

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 9

Immunology
2019 MLE-M2



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

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Evaluation Criteria

The evaluation criteria used in the 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/semi-quantitative 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.

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

Semi-Quantitative

| | |
|----------------------------------|---------------------------|
| Antinuclear Antibody (ANA) Titer | 80% Participant Consensus |
| Anti-Streptolysin O (ASO) Titer | 80% Participant Consensus |
| Rheumatoid Factor (Titer) | 80% Participant Consensus |
| RPR Titer | 80% Participant Consensus |
| VDRL Titer | 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."

| | |
|---|------------|
| Complement C3 | ± 3 SD |
| Complement C4 | ± 3 SD |
| C-Reactive Protein | ± 3 SD |
| High Sensitivity C-Reactive Protein | ± 3 SD |
| Rheumatoid Factor (International Units) | ± 3 SD |
| Rubella (International Units) | ± 3 SD |
| Total IgA | ± 3 SD |
| Total IgE | ± 3 SD |
| Total IgG | $\pm 25\%$ |
| Total IgM | ± 3 SD |

Infectious Mononucleosis

| <u>Method</u> | <u>Specimen IM-6</u> | | <u>Specimen IM-7</u> | |
|---|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 148 | - | - | 148 |
| Alere Clearview - moderate | 1 | - | - | 1 |
| Alere Clearview - waived | 6 | - | - | 6 |
| Alere Clearview Mono Plus II - moderate | 2 | - | - | 2 |
| Alere Clearview Mono Plus II - waived | 3 | - | - | 3 |
| Beckman Coulter ICON Mono - waived | 3 | - | - | 3 |
| BioStar Aceava Mono Test | 2 | - | - | 2 |
| BioStar Aceava Mono-whole bld | 4 | - | - | 4 |
| Cardinal Health SP Brand - waived | 5 | - | - | 5 |
| Clarity Diagnostics | 1 | - | - | 1 |
| Consult Diagnostics | 21 | - | - | 21 |
| Fisher HealthCare Sure-Vue | 4 | - | - | 4 |
| Henry Schein OneStep+ - waived | 15 | - | - | 15 |
| LifeSign Status - waived | 6 | - | - | 6 |
| Other Moderate method | 4 | - | - | 4 |
| Other Waived method | 11 | - | - | 11 |
| Quidel QuickVue+ | 1 | - | - | 1 |
| Quidel QuickVue+ - waived | 4 | - | - | 4 |
| Sekisui OSOM | 5 | - | - | 5 |
| Sekisui OSOM (waived) | 47 | - | - | 47 |

Infectious Mononucleosis

| <u>Method</u> | Specimen IM-8 | | Specimen IM-9 | | Specimen IM-10 | |
|---|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 39 | - | 1 | 38 | - | 39 |
| Alere Clearview - moderate | 1 | - | - | 1 | - | 1 |
| Alere Clearview Mono Plus II - moderate | 2 | - | - | 2 | - | 2 |
| Alere Clearview Mono Plus II - waived | 1 | - | - | 1 | - | 1 |
| Beckman Coulter ICON Mono - waived | 3 | - | - | 3 | - | 3 |
| BioStar Acceava Mono Test | 1 | - | - | 1 | - | 1 |
| BioStar Acceava Mono-whole bld | 1 | - | - | 1 | - | 1 |
| Consult Diagnostics | 7 | - | 1 | 6 | - | 7 |
| Fisher HealthCare Sure-View | 1 | - | - | 1 | - | 1 |
| Henry Schein OneStep+ - waived | 2 | - | - | 2 | - | 2 |
| LifeSign Status - waived | 1 | - | - | 1 | - | 1 |
| Other Moderate method | 4 | - | - | 4 | - | 4 |
| Other Waived method | 2 | - | - | 2 | - | 2 |
| Quidel QuickVue+ | 1 | - | - | 1 | - | 1 |
| Quidel QuickVue+ - waived | 2 | - | - | 2 | - | 2 |
| Sekisui OSOM | 5 | - | - | 5 | - | 5 |
| Sekisui OSOM (waived) | 3 | - | - | 3 | - | 3 |

Rheumatoid Factor—Qualitative

| <u>Method</u> | Specimen RF-6 | | Specimen RF-7 | | Specimen RF-8 | |
|----------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 1 | 26 | 27 | - | 27 | - |
| ASI | 1 | 5 | 6 | - | 6 | - |
| Biokit Rheumajet | - | 1 | 1 | - | 1 | - |
| Diamedix | - | 1 | 1 | - | 1 | - |
| Fisher HealthCare Sure-Vue | - | 4 | 4 | - | 4 | - |
| Immunostics Inc. | - | 1 | 1 | - | 1 | - |
| INOVA Diagnostics | - | 1 | 1 | - | 1 | - |
| TheraTest | - | 5 | 5 | - | 5 | - |
| Wampole ColorCard | - | 4 | 4 | - | 4 | - |
| Wampole Rheumatex | - | 3 | 3 | - | 3 | - |

| <u>Method</u> | Specimen RF-9 | | Specimen RF-10 | |
|----------------------------|------------------------|------------------------|------------------------|------------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 27 | - | 1 | 26 |
| ASI | 6 | - | 1 | 5 |
| Biokit Rheumajet | 1 | - | - | 1 |
| Diamedix | 1 | - | - | 1 |
| Fisher HealthCare Sure-Vue | 4 | - | - | 4 |
| Immunostics Inc. | 1 | - | - | 1 |
| INOVA Diagnostics | 1 | - | - | 1 |
| TheraTest | 5 | - | - | 5 |
| Wampole ColorCard | 4 | - | - | 4 |
| Wampole Rheumatex | 3 | - | - | 3 |

Rheumatoid Factor—Semi-Quantitative (Titer)

| <u>Specimen/Method</u> | <u>N/A (Neg)</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-6 | | | | | | | | | | | | |
| ALL METHODS | 3 | - | - | - | - | - | - | - | - | - | - | - |
| Fisher HealthCare Sure-Vue | 2 | - | - | - | - | - | - | - | - | - | - | - |
| Specimen RF-7 | | | | | | | | | | | | |
| ALL METHODS | - | 1 | 2 | - | - | - | - | - | - | - | - | - |
| Fisher HealthCare Sure-Vue | - | - | 2 | - | - | - | - | - | - | - | - | - |
| Specimen RF-8 | | | | | | | | | | | | |
| ALL METHODS | - | - | 2 | 1 | - | - | - | - | - | - | - | - |
| Fisher HealthCare Sure-Vue | - | - | 1 | 1 | - | - | - | - | - | - | - | - |
| Specimen RF-9 | | | | | | | | | | | | |
| ALL METHODS | - | 1 | 2 | - | - | - | - | - | - | - | - | - |
| Fisher HealthCare Sure-Vue | - | - | 2 | - | - | - | - | - | - | - | - | - |
| Specimen RF-10 | | | | | | | | | | | | |
| ALL METHODS | 3 | - | - | - | - | - | - | - | - | - | - | - |
| Fisher HealthCare Sure-Vue | 2 | - | - | - | - | - | - | - | - | - | - | - |

Rheumatoid Factor—Quantitative (IU/mL)

| <u>Specimen/Method</u> | <u>Labs</u> | <u>Mean</u> | <u>SD</u> | <u>CV</u> | <u>Median</u> | <u>Range</u> |
|------------------------|-------------|-------------|-----------|-----------|---------------|--------------|
|------------------------|-------------|-------------|-----------|-----------|---------------|--------------|

Specimen RF-6

| | | | | | | |
|------------|----|-----|-----|------|----|--------|
| All Method | 17 | 8.4 | 4.0 | 48.2 | 7 | 0 - 21 |
| Beckman AU | 10 | 9.0 | 2.0 | 22.2 | 10 | 3 - 15 |

Specimen RF-7

| | | | | | | |
|------------|----|------|-----|------|----|---------|
| All Method | 17 | 62.9 | 7.8 | 12.5 | 66 | 39 - 87 |
| Beckman AU | 10 | 62.3 | 8.5 | 13.6 | 62 | 36 - 88 |

Specimen RF-8

| | | | | | | |
|------------|----|-------|------|-----|-----|----------|
| All Method | 17 | 127.1 | 10.8 | 8.5 | 139 | 94 - 160 |
| Beckman AU | 10 | 126.2 | 11.8 | 9.4 | 123 | 90 - 162 |

Specimen RF-9

| | | | | | | |
|------------|----|------|-----|------|----|---------|
| All Method | 17 | 63.1 | 8.4 | 13.3 | 67 | 38 - 89 |
| Beckman AU | 10 | 63.0 | 9.8 | 15.5 | 63 | 33 - 93 |

Specimen RF-10

| | | | | | | |
|------------|----|-----|-----|------|----|--------|
| All Method | 17 | 8.2 | 3.4 | 41.6 | 8 | 0 - 19 |
| Beckman AU | 10 | 8.8 | 1.6 | 18.1 | 10 | 4 - 14 |

Anti-Streptolysin O (ASO)—Qualitative

| <u>Method</u> | <u>Specimen AS-6</u> | | <u>Specimen AS-7</u> | | <u>Specimen AS-8</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-9</u> | | <u>Specimen AS-10</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-6 | | | | | | |
| All Method | 12 | 52.5 | 2.3 | 4.4 | 52 | 45 - 60 |
| Specimen IMP-7 | | | | | | |
| All Method | 12 | 151.0 | 5.3 | 3.5 | 152 | 135 - 167 |
| Specimen IMP-8 | | | | | | |
| All Method | 11 | 147.7 | 3.6 | 2.4 | 148 | 137 - 159 |
| Specimen IMP-9 | | | | | | |
| All Method | 11 | 147.0 | 3.4 | 2.3 | 146 | 136 - 158 |
| Specimen IMP-10 | | | | | | |
| All Method | 11 | 119.4 | 3.2 | 2.7 | 119 | 109 - 129 |

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-6 | | | | | | |
| All Method | 12 | 9.8 | 0.8 | 7.7 | 10 | 7 - 13 |
| Specimen IMP-7 | | | | | | |
| All Method | 12 | 30.6 | 1.7 | 5.7 | 31 | 25 - 36 |
| Specimen IMP-8 | | | | | | |
| All Method | 11 | 29.3 | 1.6 | 5.5 | 29 | 24 - 35 |
| Specimen IMP-9 | | | | | | |
| All Method | 11 | 30.5 | 1.8 | 5.8 | 30 | 25 - 36 |
| Specimen IMP-10 | | | | | | |
| All Method | 11 | 23.5 | 1.1 | 4.8 | 23 | 20 - 27 |

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-6

| | | | | | | |
|------------|----|------|-----|-----|----|---------|
| All Method | 12 | 74.2 | 5.5 | 7.5 | 75 | 57 - 91 |
| Beckman AU | 10 | 78.0 | 2.6 | 3.4 | 79 | 70 - 86 |

Specimen IMP-7

| | | | | | | |
|------------|----|-------|-----|-----|-----|-----------|
| All Method | 12 | 228.8 | 5.8 | 2.5 | 227 | 211 - 247 |
| Beckman AU | 10 | 231.0 | 6.9 | 3.0 | 227 | 210 - 252 |

Specimen IMP-8

| | | | | | | |
|------------|----|-------|-----|-----|-----|-----------|
| All Method | 12 | 215.0 | 6.0 | 2.8 | 214 | 197 - 233 |
| Beckman AU | 10 | 217.0 | 7.2 | 3.3 | 219 | 195 - 239 |

Specimen IMP-9

| | | | | | | |
|------------|----|-------|------|-----|-----|-----------|
| All Method | 12 | 472.8 | 15.1 | 3.2 | 478 | 427 - 518 |
| Beckman AU | 10 | 473.3 | 20.4 | 4.3 | 478 | 412 - 535 |

Specimen IMP-10

| | | | | | | |
|------------|----|-------|-----|-----|-----|-----------|
| All Method | 12 | 176.0 | 6.0 | 3.4 | 174 | 158 - 194 |
| Beckman AU | 10 | 179.3 | 5.0 | 2.8 | 180 | 164 - 195 |

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-6

| | | | | | | |
|------------|----|-------|------|-----|-----|-----------|
| All Method | 12 | 357.0 | 18.0 | 5.0 | 354 | 267 - 447 |
| Beckman AU | 10 | 360.3 | 12.7 | 3.5 | 354 | 270 - 451 |

Specimen IMP-7

| | | | | | | |
|------------|----|--------|-------|-----|------|-------------|
| All Method | 12 | 1902.2 | 126.9 | 6.7 | 1857 | 1426 - 2378 |
| Beckman AU | 10 | 1926.7 | 123.3 | 6.4 | 1857 | 1445 - 2409 |

Specimen IMP-8

| | | | | | | |
|------------|----|--------|------|-----|------|------------|
| All Method | 12 | 1040.6 | 47.8 | 4.6 | 1053 | 780 - 1301 |
| Beckman AU | 10 | 1060.3 | 13.6 | 1.3 | 1053 | 795 - 1326 |

Specimen IMP-9

| | | | | | | |
|------------|----|--------|------|-----|------|------------|
| All Method | 12 | 1059.6 | 75.8 | 7.2 | 1061 | 794 - 1325 |
| Beckman AU | 10 | 1091.3 | 62.3 | 5.7 | 1061 | 818 - 1365 |

Specimen IMP-10

| | | | | | | |
|------------|----|-------|------|-----|-----|------------|
| All Method | 12 | 839.6 | 35.3 | 4.2 | 848 | 629 - 1050 |
| Beckman AU | 10 | 847.0 | 5.6 | 0.7 | 848 | 635 - 1059 |

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-6 | | | | | | |
| All Method | 12 | 32.2 | 2.6 | 8.0 | 33 | 24 - 40 |
| Beckman AU | 10 | 34.0 | 1.0 | 2.9 | 34 | 31 - 37 |
| Specimen IMP-7 | | | | | | |
| All Method | 12 | 94.4 | 2.3 | 2.4 | 95 | 87 - 102 |
| Beckman AU | 10 | 95.0 | 2.6 | 2.8 | 96 | 87 - 103 |
| Specimen IMP-8 | | | | | | |
| All Method | 12 | 395.4 | 28.8 | 7.3 | 403 | 308 - 482 |
| Beckman AU | 10 | 379.7 | 27.1 | 7.1 | 386 | 298 - 461 |
| Specimen IMP-9 | | | | | | |
| All Method | 12 | 90.2 | 2.4 | 2.6 | 90 | 83 - 98 |
| Beckman AU | 10 | 91.3 | 2.1 | 2.3 | 92 | 85 - 98 |
| Specimen IMP-10 | | | | | | |
| All Method | 12 | 73.2 | 2.0 | 2.8 | 74 | 67 - 80 |
| Beckman AU | 10 | 73.3 | 2.1 | 2.8 | 74 | 67 - 80 |

C-Reactive Protein—Qualitative, Regular

| <u>Method</u> | <u>Specimen CR-3</u> | | <u>Specimen CR-4</u> | |
|-------------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 5 | - | - | 5 |
| Siemens Dimension | 5 | - | - | 5 |

C-Reactive Protein—Quantitative (mg/dL or mg/L), 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-3 | | | | | | |
| mg/dL - units | | | | | | |
| All Immunology Methods | 20 | 2.817 | 0.284 | 10.1 | 2.89 | 1.96 - 3.67 |
| mg/L - units | | | | | | |
| All Immunology Methods | 15 | 28.341 | 3.981 | 14.0 | 27.90 | 16.39 - 40.29 |
| Specimen CR-4 | | | | | | |
| mg/dL - units | | | | | | |
| All Immunology Methods | 20 | 0.145 | 0.152 | 105.3 | 0.10 | 0.00 - 0.61 |
| mg/L - units | | | | | | |
| All Immunology Methods | 15 | 1.800 | 1.961 | 108.9 | 1.00 | 0.00 - 7.69 |

C-Reactive Protein—Quantitative (mg/L), 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-3

| | | | | | | |
|------------|----|-------|-------|------|------|-------------|
| All Method | 22 | 2.480 | 0.418 | 16.9 | 2.41 | 1.22 - 3.74 |
|------------|----|-------|-------|------|------|-------------|

Specimen HCR-4

| | | | | | | |
|------------|----|--------|-------|------|-------|--------------|
| All Method | 22 | 10.527 | 1.654 | 15.7 | 10.68 | 5.56 - 15.50 |
|------------|----|--------|-------|------|-------|--------------|

Antinuclear Antibody (ANA) - Qualitative

| <u>Method</u> | <u>Specimen AE-6</u> | | <u>Specimen AE-7</u> | | <u>Specimen AE-8</u> | |
|--------------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 15 | - | - | 15 | 11 | 4 |
| ASI | 3 | - | - | 3 | - | 3 |
| Bio-Rad | 1 | - | - | 1 | 1 | - |
| GenBio ImmunoDOT Panel 1 | 1 | - | - | 1 | - | 1 |
| Immuno Concepts | 3 | - | - | 3 | 3 | - |
| INOVA Diagnostics | 2 | - | - | 2 | 2 | - |
| TheraTest | 5 | - | - | 5 | 5 | - |

| <u>Method</u> | <u>Specimen AE-9</u> | | <u>Specimen AE-10</u> | |
|--------------------------|----------------------|-----------------|-----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 12 | 3 | - | 15 |
| ASI | - | 3 | - | 3 |
| Bio-Rad | 1 | - | - | 1 |
| GenBio ImmunoDOT Panel 1 | 1 | - | - | 1 |
| Immuno Concepts | 3 | - | - | 3 |
| INOVA Diagnostics | 2 | - | - | 2 |
| TheraTest | 5 | - | - | 5 |

Antinuclear Antibody (ANA)—Semi-Quantitative (Titer)

| <u>Specimen/Method</u> | <u>N/A (Neg)</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-6 | | | | | | | | | | | | |
| ALL METHODS | - | - | - | - | - | - | - | 2 | 1 | 2 | - | - |
| Bio-Rad | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Immuno Concepts | - | - | - | - | - | - | - | 1 | 1 | 1 | - | - |
| INOVA Diagnostics | - | - | - | - | - | - | - | - | - | 1 | - | - |
| Specimen AE-7 | | | | | | | | | | | | |
| ALL METHODS | 5 | - | - | - | - | - | - | - | - | - | - | - |
| Bio-Rad | 1 | - | - | - | - | - | - | - | - | - | - | - |
| Immuno Concepts | 3 | - | - | - | - | - | - | - | - | - | - | - |
| INOVA Diagnostics | 1 | - | - | - | - | - | - | - | - | - | - | - |
| Specimen AE-8 | | | | | | | | | | | | |
| ALL METHODS | - | - | - | - | - | - | - | 2 | 1 | 1 | 1 | - |
| Bio-Rad | - | - | - | - | - | - | - | - | - | 1 | - | - |
| Immuno Concepts | - | - | - | - | - | - | - | 1 | 1 | - | 1 | - |
| INOVA Diagnostics | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Specimen AE-9 | | | | | | | | | | | | |
| ALL METHODS | - | - | - | - | - | - | 1 | 3 | 1 | - | - | - |
| Bio-Rad | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Immuno Concepts | - | - | - | - | - | - | 1 | 1 | 1 | - | - | - |
| INOVA Diagnostics | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Specimen AE-10 | | | | | | | | | | | | |
| ALL METHODS | 5 | - | - | - | - | - | - | - | - | - | - | - |
| Bio-Rad | 1 | - | - | - | - | - | - | - | - | - | - | - |
| Immuno Concepts | 3 | - | - | - | - | - | - | - | - | - | - | - |
| INOVA Diagnostics | 1 | - | - | - | - | - | - | - | - | - | - | - |

Anti-dsDNA

| <u>Method</u> | Specimen AE-6 | | Specimen AE-7 | | Specimen AE-8 | |
|--------------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 1 | 8 | - | 9 | 8 | 1 |
| GenBio ImmunoDOT Panel 1 | - | 1 | - | 1 | - | 1 |
| Immuno Concepts | - | 1 | - | 1 | 1 | - |
| INOVA Diagnostics | - | 1 | - | 1 | 1 | - |
| TheraTest | 1 | 5 | - | 6 | 6 | - |

| <u>Method</u> | Specimen AE-9 | | Specimen AE-10 | |
|--------------------------|----------------------|-----------------|-----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 9 | - | 9 |
| GenBio ImmunoDOT Panel 1 | - | 1 | - | 1 |
| Immuno Concepts | - | 1 | - | 1 |
| INOVA Diagnostics | - | 1 | - | 1 |
| TheraTest | - | 6 | - | 6 |

Anti-RNP

| <u>Method</u> | Specimen AE-6 | | Specimen AE-7 | | Specimen AE-8 | |
|-------------------|----------------------|-----------------|----------------------|-----------------|----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 2 | - | - | 2 | - | 2 |
| Immuno Concepts | 1 | - | - | 1 | - | 1 |
| INOVA Diagnostics | 1 | - | - | 1 | - | 1 |

| <u>Method</u> | Specimen AE-9 | | Specimen AE-10 | |
|-------------------|----------------------|-----------------|-----------------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 2 | - | 2 |
| Immuno Concepts | - | 1 | - | 1 |
| INOVA Diagnostics | - | 1 | - | 1 |

Anti-RNP/Sm

| <u>Method</u> | Specimen AE-6 | | Specimen AE-7 | | Specimen AE-8 | |
|--------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 8 | - | 2 | 6 | - | 8 |
| GenBio ImmunoDOT Panel 1 | 1 | - | - | 1 | - | 1 |
| Immuno Concepts | 1 | - | - | 1 | - | 1 |
| TheraTest | 6 | - | 2 | 4 | - | 6 |

| <u>Method</u> | Specimen AE-9 | | Specimen AE-10 | |
|--------------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 8 | - | 8 |
| GenBio ImmunoDOT Panel 1 | - | 1 | - | 1 |
| Immuno Concepts | - | 1 | - | 1 |
| TheraTest | - | 6 | - | 6 |

Anti-SSA

| <u>Method</u> | Specimen AE-6 | | Specimen AE-7 | | Specimen AE-8 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 8 | - | 8 | - | 8 |
| Immuno Concepts | - | 1 | - | 1 | - | 1 |
| INOVA Diagnostics | - | 1 | - | 1 | - | 1 |
| TheraTest | - | 6 | - | 6 | - | 6 |

| <u>Method</u> | Specimen AE-9 | | Specimen AE-10 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 8 | - | - | 8 |
| Immuno Concepts | 1 | - | - | 1 |
| INOVA Diagnostics | 1 | - | - | 1 |
| TheraTest | 6 | - | - | 6 |

Anti-SSB

| <u>Method</u> | Specimen AE-6 | | Specimen AE-7 | | Specimen AE-8 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 8 | - | 8 | - | 8 |
| Immuno Concepts | - | 1 | - | 1 | - | 1 |
| INOVA Diagnostics | - | 1 | - | 1 | - | 1 |
| TheraTest | - | 6 | - | 6 | - | 6 |

| <u>Method</u> | Specimen AE-9 | | Specimen AE-10 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 7 | 1 | - | 8 |
| Immuno Concepts | 1 | - | - | 1 |
| INOVA Diagnostics | 1 | - | - | 1 |
| TheraTest | 5 | 1 | - | 6 |

Anti-SSA/SSB

| <u>Method</u> | Specimen AE-6 | | Specimen AE-7 | | Specimen AE-8 | |
|--------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 1 | - | 1 | - | 1 |
| GenBio ImmunoDOT Panel 1 | - | 1 | - | 1 | - | 1 |

| <u>Method</u> | Specimen AE-9 | | Specimen AE-10 | |
|--------------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 1 | - | - | 1 |
| GenBio ImmunoDOT Panel 1 | 1 | - | - | 1 |

Anti-Sm

| <u>Method</u> | Specimen AE-6 | | Specimen AE-7 | | Specimen AE-8 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 3 | 5 | - | 8 | - | 8 |
| Immuno Concepts | - | 1 | - | 1 | - | 1 |
| INOVA Diagnostics | 1 | - | - | 1 | - | 1 |
| TheraTest | 2 | 4 | - | 6 | - | 6 |

| <u>Method</u> | Specimen AE-9 | | Specimen AE-10 | |
|-------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 8 | - | 8 |
| Immuno Concepts | - | 1 | - | 1 |
| INOVA Diagnostics | - | 1 | - | 1 |
| TheraTest | - | 6 | - | 6 |

Specimen AE-6 ungraded challenge due to less than 80% participant consensus.

Rubella—Qualitative

| <u>Method</u> | Specimen RU-6 | | Specimen RU-7 | | Specimen RU-8 | |
|-----------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 5 | - | - | 5 | 5 | - |
| INOVA Diagnostics | 2 | - | - | 2 | 2 | - |
| Siemens ADVIA Centaur | 3 | - | - | 3 | 3 | - |

| <u>Method</u> | Specimen RU-9 | | Specimen RU-10 | |
|-----------------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 5 | 5 | - |
| INOVA Diagnostics | - | 2 | 2 | - |
| Siemens ADVIA Centaur | - | 3 | 3 | - |

Rubella—Quantitative (IU/mL)

One lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values on a Beckman Access 2 for specimens RU-6 through RU-10 are: 50.0 IU/mL, <10 IU/mL, 68.8 IU/mL, <10 IU/mL, and 68.8 IU/mL, respectively.

Anti-HIV

| <u>Method</u> | Specimen HIV-6 | | Specimen HIV-7 | |
|---|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 67 | - | - | 67 |
| Alere Clearview HIV1/2 STAT-PAK | 3 | - | - | 3 |
| Alere Determine HIV - moderate | 2 | - | - | 2 |
| Alere Determine HIV - waived | 5 | - | - | 5 |
| BD LINK 2 | 2 | - | - | 2 |
| bioLytical Labs INSTI HIV - moderate | 2 | - | - | 2 |
| bioLytical Labs INSTI HIV - waived | 12 | - | - | 12 |
| Chembio HIV 1/2 Assay - waived | 10 | - | - | 10 |
| Orasure OraQuick Advance Rapid HIV-1/2 - moderate | 2 | - | - | 2 |
| Orasure OraQuick Advance Rapid HIV-1/2 - waived | 14 | - | - | 14 |
| Other Waived method | 3 | - | - | 3 |
| Trinity Biotech Uni-Gold - waived | 12 | - | - | 12 |

| <u>Method</u> | Specimen HIV-8 | | Specimen HIV-9 | | Specimen HIV-10 | |
|--------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 5 | - | - | 5 | 5 | - |
| Alere Determine HIV - moderate | 5 | - | - | 5 | 5 | - |

Allergen Specific IgE Antibodies

Specimen AL-6

Method

| | White Oak (t7) Allergen | | | | | | | Grey Alder (t2) 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 | - | - | - | 4 | - | - | - | - | - | - | - | - | 1 | - | - | - |
| Hitachi CLA-1 | - | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - |
| Hycor EIA | - | - | - | 1 | - | - | - | - | - | - | - | - | 1 | - | - | - |
| Hycor RAST (Ru/mL) | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - |

| | House Dust Mite (<i>D. farinae</i>) (d2) Allergen | | | | | | | Peanut (f13) 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 | 4 | - | - | - | - | - | - | - | 1 | 4 | 1 | - |
| Hitachi CLA-1 | - | - | - | - | 1 | - | - | - | - | - | - | - | - | 1 | 1 | - |
| Hycor EIA | - | - | - | - | 1 | - | - | - | - | - | - | - | - | 1 | - | - |
| Hycor RAST (Ru/mL) | - | - | - | - | 1 | - | - | - | - | - | - | - | - | 1 | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | 1 | - | - | - | - | - | - | - | - | 1 | - | - | - |

| | Cow Milk (f2) Allergen | | | | | | | Cladosporium herbarum (m2) 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 | - | - | 2 | 4 | - | - | - | - | 2 | 1 | 1 | 1 | - | - | - | - |
| Hitachi CLA-1 | - | - | 1 | 1 | - | - | - | - | - | - | 1 | 1 | - | - | - | - |
| Hycor EIA | - | - | - | 1 | - | - | - | - | 1 | - | - | - | - | - | - | - |
| Hycor RAST (Ru/mL) | - | - | - | 1 | - | - | - | - | 1 | - | - | - | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - |

| | English Plantain (w9) Allergen | | | | | | | |
|--------------------------|--------------------------------|-----|---|---|---|---|---|---|
| | CLASS RESULT | | | | | | | |
| | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 |
| ALL METHODS | 1 | - | 2 | - | 2 | - | - | - |
| Hitachi CLA-1 | - | - | 2 | - | - | - | - | - |
| Hycor EIA | - | - | - | - | 1 | - | - | - |
| Hycor RAST (Ru/mL) | - | - | - | - | 1 | - | - | - |
| Phadia UniCap 100 (KU/L) | 1 | - | - | - | - | - | - | - |

Allergen Specific IgE Antibodies

Specimen AL-7

| <u>Method</u> | House Dust Mite (<i>D. pteronyssinus</i>) (d1) Allergen | | | | | | | | Sweet Vernal Grass (g1) 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 | - | - | - | 4 | 1 | - | - | - | - | - | - | - | - | 2 | - | - |
| Hitachi CLA-1 | - | - | - | - | 1 | - | - | - | - | - | - | - | - | 1 | - | - |
| Hycor EIA | - | - | - | 1 | - | - | - | - | - | - | - | - | - | 1 | - | - |
| Hycor RAST (Ru/mL) | - | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - |

| <u>Method</u> | Bahia Grass (g17) Allergen | | | | | | | | Cat Epithelium (e1) 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 | - | - | - | - | 3 | - | - | - | - | - | 1 | 2 | 1 | 1 | - | - |
| Hitachi CLA-1 | - | - | - | - | - | - | - | - | - | - | - | - | 1 | 1 | - | - |
| Hycor EIA | - | - | - | - | 1 | - | - | - | - | - | 1 | - | - | - | - | - |
| Hycor RAST (Ru/mL) | - | - | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - |

| <u>Method</u> | Dog Dander (e5) Allergen | | | | | | | | Penicillium chrysogenum (m1) 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 | - | 1 | 2 | - | - | - | - | 2 | - | - | 1 | 1 | - | - | - |
| Hitachi CLA-1 | - | - | - | 2 | - | - | - | - | 1 | - | - | - | - | - | - | - |
| Hycor EIA | 1 | - | - | - | - | - | - | - | - | - | - | 1 | - | - | - | - |
| Hycor RAST (Ru/mL) | - | - | - | - | - | - | - | - | - | - | - | - | 1 | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - |

| <u>Method</u> | Alternaria alternata (m6) Allergen | | | | | | | |
|--------------------------|------------------------------------|-----|---|---|---|---|---|---|
| | CLASS RESULT | | | | | | | |
| | 0 | 0/1 | 1 | 2 | 3 | 4 | 5 | 6 |
| ALL METHODS | - | - | 6 | - | - | - | - | - |
| Hitachi CLA-1 | - | - | 2 | - | - | - | - | - |
| Hycor EIA | - | - | 1 | - | - | - | - | - |
| Hycor RAST (Ru/mL) | - | - | 1 | - | - | - | - | - |
| Phadia UniCap 100 (KU/L) | - | - | 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-6 | | | | | | |
| All Method | 5 | 464.5 | 42.4 | 9.1 | 471 | 337 - 592 |
| Specimen AL-7 | | | | | | |
| All Method | 5 | 170.0 | 32.8 | 19.3 | 174 | 71 - 269 |
| Specimen AL-8 | | | | | | |
| All Method | 5 | 17.3 | 2.6 | 15.2 | 17 | 9 - 26 |
| Specimen AL-9 | | | | | | |
| All Method | 5 | 70.3 | 18.8 | 26.7 | 70 | 13 - 127 |
| Specimen AL-10 | | | | | | |
| All Method | 5 | 17.8 | 1.9 | 10.7 | 19 | 12 - 24 |

Syphilis Serology—Qualitative: MHA-TP

| <u>Method</u> | Specimen SY-6 | | Specimen SY-7 | | Specimen SY-8 | |
|----------------------|------------------------|----------------------------|------------------------|----------------------------|------------------------|----------------------------|
| | <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 |
| Serodia | 1 | - | 1 | - | - | 1 |

| <u>Method</u> | Specimen SY-9 | | Specimen SY-10 | |
|----------------------|------------------------|----------------------------|------------------------|----------------------------|
| | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> |
| ALL METHODS | 1 | - | - | 1 |
| Serodia | 1 | - | - | 1 |

Syphilis Serology—Qualitative: Treponema pallidum antibodies

| <u>Method</u> | Specimen SY-6 | | Specimen SY-7 | | Specimen SY-8 | |
|------------------------------------|------------------------|----------------------------|------------------------|----------------------------|------------------------|----------------------------|
| | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> |
| ALL METHODS | 12 | - | 12 | - | - | 12 |
| Abbott Architect | 1 | - | 1 | - | - | 1 |
| diagnostics direct Syphilis Health | | | | | | |
| Check | 9 | - | 9 | - | - | 9 |
| INOVA Diagnostics | 1 | - | 1 | - | - | 1 |
| Siemens ADVIA Centaur | 1 | - | 1 | - | - | 1 |

| <u>Method</u> | Specimen SY-9 | | Specimen SY-10 | |
|------------------------------------|------------------------|----------------------------|------------------------|----------------------------|
| | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> |
| ALL METHODS | 12 | - | - | 12 |
| Abbott Architect | 1 | - | - | 1 |
| diagnostics direct Syphilis Health | | | | |
| Check | 9 | - | - | 9 |
| INOVA Diagnostics | 1 | - | - | 1 |
| Siemens ADVIA Centaur | 1 | - | - | 1 |

Syphilis Serology—Qualitative: RPR

| <u>Method</u> | Specimen SY-6 | | Specimen SY-7 | | Specimen SY-8 | |
|----------------------------|------------------------|----------------------------|------------------------|----------------------------|------------------------|----------------------------|
| | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> |
| ALL METHODS | 15 | - | 15 | - | - | 15 |
| ASI | 7 | - | 7 | - | - | 7 |
| Becton Dickinson | 5 | - | 5 | - | - | 5 |
| Fisher HealthCare Sure-Vue | 3 | - | 3 | - | - | 3 |

| <u>Method</u> | Specimen SY-9 | | Specimen SY-10 | |
|----------------------------|------------------------|----------------------------|------------------------|----------------------------|
| | <u>Reactive</u> | <u>Non-Reactive</u> | <u>Reactive</u> | <u>Non-Reactive</u> |
| ALL METHODS | 14 | 1 | - | 15 |
| ASI | 6 | 1 | - | 7 |
| Becton Dickinson | 5 | - | - | 5 |
| Fisher HealthCare Sure-Vue | 3 | - | - | 3 |

Syphilis Serology—Semi-Quantitative: RPR (Titer)

| <u>Specimen/Method</u> | <u>N/A</u> <u>(Neg)</u> | <u>1:1</u> | <u>1:2</u> | <u>1:4</u> | <u>1:8</u> | <u>1:16</u> | <u>1:32</u> | <u>1:64</u> | <u>1:>64</u> |
|------------------------|----------------------------|------------|------------|------------|------------|-------------|-------------|-------------|-----------------|
|------------------------|----------------------------|------------|------------|------------|------------|-------------|-------------|-------------|-----------------|

Specimen SY-6

| | | | | | | | | | |
|------------------|---|---|---|---|---|---|---|---|---|
| ALL METHODS | - | - | 6 | 1 | - | - | - | - | - |
| ASI | - | - | 2 | 1 | - | - | - | - | - |
| Becton Dickinson | - | - | 4 | - | - | - | - | - | - |

Specimen SY-7

| | | | | | | | | | |
|------------------|---|---|---|---|---|---|---|---|---|
| ALL METHODS | - | 1 | - | 5 | 1 | - | - | - | - |
| ASI | - | 1 | - | 1 | 1 | - | - | - | - |
| Becton Dickinson | - | - | - | 4 | - | - | - | - | - |

Specimen SY-8

| | | | | | | | | | |
|------------------|---|---|---|---|---|---|---|---|---|
| ALL METHODS | 7 | - | - | - | - | - | - | - | - |
| ASI | 3 | - | - | - | - | - | - | - | - |
| Becton Dickinson | 4 | - | - | - | - | - | - | - | - |

Specimen SY-9

| | | | | | | | | | |
|------------------|---|---|---|---|---|---|---|---|---|
| ALL METHODS | 1 | - | 4 | 2 | - | - | - | - | - |
| ASI | 1 | - | - | 2 | - | - | - | - | - |
| Becton Dickinson | - | - | 4 | - | - | - | - | - | - |

Specimen SY-10

| | | | | | | | | | |
|------------------|---|---|---|---|---|---|---|---|---|
| ALL METHODS | 7 | - | - | - | - | - | - | - | - |
| ASI | 3 | - | - | - | - | - | - | - | - |
| Becton Dickinson | 4 | - | - | - | - | - | - | - | - |

H. pylori Antibody Detection

| <u>Method</u> | Specimen HP-3 | | Specimen HP-4 | |
|--|------------------------|------------------------|------------------------|------------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | 50 | 1 | - | 51 |
| Alere Clearview - moderate | 3 | - | - | 3 |
| Cardinal Health SP Brand | 1 | - | - | 1 |
| Consult Diagnostics | 13 | 1 | - | 14 |
| Fisher HealthCare Sure-View | 2 | - | - | 2 |
| Henry Schein OneStep+ - waived | 8 | - | - | 8 |
| McKesson Medi-Lab Performance - waived | 1 | - | - | 1 |
| NDC Pro Advantage | 2 | - | - | 2 |
| Polymedco Poly stat | 1 | - | - | 1 |
| Quidel QuickVue | 17 | - | - | 17 |
| Sekisui OSOM | 1 | - | - | 1 |

Mycoplasma Antibody

| <u>Method</u> | Specimen MY-3 | | Specimen MY-4 | |
|----------------------|------------------------|------------------------|------------------------|------------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Positive</u> | <u>Negative</u> |
| ALL METHODS | - | 7 | 7 | - |
| Meridian ImmunoCard | - | 7 | 7 | - |

Viral Markers – Anti-HBc (IgM)

| <u>Method</u> | <u>Specimen VM-6</u> | | | <u>Specimen VM-7</u> | | | <u>Specimen VM-8</u> | | |
|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | 4 | - | - | - | 4 | - | - | 4 | - |
| Abbott Architect | 2 | - | - | - | 2 | - | - | 2 | - |
| Siemens ADVIA | | | | | | | | | |
| Centaur | 1 | - | - | - | 1 | - | - | 1 | - |
| VITROS 5600 | 1 | - | - | - | 1 | - | - | 1 | - |

| <u>Method</u> | <u>Specimen VM-9</u> | | | <u>Specimen VM-10</u> | | |
|------------------|----------------------|-----------------|------------------|-----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 4 | - | - | 4 | - |
| Abbott Architect | - | 2 | - | - | 2 | - |
| Siemens ADVIA | | | | | | |
| Centaur | - | 1 | - | - | 1 | - |
| VITROS 5600 | - | 1 | - | - | 1 | - |

Viral Markers – Anti-HBc (Total/IgG)

| <u>Method</u> | <u>Specimen VM-6</u> | | | <u>Specimen VM-7</u> | | | <u>Specimen VM-8</u> | | |
|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | 1 | - | - | - | 1 | - | 1 | - | - |
| Abbott Architect | 1 | - | - | - | 1 | - | 1 | - | - |

| <u>Method</u> | <u>Specimen VM-9</u> | | | <u>Specimen VM-10</u> | | |
|------------------|----------------------|-----------------|------------------|-----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 1 | - | - | 1 | - |
| Abbott Architect | - | 1 | - | - | 1 | - |

Viral Markers – Anti-HIV

| <u>Method</u> | Specimen VM-6 | | | Specimen VM-7 | | | Specimen VM-8 | | |
|--|----------------------|-----------------|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 8 | - | - | 8 | - | - | 8 | - |
| Abbott Architect | - | 3 | - | - | 3 | - | - | 3 | - |
| bioLytical Labs INSTI HIV - moderate | - | 1 | - | - | 1 | - | - | 1 | - |
| Orasure OraQuick Advance Rapid HIV- 1/2 - waived | - | 3 | - | - | 3 | - | - | 3 | - |
| Siemens ADVIA Centaur | - | 1 | - | - | 1 | - | - | 1 | - |

| <u>Method</u> | Specimen VM-9 | | | Specimen VM-10 | | |
|--|----------------------|-----------------|------------------|-----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 8 | - | 8 | - | - |
| Abbott Architect | - | 3 | - | 3 | - | - |
| bioLytical Labs INSTI HIV - moderate | - | 1 | - | 1 | - | - |
| Orasure OraQuick Advance Rapid HIV- 1/2 - waived | - | 3 | - | 3 | - | - |
| Siemens ADVIA Centaur | - | 1 | - | 1 | - | - |

Viral Markers – Anti-HAV (IgM)

| <u>Method</u> | Specimen VM-6 | | | Specimen VM-7 | | | Specimen VM-8 | | |
|--------------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 4 | - | - | 4 | - | - | 4 | - |
| Abbott Architect | - | 2 | - | - | 2 | - | - | 2 | - |
| Siemens ADVIA Centaur | - | 1 | - | - | 1 | - | - | 1 | - |
| VITROS 5600 | - | 1 | - | - | 1 | - | - | 1 | - |

| <u>Method</u> | Specimen VM-9 | | | Specimen VM-10 | | |
|--------------------------|----------------------|-----------------|------------------|-----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 4 | - | - | 4 | - |
| Abbott Architect | - | 2 | - | - | 2 | - |
| Siemens ADVIA Centaur | - | 1 | - | - | 1 | - |
| VITROS 5600 | - | 1 | - | - | 1 | - |

Viral Markers – Anti-HAV (Total/IgG)

| <u>Method</u> | <u>Specimen VM-6</u> | | | <u>Specimen VM-7</u> | | | <u>Specimen VM-8</u> | | |
|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 3 | - | 3 | - | - | - | 3 | - |
| Abbott Architect | - | 2 | - | 2 | - | - | - | 2 | - |
| Siemens ADVIA | | | | | | | | | |
| Centaur | - | 1 | - | 1 | - | - | - | 1 | - |

| <u>Method</u> | <u>Specimen VM-9</u> | | | <u>Specimen VM-10</u> | | |
|------------------|----------------------|-----------------|------------------|-----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | 3 | - | - | 3 | - | - |
| Abbott Architect | 2 | - | - | 2 | - | - |
| Siemens ADVIA | | | | | | |
| Centaur | 1 | - | - | 1 | - | - |

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-6 through VM-10 are: Negative, Negative, Negative, Negative, and Negative, respectively.

Viral Markers – Anti-HBs

| <u>Method</u> | <u>Specimen VM-6</u> | | | <u>Specimen VM-7</u> | | | <u>Specimen VM-8</u> | | |
|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 3 | - | 3 | - | - | 3 | - | - |
| Abbott Architect | - | 2 | - | 2 | - | - | 2 | - | - |
| Siemens ADVIA | | | | | | | | | |
| Centaur | - | 1 | - | 1 | - | - | 1 | - | - |

| <u>Method</u> | <u>Specimen VM-9</u> | | | <u>Specimen VM-10</u> | | |
|------------------|----------------------|-----------------|------------------|-----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 3 | - | 3 | - | - |
| Abbott Architect | - | 2 | - | 2 | - | - |
| Siemens ADVIA | | | | | | |
| Centaur | - | 1 | - | 1 | - | - |

Viral Markers – HBsAg

| <u>Method</u> | Specimen VM-6 | | | Specimen VM-7 | | | Specimen VM-8 | | |
|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | 6 | - | - | - | 6 | - | - | 6 | - |
| Abbott Architect | 3 | - | - | - | 3 | - | - | 3 | - |
| Siemens ADVIA | | | | | | | | | |
| Centaur | 2 | - | - | - | 2 | - | - | 2 | - |
| VITROS 5600 | 1 | - | - | - | 1 | - | - | 1 | - |

| <u>Method</u> | Specimen VM-9 | | | Specimen VM-10 | | |
|------------------|----------------------|-----------------|------------------|-----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 6 | - | - | 6 | - |
| Abbott Architect | - | 3 | - | - | 3 | - |
| Siemens ADVIA | | | | | | |
| Centaur | - | 2 | - | - | 2 | - |
| VITROS 5600 | - | 1 | - | - | 1 | - |

Viral Markers – Anti-HCV

| <u>Method</u> | Specimen VM-6 | | | Specimen VM-7 | | | Specimen VM-8 | | |
|-------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | - | 10 | - | - | 10 | - | - | 10 | - |
| Abbott Architect | - | 3 | - | - | 3 | - | - | 3 | - |
| OraSure OraQuick | | | | | | | | | |
| HCV | - | 3 | - | - | 3 | - | - | 3 | - |
| Roche cobas e 411 | - | 1 | - | - | 1 | - | - | 1 | - |
| Siemens ADVIA | | | | | | | | | |
| Centaur | - | 2 | - | - | 2 | - | - | 2 | - |
| VITROS 5600 | - | 1 | - | - | 1 | - | - | 1 | - |

| <u>Method</u> | Specimen VM-9 | | | Specimen VM-10 | | |
|-------------------|----------------------|-----------------|------------------|-----------------------|-----------------|------------------|
| | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> | <u>Positive</u> | <u>Negative</u> | <u>Equivocal</u> |
| ALL METHODS | 10 | - | - | - | 10 | - |
| Abbott Architect | 3 | - | - | - | 3 | - |
| OraSure OraQuick | | | | | | |
| HCV | 3 | - | - | - | 3 | - |
| Roche cobas e 411 | 1 | - | - | - | 1 | - |
| Siemens ADVIA | | | | | | |
| Centaur | 2 | - | - | - | 2 | - |
| VITROS 5600 | 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