Submission / Not Assigned

Device Name: HSV 1+2 IgG ELISA TEST

Product Number: H3S100

Indications For Use:

The HSV 1+2 IgG ELISA TEST is to be used manually or in conjunction with the Duet™ instrument in the testing of human serum specimens from individuals in whom the qualitative presence or absence of detectable IgG antibody to herpes simplex virus type 1 and type 2 is warranted in the determination of immunological experience pertaining to infection with herpes simplex virus type 1 and type 2 and as an aid in the diagnosis of herpes simplex virus associated disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Debaris
(Division Sign/Off)
Division of Clinical Laboratory Devices
510(k) Number 15983541

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

(Optional Format 1-2-96)