

JAN 28 1998

K974552

Appendix E. 510(k) Summary of Safety and Effectiveness

**The following section is included as required by
the Safe Medical Device Act (SMDA) of 1990.**

Name: Diamedix Corporation
Address: 2140 N. Miami Avenue
Miami, FL 33127

Contact Person: Dr. Lynne Stirling
Phone Number: 305-324-2354
Fax Number: 305-324-2585

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Applicant Information:

Date Prepared: December 3, 1997
Name: Diamedix Corporation
Address: 2140 N. Miami Avenue
Miami, FL 33127

Contact Person: Dr. Lynne Stirling
Phone Number: 305-324-2354
Fax Number: 305-324-2585

Device Information:

Trade Name: Is-Measles IgG Test System
Common Name: Measles EIA Test
Classification Name: Enzyme linked immunosorbent assay, rubeola

Equivalent Device:

Diamedix Measles IgG Microassay

Device Description: The Is-Measles IgG Test System is an enzyme-linked immunosorbent assay (ELISA) for the detection and semi-quantitation of IgG to Measles (rubeola) antigen in human serum

Intended Use: The assay is intended for the semi-quantitation of human IgG antibodies to measles virus in human serum by indirect immunoassay to aid in the assessment of the patient's immunological response to measles virus, to determine the immune status of individuals and, when evaluating paired sera, as an aid in the diagnosis of measles infection.

Principle of Procedure:

The Is-Measles IgG Test System is an enzyme-linked immunosorbent assay to detect IgG to measles virus in human serum. Partially purified measles virus antigen is attached to a solid phase (microtiter well). Diluted test sera are added to each well. If antibodies which recognize the measles antigen are present in the patient sample they will bind to the antigen in the well. After incubation, the wells are washed to remove unbound antibody. An enzyme labeled anti-human immunoglobulin (conjugate) is added to each test well. If antibody is present the enzyme-linked antibody will bind to it. After incubation, the wells are washed to remove unbound conjugate. A substrate solution is then added to each well. If enzyme is present from prior step, the reaction is stopped and the color intensity is measured photometrically producing an indirect measure of the specific antibody present in the patient sample.

SUMMARY OF SAFETY AND EFFECTIVENESS

Performance Characteristics

A. Comparison Testing

The Diamedix Is-Measles IgG test kit was evaluated relative to another commercially available anti-measles IgG EIA. Two hundred and four sera from normal blood donors were tested by the Is-Measles IgG and a commercially obtained anti-measles IgG test kit. The results are summarized in Table 1 below.

| Table 1 | Manual | | | MAGO | | |
|----------------------|----------------|-------|------------|----------------|------|-----------|
| | Number of Sera | % | 95% CI | Number of Sera | % | 95% CI |
| Relative Sensitivity | 152/159 | 95.6 | 91.1-98.2 | 156/166 | 94.0 | 89.2-97.1 |
| Relative Specificity | 25/25 | 100.0 | 86.3-100.0 | 25/26 | 96.2 | 80.4-99.9 |
| Overall Agreement | 177/184 | 96.2 | 92.3-98.5 | 181/192 | 94.3 | 90.0-97.1 |

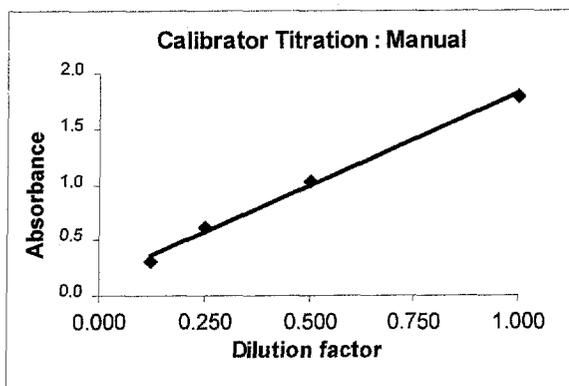
20 equivocal samples excluded from calculations

12 equivocal samples excluded from calculations

B. Linearity

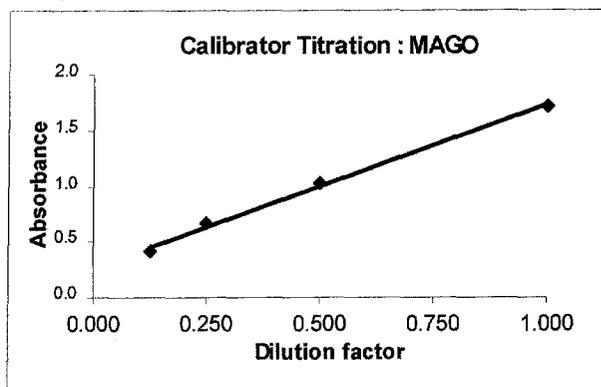
Figures 1 and 2 show typical examples of Is-Measles IgG linearity. These figures depict the results of the Calibrator tested by the Is-Measles test kit after a serial 2-fold manual dilution in Sample Diluent. Separate dilutions were tested both manually and with MAGO. These results demonstrate a high degree of linearity for the Is_Measles test kit throughout the reportable range using either test method.

Figure 1 : Manual Linearity



r : 0.9969 95% CI for r : 0.8557-0.9999

Figure 2 : MAGO Linearity



r : 0.9983 95% CI for r : 0.9161-1.0000

C. Precision

The precision of the Is-Measles IgG test kit was determined by testing 6 different sera and the kit calibrator and controls in two runs on three different days. The intra- and interassay precision, both manually and using the MAGO is shown in Table 2.

Table 2

| SERUM | Is-Measles IgG Precision | | | | |
|------------|--------------------------|-----------|-----------|-----------|-----------|
| | Overall MEAN (EU/ml) | MANUAL | | MAGO | |
| | | INTRA-CV% | INTER-CV% | INTRA-CV% | INTER-CV% |
| A (Neg) | 7.6 | 9.9 | 15.5 | 5.4 | 7.0 |
| B (Neg) | 4.3 | 15.1 | 31.6 | 10.5 | 13.2 |
| C (Pos) | 32.7 | 7.5 | 8.3 | 6.8 | 8.0 |
| D (Pos) | 50.9 | 8.6 | 8.8 | 5.7 | 7.5 |
| E (Pos) | 85.1 | 6.3 | 8.5 | 8.5 | 10.2 |
| F (Pos) | 103.3 | 7.2 | 10.7 | 5.1 | 10.6 |
| Calib. | 106.4 | 6.4 | 8.9 | 7.2 | 8.8 |
| Pos. Ctrl. | 51.1 | 6.3 | 12.1 | 6.3 | 9.4 |
| Neg. Ctrl. | 3.5 | 10.5 | 16.3 | 16.6 | 24.3 |

D. Cross-Reactivity

Twenty sera, negative for antibodies to measles virus, were tested for IgG antibody to varicella, cytomegalovirus, herpes 2 and rubella. All the measles-negative sera were positive to one or more of the analytes tested. This suggests that no specific cross-reactivity should be expected with the Is-Measles IgG from these analytes.

E. Expected Values

Sera from one hundred randomly selected South Florida blood donors were evaluated in the Is-Measles Ig test kit. Eighty-eight sera were positive, 8 were negative and 4 were equivocal for measles for measles IgG antibodies. The distribution of EU/ml values is shown in Figures 3 and 4.

Figure 3 : Is Measles IgG Positive Population

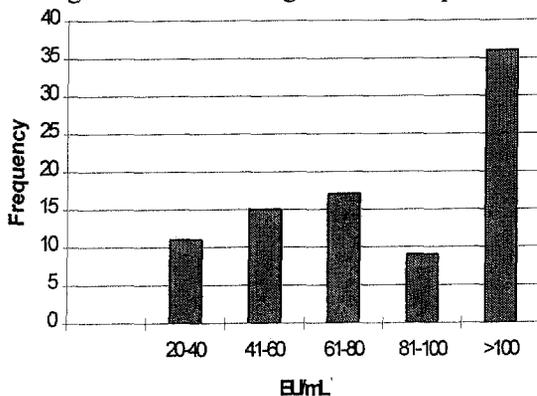
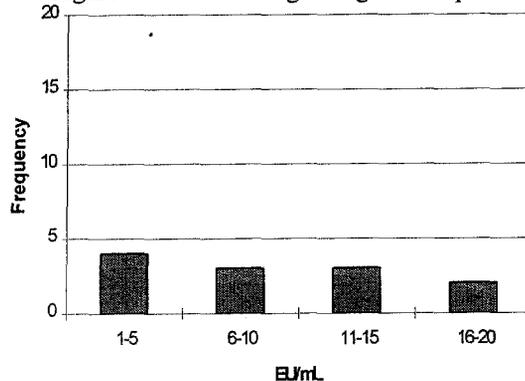


Figure 4 : Is Measles IgG Negative Population



F. Manual vs MAGO Correlation

Numerical comparison of EU/ml values, between manual and MAGO results for 204 samples in the Is-Measles test kit gave a correlation coefficient (r) of 0.961 (95%CI for r : 0.949 to 0.9708).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 28 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Lynne Stirling, Ph.D.
Vice President, Research & Development
Diamedix Corporation
2140 North Miami Avenue
Miami, FL 33127

Re: K974552
Trade Name: Diamedix *Is*-Measles IgG Test System
Regulatory Class: I
Product Code: LJB
Dated: December 3, 1997
Received: December 4, 1997

Dear Dr. Stirling:

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 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.

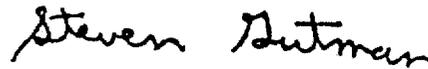
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

Appendix G. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(K) NUMBER : K974552

DEVICE NAME : **Is-Measles IgG Test System**

Indications for Use : The Diamedix Is-Measles IgG test system is an Enzyme Immunoassay (EIA) for the semi-quantitative detection of IgG antibodies in human serum to measles virus as an aid in the assessment of the patient's immunological response to measles virus, to determine the immune status of individuals, and, when evaluating paired sera, as an aid in the diagnosis of measles infection.

John Ticehurst, MD
(Division Sign-Off) *Interim Chief, Microbiol Br*
Division of Clinical Laboratory Devices
510(k) Number K974552

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use

(Optional Format 1-2-96)