

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

- A. 510(k) Number:** K093101
- B. Purpose for Submission:** Assessment of new instrument for cleared assay.
- C. Measurand:** Rubella-specific IgG in human serum
- D. Type of Test:** Enzyme-linked immunosorbent assay (ELISA)
- E. Applicant:** Diamedix Corporation
- F. Proprietary and Established Names:** Diamedix *Immunosimplicity*<sup>®</sup> (*Is*) Rubella IgG EIA Test Kit
- G. Regulatory Information:**
1. Regulation section: 21 CFR §866.3510, Rubella virus serological reagents
  2. Classification: Class II
  3. Product code: LFX (Enzyme Linked Immunoabsorbent Assay, Rubella), JJF
  4. Panel: Virology (81)

**Note:** The Diamedix *Immunosimplicity*<sup>®</sup> (*Is*) Rubella IgG EIA Test Kit was cleared as K981729. The subject of the current review is the assessment of the previously cleared Diamedix *Immunosimplicity*<sup>®</sup> (*Is*) Rubella IgG EIA Test Kit when used in conjunction with automated EIA processors (MAGO 4S Automated EIA and IFA Processor). This review serves as an assessment of the application of the MAGO 4S instrumentation and it **DOES NOT CONSTITUTE ANY ASSESSMENT FOR A NEW CLEARANCE OF A RUBELLA IGG OR OTHER ASSAY. Clearance of the Rubella IgG EIA assay is based on the original submission, K981729.**

**H. Intended Use:**

1. Intended use(s):

For the qualitative, semi-quantitative and quantitative detection of IgG antibodies to rubella in human serum by indirect enzyme immunoassay to aid in the assessment of the patient's immunological response to 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 current or recent infection with rubella.

The Mago 4S Automated EIA and IFA Processor is a pipetting, diluting, incubating, and color intensity analyzing system for *in vitro* diagnostic clinical use for the processing of FDA-cleared enzyme-linked immunoabsorbent assays (EIA) through result generation. In addition, it processes immunofluorescence assay (IFA) slides for off-platform detection and result generation.

2. Indication(s) for use:

The Diamedix *Immunosimplicity*<sup>®</sup> (*Is*) Rubella IgG EIA Test Kit can be used as an aid in the assessment of the patient's immunological response to rubella and in the determination of the immune status of individuals, including females of child-bearing age.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

The device can be used either manually or with automated EIA processor: MAGO 4S Automated EIA and IFA Processor.

**I. Device Description:**

The Diamedix *Immunosimplicity*<sup>®</sup> (*Is*) Rubella IgG Test Kit is an enzyme immunoassay (EIA) procedure intended for the qualitative and quantitative detection of antibodies to rubella antigen. The results are reported in IU/ml, which are traceable to the WHO 1st International Standard for Anti-Rubella Immunoglobulin, Human, 1996.

The MAGO 4S Automated EIA and IFA Processor is a design enhancement to the existing *MAGO Plus* Automated EIA Processor, legally marketed under K973177. *MAGO 4S*, the Diamedix Automated EIA and IFA Processor has been designed to work specifically with Diamedix *Immunosimplicity*<sup>®</sup> Test Kits. The *MAGO 4S* is designed to minimize manual operations associated with performing routine laboratory analysis by mechanizing and computerizing the test process.

For IFA sessions, the *MAGO 4S* prepares the slide; however, the reading activity is undertaken outside of the instrument, by a qualified Operator with the aid of a fluorescence microscope and/or digital camera.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

The Diamedix *Immunosimplicity*<sup>®</sup> (*Is*) Rubella IgG EIA Test Kit was previously cleared within K981729. The subject of the current review is the assessment of the MAGO 4S Automated EIA and IFA Processor when used in conjunction with the Rubella IgG EIA Test Kit. For comparative purposes, the Rubella IgG EIA Test Kit used with the automatic EIA processor MAGO 4S system was compared to the previously cleared manual-use version of the device (K981729).

2. Predicate 510(k) number(s):

See K981729

3. Comparison with predicate:

See K981729 and below, under “**Additional studies performed to assess the MAGO 4S instrumentation**”.

**K. Standard/Guidance Document Referenced (if applicable):**

CLSI I/LA6-A. Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline. Oct. 1997.

CLSI EP5-A2. Evaluation of Precision Performance

CLSI EP17-A. Determination of Limits of Detection and Limits of Quantitation.

CLSI EP12-A2. User Protocol for Evaluation of Qualitative Test Performance

**L. Test Principle:**

Diluted samples are incubated with rubella antigen bound to the solid surface of a microtiter well. If IgG antibodies against rubella are present in the patient sample they will bind to the antigen on the well forming antigen-antibody complexes. Residual sample is eliminated by aspirating and washing. Conjugate (horse-radish peroxidase-labeled anti-human IgG) is added and will bind to these complexes. Unbound conjugate is removed by aspiration and washing. Substrate is then added and incubated. In the presence of bound enzyme the substrate is converted to an end product. The absorbance of this end product can be read spectrophotometrically at 450 nm (reference 600-630 nm) and is directly proportional to the concentration of IgG antibodies to rubella antigen present in the sample. Three standard and three control reagents, all provided within the test, are used to calibrate and measure the assay results.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

See K981729 for additional details, and see also below, under “**Additional studies performed to assess the MAGO 4S instrumentation**”.

b. *Linearity/assay reportable range:*

See K981729 for details on this study, and see also below, under “**Additional studies performed to assess the MAGO 4S instrumentation**”.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The Is-Rubella IgG Test Kit has been calibrated against the WHO 1st International Standard for Anti-Rubella Immunoglobulin (code RUBI-1-94). See K981729 for details on this study.

d. *Detection limits:*

See K981729 for details on this study.

e. *Analytical specificity:*

*Cross-reactivity/Interference:*

See K981729 for details on these studies, and see also below, under “**Additional studies performed to assess the MAGO 4S instrumentation**”.

f. *Assay cut-off:*

The Diamedix *Is*-Rubella IgG Test Kit cut-off value has been set at 10 IU/ml based on the WHO 1st International Standard for Anti-Rubella Immunoglobulin, Human, in accordance with the CLSI Guideline for the Detection and Quantitation of Rubella IgG Antibody. This cut-off value is supported by a Receiver-Operator Characteristics (ROC) curve generated using the results of two hundred and seventy normal sera assayed manually by Diamedix in the *Is*-Rubella IgG Test Kit and another commercially available test method. See K981729 for additional details on this study.

2. Comparison studies:

a. *Method comparison with predicate device:*

See K981729 for details on this study.

b. *Matrix comparison:* N/A

3. Clinical studies:

a. *Clinical Sensitivity:* N/A

b. *Clinical specificity:* N/A

c. *Other clinical supportive data* (when a. and b. are not applicable):

See K981729 for details on this study, and see also below, under “**Additional studies performed to assess the MAGO 4S instrumentation**”.

4. Clinical cut-off:

The clinical cut-off for immunity to infection with rubella virus has been determined to be 10 IU/mL, as published in NCCLS I/L6-A, “Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of the Test Products in the Clinical Laboratory”.

5. Expected values/Reference range:

Reference Range:

From K981729:

| IU/ml     | Index Value | Interpretation                                |
|-----------|-------------|---|
| <8.0      | <0.80       | Negative for rubella IgG: presumed non-immune |
| 8.0 – 9.9 | 0.8 – 0.99  | Equivocal                                     |
| ≥ 10.0    | ≥ 1.0       | Positive for rubella IgG: presumed immune     |

*Expected Values*

See K981729 for details.

**Additional studies performed to assess the MAGO 4S instrumentation:**

***Precision:***

Six serum samples (QC Panels) spanning the reportable assay range were run in duplicate, twice a day, for 20 days at all three sites. The results are presented per site in the following tables. Inter- and intra-assay variability results were within acceptable limits.

| Diamedix Precision |     |            |            |            |            |            |            |            |            |            |            |            |            |
|--------------------|-----|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Intra Assay CV %   | Day | QC A Run 1 | QC A Run 2 | QC B Run 1 | QC B Run 2 | QC C Run 1 | QC C Run 2 | QC D Run 1 | QC D Run 2 | QC E Run 1 | QC E Run 2 | QC F Run 1 | QC F Run 2 |
|                    | 1   | 47.14%     | 0.00%      | 20.20%     | 17.68%     | 0.74%      | 0.74%      | 0.52%      | 4.32%      | 0.44%      | 4.00%      |            | 0.29%      |
|                    | 2   | 23.57%     | 15.71%     | 10.88%     | 10.88%     | 0.70%      | 7.78%      | 1.50%      | 5.15%      | 9.21%      | 5.08%      | 0.00%      | 3.78%      |
|                    | 3   | 20.20%     | 15.71%     | 10.88%     | 17.68%     | 0.34%      | 0.28%      | 0.49%      | 1.59%      | 2.36%      | 5.31%      | 8.48%      |            |
|                    | 4   | 0.00%      | 0.00%      | 20.20%     | 28.28%     | 3.45%      | 3.95%      | 4.49%      | 2.48%      | 7.44%      | 11.80%     |            | 2.58%      |
|                    | 5   | 0.00%      | 28.28%     | 10.88%     | 20.20%     | 8.60%      | 2.63%      | 6.46%      | 0.74%      | 3.50%      | 9.07%      | 1.45%      |            |
|                    | 6   | 12.86%     | 0.00%      | 9.43%      | 28.28%     | 2.08%      | 6.30%      | 3.60%      | 4.67%      | 0.63%      | 4.63%      |            | 5.50%      |
|                    | 7   | 7.44%      | 0.00%      | 28.28%     | 47.14%     | 8.06%      | 2.55%      | 12.62%     | 4.51%      | 3.52%      | 2.47%      |            | 0.58%      |
|                    | 8   | 12.86%     | 10.88%     | 0.00%      | 15.71%     | 0.70%      | 18.00%     | 12.20%     | 8.19%      | 1.13%      | 3.25%      | 5.95%      | 3.87%      |
|                    | 9   | 20.20%     | 23.57%     | 0.00%      | 10.88%     | 1.76%      | 8.73%      | 11.76%     | 6.35%      | 4.73%      | 9.52%      | 1.02%      | 4.30%      |
|                    | 10  | 8.32%      | 15.71%     | 28.28%     | 38.57%     | 2.27%      | 0.60%      | 11.15%     | 2.52%      | 3.34%      | 3.79%      |            | 2.67%      |
|                    | 11  | 28.28%     | 47.14%     | 35.36%     | 20.20%     | 2.12%      | 2.97%      | 6.71%      | 8.20%      | 1.15%      | 0.66%      |            | 3.45%      |
|                    | 12  | 15.71%     | 15.71%     | 40.41%     | 32.64%     | 2.32%      | 1.08%      | 9.28%      | 10.26%     | 3.83%      | 0.38%      |            |            |
|                    | 13  | 10.88%     | 8.32%      | 28.28%     | 10.88%     | 3.31%      | 5.13%      | 0.62%      | 10.41%     | 4.93%      | 3.81%      |            |            |
|                    | 14  | 8.32%      | 9.43%      | 66.00%     | 23.57%     | 3.17%      | 2.02%      | 4.73%      | 3.43%      | 3.48%      | 3.03%      |            |            |
|                    | 15  | 32.64%     | 7.44%      | 35.36%     | 15.71%     | 1.21%      | 2.34%      | 2.23%      | 4.16%      | 1.80%      | 0.64%      |            |            |
|                    | 16  | 14.14%     | 10.88%     | 38.57%     | 23.57%     | 11.67%     | 6.69%      | 0.40%      | 14.36%     | 7.07%      | 10.88%     |            |            |
|                    | 17  | 7.44%      | 0.00%      | 32.64%     | 12.86%     | 10.88%     | 8.55%      | 5.14%      | 0.47%      | 5.42%      | 1.46%      | 1.15%      | 4.19%      |
|                    | 18  | 0.00%      | 9.43%      | 9.43%      | 23.57%     | 0.63%      | 2.18%      | 4.70%      | 4.19%      | 6.42%      | 9.58%      |            |            |
|                    | 19  | 32.64%     | 17.68%     | 0.00%      | 38.57%     | 3.01%      | 1.82%      | 11.90%     | 7.20%      | 5.47%      | 12.50%     |            | 3.63%      |
|                    | 20  | 0.00%      | 9.43%      | 0.00%      | 94.28%     | 0.71%      | 0.34%      | 2.26%      | 8.94%      | 0.22%      | 0.00%      | 0.45%      | 2.35%      |
| Interassay Mean    |     | 0.668      |            | 0.624      |            | 22.853     |            | 30.308     |            | 35.104     |            | 47.649     |            |
| Interassay SD      |     | 0.230      |            | 0.189      |            | 3.423      |            | 3.799      |            | 3.881      |            | 1.945      |            |
| Interassay CV%     |     | 34.52%     |            | 30.32%     |            | 14.98%     |            | 12.54%     |            | 11.06%     |            | 4.08%      |            |

Note: Readings for QC F that were reported as >200 are shown as blanks, no statistics were possible.  
When low results are reported on an analyte, a high coefficient of variation (CV) may result. (Taken from CAP survey)

| IMMCO Precision  |     |            |            |            |            |            |            |            |            |            |            |            |            |
|------------------|-----|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Intra Assay CV % | Day | QC A Run 1 | QC A Run 2 | QC B Run 1 | QC B Run 2 | QC C Run 1 | QC C Run 2 | QC D Run 1 | QC D Run 2 | QC E Run 1 | QC E Run 2 | QC F Run 1 | QC F Run 2 |
|                  | 1   | 35.36%     | 40.41%     | 0.00%      | 60.61%     | 4.54%      | 5.33%      | 3.60%      | 6.04%      | 2.82%      | 2.74%      |            | 1.17%      |
|                  | 2   | 30.74%     | 22.33%     | 25.71%     | 60.61%     | 3.63%      | 8.67%      | 12.99%     | 6.61%      | 0.80%      | 1.60%      |            | 5.43%      |
|                  | 3   | 18.45%     | 62.85%     | 28.28%     | 25.71%     | 4.40%      | 3.11%      | 5.74%      | 5.13%      | 0.38%      | 6.03%      | 2.90%      | 1.01%      |
|                  | 4   | 18.45%     | 28.28%     | 26.19%     | 22.33%     | 5.01%      | 8.07%      | 9.12%      | 8.47%      | 0.84%      | 4.51%      |            |            |
|                  | 5   | 22.33%     | 28.28%     | 28.28%     | 37.22%     | 13.42%     | 11.45%     | 9.90%      | 5.94%      | 4.49%      | 0.54%      |            | 1.88%      |
|                  | 6   | 35.36%     | 32.64%     | 106.07%    | 10.88%     | 3.45%      | 1.98%      | 9.76%      | 7.68%      | 2.47%      | 1.46%      |            |            |
|                  | 7   | 20.20%     | 31.43%     | 17.68%     | 54.39%     | 8.55%      | 2.18%      | 6.38%      | 6.11%      | 0.39%      | 5.45%      | 0.87%      | 1.52%      |
|                  | 8   | 20.20%     | 42.43%     | 23.57%     | 47.14%     | 6.76%      | 3.37%      | 12.82%     | 3.35%      | 3.55%      | 1.13%      |            |            |
|                  | 9   | 31.43%     | 33.67%     | 31.43%     | 30.74%     | 2.95%      | 3.21%      | 3.40%      | 10.17%     | 0.00%      | 2.23%      |            |            |
|                  | 10  | 23.57%     | 25.71%     | 20.20%     | 31.43%     | 6.04%      | 0.47%      | 7.24%      | 10.24%     |            | 2.11%      |            |            |
|                  | 11  | 30.74%     | 28.28%     | 43.89%     | 23.57%     | 1.39%      | 4.96%      | 5.24%      | 6.31%      | 1.37%      | 3.33%      |            |            |
|                  | 12  | 30.74%     | 43.51%     | 21.76%     | 32.64%     | 7.58%      | 9.24%      | 23.13%     | 6.34%      | 2.05%      |            |            |            |
|                  | 13  | 47.14%     | 18.45%     | 41.59%     | 58.23%     | 9.19%      | 8.79%      | 4.30%      | 11.74%     | 6.45%      | 0.68%      | 2.00%      | 2.23%      |
|                  | 14  | 30.74%     | 38.57%     | 35.36%     | 56.57%     | 6.07%      | 1.36%      | 5.39%      | 7.84%      | 1.10%      | 3.07%      |            | 0.00%      |
|                  | 15  | 18.45%     | 37.22%     | 20.20%     | 41.59%     | 0.00%      | 2.50%      | 13.83%     | 8.07%      | 2.29%      | 2.80%      |            |            |
|                  | 16  | 23.57%     | 14.14%     | 47.14%     | 37.22%     | 6.50%      | 0.60%      | 2.93%      | 4.64%      | 6.22%      | 8.06%      |            | 0.00%      |
|                  | 17  | 16.97%     | 33.67%     | 28.28%     | 42.43%     | 1.59%      | 6.19%      | 2.54%      | 4.50%      | 0.90%      | 6.91%      |            |            |
|                  | 18  | 30.74%     | 35.36%     | 47.14%     | 64.28%     | 5.19%      | 14.18%     | 5.10%      | 1.68%      | 1.70%      | 2.53%      |            | 2.33%      |
|                  | 19  | 10.88%     | 51.43%     | 47.14%     | 47.14%     | 14.52%     | 3.50%      | 6.98%      | 4.17%      | 1.53%      | 1.67%      | 0.16%      |            |
|                  | 20  | 28.28%     | 16.97%     | 28.28%     | 0.00%      | 5.19%      | 9.95%      | 0.80%      | 2.72%      | 1.10%      | 3.47%      | 0.16%      | 0.15%      |
| Interassay Mean  |     | 1.026      |            | 0.901      |            | 25.375     |            | 31.545     |            | 37.799     |            | 47.692     |            |
| Interassay SD    |     | 0.288      |            | 0.358      |            | 4.845      |            | 5.040      |            | 5.476      |            | 1.628      |            |
| Interassay CV%   |     | 28.11%     |            | 39.69%     |            | 19.09%     |            | 15.98%     |            | 14.49%     |            | 3.41%      |            |

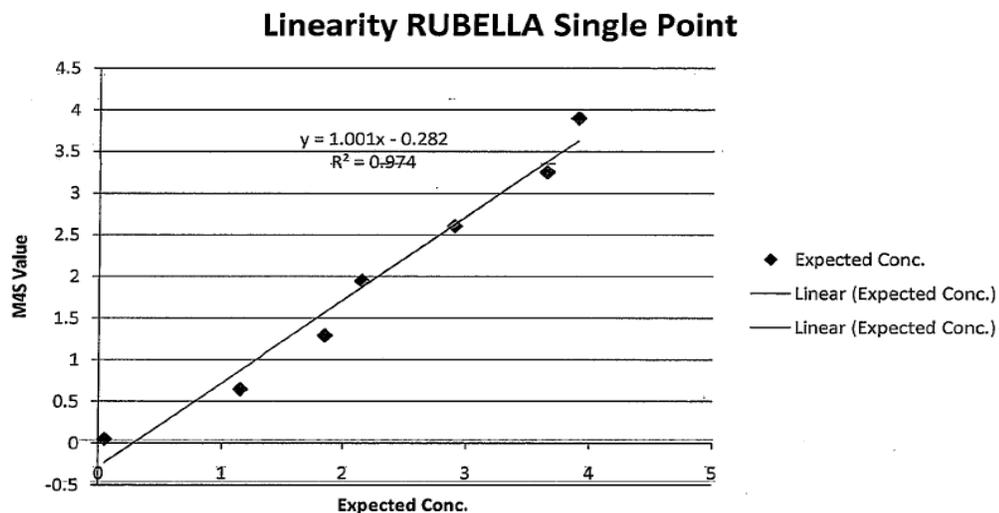
Note: Readings for QC F that were reported as >200 are shown as blanks, no statistics were possible.  
When low results are reported on an analyte, a high coefficient of variation (CV) may result. (Taken from CAP survey)

| Baptist Precision |     |            |            |            |            |            |            |            |            |            |            |            |            |
|-------------------|-----|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Intra Assay CV %  | Day | QC A Run 1 | QC A Run 2 | QC B Run 1 | QC B Run 2 | QC C Run 1 | QC C Run 2 | QC D Run 1 | QC D Run 2 | QC E Run 1 | QC E Run 2 | QC F Run 1 | QC F Run 2 |
|                   | 1   | 0.00%      | 41.59%     | 47.14%     | 20.20%     | 21.49%     | 14.63%     | 0.23%      | 3.13%      | 5.19%      | 4.81%      |            | 2.42%      |
|                   | 2   | 31.43%     | 47.14%     | 28.28%     | 35.36%     | 0.66%      | 7.99%      | 1.58%      | 4.81%      | 1.27%      | 1.04%      |            |            |
|                   | 3   | 53.03%     | 35.36%     | 41.59%     | 28.28%     | 14.59%     | 0.31%      | 2.08%      | 4.89%      | 2.63%      | 3.21%      |            |            |
|                   | 4   | 35.36%     | 41.59%     | 35.36%     | 35.36%     | 11.24%     | 3.86%      | 2.59%      | 0.92%      | 1.00%      | 0.79%      |            |            |
|                   | 5   | 30.74%     | 42.43%     | 37.22%     | 31.43%     | 4.07%      | 2.85%      | 8.86%      | 8.21%      | 1.78%      | 0.65%      |            |            |
|                   | 6   | 40.41%     | 31.43%     | 8.32%      | 31.43%     | 17.65%     | 5.26%      |            | 18.06%     | 4.93%      | 0.94%      |            |            |
|                   | 7   | 23.57%     |            | 25.71%     |            | 3.01%      |            | 29.86%     |            | 0.00%      |            |            |            |
|                   | 8   | 35.36%     | 51.43%     | 38.57%     | 47.14%     | 8.12%      | 1.38%      | 9.91%      | 13.65%     | 8.35%      | 4.16%      |            | 2.46%      |
|                   | 9   | 6.15%      | 28.28%     | 64.28%     | 42.43%     | 12.75%     | 11.93%     | 6.04%      | 7.35%      | 5.61%      | 3.23%      |            |            |
|                   | 10  | 42.43%     | 30.30%     | 37.22%     | 42.43%     | 5.22%      | 3.46%      | 4.09%      | 6.19%      | 6.36%      | 0.40%      |            |            |
|                   | 11  | 38.57%     | 28.28%     | 53.03%     | 47.14%     | 0.00%      | 2.24%      | 3.88%      | 4.74%      | 1.26%      | 5.17%      |            |            |
|                   | 12  | 64.28%     | 30.74%     | 42.43%     | 37.22%     | 4.99%      | 0.51%      | 3.84%      | 1.94%      | 0.17%      | 1.05%      |            |            |
|                   | 13  | 24.38%     | 32.64%     | 66.99%     | 33.67%     | 1.09%      | 2.89%      | 3.59%      | 6.10%      | 2.58%      | 1.54%      |            |            |
|                   | 14  | 41.59%     | 47.14%     | 31.43%     | 28.28%     | 1.86%      | 8.04%      | 11.88%     | 3.61%      | 7.79%      | 1.54%      |            |            |
|                   | 15  | 38.57%     | 40.41%     | 47.14%     | 41.59%     | 0.98%      | 3.87%      | 7.34%      | 8.32%      | 3.93%      | 1.13%      |            |            |
|                   | 16  | 37.22%     | 37.22%     | 52.10%     | 47.14%     | 24.87%     | 6.56%      | 7.44%      | 5.05%      | 2.56%      | 5.78%      |            |            |
|                   | 17  | 47.14%     | 66.00%     | 22.33%     | 54.39%     | 8.13%      | 15.41%     | 3.26%      | 2.28%      | 0.20%      | 0.69%      |            |            |
|                   | 18  | 47.14%     | 37.22%     | 28.28%     | 35.36%     | 0.56%      | 0.81%      | 8.15%      | 11.26%     | 3.36%      | 6.09%      |            |            |
|                   | 19  | 30.00%     | 32.64%     | 6.15%      | 33.67%     | 7.44%      | 2.89%      | 14.22%     | 6.10%      | 12.41%     | 1.54%      |            |            |
|                   | 20  | 40.41%     | 41.59%     | 0.00%      | 47.14%     | 8.94%      | 1.50%      | 5.77%      | 6.51%      | 2.38%      | 6.15%      | 6.59%      |            |
| Interassay Mean   |     | 1.036      |            | 0.877      |            | 25.086     |            | 32.538     |            | 36.863     |            | 46.964     |            |
| Interassay SD     |     | 0.368      |            | 0.276      |            | 3.970      |            | 5.013      |            | 4.365      |            | 1.527      |            |
| Interassay CV%    |     | 35.54%     |            | 31.45%     |            | 15.83%     |            | 15.41%     |            | 11.84%     |            | 3.25%      |            |

Note: Readings for QC F that were reported as >200 are shown as blanks, no statistics were possible.  
When low results are reported on an analyte, a high coefficient of variation (CV) may result. (Taken from CAP survey)

**Linearity/reportable range:**

One strongly positive serum sample and one weakly positive serum sample were diluted seven times at evenly spaced intervals over the linear range and tested in duplicate. Below is a graphical representation of the results.





### ***CDC Performance Panel Results***

A serum panel provided by the CDC containing 100 samples was tested for the presence of rubella IgG antibodies using the Diamedix *Is-Rubella* IgG Test Kit at Diamedix Corp., Miami, FL. Testing was performed on the MAGO 4S Automated EIA Processor. The subsequent data was sent to the CDC for evaluation, and the results of this evaluation are summarized below. The panel includes 9 negative sera resulting in 18 negative specimens and 41 positive sera resulting in 82 positive specimens. The assay run on this sera panel resulted in satisfactory results of 82/82 positive tests on 82 positive sera and 18/18 negative tests on 18 negative sera.

### ***CDC Biological Standard Results***

The CDC Low-Titer Anti Rubella Human Reference Serum, CDC Biological Standard was used to verify the Diamedix Rubella IgG assay performance. The CDC standard is set at a neat concentration of 21.0 IU/mL of Rubella IgG antibody. A dilution series (1:2, 1:4, and 1:8) was performed in duplicate. The mean result of the two-fold diluted standard was 14.1 IU/mL, which is in reasonable agreement with the CDC immunity cut-off reference level.

#### **N. Instrument Name:**

MAGO 4S Automated EIA and IFA Processor

#### **O. System Descriptions:**

1. Modes of Operation:

Automated batch mode

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes  or No

3. Specimen Identification:

Entered by user or by bar code reader.

4. Specimen Sampling and Handling:

Specimens are processed according to assay instructions.

5. Calibration:

The dispense probe calibration is to be done every three months. The MAGO Calibration Check Kit is used to verify the precision and repeatability of the dispense probe. A p-nitrophenol (pNP) calibration dye is diluted into each of the 96 wells, with the optical density (OD) subsequently measured by the plate reader. The mean, standard deviation (SD), and coefficient of variation (CV) of the OD measurements are provided.

Field service personnel calibrate the plate reader every six months.

6. Quality Control:

Quality control is addressed for each separately cleared specific assay to be run on the instrument.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

N/A

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.