NOV - 4 1997

K971857

EXHIBIT G - REVISED 07/31/97

510(k) SUMMARY
FOR
MUMPS 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: April 30, 1997

DEVICE NAME:

Trade/Proprietary Name: Mumps IgG ELISA Test

Common/Usual Name: Anti-Mumps IgG Antibody Test

Classification Name: Mumps Virus Serological Reagent

PREDICATE DEVICE: Mumps Stat Test Kit / BioWhittaker, Inc.

DEVICE DESCRIPTION:

The Mumps IgG ELISA Test is an *in vitro* diagnostic medical device intended for the qualitative and semi-quantitative detection of IgG antibody to the mumps virus in human serum by the enzyme-linked immunosorbent assay (ELISA) method.

The Mumps IgG ELISA Test is comprised of the following items:

1. Mumps Antigen-Coated ELISA Plate: One 96-well plate comprised of twelve 8-well strips with breakaway wells, each well coated with partially purified mumps antigen (Enders Strain).

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. Calibrator 1 and 2: One vial of each containing 200 µl of serum (human) with sodium azide.

8. Positive Control and Negative Control: One vial of each containing 200 µl of serum (human) with sodium azide.

9. Reference Serum: One vial containing 400 µl of serum (human) with sodium azide.

10. 20X Wash Solution: One bottle containing 60 ml of a green colored solution with detergent and sodium azide.

11. ELISA Plate Sealer: One acetate sheet with contact adhesive.

12. Resealable Storage Bag: One plastic sealable bag.

13. ELISA Worksheet: One work sheet for recording data.

14. Activity Units Graph Paper: One sheet of graph paper for activity unit computations.

When the Mumps IgG ELISA Test is employed, diluted patient serum is incubated with purified mumps virus antigen bound to the ELISA plate wells. If antibodies to the mumps 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 the mumps virus produce a color endpoint reaction which can be read with a standard ELISA plate reader.

INTENDED USE:

The Mumps IgG ELISA Test is intended for the qualitative and semi-quantitative detection of IgG antibody to the mumps virus in human serum by the enzyme-linked immunosorbent assay (ELISA) method. When performed according to instructions, the Mumps IgG ELISA Test is of value in the determination of

immunological experience pertaining to infection with mumps virus and in the diagnosis of mumps virus associated disease.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICE:

The Mumps IgG ELISA Test and the Mumps Stat Test Kit both are technologically based on the enzyme-linked immunosorbent assay (ELISA) method.

SUBSTANTIAL EQUIVALENCE PERFORMANCE DATA:

Blood samples from 144 donors at a regional blood bank were evaluated for the presence of IgG antibody to mumps virus at Gull Laboratories, Inc. with the Mumps IgG ELISA Test and the Mumps Stat Test Kit. Discordant samples were retested using the same two tests. Without incorporating the results of retesting the discordant samples, the agreement between the two test systems was 97.9% (139/142). The relative sensitivity and relative specificity of the Mumps IgG ELISA Test were 97.5% (119/122) with a 95% confidence interval of 93.0% - 99.5% and 100% (20/20) with a 95% confidence interval of 83.2% - 100% when compared to the Mumps Stat Test Kit. Two equivocal samples were not included in the calculations which were based on a 95% confidence interval as determined by the Exact Method.

Clinical specimens from 123 patients were tested for IgG antibodies to mumps virus using the Mumps IgG ELISA Test and the Mumps Stat Test Kit in a hospital in the Northeastern region of the United States. Discordant samples were retested using the same two tests. Without incorporating the results of retesting the discordant samples, the agreement between the two test systems was 96.6% (114/117). The relative sensitivity and relative specificity of the Mumps IgG ELISA Test were 98.0 (96/98) with a 95% confidence interval of 92.8% - 99.8% and 94.7% (18/19) with a 95% confidence interval of 74.0% - 99.9% respectively when compared with the Mumps Stat Test Kit. Six equivocal samples were not included in the calculations which were based on a 95% confidence interval as determined by the Exact Method.

Clinical specimens from 123 patients were tested for IgG antibodies to mumps virus using the Mumps IgG ELISA Test and the Mumps Stat Test Kit in a hospital in the Southwestern region of the United States. Discordant samples were retested on the same two tests. Without incorporating the results of retesting the discordant samples, the agreement between the two test systems was 93.2% (109/117). The relative sensitivity and relative specificity of the Mumps IgG ELISA Test were 94.3% (99/110) with a 95% confidence interval of 88.0% - 97.9% and 83.3% (10/13) with a 95% confidence interval of 51.6% - 97.9% respectively when compared with the Mumps Stat Test Kit. Six equivocal samples were not included in the calculations which were based on a 95% confidence interval as determined by the Exact Method.

CONCLUSIONS:

The Mumps IgG ELISA Test is believed to be substantially equivalent to the Mumps Stat Test Kit. This assessment is based on (1) the two tests are technologically equivalent, both being based on the enzyme-linked immunosorbent

assay methods, (2) the intended use of each test is comparable with only slight differences in the wording, and (3) the data from clinical studies conducted at Gull Laboratories, Inc. and two outside clinical institutions in most instances demonstrated that the agreement between the two test systems and the relative sensitivity and relative specificity when comparing the two test systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 4 1997

Fred W. Rachford, Ph.D.
Senior Vice President
Gull Laboratories, Inc.
1011 East 4800 South
Salt Lake City, Utah 84117

Re: K971857
Trade Name: Mumps IgG ELISA Test
Regulatory Class: I
Product Code: LJY
Dated: August 18, 1997
Received: August 19, 1997

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 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 (Premarket 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 requirement, 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.

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 Gutman

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 F - REVISED 10/02/97

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K971857

Device Name: MUMPS IgG ELISA TEST

Product Number: MPE101

Indications For Use:

The MUMPS IgG ELISA TEST is to be used in the testing of human serum specimens from asymptomatic and symptomatic children and adults for whom quantitation of the presence or the qualitative presence or absence of detectable IgG antibody to mumps virus is warranted in the determination of immunological experience pertaining to infection with mumps virus and as an aid in the diagnosis of mumps infection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971857