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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.**

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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: May 14, 1998
Name: Diamedix Corporation
Address: 2140 N. Miami Avenue
Miami, FL 33127

Contact Person: Dr. Lynne Stirling
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Device Information:

Trade Name: Is-Rubella IgG Test System
Common Name: Rubella IgG EIA Test
Classification Name: Enzyme linked immunosorbent assay, rubella (866.3510)

Equivalent Device:

Incstar Rubella IgG "fast" ELISA Kit

Device Description: The Is-Rubella IgG Test System is an enzyme-linked immunosorbent assay (ELISA) for the qualitative and quantitative detection of IgG to rubella in human serum

Intended Use: The assay is intended for use in detecting IgG antibodies to rubella antigen in human serum. The results of the assay can be used as an aid in the assessment of the patient's immunological response to infection with rubella and in the determination of immune status of individuals, including females of child-bearing age. The evaluation of paired sera can aid in the diagnosis of current or recent infection.

Principle of the Procedure: The Is-Rubella IgG Test System is an enzyme-linked immunosorbent assay to detect IgG to rubella in human serum. Partially purified rubella antigen is attached to a solid phase microtiter well. Diluted test sera are added to each well. If antibodies which recognize the rubella antigen are present in the patient sample they will bind to the antigen on 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 the 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.

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SUMMARY OF SAFETY AND EFFECTIVENESS

Performance Characteristics

A. Comparison Testing

A total of three hundred and seventy-six prospective (fresh) sera were tested for the presence of rubella IgG antibodies using the Diamedix Is-Rubella IgG Test Kit and two other marketed tests at two independent sites (site #1, Miami, FL and site #2, Salt Lake City, Utah). Site #3 (Diamedix Corp. (Miami, FL) tested 270 retrospective (frozen) sera both manually and using the MAGO Plus Automated EIA Processor. In addition, all sites tested a panel of 100 retrospective selected negative and low positive sera provided by Diamedix. Site #1 also tested the CDC Rubella Reference Panel (See Section C.)

Site #1 tested 198 samples submitted for immune status screening. Samples were obtained from the S. Florida area. Table 1 compares the results obtained for the Is-Rubella IgG Test Kit and their currently used testing method.

Site #2 tested 178 samples submitted for ToRCH screening. Samples were obtained from the West region. Table 2 compares the results obtained for the Is-Rubella IgG Test Kit and their currently used testing method.

TABLE 1

Is-Rubella IgG - Site #1

| | | Positive | Negative | Equivocal |
|----------------|----------|----------|----------|-----------|
| Comp. EIA 1 | Positive | 165 [93] | 5 [2] | 8 [7] |
| | Negative | 0 | 19 [7] | 1 [1] |

95% CI*

Relative Sensitivity 165/170 = 97.1% 93.3-99.0
 Relative Specificity 19/19 = 100.0% 82.4-100.0
 Overall Agreement** 184/189 = 97.4% 93.9-99.1

TABLE 2

Is-Rubella IgG - Site #2

| | | Positive | Negative | Equivocal |
|----------------|-----------|----------|----------|-----------|
| Comp. EIA 2 | Positive | 127 [50] | 0 | 0 |
| | Negative | 6 [3] | 31 [12] | 3 |
| | Equivocal | 7 [3] | 2 [1] | 2 [2] |

95% CI*

Relative Sensitivity 127/127 = 100.0% 97.1-100.0
 Relative Specificity 31/37 = 83.8% 68.0-93.8
 Overall Agreement** 158/164 = 96.3% 92.2-98.7

For Site #1, further resolution of the discordant samples was performed by testing such samples in a referee EIA method. Four of the samples negative by the Is-Rubella IgG Test Kit and positive by the other EIA were negative by the referee method; the remaining sample was equivocal.

For Site #2, further resolution of the discordant samples was performed in a similar manner. Five of the six samples positive by the Is-Rubella IgG Test Kit and negative by the other EIA were positive by the referee method; the remaining sample was equivocal.

Site #3 (Diamedix Corp.) tested 270 samples (all frozen) by the manual method and 263 of these samples (seven being QNS) by the MAGO Plus method. Samples were obtained from S. Florida blood donors. Tables 3 and 4 compare the results obtained for the Is-Rubella IgG Test Kit and another marketed EIA method.

TABLE 3

Is-Rubella IgG - Site #3 : Manual

| | | Positive | Negative | Equivocal |
|--------------|-----------|----------|----------|-----------|
| Other EIA | Positive | 204 [73] | 4 [2] | 6 [5] |
| | Negative | 0 | 49 [30] | 0 |
| | Equivocal | 3 [1] | 3 [2] | 1 |

95% CI*

Relative Sensitivity 204/208 = 98.1% 95.1-99.
 Relative Specificity 49/49 = 100.0% 92.7-100.0
 Overall Agreement** 253/257 = 98.4% 96.1-99.6

TABLE 4

Is-Rubella IgG - Site #3 : MAGO Plus

| | | Positive | Negative | Equivocal |
|--------------|-----------|----------|----------|-----------|
| Other EIA | Positive | 209 | 1 | 3 |
| | Negative | 0 | 43 | 0 |
| | Equivocal | 3 | 1 | 3 |

95% CI*

Relative Sensitivity 209/210 = 99.5% 97.4-100.0
 Relative Specificity 43/43 = 100.0% 91.8-100.0
 Overall Agreement** 252/253 = 99.6 % 97.8-100.0

[] denotes samples from females of childbearing age (18-45 years)

* 95% Confidence Intervals (CI) calculated by the Exact Method

** Equivocal results were excluded from calculations

For Site #3 (manual testing), further resolution of the discordant sera revealed that of the 4 sera negative in the Is-Rubella IgG Test Kit but positive in the other EIA two were negative and two were positive by a referee EIA method. For MAGO Plus testing, the sample that was negative in the Is-Rubella IgG Test Kit but positive in the other EIA was also negative by a referee EIA method.

In addition to the samples tabulated above, each site tested the same panel consisting of approximately 50 negative and 50 low positive sera provided by diamedix. Table 5 shows the results of this testing compared to the predicate method.

TABLE 5 : All Sites - Retrospective Panel of Negative and Weakly Positive Sera

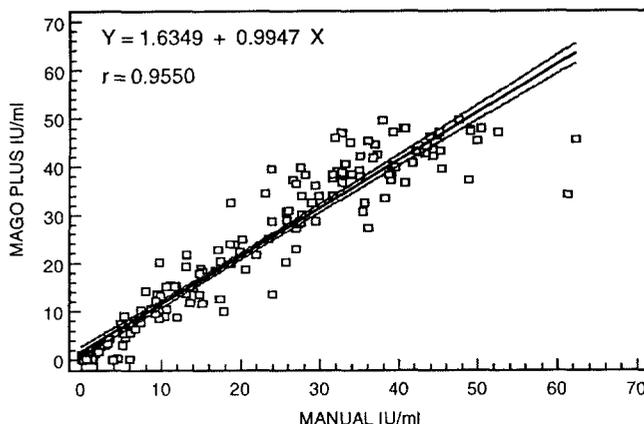
| Other EIA | Pos | Pos | Pos | Neg | Neg | Neg | Equ | Equ | Equ | Relative Sensitivity | Relative Specificity | | |
|----------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|----------------------|----------------------|------|----------|
| Is-Rubella IgG | Pos | Neg | Equ | Pos | Neg | Equ | Pos | Neg | Equ | 95%CI | 95% CI | | |
| Site #1 | 52 | 0 | 1 | 0 | 43 | 2 | 0 | 1 | 1 | 100% | 93.2-100 | 100% | 91.8-100 |
| Site #2 | 42 | 3 | 8 | 0 | 45 | 0 | 0 | 2 | 0 | 93.3% | 81.7-100 | 100% | 92.1-100 |
| Site #3 | 46 | 4 | 3 | 0 | 45 | 0 | 0 | 2 | 0 | 92.0% | 80.0-97.8 | 100% | 92.1-100 |

NOTE : Please be advised that 'relative' refers to the comparison of the assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison assay's accuracy to predict disease.

B. Correlation of Manual and MAGO Plus Results

The Is-Rubella IgG Test Kit has been developed for automated as well as manual use. To demonstrate the equivalence of the manual and MAGO Plus Procedures, the results of 193 samples tested assayed manually and by MAGO Plus were compared. Highly reactive samples that exceeded the reportable range and were excluded from this comparison. A scattergram and regression line of the results obtained with 95% confidence intervals is shown in Figure 1.

FIGURE 1 : Manual vs MAGO Plus Correlation



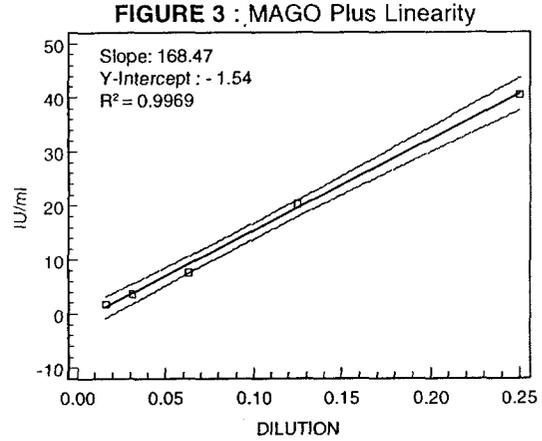
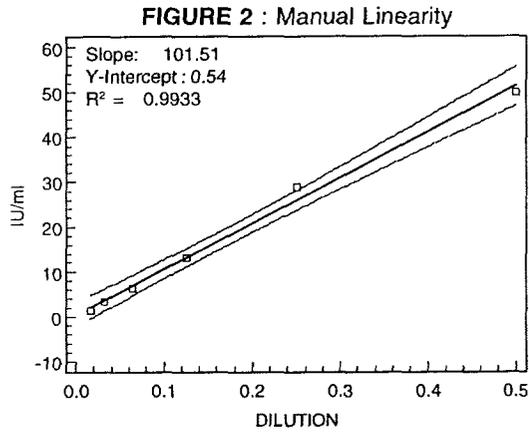
C. CDC Serum Panel Data

The following information was obtained with the Centers for Disease Control and Prevention (CDC) serum panel for rubella serology assays which was tested by the Is-Rubella IgG Test Kit both manually and using the MAGO Plus Automated Processor. For independent verification, this panel was also tested manually by outside site #1. The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. Results were submitted to the CDC for their interpretation and evaluation. This does not imply an endorsement of the assay by the CDC.

The panel consists of 82% positive and 18% negative samples. The outside testing site correctly identified all samples (100% agreement). Of the results obtained by Diamedix, there was 100% (18 of 18) agreement with the negative results using both the manual and automated methods and 97.6% (80 of 82) agreement with the positive specimens using both the manual and automated methods.

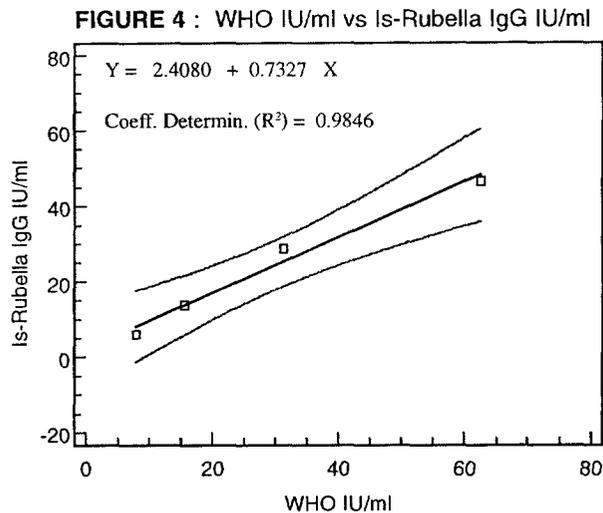
C. Linearity

Several strongly positive serum samples were serially diluted and separate dilutions were assayed, in duplicate, in the Is-Rubella IgG Test Kit both manually and using the MAGO Plus Automated EIA Processor. Representative linear regression graphs and scattergrams of the mean results with 95% confidence intervals are presented in Figures 3 and 4 for one patient sample. The results demonstrate a high degree of linearity throughout the reportable range of the assay when samples are tested either manually or by MAGO Plus.



D. Correlation to WHO Standard

The Is-Rubella IgG Test Kit has been calibrated against the WHO 1st International Standard for Anti-Rubella Immunoglobulin (code RUBI-1-94). To demonstrate the accuracy of the quantitative procedure, several dilutions of the WHO Standard were prepared and assayed manually in triplicate versus the Is-Rubella IgG Test Kit standard curve. The linear regression graph and scattergram of the mean results with 95% Confidence Intervals is shown in Figure 4.



E. Quantitative Data

Serum pairs were obtained by preparing multiple two-fold dilutions of several strongly positive sera. Ratios for dilutions representing a four-fold difference in antibody level were evaluated as a serum pair both manually and using the MAGO Plus. Overall, it was estimated that a 2.8 to 6.8 fold (mean 4.8-fold) increase in Is-Rubella IgG IU/ml values corresponded to a four-fold titer increase in rubella IgG antibody levels.

F. Cross-Reactivity Data

Sera containing IgG antibodies to viruses potentially cross-reactive to rubella have been tested in the Is-Rubella IgG Test Kit. Forty-nine sera negative for IgG antibodies to rubella in the Is-Rubella IgG Test Kit as well as in another marketed test but positive for one or more viruses were evaluated. The data in the following table suggest that no cross-reactivity should be expected with the Is-Rubella IgG Test Kit from these analytes.

TABLE 6

| Analyte | Rubella IgG | VZV IgG | HSV IgG | CMV IgG | Toxoplasma IgG | EBV IgG | Parvovirus B19 IgG | Measles IgG |
|---------------------|-------------|---------|---------|---------|----------------|---------|--------------------|-------------|
| No. of Pos. Samples | 0 | 42 | 48 | 43 | 5 | 48 | 12 | 47 |

G. Precision

Seven serum samples, spanning the reportable range, as well as the 10 IU/ml kit Standard, 50 IU/ml Standard and kit Low Positive and Negative Controls were tested quantitatively and values calculated from IU/ml results. Sites #1 and #2 tested samples in triplicate in three separate runs on three different days. Site #3 (Diamedix Corp.) tested samples in triplicate in two separate runs on three different days both manually and using the MAGO Plus Automated EIA Processor. Note that for MAGO Plus (Table 10) the 50 IU/ml Standard was replaced with an additional weakly positive sample. Tables 7-13 show the intra- and interassay precision for each site, the inter-site precision and the lot-to-lot precision for manual and MAGO Plus.

TABLE 7 : Site #1- Intra-Assay and Interassay Precision

| SERUM | INTRA-ASSAY DAY 1 | | | INTRA-ASSAY DAY 2 | | | INTRA-ASSAY DAY 3 | | | INTERASSAY (n=9) | | |
|--------|-------------------|------|-------|-------------------|------|-------|-------------------|------|-------|------------------|------|-------|
| | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% |
| A | 0.1 | 0.10 | N/A | 0.0 | 0.00 | N/A | 0.0 | 0.06 | N/A | 0.0 | 0.07 | N/A |
| B | 0.3 | 0.06 | N/A | 0.1 | 0.06 | N/A | 0.3 | 0.00 | N/A | 0.3 | 0.10 | N/A |
| C | 20.9 | 0.95 | 4.55 | 20.8 | 3.07 | 14.76 | 21.9 | 2.32 | 10.59 | 21.2 | 2.05 | 9.67 |
| D | 25.8 | 1.76 | 6.82 | 18.3 | 0.51 | 2.79 | 21.2 | 1.56 | 7.36 | 21.8 | 3.48 | 15.96 |
| E | 42.4 | 0.65 | 1.53 | 39.5 | 3.86 | 9.77 | 34.9 | 2.65 | 7.59 | 38.9 | 4.03 | 10.36 |
| F | 42.7 | 4.12 | 9.65 | 41.9 | 4.43 | 10.57 | 37.2 | 2.23 | 5.99 | 40.6 | 4.11 | 10.12 |
| G | 23.1 | 4.04 | 17.49 | 20.5 | 2.76 | 13.46 | 20.0 | 2.00 | 10.00 | 21.2 | 3.00 | 14.15 |
| 10 STD | 10.9 | 1.88 | 17.25 | 14.1 | 2.87 | 20.35 | 10.3 | 2.43 | 23.59 | 11.8 | 2.73 | 23.14 |
| 50 STD | 50.5 | 1.19 | 2.36 | 55.9 | 3.30 | 5.90 | 45.9 | 0.06 | 0.13 | 50.8 | 4.67 | 9.19 |
| LPC | 24.5 | 0.06 | 0.24 | 26.5 | 0.91 | 3.43 | 21.0 | 1.11 | 5.29 | 24.0 | 2.51 | 10.46 |
| NC | 2.7 | 0.06 | N/A | 2.8 | 0.06 | N/A | 2.2 | 0.06 | N/A | 2.6 | 0.25 | N/A |

TABLE 8 : Site #2 - Intra-Assay and Interassay Precision

| SERUM | INTRA-ASSAY DAY 1 | | | INTRA-ASSAY DAY 2 | | | INTRA-ASSAY DAY 3 | | | INTERASSAY (n=9) | | |
|--------|-------------------|------|-------|-------------------|------|-------|-------------------|------|-------|------------------|------|-------|
| | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% |
| A | 0.3 | 0.06 | N/A | 0.3 | 0.12 | N/A | 0.5 | 0.00 | N/A | 0.4 | 0.12 | N/A |
| B | 0.5 | 0.06 | N/A | 0.4 | 0.06 | N/A | 0.4 | 0.12 | N/A | 0.4 | 0.11 | N/A |
| C | 17.2 | 1.25 | 7.27 | 17.1 | 2.19 | 12.81 | 16.0 | 2.10 | 13.13 | 16.8 | 1.75 | 10.42 |
| D | 14.3 | 0.98 | 6.85 | 14.0 | 1.57 | 11.21 | 12.8 | 0.25 | 1.95 | 13.7 | 1.16 | 8.47 |
| E | 50.6 | 3.16 | 6.25 | 31.8 | 1.85 | 5.82 | 43.2 | 0.59 | 1.37 | 41.9 | 8.43 | 20.12 |
| F | 28.0 | 1.45 | 5.18 | 26.3 | 2.24 | 8.52 | 25.2 | 2.50 | 9.92 | 26.5 | 2.20 | 8.30 |
| G | 14.2 | 1.82 | 12.82 | 12.5 | 1.27 | 10.16 | 10.6 | 1.93 | 18.21 | 12.5 | 2.13 | 17.04 |
| 10 STD | 9.7 | 0.06 | 0.62 | 10.6 | 0.85 | 8.02 | 9.7 | 0.25 | 2.58 | 10.0 | 0.63 | 6.30 |
| 50 STD | 45.2 | 0.66 | 1.46 | 46.2 | 0.64 | 1.39 | 45.8 | 3.53 | 7.71 | 45.7 | 1.87 | 4.09 |
| LPC | 21.1 | 0.44 | 2.09 | 24.2 | 2.36 | 9.75 | 22.0 | 3.12 | 14.18 | 22.4 | 2.39 | 10.67 |
| NC | 2.7 | 0.06 | N/A | 2.3 | 0.85 | N/A | 2.9 | 0.28 | N/A | 2.6 | 0.44 | N/A |

TABLE 9 : Site #3-Intra-Assay and Interassay Precision (Manual)

| SERUM | INTRA-ASSAY DAY 1 | | | INTRA-ASSAY DAY 2 | | | INTRA-ASSAY DAY 3 | | | INTERASSAY (n=18) | | |
|--------|-------------------|------|-------|-------------------|------|------|-------------------|------|-------|-------------------|------|-------|
| | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% |
| A | 0.0 | 0.05 | N/A | 0.1 | 0.08 | N/A | 0.2 | 0.16 | N/A | 0.1 | 0.13 | N/A |
| B | 0.2 | 0.04 | N/A | 0.2 | 0.04 | N/A | 0.2 | 0.20 | N/A | 0.2 | 0.11 | N/A |
| C | 14.2 | 0.99 | 6.97 | 14.6 | 1.23 | 8.42 | 14.3 | 6.12 | 42.80 | 14.4 | 3.43 | 23.82 |
| D | 15.1 | 1.13 | 7.48 | 14.3 | 1.38 | 9.65 | 15.8 | 3.94 | 24.94 | 15.1 | 2.44 | 16.16 |
| E | 37.4 | 1.93 | 5.16 | 35.8 | 2.63 | 7.35 | 35.3 | 7.52 | 21.30 | 36.1 | 4.54 | 12.58 |
| F | 33.9 | 2.18 | 6.43 | 34.6 | 2.33 | 6.73 | 28.4 | 4.18 | 14.72 | 32.3 | 4.04 | 12.51 |
| G | 20.3 | 2.32 | 11.43 | 19.8 | 1.49 | 7.53 | 15.9 | 2.44 | 15.35 | 18.6 | 2.85 | 15.32 |
| 10 STD | 9.2 | 0.48 | 5.22 | 9.4 | 0.26 | 2.77 | 12.5 | 1.83 | 14.64 | 10.4 | 1.88 | 18.08 |
| 50 STD | 53.3 | 3.35 | 6.29 | 51.1 | 2.12 | 4.15 | 53.9 | 9.17 | 17.01 | 52.8 | 5.55 | 10.51 |
| LPC | 24.7 | 3.62 | 14.66 | 24.6 | 1.11 | 4.51 | 30.4 | 4.90 | 16.12 | 26.6 | 4.38 | 16.47 |
| NC | 2.8 | 0.12 | N/A | 2.8 | 0.12 | N/A | 3.1 | 0.33 | N/A | 2.9 | 0.24 | N/A |

TABLE 10 : Site #3- Intra-assay and Interassay Precision (MAGO Plus)

| SERUM | INTRA-ASSAY DAY 1 | | | INTRA-ASSAY DAY 2 | | | INTRA-ASSAY DAY 3 | | | INTERASSAY (n=18) | | |
|--------|-------------------|------|-------|-------------------|------|-------|-------------------|------|-------|-------------------|------|-------|
| | MEAN IU/ml | SD | CV% |
| A | 0.2 | 0.08 | N/A | 0.2 | 0.10 | N/A | 0.2 | 0.10 | N/A | 0.2 | 0.09 | N/A |
| B | 0.4 | 0.06 | N/A | 0.2 | 0.10 | N/A | 0.3 | 0.05 | N/A | 0.3 | 0.12 | N/A |
| C | 16.8 | 2.46 | 14.64 | 15.4 | 2.93 | 19.03 | 19.6 | 2.87 | 16.67 | 17.2 | 3.17 | 18.43 |
| D | 15.3 | 1.65 | 10.78 | 12.7 | 1.45 | 11.42 | 16.0 | 2.68 | 14.64 | 14.6 | 2.38 | 16.30 |
| E | 39.6 | 2.47 | 6.24 | 35.6 | 2.51 | 7.05 | 39.8 | 3.00 | 7.54 | 38.3 | 3.18 | 8.30 |
| F | 37.7 | 1.98 | 7.69 | 38.1 | 3.23 | 8.48 | 34.4 | 3.37 | 9.80 | 36.7 | 3.43 | 9.35 |
| G | 17.1 | 2.90 | 8.36 | 16.6 | 1.80 | 10.84 | 18.1 | 1.26 | 6.96 | 17.3 | 1.55 | 8.96 |
| H | 14.2 | 1.43 | 13.94 | 15.4 | 3.21 | 20.84 | 17.5 | 1.23 | 7.03 | 15.6 | 2.59 | 16.60 |
| 10 STD | 17.0 | 2.19 | 12.88 | 14.1 | 0.89 | 6.31 | 18.6 | 1.23 | 6.61 | 16.5 | 2.39 | 14.48 |
| LPC | 33.3 | 1.20 | 3.60 | 27.7 | 3.13 | 11.30 | 36.3 | 1.57 | 4.33 | 32.4 | 4.19 | 12.93 |
| NC | 4.2 | 0.28 | N/A | 4.1 | 0.24 | N/A | 4.9 | 0.12 | N/A | 4.4 | 0.41 | N/A |

TABLE 11 : Inter-Site Precision (manual)

| SERUM | Site #1 | Site #2 | Site #3 | INTERSITE | | |
|--------|------------|------------|------------|------------|------|-------|
| | MEAN IU/ml | MEAN IU/ml | MEAN IU/ml | MEAN IU/ml | SD | CV% |
| A | 0.0 | 0.4 | 0.1 | 0.2 | 0.21 | N/A |
| B | 0.3 | 0.4 | 0.2 | 0.3 | 0.10 | N/A |
| C | 21.2 | 16.8 | 14.4 | 17.5 | 3.45 | 19.71 |
| D | 21.8 | 13.7 | 15.1 | 16.9 | 4.33 | 25.62 |
| E | 38.9 | 41.9 | 36.1 | 39.4 | 3.63 | 9.21 |
| F | 40.6 | 26.5 | 32.3 | 33.1 | 7.09 | 21.42 |
| G | 21.2 | 12.5 | 18.6 | 17.4 | 4.47 | 25.69 |
| 10 STD | 11.8 | 10.0 | 10.4 | 10.7 | 0.95 | 8.88 |
| 50 STD | 50.8 | 45.7 | 52.8 | 49.8 | 3.66 | 7.35 |
| LPC | 24.0 | 22.4 | 26.6 | 24.3 | 2.12 | 8.72 |
| NC | 2.6 | 2.6 | 2.9 | 2.7 | 0.17 | N/A |

TABLE 12 : Lot-to-Lot Precision (manual)

| SERUM | Lot 31107 INTERASSAY | | | Lot 41307 INTERASSAY | | | Lot 50707 INTERASSAY | | | LOT-TO-LOT INTERASSAY | | |
|--------|----------------------|------|-------|----------------------|------|-------|----------------------|------|-------|-----------------------|------|-------|
| | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% |
| A | 0.1 | 0.05 | N/A | 0.1 | 0.10 | N/A | 0.1 | 0.13 | N/A | 0.1 | 0.00 | N/A |
| B | 0.2 | 0.07 | N/A | 0.2 | 0.22 | N/A | 0.2 | 0.11 | N/A | 0.2 | 0.00 | N/A |
| C | 13.9 | 1.54 | 11.08 | 13.0 | 1.45 | 11.15 | 14.4 | 3.43 | 23.82 | 13.8 | 0.71 | 5.14 |
| D | 13.4 | 1.86 | 13.88 | 13.6 | 2.12 | 15.59 | 15.1 | 2.44 | 16.16 | 14.0 | 0.93 | 6.64 |
| E | 35.2 | 3.36 | 9.55 | 33.2 | 4.21 | 12.68 | 36.1 | 4.54 | 12.58 | 34.8 | 1.48 | 4.25 |
| F | 33.3 | 1.91 | 5.74 | 33.5 | 1.81 | 5.40 | 32.3 | 4.04 | 12.51 | 33.0 | 0.64 | 1.94 |
| G | 16.9 | 1.82 | 10.77 | 20.4 | 2.24 | 10.98 | 18.6 | 2.85 | 15.32 | 18.6 | 1.75 | 9.41 |
| 10 STD | 9.1 | 0.50 | 5.49 | 9.0 | 0.80 | 8.89 | 10.4 | 1.88 | 18.08 | 9.5 | 0.78 | 8.21 |
| 50 STD | 50.2 | 3.79 | 7.55 | 49.7 | 3.29 | 6.62 | 52.8 | 5.55 | 10.51 | 50.9 | 1.66 | 3.26 |
| LPC | 21.0 | 1.75 | 8.33 | 24.6 | 3.14 | 12.76 | 26.6 | 4.38 | 16.47 | 24.1 | 2.84 | 11.78 |
| NC | 2.8 | 0.21 | N/A | 3.0 | 0.34 | N/A | 2.9 | 0.24 | N/A | 2.9 | 0.10 | N/A |

TABLE 13 : Lot-to-Lot Precision (Mago Plus)

| SERUM | Lot 31107 INTERASSAY | | | Lot 41307 INTERASSAY | | | Lot 50707 INTERASSAY | | | LOT-TO-LOT INTERASSAY | | |
|--------|----------------------|------|-------|----------------------|------|-------|----------------------|------|-------|-----------------------|------|-------|
| | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% |
| A | 0.3 | 0.16 | N/A | 0.2 | 0.10 | N/A | 0.2 | 0.09 | N/A | 0.2 | 0.06 | N/A |
| B | 0.3 | 0.14 | N/A | 0.4 | 0.60 | N/A | 0.3 | 0.12 | N/A | 0.3 | 0.06 | N/A |
| C | 19.7 | 1.96 | 9.95 | 17.0 | 1.76 | 10.40 | 17.2 | 3.17 | 18.43 | 18.0 | 1.50 | 8.30 |
| D | 20.3 | 2.45 | 12.07 | 16.3 | 2.79 | 17.12 | 14.6 | 2.38 | 16.30 | 17.1 | 2.93 | 17.10 |
| E | 42.3 | 3.67 | 8.68 | 36.7 | 2.60 | 7.08 | 38.3 | 3.18 | 8.30 | 39.1 | 2.88 | 7.40 |
| F | 34.0 | 6.64 | 19.53 | 34.1 | 1.45 | 4.25 | 36.7 | 3.43 | 9.35 | 34.9 | 1.53 | 4.38 |
| G | 16.6 | 1.48 | 8.92 | 17.1 | 1.78 | 10.41 | 17.3 | 1.55 | 8.96 | 17.0 | 0.36 | 2.12 |
| H | 18.9 | 2.60 | 13.76 | 13.3 | 1.65 | 12.41 | 15.6 | 2.59 | 16.60 | 15.9 | 3.27 | 20.57 |
| 10 STD | 18.7 | 1.14 | 6.10 | 15.9 | 2.08 | 13.08 | 16.5 | 2.39 | 14.48 | 17.0 | 1.47 | 8.65 |
| LPC | 33.5 | 1.90 | 5.67 | 29.0 | 3.99 | 13.76 | 32.4 | 4.19 | 12.93 | 31.6 | 2.35 | 7.44 |
| NC | 4.4 | 0.43 | N/A | 3.7 | 0.36 | N/A | 4.4 | 0.41 | N/A | 4.2 | 0.40 | N/A |

Expected Values

The incidence of rubella IgG antibodies varies among populations depending on vaccination practices. In a recent national survey of military recruits the seronegativity rate was 17.4% for males and 12.8% for females.

In the present studies sera from 100 healthy South Florida donors (52 female and 48 male) were evaluated in the Is-Rubella IgG Test Kit. Of the 100 samples, 89 (89%) were found to be positive, 9 (9%) were negative and 2 (2%) were equivocal. Age distribution, geographic location and prevalence is provided in Table 14. Histograms demonstrating the distribution of IU/ml values are shown in Figures 5 and 6.

Thirty-seven of the female donors were of child-bearing age (18-45 years). Of the sera from these donors, 29 (79%) were positive, 6 (16%) were negative and 2 (5%) were equivocal. A total of 45 sera from pregnant females (15 from each trimester) were also tested in the Is-Rubella IgG Test Kit. Forty one (92%) were positive, 2 (4%) were negative and 2 (4%) were equivocal for anti-rubella IgG. In addition, a total of 294 samples from females of childbearing age were identified in the outside and in-house clinical studies (these included the 45 sera from pregnant females already referenced). Of these samples, 223 (76%) were positive, 56 (19%) were negative and 15 (5%) were equivocal for anti-rubella IgG when evaluated in the Is-Rubella IgG Test Kit.

TABLE 14

| | Number of Donors | Prevalence |
|------------------------------------------|------------------|------------|
| Total Number | 100 | 89.0% |
| Geographic Location: South-Eastern US | 100 | 89.0% |
| Age | | |
| 10-19 | 13 | 92.3% |
| 20-29 | 23 | 73.9% |
| 30-39 | 40 | 92.5% |
| 40-49 | 13 | 92.3% |
| 50-59 | 5 | 100.0% |
| 60-69 | 6 | 100.0% |

FIGURE 5

Is-Rubella IgG Positive Population

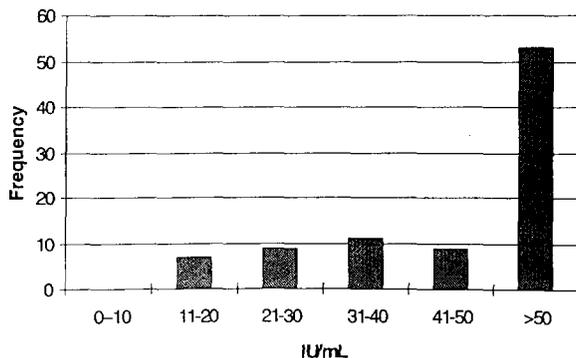
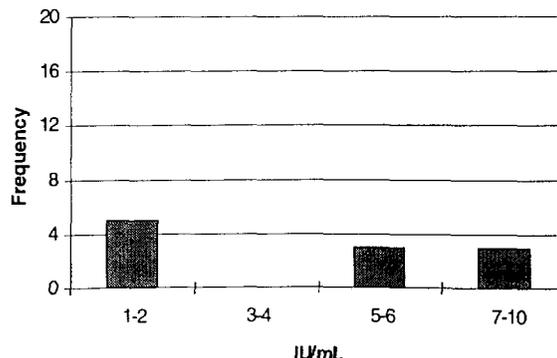


FIGURE 6

Is-Rubella IgG Negative Population





JAN 28 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Lynne Stirling, Ph.D.
Vice President, Regulatory Affairs
Diamedix Corporation
2140 North Miami Ave.
Miami, FL 33127

Re: K981729
Trade Name: Is-Rubella IgG Test System
Regulatory Class: III
Product Code: LFX
Dated: November 23, 1998
Received: November 24, 1998

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 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 (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.

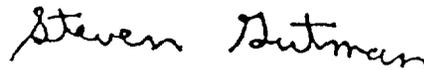
Page 2

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 : _____

DEVICE NAME : Is-Rubella IgG Test System

Indications for Use : The Diamedix Is-Rubella IgG Test Kit is an Enzyme Immunoassay (EIA) for the qualitative and quantitative determination of IgG antibodies in human serum to aid in the assessment of the patient's immunological response to infection with rubella and in the determination of the immune status of individuals, including females of child-bearing age. The evaluation of acute and convalescent sera can aid in the diagnosis of recent or current infection with rubella. These reagents can be used either manually or in conjunction with the MAGO® Plus Automated EIA Processor.

Woody Deboer
(Division Sign Off)
Division of Clinical Laboratory Devices
510(k) Number K981729

PRESCRIPTION USE X