

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 8

Immunology
2018 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)	± 2 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	168	2	-	170
Alere Clearview - moderate	2	-	-	2
Alere Clearview - waived	7	-	-	7
Alere Clearview Mono Plus II - moderate	1	-	-	1
Alere Clearview Mono Plus II - waived	5	-	-	5
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	10	-	-	10
BioStar Aceava Mono Test	1	-	-	1
BioStar Aceava Mono-whole bld	4	-	-	4
BTNX Rapid Response – moderate	1	-	-	1
Cardinal Health SP Brand - waived	6	-	-	6
Clarity Diagnostics	1	-	-	1
Consult Diagnostics	23	-	-	23
Fisher HealthCare Sure-Vue	5	-	-	5
Henry Schein OneStep+ - waived	16	-	-	16
LifeSign Status - waived	8	-	-	8
McKesson Medi-Lab Performance - waived	1	-	-	1
Other Moderate method	3	-	-	3
Other Waived method	11	1	-	12
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	3	1	-	4
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	53	-	-	53
Seradyn	1	-	-	1

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	49	-	2	47	48	1
Alere Clearview - moderate	2	-	-	2	2	-
Alere Clearview Mono Plus II - moderate	1	-	-	1	1	-
Alere Clearview Mono Plus II - waived	1	-	-	1	1	-
ASI	1	-	-	1	1	-
Beckman Coulter ICON Mono - waived	9	-	-	9	9	-
BioStar Acceava Mono-whole bld	2	-	1	1	1	1
BTNX Rapid Response – moderate	1	-	-	1	1	-
Consult Diagnostics	6	-	-	6	6	-
Fisher HealthCare Sure-View	2	-	-	2	2	-
Henry Schein OneStep+ - waived	4	-	-	4	4	-
LifeSign Status - waived	1	-	-	1	1	-
Other Moderate method	3	-	-	3	3	-
Other Waived method	2	-	-	2	2	-
Quidel QuickVue+	1	-	-	1	1	-
Quidel QuickVue+ - waived	2	-	-	2	2	-
Sekisui OSOM	4	-	-	4	4	-
Sekisui OSOM (waived)	6	-	-	6	6	-
Seradyn	1	-	1	-	1	-

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-6		Specimen RF-7		Specimen RF-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	31	-	-	31	30	1
ASI	9	-	-	9	9	-
Biokit Rheumajet	2	-	-	2	2	-
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	4	-	-	4	4	-

<u>Method</u>	Specimen RF-9		Specimen RF-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	31	31	-
ASI	-	9	9	-
Biokit Rheumajet	-	2	2	-
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	-	4	4	-

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	-	-	2	1	-	1	-	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	1	-	-	-	-	-	-
Specimen RF-7												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	1	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-8												
ALL METHODS	-	-	2	1	-	1	-	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	1	-	-	-	-	-	-
Specimen RF-9												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	1	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-10												
ALL METHODS	-	-	1	3	-	-	-	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	1	1	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	1	-	-	-	-	-	-	-	-

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	12	115.4	9.1	7.9	118	97 - 134
Specimen RF-7						
All Method	13	8.7	3.5	40.5	9	1 - 16
Specimen RF-8						
All Method	12	67.5	8.6	12.7	68	50 - 85
Specimen RF-9						
All Method	13	9.2	3.7	40.6	9	1 - 17
Specimen RF-10						
All Method	12	67.5	7.9	11.7	68	51 - 84

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
<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		

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	154.1	4.4	2.8	154	141 - 168
Specimen IMP-7						
All Method	12	157.2	8.2	5.2	156	132 - 182
Specimen IMP-8						
All Method	12	165.3	4.5	2.7	165	151 - 179
Specimen IMP-9						
All Method	12	69.3	2.1	3.0	69	63 - 76
Specimen IMP-10						
All Method	12	178.8	6.7	3.8	179	158 - 199

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	30.8	2.2	7.2	32	24 - 38
Specimen IMP-7						
All Method	12	28.8	2.8	9.9	29	20 - 38
Specimen IMP-8						
All Method	12	33.3	2.5	7.4	33	25 - 41
Specimen IMP-9						
All Method	12	13.3	0.8	5.7	13	10 - 16
Specimen IMP-10						
All Method	12	36.2	2.6	7.3	37	28 - 45

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	10	209.3	4.3	2.1	211	196 - 223
Specimen IMP-7						
All Method	10	218.5	6.7	3.0	217	198 - 239
Specimen IMP-8						
All Method	10	497.5	34.0	6.8	505	395 - 600
Specimen IMP-9						
All Method	10	94.0	4.8	5.1	96	79 - 109
Specimen IMP-10						
All Method	10	249.8	9.7	3.9	248	220 - 279

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	10	1048.8	70.4	6.7	1042	786 - 1311
Specimen IMP-7						
All Method	10	1092.5	51.9	4.8	1083	819 - 1366
Specimen IMP-8						
All Method	10	1106.5	72.7	6.6	1089	829 - 1384
Specimen IMP-9						
All Method	10	466.0	12.9	2.8	465	349 - 583
Specimen IMP-10						
All Method	10	1909.5	115.7	6.1	1853	1432 - 2387

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	10	91.5	3.7	4.0	92	80 - 103
Specimen IMP-7						
All Method	10	433.8	59.7	13.8	453	254 - 613
Specimen IMP-8						
All Method	10	96.0	4.7	4.9	98	81 - 111
Specimen IMP-9						
All Method	10	40.5	1.7	4.3	40	35 - 46
Specimen IMP-10						
All Method	10	110.3	5.7	5.2	111	93 - 128

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	-	11	11	-
Fisher HealthCare Sure-View	-	8	8	-
Siemens Dimension	-	2	2	-
Wampole	-	1	1	-

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	0.156	0.165	106.4	0.10	0.00 - 0.66
mg/L - units						
All Immunology Methods	16	2.338	2.590	110.8	1.35	0.00 - 10.11
Specimen CR-4						
mg/dL - units						
All Immunology Methods	19	1.238	0.175	14.1	1.30	0.71 - 1.77
mg/L - units						
All Immunology Methods	16	15.274	4.819	31.6	12.70	0.81 - 29.74

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	20	10.036	0.639	6.4	10.02	8.12 - 11.96
Specimen HCR-4						
All Method	20	2.554	0.505	19.8	2.49	1.03 - 4.07

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	-	14	13	1	-	14
ASI	-	2	2	-	-	2
Bio-Rad	-	1	1	-	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	3	3	-	-	3
INOVA Diagnostics	-	3	3	-	-	3
TheraTest	-	4	4	-	-	4

<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	14	-	12	2
ASI	2	-	-	2
Bio-Rad	1	-	1	-
GenBio ImmunoDOT Panel 1	1	-	1	-
Immuno Concepts	3	-	3	-
INOVA Diagnostics	3	-	3	-
TheraTest	4	-	4	-

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	4	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-7												
ALL METHODS	-	-	-	-	-	-	2	-	2	-	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	-	2	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-	-
Specimen AE-8												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-9												
ALL METHODS	-	-	-	-	-	1	1	1	1	-	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	1	-	-	1	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
Specimen AE-10												
ALL METHODS	-	-	-	-	-	-	1	2	1	-	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	-	1	-	-	-
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	-	10	1	9	-	10
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
TheraTest	-	6	1	5	-	6

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	9	1	9
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	1	-
INOVA Diagnostics	-	2	-	2
TheraTest	1	5	-	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	1	8	5	4	1	8
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	1	5	5	1	1	5

Specimen AE-7 ungraded challenge due to less than 80% participant consensus.

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	1	-	9
GenBio ImmunoDOT Panel 1	1	-	-	1
Immuno Concepts	1	-	-	1
INOVA Diagnostics	1	-	-	1
TheraTest	5	1	-	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	-	9	-	9	-	9
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
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	-	9	9	-
Immuno Concepts	-	1	1	-
INOVA Diagnostics	-	2	2	-
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	-	9	-	9	-	9
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
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	-	9	8	1
Immuno Concepts	-	1	1	-
INOVA Diagnostics	-	2	2	-
TheraTest	-	6	5	1

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	-	9	-	9	-	9
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
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	1	8	-	9
Immuno Concepts	-	1	-	1
INOVA Diagnostics	1	1	-	2
TheraTest	-	6	-	6

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	-
bioMerieux Vidas, Mini Vidas	2	-	-	2	2	-
DiaSorin	1	-	-	1	1	-
INOVA Diagnostics	1	-	-	1	1	-
Siemens ADVIA Centaur	1	-	-	1	1	-

<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
bioMerieux Vidas, Mini Vidas	2	-	-	2
DiaSorin	1	-	-	1
INOVA Diagnostics	1	-	-	1
Siemens ADVIA Centaur	1	-	-	1

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: 57.4 IU/mL, <10 IU/mL, 57.4 IU/mL, 36.8 IU/mL, and <10 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	62	-	3	59
Alere Clearview Complete HIV 1/2	1	-	-	1
Alere Clearview HIV1/2 STAT-PAK	4	-	-	4
Alere Determine HIV - moderate	4	-	1	3
Alere Determine HIV - waived	4	-	1	3
BD LINK 2	2	-	-	2
bioLytical Labs INSTI HIV - waived	10	-	-	10
Chembio HIV 1/2 Assay - waived	5	-	-	5
Orasure OraQuick Advance Rapid HIV-1/2 - waived	14	-	1	13
Other Waived method	4	-	-	4
Trinity Biotech Uni-Gold - waived	13	-	-	13

<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

<u>Method</u>	Orchard Grass (Cocksfoot) (g3) Allergen CLASS RESULT								Meadow Fescue (g4) Allergen CLASS RESULT								
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6	
	ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia Unicap 100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-

<u>Method</u>	Wheat (f4) Allergen CLASS RESULT								Apple (f49) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
	ALL METHODS	1	-	2	1	-	-	-	-	-	-	2	-	-	1	-
DPC-Standard Microplate	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-
Phadia Unicap 100	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-

<u>Method</u>	Cashew Nut (f443) Allergen CLASS RESULT								Dog Dander (e5) Allergen 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	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	1	-	-	-	-	-	-	-
Phadia Unicap 100	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-

<u>Method</u>	House Dust Mite (D. farinae) (d2) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
	ALL METHODS	-	-	-	3	2	1	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-7

<u>Method</u>	Sheep Sorrel (w18) Allergen								Common (Short) Ragweed (w1) Allergen							
	<i>CLASS RESULT</i>								<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	-	-	-	-	-	3	2	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	1	-	1	-	-	-	-	-	-	1	-	-	-
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-
Phadia Unicap 100	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
	Silver Birch Tree (t3) Allergen								Maple (Box Elder) (t1) Allergen							
	<i>CLASS RESULT</i>								<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	2	-	-	-	-	1	1	1	2	-	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	1	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia Unicap 100	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-
	Bermuda Grass (g2) Allergen								Perennial Rye (g5) Allergen							
	<i>CLASS RESULT</i>								<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	-	-	-	-	-	-	-	-	1	1	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Phadia Unicap 100	-	-	1	-	-	-	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-
	Cockroach - German (i6) Allergen															
	<i>CLASS RESULT</i>															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	-	-	-	-	1	-	-	-								
DPC-Standard Microplate	-	-	-	-	-	-	-	-								
Hitachi CLA-1	-	-	-	-	-	-	-	-								
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-								
Phadia Unicap 100	-	-	-	-	-	-	-	-								
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-								

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	546.7	24.5	4.5	545	473 - 621
Specimen AL-7						
All Method	5	556.3	26.6	4.8	554	476 - 637
Specimen AL-8						
All Method	5	19.0	0.1	0.0	19	18 - 20
Specimen AL-9						
All Method	5	62.3	6.4	10.3	65	43 - 82
Specimen AL-10						
All Method	5	19.0	0.1	0.0	19	18 - 20

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 diagnostics direct Syphilis Health Check	1	-	1	-	1	-
INOVA Diagnostics	9	-	9	-	9	-
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 diagnostics direct Syphilis Health Check	-	1	-	1
INOVA Diagnostics	-	9	-	9
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	16	1	16	1	17	-
ASI	4	-	4	-	4	-
Becton Dickinson	7	-	7	-	7	-
Fisher HealthCare Sure-View	3	-	3	-	3	-
Stanbio Laboratory	-	1	-	1	1	-
Wampole Impact RPR	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	-	17	-	17
ASI	-	4	-	4
Becton Dickinson	-	7	-	7
Fisher HealthCare Sure-View	-	3	-	3
Stanbio Laboratory	-	1	-	1
Wampole Impact RPR	-	1	-	1

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>
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Specimen SY-6

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

Specimen SY-7

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

Specimen SY-8

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

Specimen SY-9

ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
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	59	1	1	59
Alere Clearview - moderate	5	-	-	5
Alfa Scientific Instant-View	1	-	-	1
Beckman Coulter ICON HP	1	-	-	1
BTNX Rapid Response - waived	1	-	-	1
Cardinal Health SP Brand	1	-	-	1
Consult Diagnostics	18	-	-	18
Fisher HealthCare Sure-View	2	-	-	2
Henry Schein OneStep+ - waived	7	1	1	7
McKesson Medi-Lab Performance - waived	2	-	-	2
NDC Pro Advantage	1	-	-	1
Polymedco Poly stat	1	-	-	1
Quidel QuickVue	18	-	-	18
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	2	-	-	2
Meridian ImmunoCard	2	-	-	2

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	-	3	-	-	3	-	-	3	-
Abbott Architect	-	1	-	-	1	-	-	1	-
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	-	3	-	-	3	-
Abbott Architect	-	1	-	-	1	-
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	-	6	-	-	6	-	4	2	-
Abbott Architect	-	3	-	-	3	-	3	-	-
bioLytical Labs INSTI									
HIV - moderate	-	1	-	-	1	-	-	1	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	-	1	-	-	1	-	-	1	-
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	-	6	-	6	-	-
Abbott Architect	-	3	-	3	-	-
bioLytical Labs INSTI						
HIV - moderate	-	1	-	1	-	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	-	1	-	1	-	-
Siemens ADVIA						
Centaur	-	1	-	1	-	-

Specimen VM-8 is an ungraded challenge due to less than 80% participant consensus

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	-	3	-	-	3	-	3	-	-
Abbott Architect	-	1	-	-	1	-	1	-	-
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	-	3	-	-	3	-
Abbott Architect	-	1	-	-	1	-
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	-	2	-	2	-	-	2	-	-
Abbott Architect	-	1	-	1	-	-	1	-	-
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	2	-	-	2	-	-
Abbott Architect	1	-	-	1	-	-
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 Positive, 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	5	-	-	-	5	-	-	5	-
Abbott Architect	3	-	-	-	3	-	-	3	-
Siemens ADVIA									
Centaur	2	-	-	-	2	-	-	2	-

<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	5	-	-	5	-	-
Abbott Architect	3	-	-	3	-	-
Siemens ADVIA						
Centaur	2	-	-	2	-	-

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	-	5	-	-	5	-	-	5	-
Abbott Architect	-	2	-	-	2	-	-	2	-
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	-	5	-	-	5	-
Abbott Architect	-	2	-	-	2	-
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	-	7	-	7	-	-	1	6	-
Abbott Architect	-	2	-	2	-	-	-	2	-
OraSure OraQuick									
HCV	-	1	-	1	-	-	-	1	-
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	1	6	-	-	7	-
Abbott Architect	-	2	-	-	2	-
OraSure OraQuick						
HCV	-	1	-	-	1	-
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

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