Diamedix®
A Subsidiary of ERBA Diagnostics, Inc.

# Rubella IgG

*Enzyme Immunoassay Test Kit*
**For *In Vitro* Diagnostic Use**
**Catalog No. 720-360 - 96 Tests**

## SUMMARY OF PROCEDURE

1. Prepare 1:101 dilutions of patient samples in Sample Diluent. Mix well. Note that Standards and Controls are ready-to-use.
2. Add 100 µl of Standards, Controls and diluted patient samples into the antigen wells.
3. Incubate at 37 ± 3° C for 60 ± 5 min.
4. Discard contents of the wells. Wash the wells 3 times with Wash Solution.
5. Add 100 µl of Conjugate to each well.
6. Incubate at 37 ± 3° C for 60 ± 5 min.
7. Wash the wells as in #4 above.
8. Add 100 µl Substrate Solution to each well.
9. Incubate at 37 ± 3° C for 20 ± 2 min.
10. Add 100 µl Stop Solution to each well.
11. Read the absorbances at 450/600-630 nm.

## INTENDED USE

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.

## SUMMARY AND EXPLANATION

Rubella (German or '3-day' measles) is a mild, contagious rash primarily of children and young adults. Acute rubella virus infection in a child or adult is usually a self-limited, benign disease, characterized by a low-grade fever, mild upper respiratory symptoms, an erythematosus maculopapular rash and suboccipital lymphodenopathy. However, rubella can be a very serious disease early in pregnancy, leading to miscarriages, stillbirths or birth defects (congenital rubella syndrome, or CRS). Common manifestations of congenital rubella include deafness, ocular problems including cataracts and glaucoma, congenital heart disease and mental retardation (1, 2).

The severity and risk of the effects of rubella virus on the fetus depend on the time during pregnancy when the rubella infection occurs. Up to 85% of infants infected in the first trimester will be found to be affected after birth and even an inapparent rubella infection in the mother can result in birth defects. After an attack of rubella or vaccination against rubella most mothers are protected against the disease for life. However, reinfection with rubella can occur (3,4). Reinfection occurs more frequently in vaccinated that in naturally Immune individuals (5). The overwhelming majority of these reinfections occur without symptoms. Rubella reinfection during pregnancy, however, rarely results in transmission of the virus to the unborn child (2,3).

Since rubella vaccines were first licensed for use in 1969 the number of reportable cases has dropped dramatically. However, in recent years a moderate resurgence of rubella has occurred. Although rash is the most conspicuous feature of the disease, it is of such a variable character that it may be confused with that produced by other infectious diseases and even by drugs. Thus, diagnosis of rubella on clinical grounds may be somewhat inaccurate and there is a need for continued surveillance to identify susceptible individuals and reduce the risk of CRS (2,3).

Serologic techniques for the detection of antibodies to rubella virus provide the approach of choice for the laboratory diagnosis of acute and congenital rubella infections and for the determination of rubella immune status. The presence of IgM antibody or a significant rise in IgG for acute and convalescent specimens is evidence of acute rubella infection. The acute phase specimen should be drawn as soon after rash onset as possible; the convalescent-phase serum should be drawn 10 or more days after the acute-phase specimen (3,6).

Historically, hemagglutination inhibition (HI or HAI) has been the most frequently used method of screening for the presence of rubella antibodies. The first enzyme immunoassay (EIA) for rubella was reported in 1975 (7) and since then this method has gained widespread acceptance.

The Diamedix *Immunosimplicity® (Is)* Rubella IgG Test Kit is an 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 (8).

## PRINCIPLE OF THE PROCEDURE

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 samples they will bind to the antigen forming antigen-antibody complexes. Residual sample is eliminated by aspirating and washing. Conjugate (horseradish 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.

## REAGENTS

***Each Is Rubella IgG Test Kit contains reagents for 96 tests.***

| | |
|---|---|
| Antigen Wells | Twelve, 8-well microwell breakapart strips, color-coded purple, coated with grade IV sucrose purified rubella antigen (strain HPV 77 produced in Vero cells). |
| 0 IU/ ml Standard | One vial with yellow cap containing 1.8 ml of pre-diluted human serum, non-reactive for rubella IgG antibodies, 0.2% sodium azide and Proclin® 300, 90 ppm active ingredient. Assigned IU/ml value printed on label. |
| 10 IU/ml Standard | Two vials with green caps containing 1.8 ml of pre-diluted human serum, weakly reactive for rubella IgG antibodies, 0.2% sodium azide and Proclin® 300, 90 ppm active ingredient. Assigned IU/ml value printed on label. |
| 50 IU/ml Standard | One vial with red cap containing 1.8 ml of pre-diluted human serum, moderately reactive for rubella IgG antibodies, 0.2% sodium azide and Proclin® 300, 90 ppm active ingredient. Assigned IU/ml value printed on label. |
| High Positive Control | One vial with white cap containing 1.8 ml of pre-diluted human serum, highly reactive for rubella IgG antibodies, 0.2% sodium azide and Proclin® 300, 90 ppm active ingredient. Assigned IU/ml range printed on label. |
| Low Positive Control | One vial with blue cap containing 1.8 ml of pre-diluted human serum, weakly reactive for rubella IgG antibodies, 0.2% sodium azide and Proclin® 300, 90 ppm active ingredient. Assigned IU/ml range printed on label. |
| Negative Control | One vial with black cap containing 1.8 ml of pre-diluted human serum, non-reactive for rubella IgG antibodies, 0.2% sodium azide and Proclin® 300, 90 ppm active ingredient. |

*Note: Standards and Controls are prepared from different serum lots.*

| | |
|---|---|
| Sample **A** Diluent | One bottle with blue cap containing 60 ml Phosphate buffer with protein stabilizers. Contains 0.2% sodium azide and Proclin® 300, 90 ppm active ingredient. Color-coded blue. |
| Wash **S** Concentrate (20X) | Two bottles with clear caps containing 50 ml of Phosphate buffered saline with Proclin® 300, 15ppm active ingredient. Color-coded light blue/green. Each bottle is sufficient to make 1050 ml of wash solution. |
| Conjugate | One bottle with red cap containing 25 ml goat anti-human immunoglobulin G labeled with horseradish peroxidase. Also includes protein stabilizers and preservatives. Color-coded pink. |
| Substrate **HRP** | One amber bottle with brown cap containing 25 ml buffered TMB solution (3,3',5,5' tetramethylbenzidine). |
| Stop **M** Solution | One bottle with white cap containing 30 ml of 1 N Phosphoric and 1N Hydrochloric acids. **CAUTION:** Acids are corrosive. Avoid contact with skin or eyes. If contact is made, flush area with copious amounts of water. See Precautions section. |

**Store these reagents at 2 to 8°C.**

## OTHER MATERIALS REQUIRED

**Manual Users:**

Wash bottle or automated microplate washer

Pipettors capable of dispensing appropriate volumes

Timer

One liter graduated cylinder

One liter wash solution reservoir

Deionized or distilled water

Absorbent toweling

Tubes or microwell plate for sample dilution

Reader capable of reading absorbance at 450 nm, reference at 600-630 nm

Incubator capable of maintaining temperature of 37 ± 3° C

**Automated MAGO EIA Processor Family Users (Plus, 4S):**

One liter graduated cylinder

Deionized or distilled water

Pre-dilution cups, strips or plates.

ProbeClean™ Concentrate, or tip washing detergent solution, if applicable.

## PRECAUTIONS

REAGENTS: For *in vitro* Diagnostic Use.

1. Handle samples, Standards, controls and the materials that contact them as potential biohazards. Each donor unit in the Standards and controls has been found negative for Hepatitis B surface antigen and HIV-I antibodies by FDA-approved third generation tests. However, because no method can offer complete assurance that HIV-1, Hepatitis B virus, or other infectious agents are absent, these materials should be handled at the Biosafety Level 2 as recommended for any potentially infectious serum or blood specimen in the Centers for Disease Control/National Institutes of Health Manual, "Biosafety in Microbiological and Biomedical Laboratories", 1993.
2. Never pipette by mouth.
3. Avoid contact with open skin and mucous membranes.
4. Certain of the test reagents contain Proclin® 300 as a preservative. When disposing of reagents containing Proclin® 300, flush drains with copious amounts of water to dilute the active components below active levels.
5. Reagents containing Sodium Azide:

   (a) **CAUTION:** Some reagents in this kit contain Sodium Azide as preservative. Sodium Azide may react with lead or copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts", in the Manual Guide – Safety Management No. CDC-22, issued by the Centers for Disease Control and Prevention, Atlanta, GA, 1976.

   **European Communities Hazardous Substance Risk Phrases (Regulation (EC) No 1272/2008)**

   H300 –Fatal if swallowed.
   H310 – Fatal if contact with skin.
   EUH032 – Contact with acids liberates very toxic gas.
   H410 – Very toxic to aquatic life with long lasting effect.
   P264 – Wash all exposed external body areas thoroughly after handling.
   P302+P352 – IF ON SKIN: Wash with plenty of water and soap.
   P301+P310/P330 – IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.
   P270 – Do not eat, drink or smoke when using this product.
   P501 – Dispose of contents/container as hazardous waste.
   P391 – Collect spillage.
   P273 – Avoid release to the environment. Refer to special instructions/ Safety Data Sheet.

   (b) Sodium Azide inhibits horseradish peroxidase activity. Care must be taken to ensure that azide is not carried over from other reagents into conjugate and substrate steps.
6. Avoid contamination of the TMB substrate solution with conjugate or other oxidants, which will cause the solution to change color prematurely.

**ADDITIONAL PRECAUTIONS:**

1. Do not interchange reagents from different reagent lots except for Sample **A** Diluent, Wash **S** Concentrate, Substrate **HRP** and Stop **M** Solution.
2. Do not use reagents beyond their expiration date. Expiration dates are printed on the reagent labels.
3. Store unused reagents at 2 to 8°C.
4. Incubations above or below the recommended temperatures or times may give erroneous results.
5. The EIA method is a very sensitive technique. Maintain consistent pipetting technique, incubation times, and temperature conditions throughout the test procedure. Cross contamination between reagents can invalidate the test.
6. Antigen coated microwells should be stored with the desiccant in the resealable bag provided and returned to the refrigerator immediately after use.
7. *(Manual Procedure Only)* The washing procedure is very important and requires special attention. (Please refer to the Procedure section.)

   ***NOTE:*** *Improperly washed wells may give erroneous results.*
8. The concentrations of anti-rubella IgG in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.

## SPECIMEN COLLECTION

Whole blood should be collected by accepted medical techniques. Separated serum should remain at 22°C for no longer than 8 hours. If assays are not completed within 8 hours, serum should be refrigerated (2-8°C). If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at –20°C. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen sera to room temperature slowly and mix gently, avoiding foam formation. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Grossly contaminated, hemolyzed, lipemic, or icteric specimens should not be used. The CLSI, formerly NCCLS, provides recommendations for collecting and storing blood specimens, (Approved Standard - Procedures for the Handling and Process-ing of Blood Specimens, H18A3.)

For the diagnosis of acute rubella infection, the acute-phase serum sample should be drawn as soon as possible after rash onset, preferably within the first 7 days. The convalescent-phase sample should be drawn 10-14 days after the acute-phase specimen.

***CAUTION:*** *Serum samples must not be heat-inactivated prior to use.*

## PROCEDURE

Allow all test components and patient samples to warm to room temperature before use. Invert reagent bottles gently several times before use. Return promptly to the refrigerator after use.

Prepare Wash Solution by adding 50 ml of Wash Concentrate (20X) to one liter of deionized or distilled $H_2O$.

**MANUAL USERS:**

**The Standards and Controls are provided ready to use: DO NOT DILUTE FURTHER.**

**Note**: *For qualitative assays*, the 10 IU/ml Standard only is required. This Standard should be assayed in triplicate. In addition, a Blank (100 µl Sample Diluent only, in the first well of the first strip) is required and will be used to "zero" the photometer before reading test results.

*For quantitative assays,* all three Standards are required. No Blank is required; the 0 IU/ml Standard will function as the „zero" and will be placed in the first well of the first strip. Standards can be run singly or in duplicate.

**High Positive, Low Positive and Negative Controls must be run for either assay option.**

1. Prepare 1:101 dilutions of the patient samples in Sample Diluent. (e.g., by addition of 2 µl sample to 200 µl Sample Diluent or 5 µl sample to 500 µl Sample Diluent).
2. Mix sample dilutions gently by withdrawing and expelling in a pipette tip 2 or 3 times or by vortex mixing for 2 or 3 seconds. Transfer 100 µl of Standards, controls and diluted patient samples, to the antigen wells. Avoid formation of bubbles when transferring diluted samples.

3. Allow the wells to incubate uncovered at 37 ± 3°C for 60 ± 5 minutes.
4. Aspirate or discard the contents of the wells. Remove any excess moisture in the wells by tapping on paper toweling. Wash the wells by rinsing 3 times with at least 300 µl of Wash Solution. Remove excess moisture from the wells after washing. When using an automated washer, follow the manufacturer"s instructions.
5. Place 100 µl of Conjugate into each well, avoiding bubble formation.
6. Allow the wells to incubate uncovered at 37 ± 3°C for 60 ± 5 minutes.
7. Wash the wells as described in Step 4 above.
8. Place 100 µl of Substrate into each well, avoiding bubble formation.
9. Allow the wells to incubate uncovered at 37 ± 3°C for 20 ± 2 minutes.
10. Place 100 µl of Stop Solution into each well, avoiding bubble formation.
11. Read the absorbance of the wells at 450 nm using a reference wavelength of 600-630 nm. The plate should be read within 60 minutes of adding Stop Solution.

**AUTOMATED MAGO EIA Processor Family Users (Plus, 4S):**

When using an Automated EIA Processor, refer to the Operator"s Manual for the test setup and procedures.

***NOTE:*** *Automated EIA Processor users must validate their equipment to demonstrate that the results obtained are equivalent to those obtained using manual assay.*

## QUALITY CONTROL

*For Quantitative Assays*

1. The High Positive, Low Positive and Negative Controls must be included in each test run.
2. The absorbance of the 0 IU/ml Standard must be < 0.2.
3. The absorbance of the 10 IU/ml Standard must be higher than that of the Negative Control.
4. The absorbance of the 10 IU/ml Standard must be lower than that of the Low Positive Control.
5. The absorbance of the 50 IU/ml Standard must be higher than that of the Low Positive Control.
6. The Low Positive Control must be within its assigned range. This control is used to validate the low end of the of the assay.
7. The High Positive Control must be >50 IU/ml. This control is used to validate the upper range of the assay.
8. The Negative Control must be < 8 IU/ml. This control is used to validate the assay below the cut- off.

If any one of these criteria is not met, the results are invalid and the test should be repeated.

*For Qualitative Testing*

1. The High Positive, Low Positive and Negative Controls must be included in each test run.
2. The absorbance of the Blank must be < 0.2.
3. The Low Positive Control Index should be between 1.1-2.5
4. The High Positive Control Index should be > 2.5
5. The Negative Control Index must be < 0.8

If any one of these criteria is not met, the results are invalid and the test should be repeated.

NOTES: The Negative and Positive Controls are intended to monitor substantial reagent failure. The controls will not control all parts of the procedure such as technical dilution of patient specimens. The Positive Controls will not ensure precision at the assay cut-off. Users may wish to establish an in-house control having a quantitative value determined by replicate testing, at or near the cut-off to monitor the precision of the assay cut-off. Additional controls may be tested according to guidelines or requirements of local, state or federal regulations or accrediting organizations. For guidance on appropriate quality control practices, please refer to CLSI, formerly NCCLS, document C24-A2, Statistical Quality Control for Quantitative Measurements: Principles and Definitions.

## RESULTS

**1. Calculations**

***Qualitative Assay*:** Qualitative results may be obtained using the 10 IU/ml Standard only in triplicate, following a single Blank well (100 µl Sample Diluent only). If performing the qualitative assay option, manually set the reader for absorbance mode or cut-off control test mode and calculate the mean absorbance for the three Standard wells.

**Note:** When calculating the mean absorbance exclude any absorbance value that deviates by more than 15% from the mean absorbance value. Calculate the mean absorbance value from the two remaining absorbances. Exclusion of more than one of the 3 absorbance values invalidates the run.

*Example: Absorbance values obtained for 10 IU/ml Standard: 0.456, 0.445, 0.458 (after subtraction of the Blank)*

*Mean Absorbance of the 10 IU/ml Standard = 0.453*

*Sample Absorbance = 0.959*

*Index Values are then calculated as follows:*

*Sample Absorbance/Mean Absorbance of 10 IU/ml Standard = 2.13*

When using Automated EIA Processors (e.g. the MAGO Plus Automated EIA Processor), results are automatically calculated and expressed as Positive, Equivocal or Negative.

***Quantitative Assay:*** Quantitative results may be obtained from the point-to-point curve fit using all three Standards. For plate readers, the point-to-point option should be selected and Standard values entered accordingly. Index values can be calculated by dividing the IU/ml values by 10 (the positive cut-off value). An Automated EIA Processor will automatically calculate results using the point-to-point curve fit and will then print results.

Specimens which yield absorbances greater than that of the 50 IU/ml Standard may be reported as 'greater than 50 IU/ml' or Index >5.0. Alternatively, such samples may be pre-diluted in Sample Diluent and retested. The resulting IU/ml or Index Value must be multiplied by the dilution factor for reporting.

*Example: If the specimen has been pre-diluted 1:5 before testing, the resulting IU/ml or Index Value should be multiplied by 5.*

**2. Interpretation**

| 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 |

Note that when using the assay qualitatively the magnitude of the Index Value has no significance and results should be reported as under 'Interpretation' above.

* When equivocal results are obtained, another specimen should be collected ten to fourteen days later and tested in parallel with the initial specimen. If the second sample is also equivocal, the patient is negative for primary or recent infection, and equivocal for antibody status. If the second sample is positive, the patient may be considered to have a primary infection (see Section 4. Paired Sera). The conversion of an individual patient"s serum from negative to positive for antibodies to the infectious agent in question, is defined as seroconversion, and indicates active or recent infection.

**3. Reporting Results**

When the IU/ml value is reported for a single specimen the following statement should be included: "The following results were obtained with the Diamedix *Immunosimplicity Is*-Rubella IgG EIA Test System. The magnitude of the measured result, above the cut-off, is not indicative of the total amount of antibody present. The magnitude of the reported IgG level cannot be correlated to an end-point titer".

When the assay is used semi-quantitatively, the following statement should be included when reporting results: "Timing of specimen collection for paired sera may be critical. In some patients, antibody titers may rise to significant levels and fall again to lower or undetectable levels within a month. Other patients may not develop significant antibody levels. Culture results, serology and antigen detection methods should all be appropriately used along with clinical findings for diagnosis".

**4. Paired Sera**

To determine a significant difference between acute/convalescent sera, both specimens must be run within the same assay. In addition, paired sera should be evaluated within the reportable range of the assay. The upper limit of the reportable range has been set at 50 IU/ml. In-house studies performed both manually and using the MAGO Plus have shown that a 2.6-fold or greater increase in the IU/ml ratio(convalescent serum IU/ml value / acute serum IU/ml value) corresponds to a four-fold increase in Rubella IgG antibody level and a 1.9-fold increase in the IU/ml ratio corresponds to a two-fold increase in Rubella IgG antibody level. Ratios in the range of 1.9 to less than 2.6 indicate an equivocal status for the paired samples. In this case, paired samples can be retested or additional samples collected if necessary. If paired sera controls are desired, it is recommended that a 1:4 dilution of a sample with an IU/ml value of between 40 and 50 be prepared in Sample Diluent. The undilute and 1:4 diluted material will provide a simulated serum pair. The Ratio of the undilute and 1:4 diluted material can then be compared against the established range.

## Cut-Off Establishment

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, (1994) in accordance with the NCCLS Guideline for the Detection and Quantitation of Rubella IgG Antibody (9). 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. At the optimized cut-off level, the Diamedix *Is*-Rubella IgG Test Kit has a relative sensitivity of 95% and a relative specificity of 100% based on comparison to the marketed test. The cut-off of 10 IU/ml has also been validated by replicate testing of the WHO Standard diluted to 10 IU/ml. Sixteen replicates of this dilution were tested on three lots of *Is*-Rubella IgG both manually and using the MAGO Plus. The overall mean value for the 96 replicates was 9.1 IU/ml with a Standard Deviation (SD) of 0.9. The appropriateness of the cut-off has been further verified by the results of the CDC Rubella Panel (see Performance Characteristics).

## LIMITATIONS

1. The results obtained with the *Is*-Rubella IgG Test Kit serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves.
2. Rubella IgG ELISA assays are not intended to replace virus isolation and/or identification.
3. The prevalence of the analyte will affect the assay's predictive value.
4. Assay performance characteristics have not been established for visual result determination.
5. Performance of this assay has not been established on spectrophotometry utilizing a single wavelength.
6. The test should be performed on serum. The use of whole blood or plasma has not been established.
7. A single positive result only indicates previous immunologic exposure and cannot be used to distinguish between active and past infection. Paired samples (acute and convalescent) are required to detect seroconversion or a significant rise in antibody level.
8. A negative result does not always exclude the possibility of active rubella infection. The sample may have been collected before appearance of IgG antibody. If infection is suspected, a second sample should be collected at least 10 days after onset of rash and tested concurrently with the first sample to determine if seroconversion has occurred.
9. The performance characteristics have not been established for newborns using cord blood.
10. The results on serum from immunosuppressed individuals must be interpreted with caution.
11. The performance characteristics of the Diamedix *Is*-Rubella IgG Test Kit with automated equipment other than the MAGO Family of Automated EIA Processors have not been established.

## 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 (10).

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 1. Histograms demonstrating the distribution of IU/ml values are shown in Figures 1 and 2.

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 1**

| Total Number | Number of Donors<br>100 | Prevalence<br>89.0% |
|---|---|---|
| Geographic Location:<br>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 1**
***Is*-Rubella IgG Positive Population**

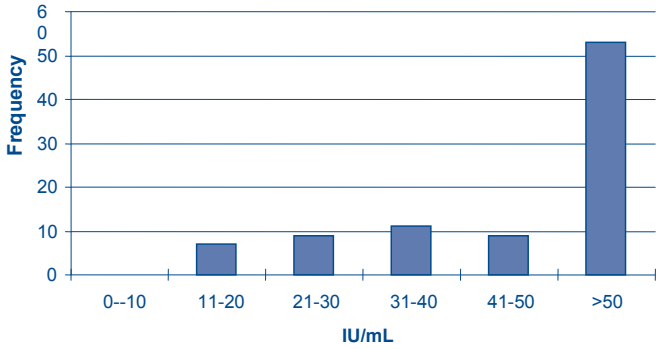
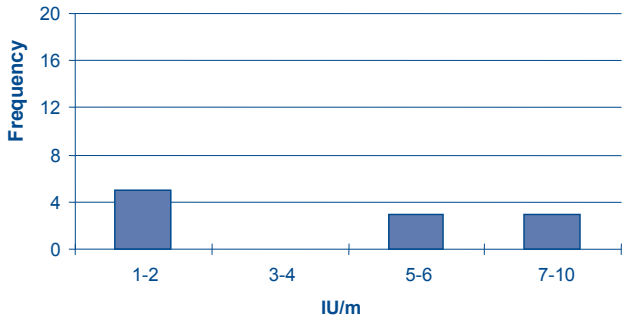



**FIGURE 2**
***Is*-Rubella IgG Negative Population**




## 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 2 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 3 compares the results obtained for the *Is*-Rubella IgG Test Kit and their currently used testing method.

**TABLE 2**
***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 | 165/70 | = 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 3**
***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 |

[ ] denotes samples from females of child-bearing age (18-45 years).

* 95% Confidence Intervals (CI) calculated by the Exact Method (11).

** Equivocal results were excluded from calculations.

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.

Note that the tabulated data were not recalculated after resolution of discordant samples.

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 4 and 5 compare the results obtained for the *Is*-Rubella IgG Test Kit and another marketed EIA method. Table 6 provides the comparative data for 45 samples from pregnant females.

**TABLE 4**
***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% | 95.1-99.5 |
| Relative Specificity | 49/49 | = 100.0% | 92.7-100.0 |
| Overall Agreement ** | 253/257 | = 98.4% | 96.1-99.6 |

**TABLE 5**
***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% | 91.7-100.0 |
| Overall Agreement | **252/25 | = 99.6% | 97.8-100.0 |

[ ] denotes samples from females of child-bearing age (18-45 years).

* 95% Confidence Intervals (CI) calculated by the Exact Method (11).

** 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.

**TABLE 6**
***Is-Rubella IgG – Site #3: Manual***

| | | Positive | Negative | Equivocal |
|---|---|---|---|---|
| Other EIA | Positive | 41 | 0 | 2 |
| | Negative | 0 | 2 | 0 |
| | Equivocal | 0 | 0 | 0 |

| | | | *95% CI** |
|---|---|---|---|
| Relative Sensitivity | 41/41 | = 100.0% | 95.1-99.5 |
| Relative Specificity | 2/2 | = 100.0% | 92.7-100.0 |

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 7 shows the results of this testing compared to the predicate method.

**TABLE 7**
**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 | 100.0% | 93.2-100 | 100.0% | 91.8-100 |
| Site #2 | 42 | 3 | 8 | 0 | 45 | 0 | 0 | 2 | 0 | 93.3% | 81.7-100 | 100.0% | 92.1-100 |
| Site #3 | 46 | 4 | 3 | 0 | 45 | 0 | 0 | 2 | 0 | 92.0% | 80.0-97.8 | 100.0% | 92.1-101 |

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.

**MAGO 4S Comparison**

A total of 208 sera, including at least 50 samples with Rubella IgG on the 10-20 IU/mL concentration range, 50 samples with a >20 IU/mL concentration, and 80 with <9 IU/mL, were tested with the Diamedix *Is* Rubella IgG Test Kit once manually and once on the Mago 4S instrument.

| | | Manual | | | |
|---|---|---|---|---|---|
| | | Positive | Equivocal | Negative | Total |
| Mago 4S | Positive | 98 | 10 | 2 | 110 |
| | Equivocal | 2 | 12 | 3 | 17 |
| | Negative | 0 | 1 | 80 | 81 |
| | Total | 100 | 23 | 85 | 208 |

Positive Percent Agreement*: 97% (98/101) 95% CI: 92%-99%

Negative Percent Agreement*: 84.2% (80/95) 95% CI: 75%-90%

* Equivocal results are counted against the Mago 4S in the calculations.

***Assessment of equivocal zone results:***

To assess the variability due to equivocal results, a total of 20 patient samples identified in a requested (retest) zone that tested manually between 7 and 13 IU/mL, were re-tested twice for the presence of rubella IgG antibodies using the Diamedix *Is* Rubella IgG Test Kit at Diamedix Corp., Miami, FL. The 20 samples included within the 7-13 IU/ml range were selected based on the largest difference/changed status between manual and MAGO 4S testing. Testing was performed on the MAGO 4S Automated EIA Processor and manually. The mean of the 3 total (quantitative) results for the manual test and the mean of the total 3 (quantitative) results for the MAGO 4S were calculated, and PPA and NPA results were evaluated.

Comparison of Mago 4S vs. Manual for samples near the equivocal range:

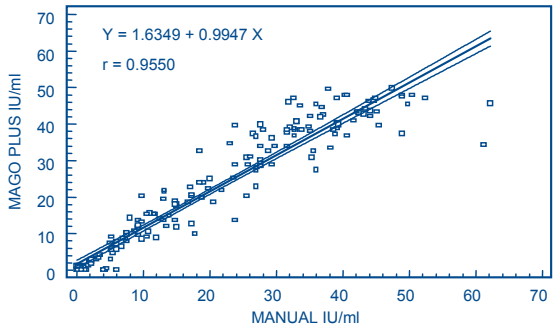
| | | Predicate (manual) | | |
|---|---|---|---|---|
| | | ≥10 (+) | <10 | Total |
| New Test (Mago 4S) | ≥10 | 17 | 0 | 17 |
| | <10 | 1 | 2 | 3 |
| | Total | 18 | 2 | 20 |

| | |
|---|---|
| Positive Percent Agreement | 94.44% (17/18) |
| Negative Percent Agreement | 100.00% (2/2) |

## B. Correlation of Manual and MAGO Plus Results

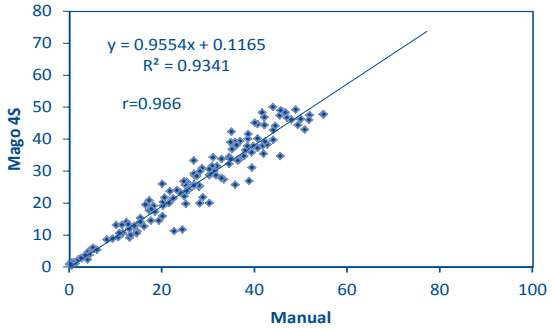
The *Is*-Rubella IgG Test Kit has been developed for automated as well as manual use. To demonstrate the equivalence of the manual and MAGO Plus Procedures, the results of 193 samples tested assayed manually and by MAGO Plus were compared. Highly reactive samples that exceeded the reportable range and excluded from this comparison. A scattergram and regression line of the results obtained with 95% confidence intervals is shown in Figure 3A.

**FIGURE 3A**
**Manual vs. MAGO Plus Correlation**




**Results for similar studies using the MAGO 4S including the new cohort of 208 patient samples are described below in Figure3B**

**Figure 3B**
**Manual vs. MAGO 4S Correlation**




## C. CDC Serum Panel Data and Correlation to HAI Titers

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 EIA 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 by hemagglutination inhibition (HAI). 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.

The *Is*-Rubella IgG IU/ml values obtained were then compared to the HAI titers. Figure 4 shows the mean IU/ml, +/- 2 SEM, for the 3 lots used compared to the HAI titers. A linear regression graph and scattergram with 95% Confidence Intervals for the overall mean IU/ml value versus the log of the HAI titer is shown in Figure 5.

**FIGURE 4**
***Is*-Rubella IgG Mean IU/ml, +/- 2 SEM, (for 3 lots) compared to HAI titers**

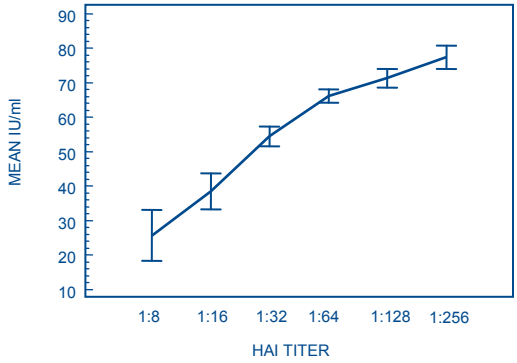
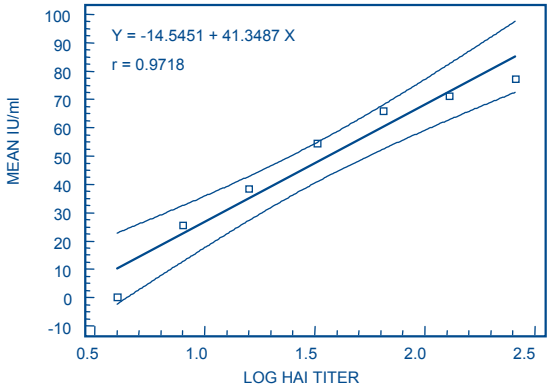



**FIGURE 5**
**Correlation of *Is*-Rubella IgG IU/ml Values to HAI titers**




**MAGO 4S CDC panel Studies:**

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 on18 negative sera.

## D. CDC Low Titer Anti-Rubella Human Reference Serum, CDC Biological Standard

During quality control testing, the low titer reference serum (21.0 IU/ml) was tested at a 1:2 dilution in all three lots of *Is*-Rubella IgG used to generate performance data. Values obtained for the 1:2 diluted material were 12.9 IU/ml, 13.3 IU/ml and 14.2 IU/ml. In addition, replicate testing of this reference material both undiluted and diluted 1:2 at an outside testing site gave mean values of 26.5 IU/ml and 12.5 IU/ml respectively.

### MAGO 4S-CDC Low Titer studies:

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

## E. 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 6 and 7A 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.

**FIGURE 6**
**Manual Linearity**

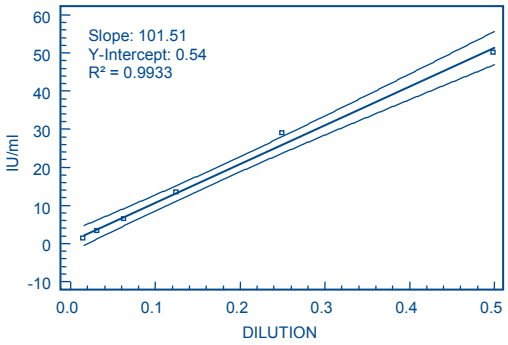
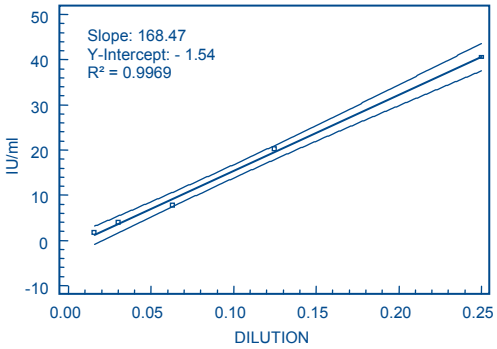
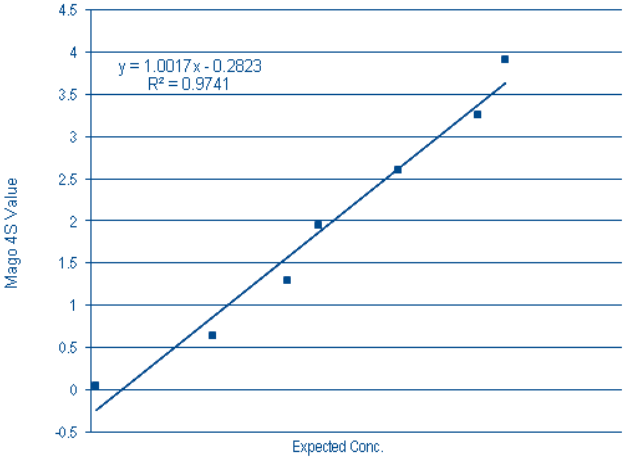



**FIGURE 7A**
**MAGO Plus Linearity**




**The same corresponding linearity studies for the MAGO 4S are represented below in Figure 7B.**

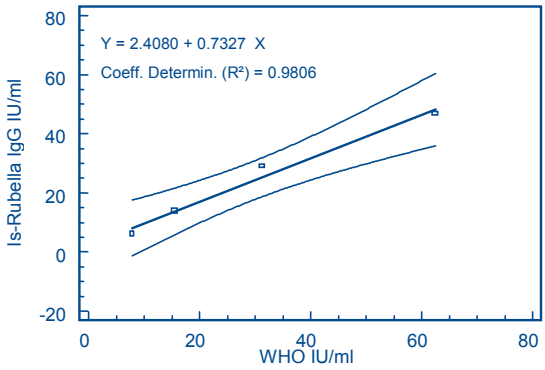
**FIGURE 7B**
**MAGO 4S Linearity:**




## F. Correlation/Calibration 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 8.

**FIGURE 8**
**WHO IU/ml vs. *Is*-Rubella IgG IU/ml**




| EXPECTED IU/ML VALUE | RECOVERED MEAN IU/ML VALUE |
|---|---|
| 62.5 | 46.7 |
| 31.25 | 28.8 |
| 15.63 | 13.9 |
| 7.81 | 6.1 |

## G. Semi-Quantitative Data

Serum pairs were obtained by preparing multiple two-fold dilutions of several strongly positive sera. Ratios for dilutions representing a four-fold and two-fold difference in antibody level were evaluated as a serum pair both manually and using the MAGO Plus. The mean ratio obtained for four-fold dilutions when tested manually was 3.30 (SD 0.73). The overall mean ratio obtained for two-fold dilutions was 1.90. Thus, it was estimated that a 2.6-fold or greater (mean ratio minus 1 SD) increase in *Is*-Rubella IgG IU/ml ratio corresponded to a four-fold increase in Rubella IgG antibody level. A ratio in the range of 1.9 to less than 2.6 was considered equivocal for significant increase determination. All estimated ratios obtained using the MAGO Plus exceeded 2.6-fold.

## H. Cross Reactivity

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 8**

| 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 |

## I. 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 11) the 50 IU/ml Standard was replaced with an additional weakly positive sample. Tables 9-15 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 9**
**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 10**
**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 | 0.62 | 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 11**
**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 | 19.3 | 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 12**
**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% | MEAN IU/ml | SD | CV% | MEAN IU/ml | SD | CV% | 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 | 1.25 | 6.61 | 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 13**
**Inter-Site Precision (Manual)**

| SERUM | Site #1 | Site #2 | Site #3 | INTERSITE | | |
|---|---|---|---|---|---|---|
| | MEAN IU/ml | MEAN | 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 14**
**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 15**
**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 |
| 10 STD | 18.9 | 2.60 | 13.76 | 13.3 | 1.62 | 12.41 | 15.6 | 2.59 | 16.60 | 15.9 | 3.27 | 20.57 |
| 50 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 |

## MAGO 4S Precision

For the MAGO 4S Precision study, 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 Tables 16-18.

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 anlyte, 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 anlyte, 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 anlyte, a high coefficient of variation (CV) may result. (Taken from CAP survey)

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