

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 2



Total Commitment to Education and Service
Provided by ACP, Inc.

Immunology
MLE – M1

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2012 Evaluation Criteria

The evaluation criteria used in the 2012 MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

Qualitative

For qualitative procedures, evaluation is based on participant or referee consensus. A minimum percentage of participants must receive a passing score or the challenge is not evaluated due to lack of consensus. These percentages are listed below.

| | |
|-------------------------------------|---------------------------|
| Infectious Mononucleosis | 80% Participant Consensus |
| Rheumatoid Factor | 80% Participant Consensus |
| Anti-Streptolysin O (ASO) | 80% Participant Consensus |
| Antinuclear Antibody (ANA) | 80% Participant Consensus |
| Anti-dsDNA | 80% Participant Consensus |
| Anti-RNP | 80% Participant Consensus |
| Anti-RNP/Sm | 80% Participant Consensus |
| Anti-SSA | 80% Participant Consensus |
| Anti-SSB | 80% Participant Consensus |
| Anti-SSA/SSB | 80% Participant Consensus |
| Anti-Sm | 80% Participant Consensus |
| C-Reactive Protein | 80% Participant Consensus |
| Rubella Antibody | 80% Participant Consensus |
| H. <i>pylori</i> Antibody Detection | 80% Participant Consensus |
| Total IgE | 80% Participant Consensus |
| Diagnostic Allergy | 80% Participant Consensus |
| Syphilis Serology | 80% Participant Consensus |
| Lyme Disease Serology | 80% Participant Consensus |
| Mycoplasma Antibody | 80% Participant Consensus |
| Anti-HIV | 80% Participant Consensus |
| Viral Markers | 80% Participant Consensus |

Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each peer group consisting of 10 or more laboratories. Acceptable performance is established based on a target value \pm the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on page 37 under the heading "Acceptable Ranges for Quantitative Results."

| | |
|---|---------------|
| Rheumatoid Factor (International Units) | \pm 3 SD |
| Rheumatoid Factor (Titer) | Not Evaluated |
| Anti-Streptolysin O (ASO) Titer | Not Evaluated |
| Complement C3 | \pm 3 SD |
| Complement C4 | \pm 3 SD |
| Antinuclear Antibody (ANA) Titer | Not Evaluated |
| C-Reactive Protein | \pm 3 SD |
| High Sensitivity C-Reactive Protein | \pm 3 SD |
| Rubella (International Units) | \pm 3 SD |
| Total IgE | \pm 3 SD |
| Total IgA | \pm 3 SD |
| Total IgG | \pm 25% |
| Total IgM | \pm 3 SD |

Infectious Mononucleosis

| <u>Method</u> | <u>Specimen IM-1</u> | | <u>Specimen IM-2</u> | |
|--|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 259 | 4 | 2 | 261 |
| ASI | 1 | - | - | 1 |
| Beckman Coulter ICON Mono - waived | 8 | - | - | 8 |
| BioStar Acceava Mono Test | 2 | 1 | 1 | 2 |
| BioStar Acceava Mono-whole bld | 8 | - | - | 8 |
| Cardinal Health SP Brand | 2 | - | - | 2 |
| Cardinal Health SP Brand - waived | 9 | - | - | 9 |
| Consult Diagnostics | 1 | - | - | 1 |
| Fisher HealthCare Sure-Vue | 8 | - | - | 8 |
| Genzyme OSOM | 14 | - | - | 14 |
| Genzyme OSOM (waived) | 93 | 1 | - | 94 |
| Henry Schein OneStep+ - waived | 11 | - | - | 11 |
| Immunostics - IMMUNO/IM | 1 | - | - | 1 |
| Inverness (Wampole) Clearview | 14 | 1 | - | 15 |
| Inverness Clearview Mono Plus II | 9 | 1 | 1 | 9 |
| Inverness Signify Mono Test | 1 | - | - | 1 |
| LifeSign Status - waived | 15 | - | - | 15 |
| McKesson Medi-Lab Performance - waived | 9 | - | - | 9 |
| Meridian ImmunoCard STAT! | 1 | - | - | 1 |
| Other Moderate method | 4 | - | - | 4 |
| Other Waived method | 21 | - | - | 21 |
| Polymedco Poly stat | 1 | - | - | 1 |
| Polymedco Poly stat - waived | 7 | - | - | 7 |
| Quidel QuickVue+ | 1 | - | - | 1 |
| Quidel QuickVue+ - waived | 9 | - | - | 9 |
| Seradyn | 6 | - | - | 6 |
| Wampole Mono-Plus II | 2 | - | - | 2 |

Infectious Mononucleosis

| <u>Method</u> | Specimen IM-3 | | Specimen IM-4 | | Specimen IM- 5 | |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 116 | - | - | 116 | 116 | - |
| ASI | 1 | - | - | 1 | 1 | - |
| Beckman Coulter ICON Mono - waived | 8 | - | - | 8 | 8 | - |
| BioStar Acceava Mono Test | 3 | - | - | 3 | 3 | - |
| BioStar Acceava Mono-whole bld | 2 | - | - | 2 | 2 | - |
| Cardinal Health SP Brand | 2 | - | - | 2 | 2 | - |
| Cardinal Health SP Brand - waived | 2 | - | - | 2 | 2 | - |
| Consult Diagnostics | 1 | - | - | 1 | 1 | - |
| Fisher HealthCare Sure-Vue | 8 | - | - | 8 | 8 | - |
| Genzyme OSOM | 13 | - | - | 13 | 13 | - |
| Genzyme OSOM (waived) | 32 | - | - | 32 | 32 | - |
| Henry Schein OneStep+ - waived | 4 | - | - | 4 | 4 | - |
| Inverness (Wampole) Clearview | 8 | - | - | 8 | 8 | - |
| Inverness Clearview Mono Plus II | 5 | - | - | 5 | 5 | - |
| LifeSign Status - waived | 2 | - | - | 2 | 2 | - |
| McKesson Medi-Lab Performance - waived | 2 | - | - | 2 | 2 | - |
| Meridian ImmunoCard STAT! | 1 | - | - | 1 | 1 | - |
| Other Moderate method | 4 | - | - | 4 | 4 | - |
| Other Waived method | 2 | - | - | 2 | 2 | - |
| Polymedco Poly stat | 1 | - | - | 1 | 1 | - |
| Polymedco Poly stat - waived | 5 | - | - | 5 | 5 | - |
| Quidel QuickVue+ | 1 | - | - | 1 | 1 | - |
| Quidel QuickVue+ - waived | 2 | - | - | 2 | 2 | - |
| Seradyn | 6 | - | - | 6 | 6 | - |
| Wampole Mono-Plus II | 1 | - | - | 1 | 1 | - |

Rheumatoid Factor—Qualitative

| <u>Method</u> | Specimen RF-1 | | Specimen RF-2 | | Specimen RF-3 | |
|----------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 68 | 1 | 67 | 68 | - |
| Abbott Architect | - | 1 | - | 1 | 1 | - |
| ASI | - | 8 | - | 8 | 8 | - |
| Biokit Rheumajet | - | 4 | - | 4 | 4 | - |
| Diamedix | - | 2 | - | 2 | 2 | - |
| Fisher HealthCare Sure-Vue | - | 7 | 1 | 6 | 7 | - |
| Immunostics Inc. | - | 4 | - | 4 | 4 | - |
| JAS Diagnostics, Inc. | - | 1 | - | 1 | 1 | - |
| Olympus AU | - | 1 | - | 1 | 1 | - |
| Remel SeraTest | - | 13 | - | 13 | 13 | - |
| Seradyn | - | 1 | - | 1 | 1 | - |
| Stanbio Laboratory | - | 1 | - | 1 | 1 | - |
| Sterling Diagnostics, Inc. | - | 1 | - | 1 | 1 | - |
| Teco Diagnostics | - | 5 | - | 5 | 5 | - |
| TheraTest | - | 3 | - | 3 | 3 | - |
| Wampole ColorCard | - | 9 | - | 9 | 9 | - |
| Wampole Rheumatex | - | 7 | - | 7 | 7 | - |

| <u>Method</u> | Specimen RF-4 | | Specimen RF-5 | |
|----------------------------|------------------------|------------------------|------------------------|------------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 68 | - | 67 | 1 |
| Abbott Architect | 1 | - | 1 | - |
| ASI | 8 | - | 8 | - |
| Biokit Rheumajet | 4 | - | 3 | 1 |
| Diamedix | 2 | - | 2 | - |
| Fisher HealthCare Sure-Vue | 7 | - | 7 | - |
| Immunostics Inc. | 4 | - | 4 | - |
| JAS Diagnostics, Inc. | 1 | - | 1 | - |
| Olympus AU | 1 | - | 1 | - |
| Remel SeraTest | 13 | - | 13 | - |
| Seradyn | 1 | - | 1 | - |
| Stanbio Laboratory | 1 | - | 1 | - |
| Sterling Diagnostics, Inc. | 1 | - | 1 | - |
| Teco Diagnostics | 5 | - | 5 | - |
| TheraTest | 3 | - | 3 | - |
| Wampole ColorCard | 9 | - | 9 | - |
| Wampole Rheumatex | 7 | - | 7 | - |

Rheumatoid Factor—Quantitative (Titer)

This portion is not evaluated. Results reported are as follows:

| <u>Specimen/Method</u> | <u>2/ 4</u> | <u>8/ 10</u> | <u>16/ 20</u> | <u>32/ 40</u> | <u>64/ 80</u> | <u>128/ 160</u> | <u>256/ 320</u> | <u>512/ 640</u> | <u>1024/ 1280</u> | <u>2048/ 2560</u> | <u>>2560</u> |
|----------------------------|-----------------|------------------|-------------------|-------------------|-------------------|---------------------|---------------------|---------------------|-----------------------|-----------------------|-----------------|
| Specimen RF-3 | | | | | | | | | | | |
| ALL METHODS | 1 | 6 | - | 2 | 2 | 1 | - | - | - | - | - |
| ASI | - | - | - | 1 | - | - | - | - | - | - | - |
| Fisher HealthCare Sure-Vue | 1 | 2 | - | - | 1 | - | - | - | - | - | - |
| Remel SeraTest | - | 3 | - | 1 | 1 | - | - | - | - | - | - |
| Wampole ColorCard | - | 1 | - | - | - | 1 | - | - | - | - | - |
| Specimen RF-4 | | | | | | | | | | | |
| ALL METHODS | - | 3 | 4 | 1 | - | 4 | - | - | - | - | - |
| ASI | - | - | - | - | - | 1 | - | - | - | - | - |
| Fisher HealthCare Sure-Vue | - | 1 | 2 | - | - | 1 | - | - | - | - | - |
| Remel SeraTest | - | 1 | 2 | 1 | - | 1 | - | - | - | - | - |
| Wampole ColorCard | - | 1 | - | - | - | 1 | - | - | - | - | - |
| Specimen RF-5 | | | | | | | | | | | |
| ALL METHODS | 1 | 5 | 2 | - | 2 | 1 | 1 | - | - | - | - |
| ASI | - | - | - | - | - | - | 1 | - | - | - | - |
| Fisher HealthCare Sure-Vue | 1 | 2 | - | - | 1 | - | - | - | - | - | - |
| Remel SeraTest | - | 2 | 2 | - | 1 | - | - | - | - | - | - |
| Wampole ColorCard | - | 1 | - | - | - | 1 | - | - | - | - | - |

Rheumatoid Factor—Quantitative (IU)

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|------------------------|-------------|-------------|-----------|-----------|---------------|--------------|
| Specimen RF-1 | | | | | | |
| All Method | 18 | 4.8 | 4.2 | 87.5 | 4 | 0 - 18 |
| Specimen RF-2 | | | | | | |
| All Method | 18 | 4.9 | 4.4 | 90.9 | 3 | 0 - 19 |
| Specimen RF-3 | | | | | | |
| All Method | 15 | 64.5 | 5.9 | 9.1 | 64 | 46 - 83 |
| Specimen RF-4 | | | | | | |
| All Method | 15 | 104.2 | 7.5 | 7.2 | 102 | 81 - 127 |
| Specimen RF-5 | | | | | | |
| All Method | 16 | 66.1 | 10.8 | 16.4 | 64 | 33 - 99 |

Anti-Streptolysin O (ASO)—Qualitative

| <u>Method</u> | <u>Specimen AS-1</u> | | <u>Specimen AS-2</u> | | <u>Specimen AS-3</u> | |
|---------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 1 | - | - | 1 | 1 | - |
| ASI | 1 | - | - | 1 | 1 | - |
| <u>Method</u> | <u>Specimen AS-4</u> | | <u>Specimen AS-5</u> | | | |
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | | |
| ALL METHODS | - | 1 | 1 | - | | |
| ASI | - | 1 | 1 | - | | |

Complement C3 (mg/dL)

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|------------------------|-------------|-------------|-----------|-----------|---------------|--------------|
| Specimen IMP-1 | | | | | | |
| All Method | 22 | 80.5 | 13.4 | 16.6 | 85 | 40 - 121 |
| Specimen IMP-2 | | | | | | |
| All Method | 22 | 87.9 | 16.4 | 18.7 | 96 | 38 - 138 |
| Specimen IMP-3 | | | | | | |
| All Method | 22 | 120.3 | 26.0 | 21.6 | 130 | 42 - 199 |
| Specimen IMP-4 | | | | | | |
| All Method | 22 | 123.0 | 21.9 | 17.8 | 135 | 57 - 189 |
| Specimen IMP-5 | | | | | | |
| All Method | 22 | 119.9 | 25.1 | 21.0 | 129 | 44 - 196 |

Complement C4 (mg/dL)

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|------------------------|-------------|-------------|-----------|-----------|---------------|--------------|
| Specimen IMP-1 | | | | | | |
| All Method | 22 | 14.5 | 1.4 | 9.7 | 15 | 10 - 19 |
| Specimen IMP-2 | | | | | | |
| All Method | 22 | 15.4 | 2.1 | 13.4 | 16 | 9 - 22 |
| Specimen IMP-3 | | | | | | |
| All Method | 22 | 24.3 | 3.2 | 13.1 | 25 | 14 - 34 |
| Specimen IMP-4 | | | | | | |
| All Method | 22 | 21.2 | 2.5 | 12.0 | 22 | 13 - 29 |
| Specimen IMP-5 | | | | | | |
| All Method | 22 | 24.9 | 3.8 | 15.2 | 25 | 13 - 37 |

Antinuclear Antibody (ANA)—Qualitative Latex Methods

| <u>Method</u> | <u>Specimen AN-1</u> | | <u>Specimen AN-2</u> | | <u>Specimen AN-3</u> | |
|--------------------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 6 | - | 6 | 6 | - |
| Alpha Scientific Medical, Inc. | - | 1 | - | 1 | 1 | - |
| Diagnostic Technology | - | 4 | - | 4 | 4 | - |
| Wampole | - | 1 | - | 1 | 1 | - |

| <u>Method</u> | <u>Specimen AN-4</u> | | <u>Specimen AN-5</u> | |
|--------------------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 6 | - | 1 | 5 |
| Alpha Scientific Medical, Inc. | 1 | - | - | 1 |
| Diagnostic Technology | 4 | - | 1 | 3 |
| Wampole | 1 | - | - | 1 |

C-Reactive Protein—Qualitative, Regular

| <u>Method</u> | <u>Specimen CR-1</u> | | <u>Specimen CR-2</u> | |
|-----------------------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 5 | 13 | 13 | 5 |
| ASI | - | 2 | 2 | - |
| Biokit Rheumajet | - | 1 | 1 | - |
| Fisher HealthCare Sure-Vue | - | 8 | 8 | - |
| Siemens Dimension/AR/ES/RxL/Xpand | - | 1 | 1 | - |
| Teco Diagnostics | 5 | - | - | 5 |
| Wampole | - | 1 | 1 | - |

These challenges were graded by 85% referee consensus.

C-Reactive Protein—Quantitative (mg/dL), Regular

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|------------------------|-------------|-------------|-----------|-----------|---------------|---------------|
| Specimen CR-1 | | | | | | |
| mg/dL - units | | | | | | |
| All Immunology Methods | 28 | 0.241 | 0.223 | 92.5 | 0.20 | 0.00 - 0.92 |
| mg/L - units | | | | | | |
| All Immunology Methods | 11 | 1.932 | 2.239 | 115.9 | 0.43 | 0.00 - 8.66 |
| Specimen CR-2 | | | | | | |
| mg/dL - units | | | | | | |
| All Immunology Methods | 28 | 2.609 | 0.364 | 14.0 | 2.73 | 1.51 - 3.71 |
| mg/L - units | | | | | | |
| All Immunology Methods | 11 | 25.705 | 4.904 | 19.1 | 26.90 | 10.99 - 40.42 |

C-Reactive Protein—Quantitative (mg/dL), High Sensitivity

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|----------------------------------|-------------|-------------|-----------|-----------|---------------|---------------|
| Specimen HCR-1 | | | | | | |
| All Method | 51 | 0.713 | 0.190 | 26.7 | 0.72 | 0.14 - 1.29 |
| Siemens Dimension High Sensi CRP | 10 | 0.928 | 0.460 | 49.6 | 0.94 | 0.00 - 2.31 |
| Specimen HCR-2 | | | | | | |
| All Method | 50 | 14.135 | 0.895 | 6.3 | 14.00 | 11.44 - 16.83 |
| Siemens Dimension High Sensi CRP | 9 | - | - | - | 13.32 | 11.44 - 16.83 |

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

| <u>Method</u> | <u>Specimen AE-1</u> | | <u>Specimen AE-2</u> | | <u>Specimen AE-3</u> | |
|-------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 15 | 15 | - | 15 | - |
| Immuno Concepts | - | 5 | 5 | - | 5 | - |
| INOVA Diagnostics | - | 2 | 2 | - | 2 | - |
| Kallestad | - | 2 | 2 | - | 2 | - |
| TheraTest | - | 4 | 4 | - | 4 | - |
| Wampole | - | 1 | 1 | - | 1 | - |

| <u>Method</u> | <u>Specimen AE-4</u> | | <u>Specimen AE-5</u> | |
|-------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 15 | - | - | 15 |
| Immuno Concepts | 5 | - | - | 5 |
| INOVA Diagnostics | 2 | - | - | 2 |
| Kallestad | 2 | - | - | 2 |
| TheraTest | 4 | - | - | 4 |
| Wampole | 1 | - | - | 1 |

Antinuclear Antibody (ANA)—Quantitative (Titer)

This portion is not evaluated. Titers reported are as follows:

| <u>Specimen/Method</u> | <u>8/ 10</u> | <u>16/ 20</u> | <u>32/ 40</u> | <u>64/ 80</u> | <u>128/ 160</u> | <u>256/ 320</u> | <u>512/ 640</u> | <u>>640</u> | <u>1024/ 1280</u> | <u>2048/ 2560</u> | <u>≥2560</u> |
|------------------------|------------------|-------------------|-------------------|-------------------|---------------------|---------------------|---------------------|----------------|-----------------------|-----------------------|--------------|
|------------------------|------------------|-------------------|-------------------|-------------------|---------------------|---------------------|---------------------|----------------|-----------------------|-----------------------|--------------|

Specimen AE-2

| | | | | | | | | | | | |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|
| ALL METHODS | - | - | - | - | - | - | 2 | 2 | - | - | - |
| Immuno Concepts | - | - | - | - | - | - | 1 | 2 | - | - | - |
| INOVA Diagnostics | - | - | - | - | - | - | 1 | - | - | - | - |

Specimen AE-3

| | | | | | | | | | | | |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|
| ALL METHODS | - | - | - | - | 1 | 2 | - | 1 | - | - | - |
| Immuno Concepts | - | - | - | - | 1 | 1 | - | 1 | - | - | - |
| INOVA Diagnostics | - | - | - | - | - | 1 | - | - | - | - | - |

Specimen AE-4

| | | | | | | | | | | | |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|
| ALL METHODS | - | - | - | - | - | - | 1 | 2 | 1 | - | - |
| Immuno Concepts | - | - | - | - | - | - | 1 | 2 | - | - | - |
| INOVA Diagnostics | - | - | - | - | - | - | - | - | 1 | - | - |

Anti-dsDNA

| <u>Method</u> | <u>Specimen AE-1</u> | | <u>Specimen AE-2</u> | | <u>Specimen AE-3</u> | |
|-------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 11 | 1 | 10 | 11 | - |
| Immuno Concepts | - | 1 | 1 | - | 1 | - |
| INOVA Diagnostics | - | 1 | - | 1 | 1 | - |
| Kallestad | - | 2 | - | 2 | 2 | - |
| TheraTest | - | 5 | - | 5 | 5 | - |
| Wampole | - | 1 | - | - | 1 | - |

| <u>Method</u> | <u>Specimen AE-4</u> | | <u>Specimen AE-5</u> | |
|-------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 1 | 10 | - | 11 |
| Immuno Concepts | 1 | - | - | 1 |
| INOVA Diagnostics | - | 1 | - | 1 |
| Kallestad | - | 2 | - | 2 |
| TheraTest | - | 5 | - | 5 |
| Wampole | - | 1 | - | 1 |

Anti-RNP

| <u>Method</u> | Specimen AE-1 | | Specimen AE-2 | | Specimen AE-3 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 3 | 2 | 1 | 3 | - |
| INOVA Diagnostics | - | 2 | 2 | - | 2 | - |

| <u>Method</u> | Specimen AE-4 | | Specimen AE-5 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 3 | - | - | 3 |
| INOVA Diagnostics | 2 | - | - | 2 |

Specimen AE-2 is an ungraded challenge due to less than 80% participant consensus.

Anti-RNP/Sm

| <u>Method</u> | Specimen AE-1 | | Specimen AE-2 | | Specimen AE-3 | |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 8 | 7 | 1 | 8 | - |
| Diamedix | - | 1 | 1 | - | 1 | - |
| Immuno Concepts | - | 1 | - | 1 | 1 | - |
| TheraTest | - | 5 | 5 | - | 5 | - |
| Wampole | - | 1 | 1 | - | 1 | - |

| <u>Method</u> | Specimen AE-4 | | Specimen AE-5 | |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 8 | - | - | 8 |
| Diamedix | 1 | - | - | 1 |
| Immuno Concepts | 1 | - | - | 1 |
| TheraTest | 5 | - | - | 5 |
| Wampole | 1 | - | - | 1 |

Anti-SSA

| <u>Method</u> | Specimen AE-1 | | Specimen AE-2 | | Specimen AE-3 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 10 | 6 | 4 | 10 | - |
| Diamedix | - | 1 | 1 | - | 1 | - |
| INOVA Diagnostics | - | 2 | - | 2 | 2 | - |
| TheraTest | - | 5 | 5 | - | 5 | - |
| Wampole | - | 1 | - | 1 | 1 | - |

| <u>Method</u> | Specimen AE-4 | | Specimen AE-5 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 10 | - | - | 10 |
| Diamedix | 1 | - | - | 1 |
| INOVA Diagnostics | 2 | - | - | 2 |
| TheraTest | 5 | - | - | 5 |
| Wampole | 1 | - | - | 1 |

Specimen AE-2 is an ungraded challenge due to less than 80% participant consensus.

Anti-SSB

| <u>Method</u> | Specimen AE-1 | | Specimen AE-2 | | Specimen AE-3 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 10 | 3 | 7 | 10 | - |
| Diamedix | - | 1 | - | 1 | 1 | - |
| INOVA Diagnostics | - | 2 | - | 2 | 2 | - |
| TheraTest | - | 5 | 3 | 2 | 5 | - |
| Wampole | - | 1 | - | 1 | 1 | - |

| <u>Method</u> | Specimen AE-4 | | Specimen AE-5 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 10 | - | 1 | 9 |
| Diamedix | 1 | - | - | 1 |
| INOVA Diagnostics | 2 | - | - | 2 |
| TheraTest | 5 | - | 1 | 4 |
| Wampole | 1 | - | - | - |

Specimen AE-2 is an ungraded challenge due to less than 80% participant consensus.

Anti-SSA/SSB

| <u>Method</u> | Specimen AE-1 | | Specimen AE-2 | | Specimen AE-3 | |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 2 | 1 | 1 | 1 | 1 |
| Immuno Concepts | - | 1 | - | 1 | - | 1 |

| <u>Method</u> | Specimen AE-4 | | Specimen AE-5 | |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 2 | - | - | 2 |
| Immuno Concepts | 1 | - | - | 1 |

Specimens AE-2 and A-3 are ungraded challenges due to less than 80% participant consensus.

Anti-Sm

| <u>Method</u> | Specimen AE-1 | | Specimen AE-2 | | Specimen AE-3 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 10 | - | 10 | - | 10 |
| Diamedix | - | 1 | - | 1 | - | 1 |
| INOVA Diagnostics | - | 2 | - | 2 | - | 2 |
| TheraTest | - | 5 | - | 5 | - | 5 |
| Wampole | - | 1 | - | 1 | - | 1 |

| <u>Method</u> | Specimen AE-4 | | Specimen AE-5 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 6 | 4 | - | 10 |
| Diamedix | - | 1 | - | 1 |
| INOVA Diagnostics | 1 | 1 | - | 2 |
| TheraTest | 5 | - | - | 5 |
| Wampole | - | 1 | - | 1 |

Specimen AE-4 is an ungraded challenge due to less than 80% participant consensus.

Rubella—Qualitative

| <u>Method</u> | Specimen RU-1 | | Specimen RU-2 | | Specimen RU-3 | |
|------------------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 8 | 8 | - | 8 | - |
| Bayer ADVIA Centaur | - | 2 | 2 | - | 2 | - |
| bioMerieux Vidas, Mini Vidas | - | 3 | 3 | - | 3 | - |
| DiaSorin | - | 2 | 2 | - | 2 | - |
| Seradyn | - | 1 | 1 | - | 1 | - |

| <u>Method</u> | Specimen RU-4 | | Specimen RU-5 | |
|------------------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 8 | - | - | 8 |
| Bayer ADVIA Centaur | 2 | - | - | 2 |
| bioMerieux Vidas, Mini Vidas | 3 | - | - | 3 |
| DiaSorin | 2 | - | - | 2 |
| Seradyn | 1 | - | - | 1 |

Rubella—Quantitative (IU/mL)

Two labs reported results for Rubella – Quantitative (IU/mL). The vendor assay values for specimens RU-1 through RU-5 are: 0 IU/mL, 65 IU/mL, 22 IU/mL, 141 IU/mL and 0 IU/mL, respectively.

Anti-HIV

| <u>Method</u> | <u>Specimen HIV-1</u> | | <u>Specimen HIV-2</u> | |
|---|-----------------------|-----------------|-----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 33 | 33 | - |
| Inverness Clearview Complete HIV 1/2 | - | 12 | 12 | - |
| Orasure OraQuick Advance Rapid HIV-1/2 - moderate | - | 3 | 3 | - |
| Orasure OraQuick Advance Rapid HIV-1/2 - waived | - | 11 | 11 | - |
| Other Waived method | - | 7 | 7 | - |

| <u>Method</u> | <u>Specimen HIV-3</u> | | <u>Specimen HIV-4</u> | | <u>Specimen HIV-5</u> | |
|---|-----------------------|-----------------|-----------------------|-----------------|-----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 5 | 5 | - | 5 | - |
| Inverness Clearview Complete HIV 1/2 | - | 2 | 2 | - | 2 | - |
| Orasure OraQuick Advance Rapid HIV-1/2 - waived | - | 2 | 2 | - | 2 | - |
| Other Waived method | - | 1 | 1 | - | 1 | - |

Total IgE—Quantitative (U/mL)

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|------------------------|-------------|-------------|-----------|-----------|---------------|--------------|
| Specimen AL-1 | | | | | | |
| All Method | 9 | 95.2 | 11.8 | 12.4 | 93 | 59 - 131 |
| Specimen AL-2 | | | | | | |
| All Method | 9 | 119.2 | 13.2 | 11.1 | 113 | 79 - 159 |
| Specimen AL-3 | | | | | | |
| All Method | 9 | 59.3 | 9.7 | 16.4 | 53 | 30 - 89 |
| Specimen AL-4 | | | | | | |
| All Method | 9 | 21.6 | 3.6 | 16.6 | 20 | 10 - 33 |
| Specimen AL-5 | | | | | | |
| All Method | 9 | 22.6 | 4.1 | 18.2 | 20 | 10 - 35 |

Allergen Specific IgE Antibodies

Specimen AL-1

| <u>Method</u> | House Dust Mite Allergen <i>CLASS RESULT</i> | | | | | | | | Cat Epithelium Allergen <i>CLASS RESULT</i> | | | | | | | |
|---------------------------|--|-----|---|----|---|---|---|---|--|-----|---|----|---|---|---|---|
| | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 |
| ALL METHODS | 1 | 3 | 1 | 10 | 1 | 1 | - | - | 1 | - | 1 | 8 | 4 | 1 | - | - |
| DPC Immulite 2000/2500 | - | - | - | 1 | - | - | - | - | - | - | - | 1 | - | - | - | - |
| DPC-Standard Microplate | - | - | - | 1 | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Hitachi CLA-1 | 1 | 3 | - | 3 | 1 | 1 | - | - | 1 | - | - | 1 | 4 | 1 | - | - |
| Phadia ImmunoCAP Rapid | - | - | - | 2 | - | - | - | - | - | - | - | 2 | - | - | - | - |
| Phadia UniCap 100 (% ref) | - | - | - | 1 | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | 1 | 1 | - | - | - | - | - | - | 1 | 1 | - | - | - | - |
| | Common (Short) Ragweed Allergen <i>CLASS RESULT</i> | | | | | | | | English Plantain Allergen <i>CLASS RESULT</i> | | | | | | | |
| | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 |
| ALL METHODS | 1 | - | 1 | 10 | 4 | - | - | - | 4 | 1 | 7 | - | 1 | - | - | - |
| DPC Immulite 2000/2500 | - | - | - | 1 | - | - | - | - | - | - | 1 | - | - | - | - | - |
| DPC-Standard Microplate | - | - | - | 1 | - | - | - | - | - | - | 1 | - | - | - | - | - |
| Hitachi CLA-1 | 1 | - | 1 | 4 | 3 | - | - | - | 4 | 1 | 4 | - | 1 | - | - | - |
| Phadia ImmunoCAP Rapid | - | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - |
| Phadia UniCap 100 (% ref) | - | - | - | 1 | - | - | - | - | - | - | 1 | - | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | 1 | 1 | - | - | - | - | - | - | - | - | - | - | - |
| | Silver Birch Tree Allergen <i>CLASS RESULT</i> | | | | | | | | Bermuda Grass Allergen <i>CLASS RESULT</i> | | | | | | | |
| | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 |
| ALL METHODS | - | - | 2 | 1 | 2 | - | - | - | - | - | 3 | 11 | 1 | 1 | - | - |
| DPC Immulite 2000/2500 | - | - | - | - | 1 | - | - | - | - | - | - | 1 | - | - | - | - |
| DPC-Standard Microplate | - | - | - | - | 1 | - | - | - | - | - | - | 1 | - | - | - | - |
| Hitachi CLA-1 | - | - | 2 | 1 | - | - | - | - | - | - | 2 | 5 | 1 | 1 | - | - |
| Phadia ImmunoCAP Rapid | - | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - | - |
| Phadia UniCap 100 (% ref) | - | - | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | - | - | - | - | - | - | - | - | 2 | - | - | - | - |

Allergen Specific IgE Antibodies

Specimen AL-2

| <u>Method</u> | Sweet Vernal Grass Allergen | | | | | | | | Bermuda Grass Allergen | | | | | | | |
|---------------------------|------------------------------------|------------|----------|----------|----------|----------|----------|----------|-------------------------------|------------|----------|----------|----------|----------|----------|----------|
| | CLASS RESULT | | | | | | | | CLASS RESULT | | | | | | | |
| | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 |
| ALL METHODS | - | - | - | - | - | - | - | - | 1 | 2 | 7 | 7 | - | 1 | - | - |
| DPC Immulite 2000/2500 | - | - | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - |
| DPC-Standard Microplate | - | - | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Hitachi CLA-1 | - | - | - | - | - | - | - | - | 1 | 1 | 3 | 4 | - | 1 | - | - |
| Phadia ImmunoCAP Rapid | - | - | - | - | - | - | - | - | - | - | 2 | - | - | - | - | - |
| Phadia UniCap 100 (% ref) | - | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | - | - | - | - | - | - | 1 | - | 1 | - | - | - | - |

| <u>Method</u> | Dog Dander Allergen | | | | | | | | White Oak Allergen | | | | | | | |
|---------------------------|----------------------------|------------|----------|----------|----------|----------|----------|----------|---------------------------|------------|----------|----------|----------|----------|----------|----------|
| | CLASS RESULT | | | | | | | | CLASS RESULT | | | | | | | |
| | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 |
| ALL METHODS | - | - | - | 7 | 3 | 3 | - | - | 1 | 1 | 3 | 6 | 1 | - | - | - |
| DPC Immulite 2000/2500 | - | - | - | 1 | - | - | - | - | 1 | - | - | - | - | - | - | - |
| DPC-Standard Microplate | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Hitachi CLA-1 | - | - | - | 2 | 3 | 3 | - | - | - | 1 | 2 | 3 | 1 | - | - | - |
| Phadia ImmunoCAP Rapid | - | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - |
| Phadia UniCap 100 (% ref) | - | - | - | 1 | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | 1 | - | - | - | - | - | - | 1 | 1 | - | - | - | - |

| <u>Method</u> | Maple (Box Elder) Allergen | | | | | | | | House Dust Mite Allergen | | | | | | | |
|---------------------------|-----------------------------------|------------|----------|----------|----------|----------|----------|----------|---------------------------------|------------|----------|----------|----------|----------|----------|----------|
| | CLASS RESULT | | | | | | | | CLASS RESULT | | | | | | | |
| | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 |
| ALL METHODS | 5 | 5 | 3 | - | - | - | - | - | - | 1 | 3 | 7 | 1 | 4 | - | - |
| DPC Immulite 2000/2500 | 1 | - | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - |
| DPC-Standard Microplate | - | 1 | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Hitachi CLA-1 | 4 | 3 | 2 | - | - | - | - | - | - | 1 | 3 | 1 | - | 4 | - | - |
| Phadia ImmunoCAP Rapid | - | 1 | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Phadia UniCap 100 (% ref) | - | - | 1 | - | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Phadia UniCap 100 (KU/L) | 5 | 5 | 3 | - | - | - | - | - | - | - | - | 1 | 1 | - | - | - |

Maple (Box Elder) Allergen is an ungraded challenge due to less than 80% participant consensus.

| <u>Method</u> | Peanut Allergen | | | | | | | |
|---------------------------|------------------------|------------|----------|----------|----------|----------|----------|----------|
| | CLASS RESULT | | | | | | | |
| | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 |
| ALL METHODS | - | - | - | 4 | - | 4 | - | - |
| DPC Immulite 2000/2500 | - | - | - | 1 | - | - | - | - |
| DPC-Standard Microplate | - | - | - | - | - | - | - | - |
| Hitachi CLA-1 | - | - | - | - | - | 4 | - | - |
| Phadia ImmunoCAP Rapid | - | - | - | - | - | - | - | - |
| Phadia UniCap 100 (% ref) | - | - | - | 1 | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | 1 | - | - | - | - |

IgA (mg/dL)

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|------------------------|-------------|-------------|-----------|-----------|---------------|--------------|
| Specimen IMP-1 | | | | | | |
| All Method | 22 | 558.1 | 46.2 | 8.3 | 567 | 419 - 697 |
| Specimen IMP-2 | | | | | | |
| All Method | 22 | 139.3 | 13.6 | 9.8 | 138 | 98 - 181 |
| Specimen IMP-3 | | | | | | |
| All Method | 22 | 209.7 | 11.5 | 5.5 | 212 | 175 - 245 |
| Specimen IMP-4 | | | | | | |
| All Method | 22 | 186.1 | 14.4 | 7.7 | 185 | 142 - 230 |
| Specimen IMP-5 | | | | | | |
| All Method | 22 | 211.5 | 11.8 | 5.6 | 210 | 176 - 247 |

IgG (mg/dL)

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|------------------------|-------------|-------------|-----------|-----------|---------------|--------------|
| Specimen IMP-1 | | | | | | |
| All Method | 22 | 909.9 | 51.2 | 5.6 | 929 | 682 - 1138 |
| Specimen IMP-2 | | | | | | |
| All Method | 22 | 664.7 | 38.7 | 5.8 | 667 | 498 - 831 |
| Specimen IMP-3 | | | | | | |
| All Method | 22 | 929.1 | 49.8 | 5.4 | 936 | 696 - 1162 |
| Specimen IMP-4 | | | | | | |
| All Method | 22 | 1879.6 | 160.0 | 8.5 | 1912 | 1409 - 2350 |
| Specimen IMP-5 | | | | | | |
| All Method | 22 | 934.0 | 50.4 | 5.4 | 950 | 700 - 1168 |

IgM (mg/dL)

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|------------------------|-------------|-------------|-----------|-----------|---------------|--------------|
| Specimen IMP-1 | | | | | | |
| All Method | 22 | 484.4 | 28.6 | 5.9 | 487 | 398 - 571 |
| Specimen IMP-2 | | | | | | |
| All Method | 22 | 698.2 | 31.0 | 4.4 | 695 | 605 - 792 |
| Specimen IMP-3 | | | | | | |
| All Method | 22 | 102.2 | 16.8 | 16.5 | 98 | 51 - 153 |
| Specimen IMP-4 | | | | | | |
| All Method | 22 | 444.5 | 22.6 | 5.1 | 446 | 376 - 513 |
| Specimen IMP-5 | | | | | | |
| All Method | 22 | 103.0 | 15.7 | 15.2 | 99 | 55 - 151 |

Syphilis Serology—Qualitative: Treponema pallidum antibodies

| <u>Method</u> | <u>Specimen SY-1</u> | | <u>Specimen SY-2</u> | | <u>Specimen SY-3</u> | |
|------------------------|----------------------|---------------------|----------------------|---------------------|----------------------|---------------------|
| | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> |
| ALL METHODS | - | 1 | - | 1 | 1 | - |
| DPC Immulite 2000/2500 | - | 1 | - | 1 | 1 | - |

| <u>Method</u> | <u>Specimen SY-4</u> | | <u>Specimen SY-5</u> | |
|------------------------|----------------------|---------------------|----------------------|---------------------|
| | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> |
| ALL METHODS | 1 | - | 1 | - |
| DPC Immulite 2000/2500 | 1 | - | 1 | - |

Syphilis Serology—Qualitative: RPR

| <u>Method</u> | <u>Specimen SY-1</u> | | <u>Specimen SY-2</u> | | <u>Specimen SY-3</u> | |
|----------------------------|----------------------|---------------------|----------------------|---------------------|----------------------|---------------------|
| | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> |
| ALL METHODS | - | 28 | 1 | 27 | 27 | 1 |
| ASI | - | 9 | - | 9 | 9 | - |
| Becton Dickinson | - | 13 | 1 | 12 | 12 | 1 |
| Cardinal Health SP Brand | - | 1 | - | 1 | 1 | - |
| Fisher HealthCare Sure-Vue | - | 3 | - | 3 | 3 | - |
| Wampole Impact RPR | - | 1 | - | 1 | 1 | - |

| <u>Method</u> | <u>Specimen SY-4</u> | | <u>Specimen SY-5</u> | |
|----------------------------|----------------------|---------------------|----------------------|---------------------|
| | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> |
| ALL METHODS | 27 | 1 | 28 | - |
| ASI | 8 | 1 | 9 | - |
| Becton Dickinson | 13 | - | 13 | - |
| Cardinal Health SP Brand | 1 | - | 1 | - |
| Fisher HealthCare Sure-Vue | 3 | - | 3 | - |
| Wampole Impact RPR | 1 | - | 1 | - |

Syphilis Serology—Quantitative: RPR (Titer)

| <u>Specimen/Method</u> | <u>1</u> | <u>2</u> | <u>4</u> | <u>8</u> | <u>16</u> | <u>32</u> | <u>64</u> | <u>>64</u> |
|------------------------|----------|----------|----------|----------|-----------|-----------|-----------|---------------|
| Specimen SY-3 | | | | | | | | |
| ALL METHODS | - | 4 | 9 | - | - | - | - | - |
| ASI | - | 3 | 2 | - | - | - | - | - |
| Becton Dickinson | - | 1 | 6 | - | - | - | - | - |
| Specimen SY-4 | | | | | | | | |
| ALL METHODS | - | 12 | 1 | - | - | - | - | - |
| ASI | - | 4 | 1 | - | - | - | - | - |
| Becton Dickinson | - | 7 | - | - | - | - | - | - |
| Specimen SY-5 | | | | | | | | |
| ALL METHODS | - | 1 | 4 | 7 | 1 | - | - | - |
| ASI | - | 1 | 2 | 1 | 1 | - | - | - |
| Becton Dickinson | - | - | 1 | 6 | - | - | - | - |

H. pylori Antibody Detection

| <u>Method</u> | <u>Specimen HP-1</u> | | <u>Specimen HP-2</u> | |
|--|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 119 | 4 | 3 | 120 |
| Alfa Scientific Instant-View | 2 | - | - | 2 |
| Alpha Scientific Medical, Inc. | 1 | - | - | 1 |
| Beckman Coulter ICON HP | 8 | 1 | - | 9 |
| bioMerieux Vidas, Mini Vidas | 2 | - | - | 2 |
| Cardinal Health SP Brand | 7 | - | - | 7 |
| Consult Diagnostics | 14 | 2 | 2 | 14 |
| DPC Immulite 2000/2500 | - | 1 | 1 | - |
| Fisher HealthCare Sure-Vue | 5 | - | - | 5 |
| Henry Schein OneStep+ - waived | 5 | - | - | 5 |
| Inverness (Wampole) Clearview | 12 | - | - | 12 |
| McKesson Medi-Lab Performance - waived | 10 | - | - | 10 |
| Polymedco Poly stat | 4 | - | - | 4 |
| PSS Select Diagnostics | 5 | - | - | 5 |
| Quidel QuickVue | 43 | - | - | 43 |
| SDI Biomed, Inc. | 1 | - | - | 1 |

Lyme Disease Serology

| <u>Method</u> | <u>Specimen LY-1</u> | | <u>Specimen LY-2</u> | |
|---------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 4 | - | - | 4 |
| DiaSorin | 2 | - | - | 2 |

Mycoplasma Antibody

| <u>Method</u> | <u>Specimen MY-1</u> | | <u>Specimen MY-2</u> | |
|---------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 3 | 3 | - |
| Meridian ImmunoCard | - | 3 | 3 | - |

Viral Markers – Anti-HBc

| <u>Method</u> | Specimen VM-1 | | Specimen VM-2 | | Specimen VM-3 | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 3 | - | 3 | - | 3 |
| Bayer ADVIA Centaur – IgM | - | 1 | - | 1 | - | 1 |
| Bayer ADVIA Centaur – Total | - | 1 | - | 1 | - | 1 |
| VITROS ECI – Total | - | 1 | - | 1 | - | - |

| <u>Method</u> | Specimen VM-4 | | Specimen VM-5 | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 3 | - | 3 | - |
| Bayer ADVIA Centaur – IgM | 1 | - | 1 | - |
| Bayer ADVIA Centaur – Total | 1 | - | 1 | - |
| VITROS ECI – Total | 1 | - | 1 | - |

Viral Markers – Anti-HIV

| <u>Method</u> | Specimen VM-1 | | Specimen VM-2 | | Specimen VM-3 | |
|---|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 10 | 10 | - | - | 10 |
| Abbott Architect - Total | - | 1 | 1 | - | - | 1 |
| Bayer ADVIA Centaur - Total | - | 2 | 2 | - | - | 2 |
| Orasure OraQuick Advance Rapid HIV-1/2 - moderate | - | 4 | 4 | - | - | 4 |
| Orasure OraQuick Advance Rapid HIV-1/2 - waived | - | 2 | 2 | - | - | 2 |

| <u>Method</u> | Specimen VM-4 | | Specimen VM-5 | |
|---|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 10 | - | 10 |
| Abbott Architect - Total | - | 1 | - | 1 |
| Bayer ADVIA Centaur - Total | - | 2 | - | 2 |
| Orasure OraQuick Advance Rapid HIV-1/2 - moderate | - | 4 | - | 4 |
| Orasure OraQuick Advance Rapid HIV-1/2 - waived | - | 2 | - | 2 |

Viral Markers – HAV

| <u>Method</u> | <u>Specimen VM-1</u> | | <u>Specimen VM-2</u> | | <u>Specimen VM-3</u> | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 2 | - | - | 3 | 1 | 2 |
| Abbott Architect - IgM | - | - | - | 1 | - | 1 |
| Bayer ADVIA Centaur - IgM | 1 | - | - | 1 | - | 1 |
| Bayer ADVIA Centaur - Total | 1 | - | - | 1 | 1 | - |

| <u>Method</u> | <u>Specimen VM-4</u> | | <u>Specimen VM-5</u> | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 3 | - | 3 |
| Abbott Architect - IgM | - | 1 | - | 1 |
| Bayer ADVIA Centaur - IgM | - | 1 | - | 1 |
| Bayer ADVIA Centaur - Total | - | 1 | - | 1 |

Viral Markers – HBeAg

The vendor assay for specimens VM-1 through VM-5 is: Negative, Negative, Negative, Negative and Positive, respectively.

Viral Markers – HBsAb

| <u>Method</u> | <u>Specimen VM-1</u> | | <u>Specimen VM-2</u> | | <u>Specimen VM-3</u> | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 5 | - | 5 | - | 5 | - |
| Abbott AxSYM - Total | 1 | - | 1 | - | 1 | - |
| Bayer ADVIA Centaur - Total | 2 | - | 2 | - | 2 | - |
| VITROS ECI - Total | 1 | - | 1 | - | - | - |

| <u>Method</u> | <u>Specimen VM-4</u> | | <u>Specimen VM-5</u> | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 5 | - | 5 |
| Abbott AxSYM - Total | - | 1 | - | 1 |
| Bayer ADVIA Centaur - Total | - | 2 | - | 2 |
| VITROS ECI - Total | - | 1 | - | 1 |

Viral Markers – HBsAg

| <u>Method</u> | Specimen VM-1 | | Specimen VM-2 | | Specimen VM-3 | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 6 | - | 7 | - | 6 |
| Abbott Architect | - | 1 | - | 1 | - | 1 |
| Abbott Architect - Total | - | 1 | - | 1 | - | 1 |
| Bayer ADVIA Centaur - Total | - | 2 | - | 2 | - | 2 |
| Other Total Method | - | 1 | - | 1 | - | 1 |
| VITROS ECI - Total | - | 1 | - | 2 | - | 1 |

| <u>Method</u> | Specimen VM-4 | | Specimen VM-5 | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 7 | - | 7 | - |
| Abbott Architect | 1 | - | 1 | - |
| Abbott Architect - Total | 1 | - | 1 | - |
| Bayer ADVIA Centaur - Total | 2 | - | 2 | - |
| Other Total Method | 1 | - | 1 | - |
| VITROS ECI - Total | 2 | - | 2 | - |

Viral Markers – HCV

| <u>Method</u> | Specimen VM-1 | | Specimen VM-2 | | Specimen VM-3 | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 5 | - | 5 | - | 5 |
| Abbott Architect - Total | - | 2 | - | 2 | - | 2 |
| Bayer ADVIA Centaur - Total | - | 2 | - | 2 | - | 2 |
| VITROS ECI - IgG | - | 1 | - | 1 | - | 1 |

| <u>Method</u> | Specimen VM-4 | | Specimen VM-5 | |
|-----------------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 5 | - | 5 |
| Abbott AxSYM - Total | - | 2 | - | 2 |
| Bayer ADVIA Centaur - Total | - | 2 | - | 2 |
| VITROS ECI - IgG | - | 1 | - | 1 |

Medical Laboratory Evaluation

25 Massachusetts Ave NW Ste 700

Washington, DC 20001-7401

800-338-2746 • 202-261-4500 • Fax: 202-835-0440

www.acponline.org/mle