

**New York State Department of Health
Wadsworth Center**

Proficiency Testing Program

7-May-08

**DIAGNOSTIC IMMUNOLOGY &
HUMAN IMMUNODEFICIENCY VIRUS
SUMMARY ANALYSIS**

**Proficiency Test Event
7-May-08**

**Diagnostic Immunology & Human Immunodeficiency Virus
Summary Report**

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The data summarized in this report were tabulated from test results and accompanying information submitted by laboratories that participated in the May 7, 2008 Diagnostic Immunology and Human Immunodeficiency Virus proficiency test events. Participants are encouraged to review the data and to compare results and test kit performances.

Laboratories were evaluated on the basis of their responses for each analyte and on overall performance for all the analytes tested in the permit category. Appropriate responses were determined by participant consensus requiring 80% agreement in each test.

Qualitative/quantitative results were graded in relation to results given by participants for specific test kits. When the number of participants that used a specific test kit was less than 10, results were graded considering results given for the method used. Target values and acceptable ranges were determined as indicated in Page 5.

Grading Criteria:

- ▶ For each separate analyte where results were reported, qualitative or quantitative, twenty points were deducted for each incorrect answer. For Syphilis-Reagin (RPR), where both qualitative and quantitative results are reported under one analyte, ten points were deducted for each incorrect quantitative or qualitative result. Titering of positive Syphilis-Reagin samples is mandatory for all Diagnostic Services laboratories who perform this test, unless given an exemption. Failure to titer the positive samples to the endpoint will result in failure for the Syphilis-Reagin analyte.
- ▶ For **Diagnostic Services** failure to attain an overall testing score of at least 80% is unsatisfactory performance
- ▶ For **Donor Services** failure to attain an overall testing score of 100% is unsatisfactory performance.
- ▶ For **HIV** failure to attain an overall testing score of 100% is unsatisfactory performance.
- ▶ Laboratories failing two out of three consecutive proficiency test events for an analyte or for the permit category will fail the proficiency testing program for the analyte or for the permit category and may be required to cease patient testing for that analyte/category.

Summary Tables

Test kit manufacturer names are in *italics*. In some tables, test kits are grouped under test methods shown in bold letters. In all tables, test methods and test kit manufacturer names are listed in alphabetic order. Only the testing systems used by 10 or more laboratories are listed in this report.

For qualitative tests, results are summarized as the number of laboratories that reported a test sample as reactive to the number that reported it as non-reactive. In addition, where test results depend on a quantitative value (e.g. titer, IU/ml) the values reported are given in separate tables. They are expressed, where applicable, as the Mean \pm S.D. when ten or more laboratories reported data.

For quantitative tests, values reported variously as mg/dl, IU/ml, etc. are given as the Mean \pm S.D. when ten or more laboratories reported results. Titers are given as endpoint titers.

Disclaimer

The use of brand and/or trade names in this report does not constitute an endorsement of the products on the part of the Wadsworth Center or the New York State Department of Health.

Determination of Acceptable Responses

| Analyte or Test | Criteria |
|--|--|
| Alpha-1 Antitrypsin | Target value \pm 3 S.D. |
| Antinuclear Antibody | Positive or negative |
| Antinuclear Antibody Quantitative (IFA systems only) | Target value \pm 2 dilutions |
| Antistreptolysin O | Positive or negative |
| Antistreptolysin O Quantitative | Target value \pm 2 dilutions or Target value \pm 3 S.D. |
| Complement C'3, C'4 | Target value \pm 3 S.D. |
| Cytomegalovirus Antibody | Positive or negative |
| Hepatitis (HbsAg, anti-HBc, HBeAg, and HCAb) | Reactive or nonreactive |
| HIV 1 Ab, Ag | Reactive or nonreactive |
| HTLV 1 Ab | Positive or negative |
| Lyme Disease Ab, WB IgG, IgM | Positive or negative |
| Immunoglobulin A, E, M | Target value \pm 3 S.D. |
| Immunoglobulin G | Target value \pm 25 % |
| Infectious Mononucleosis | Positive or negative |
| Rheumatoid Factor | Positive or negative |
| Rheumatoid Factor Quantitative | Target value \pm 2 dilutions or Target value \pm 3 S.D. |
| Rubella Ab, IgM | Positive or negative or Immune or nonimmune |
| Rubella Ab Quantitative | Target value \pm 3 S.D. |
| Syphilis Reagin Antibody | Reactive or nonreactive Target value \pm 1 dilution |
| Syphilis Treponemal Antibody | Reactive or nonreactive |

Antinuclear Antibody

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|-------------|--------------|-----------|------------|------------|------------|------------|----------|-----------|------------|-------------|----------|-----------|----------|-----------|------------|------------|------------|-------------|----------|-----------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 46 R | | | | 47 N | | | | 48 N | | | | 49 R | | | | 50 N | | | |
| | | Manufacturer | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R |
| EIA | 44 | 1 | 2% | 43 | 98% | 44 | 100% | 0 | 0% | 44 | 100% | 0 | 0% | 0 | 0% | 43 | 98% | 44 | 100% | 0 | 0% |
| <i>Bio-Rad</i> | 11 | | 0% | 11 | 100% | 11 | 100% | | 0% | 11 | 100% | | 0% | | 0% | 11 | 100% | 11 | 100% | | 0% |
| <i>Diamedix</i> | 10 | | 0% | 10 | 100% | 10 | 100% | | 0% | 10 | 100% | | 0% | | 0% | 10 | 100% | 10 | 100% | | 0% |
| <i>Others ¹</i> | 23 | 1 | 4% | 22 | 96% | 23 | 100% | | 0% | 23 | 100% | | 0% | | 0% | 22 | 96% | 23 | 100% | | 0% |
| IFA | 64 | 2 | 3% | 62 | 97% | 63 | 98% | 1 | 2% | 64 | 100% | 0 | 0% | 2 | 3% | 62 | 97% | 64 | 100% | 0 | 0% |
| <i>Bio-Rad</i> | 18 | | 0% | 18 | 100% | 17 | 94% | 1 | 6% | 18 | 100% | | 0% | | 0% | 18 | 100% | 18 | 100% | | 0% |
| <i>The Binding Site</i> | 11 | | 0% | 11 | 100% | 11 | 100% | | 0% | 11 | 100% | | 0% | | 0% | 11 | 100% | 11 | 100% | | 0% |
| <i>Wampole/Zeus</i> | 16 | | 0% | 16 | 100% | 16 | 100% | | 0% | 16 | 100% | | 0% | 1 | 6% | 15 | 94% | 16 | 100% | | 0% |
| <i>Others</i> | 19 | 2 | 11% | 17 | 89% | 19 | 100% | | 0% | 19 | 100% | | 0% | 1 | 5% | 18 | 95% | 19 | 100% | | 0% |
| Multiplexed Bead | 15 | | 0% | 15 | 100% | 15 | 100% | | 0% | 15 | 100% | | 0% | 1 | 7% | 14 | 93% | 15 | 100% | | 0% |
| Other Methods | 5 | | 0% | 5 | 100% | 4 | 80% | 1 | 20% | 5 | 100% | | 0% | 2 | 40% | 3 | 60% | 5 | 100% | | 0% |
| Analyte Total | 128 | 3 | 2% | 125 | 98% | 126 | 98% | 2 | 2% | 128 | 100% | 0 | 0% | 5 | 4% | 122 | 95% | 128 | 100% | 0 | 0% |

¹ One laboratory reported an equivocal result on sample #49

Antinuclear Antibody Quantitative (IFA systems only)

The number of laboratories that reported titers is listed for positive test samples 46 and 49. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

| Method | No. Labs | Sample 46 Titer | | | | | | | Sample 49 Titer | | | | | | | | |
|--------|-------------------------|--------------------|----|-----|-----|-----|------|------|--------------------|----|----|-----|-----|-----|------|------|------|
| | | 40 | 80 | 160 | 320 | 640 | 1280 | 2560 | 5120 | 40 | 80 | 160 | 320 | 640 | 1280 | 2560 | 5120 |
| IFA | <i>Total</i> | 80 | 1 | 9 | 22 | 32 | 19 | 1 | 3 | | | 15 | 27 | 29 | 13 | 2 | 2 |
| | <i>Bio-Rad</i> | 24 | 1 | 4 | 6 | 12 | | | | | | 5 | 11 | 7 | | | |
| | <i>Immuno</i> | 11 | | | 1 | 3 | 5 | | | | | 1 | | 5 | 4 | | |
| | <i>The Binding site</i> | 18 | | 2 | 4 | 7 | 5 | | | | | 1 | 7 | 6 | 4 | | |
| | <i>Wampole/ Zeus</i> | 21 | | 2 | 8 | 5 | 2 | 1 | 1 | | | 6 | 5 | 4 | 2 | 1 | 1 |

Note: The number of labs reporting specific titers may not add up to the total number of labs for that system because some labs are not reporting endpoint titers.

Antinuclear Antibody Staining Patterns

| Staining Pattern | Sample 46 | | Sample 49 | |
|-------------------|-----------|----|-----------|-----|
| | # | % | # | % |
| <i>Homogenous</i> | 90 | 97 | 94 | 100 |
| <i>Nucleolar</i> | | | | |
| <i>Peripheral</i> | 1 | 1 | | |
| <i>Speckled</i> | 2 | 2 | | |

The reporting of a staining pattern here is for informational purposes only and is not used for grading.

Antistreptolysin O

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|------------|------------|-------------|----------|-----------|------------|-------------|----------|-----------|----------|-----------|------------|-------------|------------|-------------|----------|-----------|----------|-----------|------------|-------------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 16 N | | | | 17 N | | | | 18 R | | | | 19 N | | | | 20 R | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| Latex Agglutination | 73 | 73 | 100% | 0 | 0% | 72 | 99% | 1 | 1% | 0 | 0% | 73 | 100% | 71 | 97% | 2 | 3% | 1 | 1% | 72 | 99% |
| <i>Dade Behring</i> | 19 | 19 | 100% | | 0% | 19 | 100% | | 0% | | 0% | 19 | 100% | 18 | 95% | 1 | 5% | 1 | 5% | 18 | 95% |
| <i>Fisher</i> | 20 | 20 | 100% | | 0% | 20 | 100% | | 0% | | 0% | 20 | 100% | 20 | 100% | | 0% | | 0% | 20 | 100% |
| <i>Remel</i> | 15 | 15 | 100% | | 0% | 15 | 100% | | 0% | | 0% | 15 | 100% | 15 | 100% | | 0% | | 0% | 15 | 100% |
| <i>Others</i> | 19 | 19 | 100% | | 0% | 18 | 95% | 1 | 5% | | 0% | 19 | 100% | 18 | 95% | 1 | 5% | | 0% | 19 | 100% |
| Nephelometry | 12 | 12 | 100% | 0 | 0% | 12 | 100% | 0 | 0% | 0 | 0% | 12 | 100% | 12 | 100% | 0 | 0% | 0 | 0% | 12 | 100% |
| <i>Others</i> | 12 | 12 | 100% | | 0% | 12 | 100% | | 0% | | 0% | 12 | 100% | 12 | 100% | | 0% | | 0% | 12 | 100% |
| Hemagglutination | 11 | 11 | 100% | 0 | 0% | 10 | 91% | 1 | 9% | 0 | 0% | 11 | 100% | 11 | 100% | 0 | 0% | 1 | 9% | 10 | 91% |
| <i>Wampole/Zeus</i> | 11 | 11 | 100% | | 0% | 10 | 91% | 1 | 9% | | 0% | 11 | 100% | 11 | 100% | | 0% | 1 | 9% | 10 | 91% |
| Turbidimetry | 10 | 10 | 100% | 0 | 0% | 10 | 100% | 0 | 0% | 0 | 0% | 10 | 100% | 10 | 100% | 0 | 0% | 0 | 0% | 10 | 100% |
| <i>Others</i> | 10 | 10 | 100% | | 0% | 10 | 100% | | 0% | | 0% | 10 | 100% | 10 | 100% | | 0% | | 0% | 10 | 100% |
| Other Methods | 1 | 1 | 100% | | 0% | 1 | 100% | | 0% | | 0% | 1 | 100% | 1 | 100% | | 0% | | 0% | 1 | 100% |
| Analyte Total | 107 | 107 | 100% | 0 | 0% | 105 | 98% | 2 | 2% | 0 | 0% | 107 | 100% | 105 | 98% | 2 | 2% | 2 | 2% | 105 | 98% |

Antistreptolysin O Quantitative Latex Agglutination Procedures

The number of laboratories that reported titers is listed for positive test samples 18 and 20. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

| Method <i>Manufacturer</i> | No. Labs | Sample 18 Titer | | | | | Sample 20 Titer | | | | | |
|-------------------------------|-------------|--------------------|-----|-----|------|------|--------------------|-----|-----|-----|------|------|
| | | 200 | 400 | 800 | 1600 | 3200 | 6400 | 200 | 400 | 800 | 1600 | 3200 |
| Latex Total | 56 | 2 | 17 | 21 | 1 | 1 | | 3 | 15 | 22 | 1 | 1 |
| <i>Dade Behring</i> | 17 | | 6 | 5 | | | | 1 | 4 | 6 | | |
| <i>Fisher</i> | 15 | | 6 | 8 | | | | 1 | 6 | 7 | | |
| <i>Remel</i> | 13 | 1 | 4 | 6 | | | | 1 | 3 | 7 | | |

Note: The number of labs reporting specific titers may not add up to the total number of labs for that system because some labs are not reporting endpoint titers.

Antistreptolysin O Quantitative

Results are summarized for positive test samples 18 and 20. The Mean values \pm S.D. are given where 10 or more laboratories reported quantitative results. Outlier values are omitted.

| Method | Manufacturer | No. Labs | Unit | Sample 18 | Sample 20 |
|---------------------|--------------------------------|-----------------|-------------|------------------|------------------|
| Nephelometry | Total | 25 | IU/ml | 690 \pm 150 | 679 \pm 147 |
| | <i>Beckman Immage</i> | 10 | IU/ml | 544 \pm 18 | 532 \pm 19 |
| | <i>Dade Behring Neph.</i> | 12 | IU/ml | 831 \pm 76 | 818 \pm 70 |
| Turbidimetry | Total | 27 | IU/ml | 717 \pm 127 | 707 \pm 130 |
| | <i>Roche Diagnostics Cobas</i> | 13 | IU/ml | 743 \pm 28 | 728 \pm 26 |

Cytomegalovirus Antibody

Participant Results/ Sample Number

R = Reactive/ Positive; N = Non-Reactive/ Negative

| Method <i>Manufacturer</i> | No. Labs | 11 R | | | | 12 R | | | | 13 N | | | | 14 N | | | | 15 N | | | |
|-------------------------------|-------------|----------|-----------|-----------|-------------|-----------|-------------|----------|-----------|-----------|-------------|----------|-----------|-----------|-------------|----------|-----------|-----------|-------------|----------|-----------|
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| EIA | 40 | 0 | 0% | 40 | 100% | 40 | 100% | 0 | 0% | 40 | 100% | 0 | 0% | 40 | 100% | 0 | 0% | 40 | 100% | 0 | 0% |
| <i>Wampole /Zeus</i> | 18 | | 0% | 18 | 100% | 18 | 100% | | 0% | 18 | 100% | | 0% | 18 | 100% | | 0% | 18 | 100% | | 0% |
| <i>Others</i> | 22 | | 0% | 22 | 100% | 22 | 100% | | 0% | 22 | 100% | | 0% | 22 | 100% | | 0% | 22 | 100% | | 0% |
| ELFA | 20 | 0 | 0% | 20 | 100% | 20 | 100% | 0 | 0% | 20 | 100% | 0 | 0% | 20 | 100% | 0 | 0% | 20 | 100% | 0 | 0% |
| <i>bioMérieux Vidas</i> | 20 | | 0% | 20 | 100% | 20 | 100% | | 0% | 20 | 100% | | 0% | 20 | 100% | | 0% | 20 | 100% | | 0% |
| Chemiluminescence | 14 | 0 | 0% | 14 | 100% | 14 | 100% | 0 | 0% | 14 | 100% | 0 | 0% | 14 | 100% | 0 | 0% | 14 | 100% | 0 | 0% |
| <i>Diagnostic Products</i> | 12 | | 0% | 12 | 100% | 12 | 100% | | 0% | 12 | 100% | | 0% | 12 | 100% | | 0% | 12 | 100% | | 0% |
| <i>Others</i> | 2 | | 0% | 2 | 100% | 2 | 100% | | 0% | 2 | 100% | | 0% | 2 | 100% | | 0% | 2 | 100% | | 0% |
| Hemagglutination | 10 | 0 | 0% | 10 | 100% | 10 | 100% | 0 | 0% | 10 | 100% | 0 | 0% | 10 | 100% | 0 | 0% | 10 | 100% | 0 | 0% |
| <i>Olympus</i> | 10 | | 0% | 10 | 100% | 10 | 100% | | 0% | 10 | 100% | | 0% | 10 | 100% | | 0% | 10 | 100% | | 0% |
| Other Methods | 7 | | 0% | 7 | 100% | 7 | 100% | | 0% | 7 | 100% | | 0% | 7 | 100% | | 0% | 7 | 100% | | 0% |
| Analyte Total | 91 | 0 | 0% | 91 | 100% | 91 | 100% | 0 | 0% | 91 | 100% | 0 | 0% | 91 | 100% | 0 | 0% | 91 | 100% | 0 | 0% |

Hepatitis B Core Antibody

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|------------|---------------------|-----------|------------|-------------|------------|------------|-----------|------------|------------|------------|-----------|------------|----------|-----------|------------|-------------|------------|------------|-----------|------------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 6 R | | | | 7 N * | | | | 8 N | | | | 9 R * | | | | 10 N * | | | |
| | | <i>Manufacturer</i> | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R |
| Chemiluminescence | 95 | 1 | 1% | 94 | 99% | 91 | 96% | 4 | 4% | 92 | 97% | 3 | 3% | 1 | 1% | 94 | 99% | 89 | 94% | 6 | 6% |
| <i>Abbott</i> | 12 | | 0% | 12 | 100% | 8 | 67% | 4 | 33% | 9 | 75% | 3 | 25% | | 0% | 12 | 100% | 6 | 50% | 6 | 50% |
| <i>Bayer</i> | 37 | 1 | 3% | 36 | 97% | 37 | 100% | | 0% | 37 | 100% | | 0% | | 0% | 36 | 97% | 37 | 100% | | 0% |
| <i>Diagnostic Products</i> | 20 | | 0% | 20 | 100% | 20 | 100% | | 0% | 20 | 100% | | 0% | | 0% | 20 | 100% | 20 | 100% | | 0% |
| <i>Ortho</i> | 26 | | 0% | 26 | 100% | 26 | 100% | | 0% | 26 | 100% | | 0% | 1 | 4% | 26 | 100% | 26 | 100% | | 0% |
| EIA | 50 | 0 | 0% | 50 | 100% | 22 | 44% | 27 | 54% | 21 | 42% | 27 | 54% | 0 | 0% | 50 | 100% | 22 | 44% | 27 | 54% |
| <i>Abbott AxSYM</i> ¹ | 21 | | 0% | 21 | 100% | 1 | 5% | 20 | 95% | 1 | 5% | 19 | 90% | | 0% | 21 | 100% | 1 | 5% | 20 | 95% |
| <i>Abbott Corzyme</i> | 13 | | 0% | 13 | 100% | 12 | 92% | 1 | 8% | 12 | 92% | 1 | 8% | | 0% | 13 | 100% | 12 | 92% | 1 | 8% |
| <i>DiaSorin</i> ² | 10 | | 0% | 10 | 100% | 3 | 30% | 6 | 60% | 2 | 20% | 7 | 70% | | 0% | 10 | 100% | 3 | 30% | 6 | 60% |
| <i>Other</i> | 6 | | 0% | 6 | 100% | 6 | 100% | | 0% | 6 | 100% | | 0% | | 0% | 6 | 100% | 6 | 100% | | 0% |
| Analyte Total | 145 | 1 | 1% | 144 | 99% | 113 | 78% | 31 | 21% | 113 | 78% | 30 | 21% | 1 | 1% | 144 | 99% | 111 | 77% | 33 | 23% |

* Samples #7, 8 & 10 are not authenticated, the expected result is nonreactive. Labs reporting other results should critically examine their test kit/method protocol. When a consensus agreement cannot be reached among participants, by regulation requirements, the sample cannot be graded (scored) and all participating laboratories get credit for this sample.

¹ One laboratory reported an equivocal result on sample #8.

² One laboratory reported an equivocal result on samples #7, 8 and 10.

Hepatitis B Surface Antigen

| | | Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | |
|----------------------------|------------|--|-------------|----------|-----------|------------|-------------|----------|-----------|------------|-------------|-----------|-----------|----------|-----------|------------|-------------|------------|-------------|-----------|-----------|--|
| | | R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 6 N | | | | 7 N | | | | 8 N | | | | 9 R | | | | 10 N | | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | |
| Manufacturer | | | | | | | | | | | | | | | | | | | | | | |
| Chemiluminescence | 126 | 126 | 100% | 0 | 0% | 121 | 96% | 3 | 2% | 117 | 93% | 7 | 6% | 1 | 1% | 125 | 99% | 116 | 92% | 8 | 6% | |
| <i>Abbott</i> | 12 | 12 | 100% | | 0% | 12 | 100% | | 0% | 12 | 100% | | 0% | | 0% | 12 | 100% | 12 | 100% | | 0% | |
| <i>Bayer</i> | 49 | 49 | 100% | | 0% | 49 | 100% | | 0% | 49 | 100% | | 0% | | 0% | 49 | 100% | 48 | 98% | 1 | 2% | |
| <i>Diagnostic Products</i> | 20 | 20 | 100% | | 0% | 20 | 100% | | 0% | 19 | 95% | 1 | 5% | 1 | 5% | 19 | 95% | 19 | 95% | 1 | 5% | |
| <i>Ortho</i> ¹ | 34 | 34 | 100% | | 0% | 29 | 85% | 3 | 9% | 26 | 76% | 6 | 18% | | 0% | 34 | 100% | 27 | 79% | 5 | 15% | |
| <i>Roche</i> | 11 | 11 | 100% | | 0% | 11 | 100% | | 0% | 11 | 100% | | 0% | | 0% | 11 | 100% | 10 | 91% | 1 | 9% | |
| EIA | 70 | 69 | 99% | 1 | 1% | 70 | 100% | 0 | 0% | 69 | 99% | 1 | 1% | 0 | 0% | 70 | 100% | 70 | 100% | 0 | 0% | |
| <i>Abbott</i> | 47 | 46 | 98% | 1 | 2% | 47 | 100% | | 0% | 47 | 100% | | 0% | | 0% | 47 | 100% | 47 | 100% | | 0% | |
| <i>Bio-Rad</i> | 14 | 14 | 100% | | 0% | 14 | 100% | | 0% | 13 | 93% | 1 | 7% | | 0% | 14 | 100% | 14 | 100% | | 0% | |
| <i>Other</i> | 9 | 9 | 100% | | 0% | 9 | 100% | | 0% | 9 | 100% | | 0% | | 0% | 9 | 100% | 9 | 100% | | 0% | |
| Confirmation | 120 | 120 | 100% | 0 | 0% | 120 | 100% | 0 | 0% | 117 | 98% | 3 | 3% | 0 | 0% | 120 | 100% | 118 | 98% | 2 | 2% | |
| <i>Abbott EIA</i> | 12 | 12 | 100% | | 0% | 12 | 100% | | 0% | 12 | 100% | | 0% | | 0% | 12 | 100% | 12 | 100% | | 0% | |
| <i>Abbott Neut.</i> | 18 | 18 | 100% | | 0% | 18 | 100% | | 0% | 18 | 100% | | 0% | | 0% | 18 | 100% | 18 | 100% | | 0% | |
| <i>Bayer/Siemens</i> | 32 | 32 | 100% | | 0% | 32 | 100% | | 0% | 32 | 100% | | 0% | | 0% | 32 | 100% | 32 | 100% | | 0% | |
| <i>Diagnostic Products</i> | 12 | 12 | 100% | | 0% | 12 | 100% | | 0% | 12 | 100% | | 0% | | 0% | 12 | 100% | 12 | 100% | | 0% | |
| <i>Ortho</i> | 23 | 23 | 100% | | 0% | 23 | 100% | | 0% | 20 | 87% | 3 | 13% | | 0% | 23 | 100% | 21 | 91% | 2 | 9% | |
| <i>Other</i> | 23 | 23 | 100% | | 0% | 23 | 100% | | 0% | 23 | 100% | | 0% | | 0% | 23 | 100% | 23 | 100% | | 0% | |
| Other Methods | 4 | 4 | 100% | | 0% | 4 | 100% | | 0% | 4 | 100% | | 0% | | 0% | 4 | 100% | 4 | 100% | | 0% | |
| Analyte Total | 320 | 319 | 100% | 1 | 0% | 315 | 98% | 3 | 1% | 307 | 96% | 11 | 3% | 1 | 0% | 319 | 100% | 308 | 96% | 10 | 3% | |

¹ Two laboratories reported a result of equivocal on samples #7, 8 and 10.

Hepatitis Be Antigen

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|-----------|----------|-----------|-----------|-------------|-----------|-------------|----------|-----------|----------|-----------|-----------|-------------|-----------|-------------|----------|-----------|-----------|-------------|----------|-----------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 66 R | | | | 67 N | | | | 68 R | | | | 69 N | | | | 70 N | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| EIA | 28 | 0 | 0% | 28 | 100% | 28 | 100% | 0 | 0% | 0 | 0% | 28 | 100% | 28 | 100% | 0 | 0% | 28 | 100% | 0 | 0% |
| <i>DiaSorin</i> | 27 | | 0% | 27 | 100% | 27 | 100% | | 0% | | 0% | 27 | 100% | 27 | 100% | | 0% | 27 | 100% | | 0% |
| <i>Other</i> | 1 | | 0% | 1 | 100% | 1 | 100% | | 0% | | 0% | 1 | 100% | 1 | 100% | | 0% | 1 | 100% | | 0% |
| Other Methods | 4 | | 0% | 4 | 100% | 4 | 100% | | 0% | | 0% | 4 | 100% | 4 | 100% | | 0% | 4 | 100% | | 0% |
| Analyte Total | 32 | 0 | 0% | 32 | 100% | 32 | 100% | 0 | 0% | 0 | 0% | 32 | 100% | 32 | 100% | 0 | 0% | 32 | 100% | 0 | 0% |

Hepatitis C Antibody

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|------------|------------|-------------|-----------|------------|----------|-----------|------------|-------------|------------|-------------|-----------|------------|------------|-------------|-----------|------------|----------|-----------|------------|-------------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 71 N * | | | | 72 R | | | | 73 N * | | | | 74 N * | | | | 75 R | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| Chemiluminescence | 85 | 51 | 60% | 31 | 36% | 0 | 0% | 85 | 100% | 52 | 61% | 31 | 36% | 51 | 60% | 31 | 36% | 0 | 0% | 85 | 100% |
| <i>Bayer</i> | 46 | 46 | 100% | | 0% | | 0% | 46 | 100% | 46 | 100% | | 0% | 46 | 100% | | 0% | | 0% | 46 | 100% |
| <i>Ortho</i> ¹ | 34 | | 0% | 31 | 91% | | 0% | 34 | 100% | 1 | 3% | 31 | 91% | | 0% | 31 | 91% | | 0% | 34 | 100% |
| <i>Other</i> | 5 | 5 | 100% | | 0% | | 0% | 5 | 100% | 5 | 100% | | 0% | 5 | 100% | | 0% | | 0% | 5 | 100% |
| EIA | 84 | 72 | 86% | 10 | 12% | 0 | 0% | 84 | 100% | 74 | 88% | 10 | 12% | 79 | 94% | 5 | 6% | 0 | 0% | 84 | 100% |
| <i>Abbott</i> ² | 57 | 46 | 81% | 9 | 16% | | 0% | 57 | 100% | 47 | 82% | 10 | 18% | 52 | 91% | 5 | 9% | | 0% | 57 | 100% |
| <i>Ortho</i> | 26 | 26 | 100% | | 0% | | 0% | 26 | 100% | 26 | 100% | | 0% | 26 | 100% | | 0% | | 0% | 26 | 100% |
| <i>Other</i> | 1 | | 0% | 1 | 100% | | 0% | 1 | 100% | 1 | 100% | | 0% | 1 | 100% | | 0% | | 0% | 1 | 100% |
| Confirmation | 26 | 26 | 100% | 0 | 0% | 1 | 4% | 25 | 96% | 26 | 100% | 0 | 0% | 26 | 100% | 0 | 0% | 0 | 0% | 26 | 100% |
| <i>Chiron</i> | 20 | 20 | 100% | | 0% | | 0% | 20 | 100% | 20 | 100% | | 0% | 20 | 100% | | 0% | | 0% | 20 | 100% |
| <i>Other</i> | 6 | 6 | 100% | | 0% | 1 | 17% | 5 | 83% | 6 | 100% | | 0% | 6 | 100% | | 0% | | 0% | 6 | 100% |
| Other Methods | 3 | 3 | 100% | | 0% | | 0% | 3 | 100% | 3 | 100% | | 0% | 3 | 100% | | 0% | | 0% | 3 | 100% |
| Analyte Total | 198 | 152 | 77% | 41 | 21% | 1 | 1% | 197 | 99% | 155 | 78% | 41 | 21% | 159 | 80% | 36 | 18% | 0 | 0% | 198 | 100% |

* Samples #71, 73 & 74 are not authenticated, the expected result is nonreactive. Labs reporting other results should critically examine their test kit/method protocol. When a consensus agreement cannot be reached among participants, by regulation requirements, the sample cannot be graded (scored) and all participating laboratories get credit for this sample.

¹ Three laboratories reported an equivocal result on samples #72 and #74 and two reported equivocal on #73.

² Two laboratories reported an equivocal result on sample #71.

HIV Antibody

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|------------|----------|-----------|------------|-------------|------------|-------------|----------|-----------|------------|-------------|----------|-----------|------------|-------------|----------|-----------|----------|-----------|------------|-------------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 31 R | | | | 32 N | | | | 33 N | | | | 34 N | | | | 35 R | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| Chemiluminescence | 20 | 0 | 0% | 20 | 100% | 20 | 100% | 0 | 0% | 20 | 100% | 0 | 0% | 20 | 100% | 0 | 0% | 0 | 0% | 20 | 100% |
| <i>Bayer</i> | 20 | | 0% | 20 | 100% | 20 | 100% | | 0% | 20 | 100% | | 0% | 20 | 100% | | 0% | | 0% | 20 | 100% |
| EIA | 108 | 0 | 0% | 108 | 100% | 108 | 100% | 0 | 0% | 107 | 99% | 1 | 1% | 108 | 100% | 0 | 0% | 0 | 0% | 108 | 100% |
| <i>Abbott</i> | 53 | | 0% | 53 | 100% | 53 | 100% | | 0% | 53 | 100% | | 0% | 53 | 100% | | 0% | | 0% | 53 | 100% |
| <i>Bio-Rad</i> | 53 | | 0% | 53 | 100% | 53 | 100% | | 0% | 52 | 98% | 1 | 2% | 53 | 100% | | 0% | | 0% | 53 | 100% |
| <i>Others</i> | 2 | | 0% | 2 | 100% | 2 | 100% | | 0% | 2 | 100% | | 0% | 2 | 100% | | 0% | | 0% | 2 | 100% |
| Rapid EIA | 100 | 0 | 0% | 100 | 100% | 100 | 100% | 0 | 0% | 100 | 100% | 0 | 0% | 100 | 100% | 0 | 0% | 0 | 0% | 100 | 100% |
| <i>Orasure</i> | 100 | | 0% | 100 | 100% | 100 | 100% | | 0% | 100 | 100% | | 0% | 100 | 100% | | 0% | | 0% | 100 | 100% |
| Rapid Immunoassay | 47 | 0 | 0% | 47 | 100% | 47 | 100% | 0 | 0% | 47 | 100% | 0 | 0% | 47 | 100% | 0 | 0% | 0 | 0% | 47 | 100% |
| <i>Medmira</i> | 15 | | 0% | 15 | 100% | 15 | 100% | | 0% | 15 | 100% | | 0% | 15 | 100% | | 0% | | 0% | 15 | 100% |
| <i>Trinity</i> | 25 | | 0% | 25 | 100% | 25 | 100% | | 0% | 25 | 100% | | 0% | 25 | 100% | | 0% | | 0% | 25 | 100% |
| <i>Other</i> | 7 | | 0% | 7 | 100% | 7 | 100% | | 0% | 7 | 100% | | 0% | 7 | 100% | | 0% | | 0% | 7 | 100% |
| Western Blot | 43 | 0 | 0% | 43 | 100% | 43 | 100% | 0 | 0% | 43 | 100% | 0 | 0% | 43 | 100% | 0 | 0% | 0 | 0% | 43 | 100% |
| <i>Bio-Rad</i> | 40 | | 0% | 40 | 100% | 40 | 100% | | 0% | 40 | 100% | | 0% | 40 | 100% | | 0% | | 0% | 40 | 100% |
| <i>Others</i> | 3 | | 0% | 3 | 100% | 3 | 100% | | 0% | 3 | 100% | | 0% | 3 | 100% | | 0% | | 0% | 3 | 100% |
| Other Methods | 5 | | 0% | 5 | 100% | 5 | 100% | | 0% | 5 | 100% | | 0% | 5 | 100% | | 0% | | 0% | 5 | 100% |
| Analyte Total | 323 | 0 | 0% | 323 | 100% | 323 | 100% | 0 | 0% | 322 | 100% | 1 | 0% | 323 | 100% | 0 | 0% | 0 | 0% | 323 | 100% |

HIV p24 Antigen

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|----------|----------|-------------|----------|-----------|----------|-------------|----------|-----------|----------|-----------|----------|-------------|----------|-------------|----------|-----------|----------|-------------|----------|-----------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 61 N | | | | 62 N | | | | 63 R | | | | 64 N | | | | 65 N | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| EIA | 2 | 2 | 100% | 0 | 0% | 2 | 100% | 0 | 0% | | 0% | 2 | 100% | 2 | 100% | | 0% | 2 | 100% | 0 | 0% |
| <i>Others</i> | 2 | 2 | 100% | | 0% | 2 | 100% | | 0% | | 0% | 2 | 100% | 2 | 100% | | 0% | 2 | 100% | | 0% |
| Analyte Total | 2 | 2 | 100% | 0 | 0% | 2 | 100% | 0 | 0% | 0 | 0% | 2 | 100% | 2 | 100% | 0 | 0% | 2 | 100% | 0 | 0% |

HTLV Antibody

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|----------|------|------|---|----|------|------|---|----|------|------|---|----|------|----|----|------|------|----|----|------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 36 N | | | | 37 N | | | | 38 N | | | | 39 R | | | | 40 R | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| EIA | 43 | 43 | 100% | 0 | 0% | 43 | 100% | 0 | 0% | 43 | 100% | 0 | 0% | 0 | 0% | 43 | 100% | 0 | 0% | 43 | 100% |
| <i>Abbott</i> | 29 | 29 | 100% | | 0% | 29 | 100% | | 0% | 29 | 100% | | 0% | | 0% | 29 | 100% | | 0% | 29 | 100% |
| <i>Other</i> | 14 | 14 | 100% | | 0% | 14 | 100% | | 0% | 14 | 100% | | 0% | | 0% | 14 | 100% | | 0% | 14 | 100% |
| Analyte Total | 43 | 43 | 100% | 0 | 0% | 43 | 100% | 0 | 0% | 43 | 100% | 0 | 0% | 0 | 0% | 43 | 100% | 0 | 0% | 43 | 100% |

Infectious Mononucleosis

| | | Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | |
|-------------------------------|-------------|--|-------------|----------|-----------|----------|-----------|------------|-------------|----------|-----------|------------|-------------|------------|-------------|----------|-----------|------------|-------------|----------|-----------|
| | | R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | |
| Method <i>Manufacturer</i> | No. Labs | 26 N | | | | 27 R | | | | 28 R | | | | 29 N | | | | 30 N | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| CICA | 16 | 16 | 100% | 0 | 0% | 0 | 0% | 16 | 100% | 0 | 0% | 16 | 100% | 16 | 100% | 0 | 0% | 16 | 100% | 0 | 0% |
| <i>Others</i> | 16 | 16 | 100% | | 0% | | 0% | 16 | 100% | | 0% | 16 | 100% | 16 | 100% | | 0% | 16 | 100% | | 0% |
| Hemagglutination | 49 | 47 | 96% | 2 | 4% | 0 | 0% | 49 | 100% | 1 | 2% | 48 | 98% | 48 | 98% | 1 | 2% | 45 | 92% | 4 | 8% |
| <i>Fisher</i> | 20 | 18 | 90% | 2 | 10% | | 0% | 20 | 100% | | 0% | 20 | 100% | 20 | 100% | | 0% | 16 | 80% | 4 | 20% |
| <i>Wampole/Zeus</i> | 20 | 20 | 100% | | 0% | | 0% | 20 | 100% | 1 | 5% | 19 | 95% | 19 | 95% | 1 | 5% | 20 | 100% | | 0% |
| <i>Others</i> | 9 | 9 | 100% | | 0% | | 0% | 9 | 100% | | 0% | 9 | 100% | 9 | 100% | | 0% | 9 | 100% | | 0% |
| Latex Agglutination | 140 | 140 | 100% | 0 | 0% | 1 | 1% | 139 | 99% | 0 | 0% | 140 | 100% | 140 | 100% | 0 | 0% | 140 | 100% | 0 | 0% |
| <i>Fisher</i> | 42 | 42 | 100% | | 0% | 1 | 2% | 41 | 98% | | 0% | 42 | 100% | 42 | 100% | | 0% | 42 | 100% | | 0% |
| <i>Remel</i> | 26 | 26 | 100% | | 0% | | 0% | 26 | 100% | | 0% | 26 | 100% | 26 | 100% | | 0% | 26 | 100% | | 0% |
| <i>Wampole/Zeus</i> | 52 | 52 | 100% | | 0% | | 0% | 52 | 100% | | 0% | 52 | 100% | 52 | 100% | | 0% | 52 | 100% | | 0% |
| <i>Others</i> | 20 | 20 | 100% | | 0% | | 0% | 20 | 100% | | 0% | 20 | 100% | 20 | 100% | | 0% | 20 | 100% | | 0% |
| Solid Phase IA | 63 | 63 | 100% | 0 | 0% | 0 | 0% | 63 | 100% | 0 | 0% | 63 | 100% | 63 | 100% | 0 | 0% | 63 | 100% | 0 | 0% |
| <i>Inverness</i> | 31 | 31 | 100% | | 0% | | 0% | 31 | 100% | | 0% | 31 | 100% | 31 | 100% | | 0% | 31 | 100% | | 0% |
| <i>Seradyn</i> | 26 | 26 | 100% | | 0% | | 0% | 26 | 100% | | 0% | 26 | 100% | 26 | 100% | | 0% | 26 | 100% | | 0% |
| <i>Others</i> | 6 | 6 | 100% | | 0% | | 0% | 6 | 100% | | 0% | 6 | 100% | 6 | 100% | | 0% | 6 | 100% | | 0% |
| Other Methods | 4 | 4 | 100% | | 0% | | 0% | 4 | 100% | | 0% | 4 | 100% | 4 | 100% | | 0% | 4 | 100% | | 0% |
| Analyte Total | 272 | 270 | 99% | 2 | 1% | 1 | 0% | 271 | 100% | 1 | 0% | 271 | 100% | 271 | 100% | 1 | 0% | 268 | 99% | 4 | 1% |

Lyme Disease Antibody

Participant Results/ Sample Number
R = Reactive/ Positive; N = Non-Reactive/ Negative

| Method <i>Manufacturer</i> | No. Labs | 41 R | | | | 42 R | | | | 43 N | | | | 44 N | | | | 45 N | | | |
|-------------------------------|-------------|----------|-----------|-----------|-------------|----------|-----------|-----------|-------------|-----------|-------------|----------|-----------|-----------|-------------|----------|-----------|-----------|-------------|----------|-----------|
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| EIA | 61 | 1 | 2% | 60 | 98% | 1 | 2% | 60 | 98% | 61 | 100% | 0 | 0% | 61 | 100% | 0 | 0% | 61 | 100% | 0 | 0% |
| <i>Immunitics</i> | 15 | | 0% | 15 | 100% | | 0% | 15 | 100% | 15 | 100% | | 0% | 15 | 100% | | 0% | 15 | 100% | | 0% |
| <i>Wampole /Zeus</i> | 33 | 1 | 3% | 32 | 97% | 1 | 3% | 32 | 97% | 33 | 100% | | 0% | 33 | 100% | | 0% | 33 | 100% | | 0% |
| <i>Others</i> | 13 | | 0% | 13 | 100% | | 0% | 13 | 100% | 13 | 100% | | 0% | 13 | 100% | | 0% | 13 | 100% | | 0% |
| ELFA | 18 | 0 | 0% | 18 | 100% | 0 | 0% | 18 | 100% | 18 | 100% | 0 | 0% | 18 | 100% | 0 | 0% | 18 | 100% | 0 | 0% |
| <i>bioMérieux</i> | 18 | | 0% | 18 | 100% | | 0% | 18 | 100% | 18 | 100% | | 0% | 18 | 100% | | 0% | 18 | 100% | | 0% |
| Other Methods | 11 | 2 | 18% | 9 | 82% | | 0% | 11 | 100% | 11 | 100% | | 0% | 11 | 100% | | 0% | 11 | 100% | | 0% |
| Analyte Total | 90 | 3 | 3% | 87 | 97% | 1 | 1% | 89 | 99% | 90 | 100% | 0 | 0% | 90 | 100% | 0 | 0% | 90 | 100% | 0 | 0% |

Lyme Western Blot IgG

| | | Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|-----------|--|-----------|----------|-----------|-----------|-------------|----------|-----------|----------|-----------|-----------|-------------|-----------|-------------|----------|-----------|----------|-----------|-----------|-------------|----------|-----------|----------|-----------|-----------|-------------|----------|-----------|----------|-----------|
| | | R = Reactive/ Positive; N = Non-Reactive/ Negative; E = Equivocal/ Indeterminate | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 41 R | | | | | | 42 R | | | | | | 43 N | | | | | | 44 N | | | | | | 45 N | | | | | |
| | | N | % | E | % | R | % | N | % | E | % | R | % | N | % | E | % | R | % | N | % | E | % | R | % | N | % | E | % | R | % |
| Western Blot - IgG | 27 | 0 | 0% | 0 | 0% | 27 | 100% | 0 | 0% | 0 | 0% | 27 | 100% | 27 | 100% | 0 | 0% | 0 | 0% | 27 | 100% | 0 | 0% | 0 | 0% | 27 | 100% | 0 | 0% | 0 | 0% |
| <i>MarDx</i> | 24 | | 0% | | 0% | 24 | 100% | | 0% | | 0% | 24 | 100% | 24 | 100% | | 0% | | 0% | 24 | 100% | | 0% | | 0% | 24 | 100% | | 0% | | 0% |
| <i>Other</i> | 3 | | 0% | | 0% | 3 | 100% | | 0% | | 0% | 3 | 100% | 3 | 100% | | 0% | | 0% | 3 | 100% | | 0% | | 0% | 3 | 100% | | 0% | | 0% |
| Other Methods | 3 | | 0% | | 0% | 3 | 100% | | 0% | | 0% | 3 | 100% | 3 | 100% | | 0% | | 0% | 3 | 100% | | 0% | | 0% | 3 | 100% | | 0% | | 0% |
| Analyte Total | 30 | 0 | 0% | 0 | 0% | 30 | 100% | 0 | 0% | 0 | 0% | 30 | 100% | 30 | 100% | 0 | 0% | 0 | 0% | 30 | 100% | 0 | 0% | 0 | 0% | 30 | 100% | 0 | 0% | 0 | 0% |

Lyme Western Blot IgM

| | | Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|-----------|--|------------|----------|-----------|-----------|------------|-----------|------------|----------|-----------|-----------|------------|-----------|-------------|----------|-----------|----------|-----------|-----------|-------------|----------|-----------|----------|-----------|-----------|-------------|----------|-----------|----------|-----------|
| | | R = Reactive/ Positive; N = Non-Reactive/ Negative; E = Equivocal/ Indeterminate | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 41 R * | | | | | | 42 R * | | | | | | 43 N | | | | | | 44 N | | | | | | 45 N | | | | | |
| | | N | % | E | % | R | % | N | % | E | % | R | % | N | % | E | % | R | % | N | % | E | % | R | % | N | % | E | % | R | % |
| Western Blot - IgM | 27 | 15 | 56% | 1 | 4% | 11 | 41% | 12 | 44% | 1 | 4% | 14 | 52% | 27 | 100% | 0 | 0% | 0 | 0% | 27 | 100% | 0 | 0% | 0 | 0% | 27 | 100% | 0 | 0% | 0 | 0% |
| <i>MarDx</i> | 24 | 15 | 63% | 1 | 4% | 8 | 33% | 12 | 50% | 1 | 4% | 11 | 46% | 24 | 100% | | 0% | | 0% | 24 | 100% | | 0% | | 0% | 24 | 100% | | 0% | | 0% |
| <i>Other</i> | 3 | | 0% | | 0% | 3 | 100% | | 0% | | 0% | 3 | 100% | 3 | 100% | | 0% | | 0% | 3 | 100% | | 0% | | 0% | 3 | 100% | | 0% | | 0% |
| Other Methods | 2 | | 0% | | 0% | 2 | 100% | | 0% | | 0% | 2 | 100% | 2 | 100% | | 0% | | 0% | 2 | 100% | | 0% | | 0% | 2 | 100% | | 0% | | 0% |
| Analyte Total | 29 | 15 | 52% | 1 | 3% | 13 | 45% | 12 | 41% | 1 | 3% | 16 | 55% | 29 | 100% | 0 | 0% | 0 | 0% | 29 | 100% | 0 | 0% | 0 | 0% | 29 | 100% | 0 | 0% | 0 | 0% |

* Samples #41 and 42 are not authenticated, the expected result is positive. Labs reporting other results should critically examine their test kit/method protocol. When a consensus agreement cannot be reached among participants, by regulation requirements, the sample cannot be graded (scored) and all participating laboratories get credit for this sample.

Rheumatoid Factor

| | | Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | |
|----------------------------|------------|--|-------------|----------|------------|------------|-------------|----------|------------|----------|-----------|------------|-------------|----------|-----------|------------|-------------|------------|-------------|----------|------------|
| | | R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 26 N | | | | 27 N | | | | 28 R | | | | 29 R | | | | 30 N | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| Latex Agglutination | 106 | 106 | 100% | 0 | 0% | 106 | 100% | 0 | 0% | 4 | 4% | 102 | 96% | 1 | 1% | 105 | 99% | 104 | 98% | 2 | 2% |
| <i>Becton Dickinson</i> | 19 | 19 | 100% | | 0% | 19 | 100% | | 0% | 1 | 5% | 18 | 95% | | 0% | 19 | 100% | 19 | 100% | | 0% |
| <i>Fisher</i> | 42 | 42 | 100% | | 0% | 42 | 100% | | 0% | | 0% | 42 | 100% | | 0% | 42 | 100% | 42 | 100% | | 0% |
| <i>Wampole/Zeus</i> | 13 | 13 | 100% | | 0% | 13 | 100% | | 0% | 2 | 15% | 11 | 85% | | 0% | 13 | 100% | 12 | 92% | 1 | 8% |
| <i>Others</i> | 32 | 32 | 100% | | 0% | 32 | 100% | | 0% | 1 | 3% | 31 | 97% | 1 | 3% | 31 | 97% | 31 | 97% | 1 | 3% |
| Nephelometry | 21 | 21 | 100% | 0 | 0% | 21 | 100% | 0 | 0% | 0 | 0% | 21 | 100% | 0 | 0% | 21 | 100% | 21 | 100% | 0 | 0% |
| <i>Beckman</i> | 10 | 10 | 100% | | 0% | 10 | 100% | | 0% | | 0% | 10 | 100% | | 0% | 10 | 100% | 10 | 100% | | 0% |
| <i>Behring</i> | 11 | 11 | 100% | | 0% | 11 | 100% | | 0% | | 0% | 11 | 100% | | 0% | 11 | 100% | 11 | 100% | | 0% |
| Turbidimetry | 19 | 16 | 84% | 3 | 16% | 14 | 74% | 5 | 26% | 0 | 0% | 19 | 100% | 0 | 0% | 19 | 100% | 15 | 79% | 4 | 21% |
| <i>Roche</i> | 10 | 10 | 100% | | 0% | 10 | 100% | | 0% | | 0% | 10 | 100% | | 0% | 10 | 100% | 10 | 100% | | 0% |
| <i>Others</i> | 9 | 6 | 67% | 3 | 33% | 4 | 44% | 5 | 56% | | 0% | 9 | 100% | | 0% | 9 | 100% | 5 | 56% | 4 | 44% |
| Other Methods | 10 | 9 | 90% | 1 | 10% | 9 | 90% | 1 | 10% | | 0% | 10 | 100% | | 0% | 10 | 100% | 9 | 90% | 1 | 10% |
| Analyte Total | 156 | 152 | 97% | 4 | 3% | 150 | 96% | 6 | 4% | 4 | 3% | 152 | 97% | 1 | 1% | 155 | 99% | 149 | 96% | 7 | 4% |

Rheumatoid Factor Quantitative Latex Agglutination Procedure

The number of laboratories that reported titers is listed for positive test samples 28 and 29. The dilution schemes laboratories used are represented by the letter A and B, testing systems with 10 or more laboratories reporting titers are listed in this table.

| <i>Manufacturer</i> | No. Labs | A B | Sample 28 Titer | | | | | | | Sample 29 Titer | | | | | | |
|-----------------------------|---------------------|----------------|----------------------------|-----------------|-----------------|-----------------|-------------------|-------------------|-------------------|----------------------------|-----------------|-----------------|-----------------|-------------------|-------------------|-------------------|
| | | | 10 1 | 20 2 | 40 4 | 80 8 | 160 16 | 320 32 | 640 64 | 10 1 | 20 2 | 40 4 | 80 8 | 160 16 | 320 32 | 640 64 |
| Total | 80 | A B | 2 | 4 2 | 20 4 | 16 12 | 4 2 | 1 | | 1 | 1 | 4 | 7 2 | 26 15 | 8 4 | 1 |
| <i>Becton Dickenson</i> | 13 | A B | | 1 | 7 | 4 | 1 | | | | | 1 | 5 | 5 | 3 | |
| <i>Fisher</i> | 30 | A B | | 1 | 9 2 | 9 8 | 1 | | | | | | 1 | 15 8 | 3 3 | |

Note: The number of labs reporting specific titers may not add up to the total number of labs for that system because some labs are not reporting endpoint titers.

Rheumatoid Factor Quantitative

Results are summarized for positive test samples 28 and 29. The Mean values \pm S.D. are given where 10 or more laboratories reported quantitative results. Outlier values are omitted.

| Method <i>Manufacturer</i> | No. Labs | Unit | Sample 28 | Sample 29 |
|----------------------------------|-------------|-------|--------------|---------------|
| Nephelometry Total | 37 | IU/ml | 60 ± 11 | 277 ± 28 |
| <i>Beckman Coulter IMMAGE</i> | 13 | IU/ml | 66 ± 4.6 | 296 ± 16 |
| <i>Dade Behring Nephelometer</i> | 21 | IU/ml | 56 ± 6.6 | 263 ± 24 |
| Turbidimetry Total | 51 | IU/ml | 58 ± 8.9 | 249 ± 151 |
| <i>Beckman Coulter Synchron</i> | 11 | IU/ml | 61 ± 4.0 | 451 ± 134 |
| <i>Roche Diag. Cobas</i> | 14 | IU/ml | 55 ± 1.2 | 162 ± 7.6 |

Rubella Antibody

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|------------|----------|-----------|------------|-------------|----------|-----------|------------|-------------|------------|-------------|----------|-----------|------------|-------------|----------|-----------|------------|-------------|----------|-----------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 11 R | | | | 12 R | | | | 13 N | | | | 14 N | | | | 15 N | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| Chemiluminescence | 54 | 0 | 0% | 54 | 100% | 0 | 0% | 52 | 96% | 54 | 100% | 0 | 0% | 54 | 100% | 0 | 0% | 54 | 100% | 0 | 0% |
| <i>Bayer</i> | 29 | | 0% | 29 | 100% | | 0% | 29 | 100% | 29 | 100% | | 0% | 29 | 100% | | 0% | 29 | 100% | | 0% |
| <i>Beckman</i> ¹ | 13 | | 0% | 13 | 100% | | 0% | 11 | 85% | 13 | 100% | | 0% | 13 | 100% | | 0% | 13 | 100% | | 0% |
| <i>Diagnostic Products</i> | 12 | | 0% | 12 | 100% | | 0% | 12 | 100% | 12 | 100% | | 0% | 12 | 100% | | 0% | 12 | 100% | | 0% |
| EIA | 52 | 0 | 0% | 52 | 100% | 0 | 0% | 51 | 98% | 52 | 100% | 0 | 0% | 52 | 100% | 0 | 0% | 52 | 100% | 0 | 0% |
| <i>Abbott</i> | 19 | | 0% | 19 | 100% | | 0% | 19 | 100% | 19 | 100% | | 0% | 19 | 100% | | 0% | 19 | 100% | | 0% |
| <i>Diamedix</i> | 10 | | 0% | 10 | 100% | | 0% | 10 | 100% | 10 | 100% | | 0% | 10 | 100% | | 0% | 10 | 100% | | 0% |
| <i>Wampole/Zeus</i> | 13 | | 0% | 13 | 100% | | 0% | 13 | 100% | 13 | 100% | | 0% | 13 | 100% | | 0% | 13 | 100% | | 0% |
| <i>Others</i> ² | 10 | | 0% | 10 | 100% | | 0% | 9 | 90% | 10 | 100% | | 0% | 10 | 100% | | 0% | 10 | 100% | | 0% |
| Latex Agglutination | 37 | 0 | 0% | 37 | 100% | 0 | 0% | 37 | 100% | 37 | 100% | 0 | 0% | 37 | 100% | 0 | 0% | 37 | 100% | 0 | 0% |
| <i>Fisher</i> | 22 | | 0% | 22 | 100% | | 0% | 22 | 100% | 22 | 100% | | 0% | 22 | 100% | | 0% | 22 | 100% | | 0% |
| <i>Others</i> | 15 | | 0% | 15 | 100% | | 0% | 15 | 100% | 15 | 100% | | 0% | 15 | 100% | | 0% | 15 | 100% | | 0% |
| Other Methods | 19 | | 0% | 19 | 100% | | 0% | 19 | 100% | 19 | 100% | | 0% | 19 | 100% | | 0% | 18 | 95% | 1 | 5% |
| Analyte Total | 162 | 0 | 0% | 162 | 100% | 0 | 0% | 159 | 98% | 162 | 100% | 0 | 0% | 162 | 100% | 0 | 0% | 161 | 99% | 1 | 1% |

Rubella Antibody Quantitative

Results are summarized for positive test samples 11 and 12. The Mean values \pm S.D. are given where 10 or more laboratories reported quantitative results. Outlier values are omitted.

| Method | No. | | | |
|--------------------------------|-------------|-------------|------------------|------------------|
| <i>Manufacturer</i> | Labs | Unit | Sample 11 | Sample 12 |
| Chemiluminescence Total | 50 | IU/ml | 52 \pm 9.4 | 16 \pm 2.8 |
| <i>Bayer</i> | 27 | IU/ml | 487 \pm 64 | 123 \pm 12 |
| <i>Diagnostic Products</i> | 15 | IU/ml | 46 \pm 3.9 | 15 \pm 1.7 |
| EIA Total | 15 | IU/ml | 46 \pm 6.0 | 18 \pm 3.7 |

Rubella IgM Specific

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|-----------|-----------|-------------|----------|-----------|-----------|-------------|----------|-----------|----------|-----------|-----------|-------------|-----------|-------------|----------|-----------|-----------|-------------|----------|-----------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 56 N | | | | 57 N | | | | 58 R | | | | 59 N | | | | 60 N | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| <i>Manufacturer</i> | | | | | | | | | | | | | | | | | | | | | |
| EIA | 8 | 8 | 100% | | 0% | 8 | 100% | | 0% | | 0% | 8 | 100% | 8 | 100% | | 0% | 8 | 100% | | 0% |
| Chemiluminescence | 10 | 10 | 100% | | 0% | 10 | 100% | | 0% | | 0% | 10 | 100% | 10 | 100% | | 0% | 10 | 100% | | 0% |
| Analyte Total | 18 | 18 | 100% | 0 | 0% | 18 | 100% | 0 | 0% | 0 | 0% | 18 | 100% | 18 | 100% | 0 | 0% | 18 | 100% | 0 | 0% |

Syphilis - Reagin Antibody

| | | Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | |
|-------------------------|------------|--|------------|----------|-----------|----------|-----------|------------|------------|----------|-----------|------------|-------------|------------|-------------|----------|-----------|------------|-------------|----------|-----------|
| | | R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 1 N | | | | 2 R | | | | 3 R | | | | 4 N | | | | 5 N | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| RPR | 261 | 259 | 99% | 2 | 1% | 3 | 1% | 258 | 99% | 1 | 0% | 260 | 100% | 260 | 100% | 1 | 0% | 261 | 100% | 0 | 0% |
| <i>ASI</i> | 39 | 39 | 100% | | 0% | | 0% | 39 | 100% | | 0% | 39 | 100% | 39 | 100% | | 0% | 39 | 100% | | 0% |
| <i>Becton Dickenson</i> | 125 | 124 | 99% | 1 | 1% | | 0% | 125 | 100% | | 0% | 125 | 100% | 125 | 100% | | 0% | 125 | 100% | | 0% |
| <i>Fisher</i> | 50 | 49 | 98% | 1 | 2% | 1 | 2% | 49 | 98% | 1 | 2% | 49 | 98% | 50 | 100% | | 0% | 50 | 100% | | 0% |
| <i>True Medix</i> | 16 | 16 | 100% | | 0% | | 0% | 16 | 100% | | 0% | 16 | 100% | 16 | 100% | | 0% | 16 | 100% | | 0% |
| <i>Wampole/Zeus</i> | 21 | 21 | 100% | | 0% | 1 | 5% | 20 | 95% | | 0% | 21 | 100% | 20 | 95% | 1 | 5% | 21 | 100% | | 0% |
| <i>Others</i> | 10 | 10 | 100% | | 0% | 1 | 10% | 9 | 90% | | 0% | 10 | 100% | 10 | 100% | | 0% | 10 | 100% | | 0% |
| Analyte Total | 261 | 259 | 99% | 2 | 1% | 3 | 1% | 258 | 99% | 1 | 0% | 260 | 100% | 260 | 100% | 1 | 0% | 261 | 100% | 0 | 0% |

Syphilis - Reagin Antibody

RPR Procedures

The number of laboratories that reported titers is listed for positive test samples 2 and 3 for the RPR procedure. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

| Method Manufacturer | No. Labs | Sample 2 Titer | | | | | Sample 3 Titer | | | | | | |
|-------------------------|-------------|-------------------|-----|---|---|----|-------------------|----|-----|----|---|----|----|
| | | 1 | 2 | 4 | 8 | 16 | 32 | 1 | 2 | 4 | 8 | 16 | 32 |
| <i>Total</i> | 238 | 95 | 130 | 7 | 1 | 1 | | 19 | 143 | 66 | 8 | | |
| <i>ASI</i> | 26 | 14 | 11 | | 1 | | | 2 | 15 | 9 | | | |
| <i>Becton Dickenson</i> | 116 | 44 | 68 | 3 | | | | 9 | 74 | 31 | 1 | | |
| <i>Fisher</i> | 82 | 24 | 24 | 1 | | | | 4 | 27 | 15 | 3 | | |
| <i>True Medix</i> | 16 | 5 | 10 | | | | | | 8 | 5 | 3 | | |
| <i>Wampole/ Zeus</i> | 21 | 6 | 12 | 2 | | | | 3 | 15 | 2 | 1 | | |

Note: The number of labs reporting specific titers may not add up to the total number of labs for that system because some labs are not reporting endpoint titers.

Syphilis - Treponemal Antibody

| Participant Results/ Sample Number | | | | | | | | | | | | | | | | | | | | | |
|--|-----------|-----------|------------|----------|-----------|----------|-----------|-----------|-------------|----------|-----------|-----------|-------------|-----------|------------|----------|-----------|-----------|------------|----------|-----------|
| R = Reactive/ Positive; N = Non-Reactive/ Negative | | | | | | | | | | | | | | | | | | | | | |
| Method | No. Labs | 1 N | | | | 2 R | | | | 3 R | | | | 4 N | | | | 5 N | | | |
| | | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % | N | % | R | % |
| EIA | 17 | 17 | 100% | 0 | 0% | 0 | 0% | 17 | 100% | 0 | 0% | 17 | 100% | 17 | 100% | 0 | 0% | 17 | 100% | 0 | 0% |
| <i>Others</i> | 17 | 17 | 100% | | 0% | | 0% | 17 | 100% | | 0% | 17 | 100% | 17 | 100% | | 0% | 17 | 100% | | 0% |
| Gel. Part. Agglut. | 32 | 32 | 100% | 0 | 0% | 0 | 0% | 32 | 100% | 0 | 0% | 32 | 100% | 32 | 100% | 0 | 0% | 32 | 100% | 0 | 0% |
| <i>Fujirebio</i> | 32 | 32 | 100% | | 0% | | 0% | 32 | 100% | | 0% | 32 | 100% | 32 | 100% | | 0% | 32 | 100% | | 0% |
| IFA | 20 | 20 | 100% | 0 | 0% | 0 | 0% | 20 | 100% | 0 | 0% | 20 | 100% | 20 | 100% | 0 | 0% | 20 | 100% | 0 | 0% |
| <i>Wampole/Zeus</i> | 20 | 20 | 100% | | 0% | | 0% | 20 | 100% | | 0% | 20 | 100% | 20 | 100% | | 0% | 20 | 100% | | 0% |
| Other Methods ¹ | 13 | 6 | 46% | 7 | 54% | | 0% | 13 | 100% | | 0% | 13 | 100% | 5 | 38% | 7 | 54% | 6 | 46% | 7 | 54% |
| Analyte Total | 82 | 75 | 91% | 7 | 9% | 0 | 0% | 82 | 100% | 0 | 0% | 82 | 100% | 74 | 90% | 7 | 9% | 75 | 91% | 7 | 9% |

¹ One laboratory reported an equivocal response on sample #4.

AAT, C'3, and C'4

The Mean mg/dl \pm S.D. is given where 10 or more laboratories reported values. Outlier values are omitted.

| Analytes | Sample NO. | | | | | |
|---|------------|---------------|---------------|---------------|---------------|---------------|
| | No. Labs | 76 | 77 | 78 | 79 | 80 |
| Alpha-1-Antitrypsin | | | | | | |
| Nephelometry/ <i>Behring Nephelometer</i> | 18 | 102 \pm 6.4 | 13 \pm 0.9 | 80 \pm 5.0 | 168 \pm 12 | 18 \pm 1.0 |
| Nephelometry/ <i>Total</i> | 26 | 94 \pm 14 | 12 \pm 0.9 | 80 \pm 6.3 | 167 \pm 11 | 19 \pm 1.6 |
| All Method/ <i>Total</i> | 37 | 93 \pm 13 | 12 \pm 1.0 | 82 \pm 7.1 | 166 \pm 14 | 19 \pm 2.5 |
| Complement C'3 | | 76 | 77 | 78 | 79 | 80 |
| Nephelometry/ <i>Beckman Coulter IMMAGE</i> | 16 | 74 \pm 4.5 | 31 \pm 1.7 | 142 \pm 6.5 | 199 \pm 10 | 23 \pm 1.7 |
| Nephelometry/ <i>Behring Nephelometer</i> | 13 | 83 \pm 2.7 | 32 \pm 1.8 | 144 \pm 5.8 | 226 \pm 12 | 24 \pm 0.9 |
| Turbidimetry/ <i>Roche Cobas Integra</i> | 14 | 71 \pm 3.4 | 31 \pm 1.6 | 137 \pm 6.2 | 186 \pm 3.5 | 23 \pm 1.0 |
| Nephelometry/ <i>Total</i> | 42 | 79 \pm 7.1 | 32 \pm 2.4 | 144 \pm 5.8 | 213 \pm 18 | 24 \pm 1.8 |
| Turbidimetry/ <i>Total</i> | 57 | 70 \pm 4.1 | 32 \pm 2.8 | 134 \pm 7.6 | 186 \pm 10 | 23 \pm 2.9 |
| All Method/ <i>Total</i> | 102 | 73 \pm 7.2 | 32 \pm 2.7 | 137 \pm 9.3 | 197 \pm 20 | 24 \pm 2.5 |
| Complement C'4 | | 76 | 77 | 78 | 79 | 80 |
| Nephelometry/ <i>Beckman Coulter IMMAGE</i> | 16 | 15 \pm 1.1 | 4.2 \pm 0.2 | 38 \pm 1.6 | 37 \pm 2.2 | 4.5 \pm 0.4 |
| Nephelometry/ <i>Behring Nephelometer</i> | 13 | 13 \pm 0.5 | 4.0 \pm 1.0 | 34 \pm 2.2 | 35 \pm 2.2 | 4.5 \pm 0.6 |
| Turbidimetry/ <i>Roche Cobas Integra</i> | 14 | 12 \pm 0.7 | 3.5 \pm 0.5 | 31 \pm 1.6 | 27 \pm 1.7 | 3.4 \pm 0.5 |
| Nephelometry/ <i>Total</i> | 42 | 14 \pm 1.4 | 4.1 \pm 0.2 | 35 \pm 2.8 | 37 \pm 3.2 | 4.4 \pm 0.4 |
| Turbidimetry/ <i>Total</i> | 47 | 12 \pm 1.3 | 3.3 \pm 0.8 | 31 \pm 2.8 | 28 \pm 1.7 | 3.3 \pm 1.0 |
| All Method/ <i>Total</i> | 99 | 13 \pm 1.8 | 3.8 \pm 0.5 | 33 \pm 3.7 | 31 \pm 5.3 | 3.8 \pm 0.9 |

IgA, IgE, IgG, and IgM

The Mean mg/dl (IU/ml for IgE) \pm S.D. is given for IgA, IgE, and IgM and Mean mg/dl \pm 25% is given for IgG where 10 or more laboratories reported values. Outlier values are omitted.

| Analytes (Unit) | No. Labs | Sample NO. | | | | |
|--|-------------|---------------|---------------|---------------|----------------|---------------|
| | | 81 | 82 | 83 | 84 | 85 |
| Immunoglobulin A (mg/dl) | | | | | | |
| Nephelometry/Beckman Coulter IMMAGE | 18 | 51 \pm 2.3 | 47 \pm 2.0 | 46 \pm 2.0 | 460 \pm 22 | 184 \pm 8.9 |
| Nephelometry/Behring Nephelometer | 16 | 60 \pm 4.3 | 49 \pm 3.2 | 49 \pm 2.2 | 504 \pm 28 | 202 \pm 8.9 |
| Turbidimetry/ Beckman Coulter Synchron | 11 | 58 \pm 1.8 | 51 \pm 2.3 | 51 \pm 2.0 | 432 \pm 8.1 | 193 \pm 2.0 |
| Turbidimetry/ Roche Cobas Integra | 14 | 47 \pm 1.8 | 45 \pm 2.6 | 46 \pm 3.4 | 418 \pm 13 | 192 \pm 3.7 |
| Nephelometry/ Total | 53 | 57 \pm 5.1 | 48 \pm 2.8 | 48 \pm 3.0 | 485 \pm 34 | 196 \pm 12 |
| Turbidimetry/ Total | 58 | 56 \pm 7.0 | 48 \pm 3.9 | 48 \pm 3.7 | 413 \pm 37 | 189 \pm 8.2 |
| All Method/ Total | 114 | 56 \pm 6.3 | 48 \pm 3.2 | 48 \pm 3.4 | 446 \pm 52 | 192 \pm 10 |
| Immunoglobulin E (IU/ml) | | | | | | |
| Chemiluminescence/Bayer Advia | 10 | 4.2 \pm 1.8 | 28 \pm 2.4 | 28 \pm 1.8 | 326 \pm 15 | 234 \pm 14 |
| Chemiluminescence/Diag. Prod. Co. | 31 | 3.4 \pm 0.4 | 29 \pm 2.3 | 28 \pm 2.2 | 299 \pm 26 | 232 \pm 18 |
| FEIA/ Pharmacia Immunocap | 13 | 4.5 \pm 0.8 | 29 \pm 1.5 | 28 \pm 2.6 | 331 \pm 28 | 226 \pm 17 |
| Chemiluminescence/ Total | 48 | 3.3 \pm 0.4 | 28 \pm 2.3 | 28 \pm 2.1 | 305 \pm 25 | 231 \pm 17 |
| FEIA/ Total | 19 | 4.7 \pm 0.7 | 28 \pm 1.5 | 28 \pm 2.2 | 328 \pm 25 | 222 \pm 16 |
| All Method/ Total | 19 | 3.7 \pm 0.8 | 28 \pm 2.3 | 28 \pm 2.2 | 310 \pm 27 | 226 \pm 18 |
| Immunoglobulin G (mg/dl) | | | | | | |
| Nephelometry/Beckman Coulter IMMAGE | 17 | 297 \pm 16 | 256 \pm 15 | 257 \pm 15 | 1873 \pm 96 | 716 \pm 44 |
| Nephelometry/Behring Nephelometer | 16 | 302 \pm 21 | 256 \pm 13 | 256 \pm 15 | 2145 \pm 114 | 725 \pm 40 |
| Turbidimetry/ Beckman Coulter Synchron | 10 | 285 \pm 15 | 240 \pm 7.8 | 243 \pm 5.5 | 1928 \pm 67 | 688 \pm 4.8 |
| Turbidimetry/Roche Cobas Integra | 14 | 273 \pm 16 | 237 \pm 5.5 | 237 \pm 3.6 | 1915 \pm 39 | 669 \pm 27 |
| Nephelometry/ Total | 52 | 296 \pm 20 | 254 \pm 14 | 253 \pm 15 | 2025 \pm 183 | 720 \pm 38 |
| Turbidimetry/ Total | 54 | 277 \pm 22 | 239 \pm 10 | 238 \pm 7.7 | 1854 \pm 125 | 676 \pm 37 |
| All Method/ Total | 108 | 288 \pm 24 | 248 \pm 19 | 249 \pm 18 | 1940 \pm 178 | 699 \pm 45 |
| Immunoglobulin M (mg/dl) | | | | | | |
| Nephelometry/Beckman Coulter IMMAGE | 17 | 21 \pm 1.0 | 24 \pm 1.6 | 25 \pm 1.4 | 161 \pm 6.7 | 87 \pm 3.1 |
| Nephelometry/Behring Nephelometer | 17 | 22 \pm 1.2 | 25 \pm 1.0 | 25 \pm 1.0 | 219 \pm 13 | 103 \pm 3.3 |
| Turbidimetry/ Beckman Coulter Synchron | 10 | 22 \pm 4 | 26 \pm 1.7 | 26 \pm 1.1 | 159 \pm 4.1 | 89 \pm 3.0 |
| Turbidimetry/Roche Cobas Integra | 14 | 19 \pm 1.7 | 22 \pm 2.9 | 23 \pm 2.7 | 134 \pm 4.2 | 84 \pm 1.8 |
| Nephelometry/ Total | 51 | 22 \pm 1.7 | 25 \pm 1.6 | 25 \pm 1.6 | 192 \pm 27 | 95 \pm 7.6 |
| Turbidimetry/ Total | 54 | 23 \pm 4.3 | 26 \pm 2.8 | 26 \pm 2.0 | 154 \pm 23 | 89 \pm 6.7 |
| All Method/ Total | 108 | 22 \pm 2.3 | 25 \pm 2.3 | 26 \pm 1.2 | 173 \pm 32 | 92 \pm 8.3 |

Acceptable Response (May 7, 2008 PT Event)
Quantitative Tests Results (Acceptable Range)

| Analytes Method/ Manufacture | Sample NO. | | | | |
|---|------------|-----------|-----------|-------------|-----------|
| | 76 | 77 | 78 | 79 | 80 |
| Alpha-1-Antitrypsin | 76 | 77 | 78 | 79 | 80 |
| Nephelometry/Dade Behring Neph. | 83 - 122 | 10 - 16 | 64 - 95 | 133 - 203 | 15 - 22 |
| Nephelometry/ Total | 52 - 137 | 9 - 16 | 61 - 100 | 133 - 201 | 14 - 24 |
| All Method/ Total | 54 - 132 | 9 - 16 | 60 - 103 | 123 - 210 | 11 - 27 |
| Complement C'3 | 76 | 77 | 78 | 79 | 80 |
| Nephelometry/Beckman Coulter Immage | 60 - 88 | 25 - 36 | 122 - 163 | 168 - 229 | 17 - 28 |
| Nephelometry/Dade Behring Neph. | 74 - 92 | 26 - 38 | 126 - 162 | 190 - 261 | 21 - 27 |
| Turbidimetry/Roche Cobas Integra | 61 - 82 | 26 - 37 | 118 - 156 | 175 - 196 | 19 - 26 |
| Nephelometry/ Total | 57 - 101 | 24 - 39 | 126 - 162 | 159 - 267 | 18 - 30 |
| Turbidimetry/ Total | 58 - 83 | 23 - 40 | 111 - 157 | 154 - 218 | 14 - 33 |
| Complement C'4 | 76 | 77 | 78 | 79 | 80 |
| Nephelometry/Beckman Coulter Immage | 11 - 18 | 3 - 5 | 33 - 43 | 30 - 44 | 3 - 6 |
| Nephelometry/Dade Behring Neph. | 11 - 15 | 3 - 6 | 27 - 41 | 28 - 42 | 2 - 7 |
| Turbidimetry/Roche Cobas Integra | 9 - 14 | 2 - 6 | 25 - 36 | 21 - 32 | 1 - 5 |
| Nephelometry/ Total | 10 - 19 | 3 - 5 | 26 - 44 | 27 - 47 | 3 - 6 |
| Turbidimetry/ Total | 8 - 16 | 1 - 6 | 22 - 39 | 22 - 33 | 1 - 7 |
| Immunoglobulin A | 81 | 82 | 83 | 84 | 85 |
| Nephelometry/Beckman Coulter Immage | 44 - 59 | 40 - 53 | 40 - 53 | 393 - 526 | 157 - 211 |
| Nephelometry/Dade Behring Neph . | 46 - 73 | 39 - 59 | 42 - 56 | 418 - 590 | 174 - 229 |
| Turbidimetry/ Beckman Coulter Synchron. | 52 - 64 | 43 - 58 | 45 - 58 | 407 - 457 | 186 - 199 |
| Turbidimetry/ Roche Cobas Integra | 41 - 53 | 37 - 53 | 35 - 56 | 377 - 458 | 180 - 204 |
| Nephelometry/ Total | 41 - 72 | 40 - 57 | 38 - 58 | 381 - 588 | 159 - 232 |
| Turbidimetry/ Total | 34 - 77 | 36 - 60 | 37 - 60 | 302 - 524 | 164 - 215 |
| Immunoglobulin E | 81 | 82 | 83 | 84 | 85 |
| Chemiluminescence/Bayer Advia | 1 - 10 | 20 - 35 | 22 - 34 | 280 - 373 | 190 - 278 |
| Chemiluminescence/Diag.Prod. Immulite | 2 - 5 | 21 - 36 | 21 - 35 | 220 - 377 | 177 - 287 |
| FEIA/Pharmacia Immucap | 2 - 7 | 24 - 34 | 20 - 36 | 246 - 416 | 174 - 277 |
| Chemiluminescence/ Total | 2 - 5 | 21 - 36 | 21 - 35 | 228 - 382 | 181 - 281 |
| FEIA/ Total | 2 - 7 | 23 - 33 | 21 - 35 | 253 - 404 | 174 - 270 |
| All Method/ Total | 1 - 7 | 21 - 35 | 20 - 35 | 229 - 392 | 173 - 280 |
| Immunoglobulin G | 81 | 82 | 83 | 84 | 85 |
| Nephelometry/Beckman Coulter Immage | 222 - 372 | 192 - 321 | 192 - 321 | 1404 - 2341 | 537 - 896 |
| Nephelometry/Dade Behring Neph . | 226 - 378 | 192 - 321 | 192 - 320 | 1608 - 2682 | 543 - 907 |
| Turbidimetry/ Beckman Coulter Synchron. | 213 - 356 | 179 - 300 | 181 - 304 | 1446 - 2411 | 516 - 861 |
| Turbidimetry/Roche Cobas Integra | 204 - 342 | 177 - 296 | 177 - 296 | 1436 - 2394 | 502 - 837 |
| Nephelometry/ Total | 222 - 371 | 190 - 318 | 189 - 317 | 1518 - 2532 | 539 - 900 |
| Turbidimetry/ Total | 207 - 387 | 179 - 333 | 178 - 339 | 1390 - 2495 | 507 - 863 |
| Immunoglobulin M | 81 | 82 | 83 | 84 | 85 |
| Nephelometry/Beckman Coulter Immage | 17 - 24 | 19 - 29 | 20 - 29 | 140 - 182 | 77 - 96 |
| Nephelometry/Dade Behring Neph . | 18 - 26 | 21 - 29 | 22 - 29 | 181 - 258 | 92 - 113 |
| Turbidimetry/ Beckman Coulter Synchron. | 22 - 25 | 20 - 31 | 22 - 30 | 147 - 172 | 80 - 99 |
| Turbidimetry/Roche Cobas Integra | 13 - 24 | 12 - 31 | 14 - 31 | 121 - 147 | 78 - 90 |
| Nephelometry/ Total | 16 - 27 | 20 - 30 | 20 - 31 | 110 - 275 | 71 - 118 |
| Turbidimetry/ Total | 9 - 49 | 17 - 42 | 17 - 52 | 85 - 253 | 68 - 131 |

Acceptable Response (May 7, 2008 PT Event)
Qualitative / Quantitative Tests Results

| Analytes | Sample NO. | | | | |
|-------------------------------|---------------------------|-----------|------------|-----------|------------|
| | 1 | 2 | 3 | 4 | 5 |
| Syphilis - Reagin | N | R | R | N | N |
| <i>RPR Titer</i> | | 1 - 4 | 1 - 4 | | |
| Syphilis - Treponemal | N | R | R | N | N |
| | 6 | 7 | 8 | 9 | 10 |
| HBcAb | R | N | N | R | N |
| HBsAg | N | N | N | R | N |
| HBsAg Confirmation | N | N | N | R | N |
| | 11 | 12 | 13 | 14 | 15 |
| CMV | R | R | N | N | N |
| Rubella Ab | R | R | N | N | N |
| Rubella Ab Quantitative | <i>IU/ml</i> | 23 - 81 | 7 - 25 | | |
| | 16 | 17 | 18 | 19 | 20 |
| ASO | N | N | R | N | R |
| ASO Quantitative | <i>Latex IU/ml</i> | | 200 - 3200 | | 200 - 3200 |
| | <i>Nephelometry IU/ml</i> | | 239 - 1141 | | 237 - 1122 |
| | <i>Turbidimetry IU/ml</i> | | 334 - 1099 | | 316 - 1097 |
| | 26 | 27 | 28 | 29 | 30 |
| Infectious Mono. | N | R | R | N | N |
| Rheumatoid Factor | N | N | R | R | N |
| RF Quantitative | <i>Latex Titer</i> | | 2 - 32 | 4 - 64 | |
| | <i>Latex IU/ml</i> | | 20 - 320 | 40 - 640 | |
| | <i>Nephelometry IU/ml</i> | | 28 - 92 | 193 - 360 | |
| | <i>Turbidimetry IU/ml</i> | | 31 - 85 | 1 - 702 | |
| | 31 | 32 | 33 | 34 | 35 |
| HIV Ab Screening/Confirmation | R | N | N | N | R |
| | 36 | 37 | 38 | 39 | 40 |
| HTLV 1 Ab | N | N | N | R | R |
| | 41 | 42 | 43 | 44 | 45 |
| LYME Disease Ab | R | R | N | N | N |
| LYME Disease Ab WB IgG | R | R | N | N | N |
| LYME Disease Ab WB IgM | R * | R * | N | N | N |
| | 46 | 47 | 48 | 49 | 50 |
| ANA | R | N | N | R | N |
| | <i>IFA Titer</i> | 80 - 1280 | | 80 - 1280 | |
| | 56 | 57 | 58 | 59 | 60 |
| Rubella IgM | N | N | R | N | N |
| | 61 | 62 | 63 | 64 | 65 |
| HIV p24 Ag | N | N | R | N | N |
| | 66 | 67 | 68 | 69 | 70 |
| HBeAg | R | N | R | N | N |
| | 71 | 72 | 73 | 74 | 75 |
| Hepatitis C Ab | N* | R | N* | N* | R |
| Hepatitis C Ab Confirmation | N | R | N | N | R |

Note: R = Reactive/ Positive; I = Indeterminate; N = Non-Reactive/ Negative

* This test sample was not authenticated, because a consensus of 80% agreement was not reached. All participating laboratories received credit for this sample.