

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 6

Immunology
2016 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 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
Lyme Disease Serology	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

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."

Antinuclear Antibody (ANA) Titer	Not Evaluated
Anti-Streptolysin O (ASO) Titer	Not Evaluated
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
Rheumatoid Factor (Titer)	Not Evaluated
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>	Specimen IM-6		Specimen IM-7	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	190	1	-	191
Alere Clearview - moderate	4	-	-	4
Alere Clearview - waived	4	-	-	4
Alere Clearview Mono Plus II - moderate	1	-	-	1
Alere Clearview Mono Plus II - waived	7	-	-	7
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	10	-	-	10
BioStar Aceava Mono Test	2	-	-	2
BioStar Aceava Mono-whole bld	5	-	-	5
Cardinal Health SP Brand - waived	9	-	-	9
Consult Diagnostics	23	-	-	23
Fisher HealthCare Sure-Vue	9	-	-	9
Henry Schein OneStep+ - waived	13	1	-	14
Immunostics Inc.	1	-	-	1
LifeSign Status - waived	5	-	-	5
McKesson Medi-Lab Performance - waived	3	-	-	3
Other Moderate method	6	-	-	6
Other Waived method	11	-	-	11
Quidel QuickVue+	2	-	-	2
Quidel QuickVue+ - waived	13	-	-	13
Sekisui OSOM	3	-	-	3
Sekisui OSOM (waived)	53	-	-	53
Seradyn	1	-	-	1
Wampole ColorCard	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	66	-	-	66	66	-
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	10	-	-	10	10	-
BioStar Acceava Mono-whole bld	2	-	-	2	2	-
Cardinal Health SP Brand - waived	1	-	-	1	1	-
Consult Diagnostics	9	-	-	9	9	-
Fisher HealthCare Sure-Vue	5	-	-	5	5	-
Henry Schein OneStep+ - waived	4	-	-	4	4	-
LifeSign Status - waived	1	-	-	1	1	-
Other Moderate method	6	-	-	6	6	-
Other Waived method	2	-	-	2	2	-
Quidel QuickVue+	2	-	-	2	2	-
Quidel QuickVue+ - waived	2	-	-	2	2	-
Sekisui OSOM	3	-	-	3	3	-
Sekisui OSOM (waived)	10	-	-	10	10	-
Seradyn	1	-	-	1	1	-
Wampole ColorCard	1	-	-	1	1	-

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	-	39	-	39	39	-
Abbott Architect	-	1	-	1	1	-
ASI	-	10	-	10	10	-
Biokit Rheumajet	-	4	-	4	4	-
Diamedix	-	1	-	1	1	-
Fisher HealthCare Sure-Vue	-	3	-	3	3	-
Immunostics Inc.	-	1	-	1	1	-
Teco Diagnostics	-	1	-	1	1	-
TheraTest	-	4	-	4	4	-
Wampole ColorCard	-	9	-	9	9	-
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	39	-	-	39
Abbott Architect	1	-	-	1
ASI	10	-	-	10
Biokit Rheumajet	4	-	-	4
Diamedix	1	-	-	1
Fisher HealthCare Sure-Vue	3	-	-	3
Immunostics Inc.	1	-	-	1
Teco Diagnostics	1	-	-	1
TheraTest	4	-	-	4
Wampole ColorCard	9	-	-	9
Wampole Rheumatex	4	-	-	4

Rheumatoid Factor—Quantitative (Titer)

<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>	<u>N/A (Neg)</u>
Specimen RF-6												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-	3
Wampole ColorCard	-	-	-	-	-	-	-	-	-	-	-	1
Specimen RF-7												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-	3
Wampole ColorCard	-	-	-	-	-	-	-	-	-	-	-	1
Specimen RF-8												
ALL METHODS	4	-	1	2	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	3	-	-	2	-	-	1	-	-	-	-	-
Wampole ColorCard	1	-	1	-	-	-	-	-	-	-	-	-
Specimen RF-9												
ALL METHODS	4	-	2	1	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	3	-	1	1	-	1	-	-	-	-	-	-
Wampole ColorCard	1	-	1	-	-	-	-	-	-	-	-	-
Specimen RF-10												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-	3
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	23	5.5	4.2	77.0	5	0 - 14
Specimen RF-7						
All Method	23	5.6	4.3	77.7	5	0 - 15
Specimen RF-8						
All Method	23	138.3	28.5	20.6	130	81 - 196
Specimen RF-9						
All Method	23	138.9	29.4	21.1	130	80 - 198
Specimen RF-10						
All Method	23	5.4	4.2	77.2	5	0 - 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><i>Specimen/Method</i></u>	<u><i>Labs</i></u>	<u><i>Mean</i></u>	<u><i>SD</i></u>	<u><i>CV</i></u>	<u><i>Median</i></u>	<u><i>Range</i></u>
Specimen IMP-6						
All Method	13	145.5	7.6	5.2	145	122 - 169
Specimen IMP-7						
All Method	13	143.5	5.8	4.1	144	126 - 161
Specimen IMP-8						
All Method	13	62.5	3.3	5.3	62	52 - 73
Specimen IMP-9						
All Method	13	144.4	5.2	3.6	145	128 - 160
Specimen IMP-10						
All Method	13	149.8	4.5	3.0	151	136 - 164

Complement C4 (mg/dL)

<u><i>Specimen/Method</i></u>	<u><i>Labs</i></u>	<u><i>Mean</i></u>	<u><i>SD</i></u>	<u><i>CV</i></u>	<u><i>Median</i></u>	<u><i>Range</i></u>
Specimen IMP-6						
All Method	13	29.8	1.5	5.1	29	25 - 35
Specimen IMP-7						
All Method	13	29.6	1.4	4.9	30	25 - 34
Specimen IMP-8						
All Method	13	12.2	1.1	8.9	12	8 - 16
Specimen IMP-9						
All Method	13	29.3	1.7	5.6	29	24 - 35
Specimen IMP-10						
All Method	13	31.3	2.2	6.9	32	24 - 38

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	13	211.4	16.4	7.8	205	162 - 261
Specimen IMP-7						
All Method	13	520.0	25.4	4.9	512	443 - 597
Specimen IMP-8						
All Method	13	86.8	4.9	5.7	85	71 - 102
Specimen IMP-9						
All Method	13	208.6	15.1	7.2	204	163 - 254
Specimen IMP-10						
All Method	13	211.0	14.1	6.7	207	168 - 254

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	13	1043.5	62.6	6.0	1050	782 - 1305
Specimen IMP-7						
All Method	13	1006.0	58.6	5.8	1006	754 - 1258
Specimen IMP-8						
All Method	13	443.8	18.1	4.1	444	332 - 555
Specimen IMP-9						
All Method	13	1037.0	62.1	6.0	1030	777 - 1297
Specimen IMP-10						
All Method	13	1051.9	67.7	6.4	1053	788 - 1315

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	13	96.1	8.5	8.8	94	70 - 122
Specimen IMP-7						
All Method	13	171.1	12.6	7.4	171	133 - 210
Specimen IMP-8						
All Method	13	39.3	2.5	6.4	39	31 - 47
Specimen IMP-9						
All Method	13	95.9	8.8	9.2	94	69 - 123
Specimen IMP-10						
All Method	13	475.6	75.2	15.8	482	249 - 702

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	<u>Specimen AN-6</u>		<u>Specimen AN-7</u>		<u>Specimen AN-8</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5	1	5
Diagnostic Technology	-	3	-	3	1	2
Wampole	-	2	-	2	-	2

<u>Method</u>	<u>Specimen AN-9</u>		<u>Specimen AN-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5
Diagnostic Technology	-	3	-	3
Wampole	-	2	-	2

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	-	12	12	-
ASI	-	1	1	-
Fisher HealthCare Sure-Vue	-	8	8	-
Immunostics Inc.	-	1	1	-
Siemens Dimension/AR/ES/RxL/Xpand	-	2	2	-

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-3						
mg/dL - units						
Siemens Dimension/AR/ES/RxL/Xpand	10	0.150	0.071	47.1	0.20	0.00 - 0.37
All Immunology Methods	26	0.193	0.172	89.4	0.19	0.00 - 0.71
mg/L - units						
All Immunology Methods	14	1.722	2.039	118.4	0.65	0.00 - 7.84
Specimen CR-4						
mg/dL - units						
Siemens Dimension/AR/ES/RxL/Xpand	10	3.268	0.185	5.7	3.26	2.71 - 3.83
All Immunology Methods	27	3.049	0.402	13.2	3.08	1.84 - 4.26
mg/L - units						
All Immunology Methods	15	29.883	6.603	22.1	27.70	10.07 - 49.70

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-3						
All Method	38	1.570	0.400	25.5	1.56	0.36 - 2.78
Beckman AU	11	1.688	1.189	70.4	1.51	0.00 - 5.26
Specimen HCR-4						
All Method	37	29.805	2.309	7.7	29.89	22.87 - 36.74
Beckman AU	11	29.930	1.920	6.4	29.45	24.16 - 35.70

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

<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	10	-	10	-	-	10
Diamedix	1	-	1	-	-	1
Immuno Concepts	3	-	3	-	-	3
INOVA Diagnostics	2	-	2	-	-	2
Phadia Elia	1	-	1	-	-	1
TheraTest	2	-	2	-	-	2

<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	-	10	8	2
Diamedix	-	1	-	1
Immuno Concepts	-	3	3	-
INOVA Diagnostics	-	2	2	-
Phadia Elia	-	1	-	1
TheraTest	-	2	2	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

<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>	<u>N/A (Neg)</u>
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Specimen AE-6

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

Specimen AE-7

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

Specimen AE-8

ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	3
Immuno Concepts	-	-	-	-	-	-	-	-	-	-	-	2
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	1

Specimen AE-9

ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	3
Immuno Concepts	-	-	-	-	-	-	-	-	-	-	-	2
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	1

Specimen AE-10

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

Anti-dsDNA

<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	-	8	8	-	-	8
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	1	1	-	-	1
Phadia ELIA	-	1	1	-	-	1

<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	-	8	-	8
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
Phadia ELIA	-	1	-	1

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	3	-	3	-	-	3
Immuno Concepts	1	-	1	-	-	1
INOVA Diagnostics	1	-	1	-	-	1
Phadia ELIA	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	-	3	-	3
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
Phadia ELIA	-	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	6	-	6	-	-	6
Immuno Concepts	1	-	1	-	-	1
TheraTest	5	-	5	-	-	5

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

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	-	1	7
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	1	1	-	-	1
Phadia ELIA	-	1	1	-	-	1
TheraTest	-	5	5	-	1	4

<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
Phadia ELIA	-	1	-	1
TheraTest	-	5	-	5

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	-	1	7
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	1	1	-	-	1
Phadia ELIA	-	1	1	-	-	1
TheraTest	-	5	5	-	1	4

<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
Phadia ELIA	-	1	-	1
TheraTest	-	5	-	5

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
Immuno Concepts	-	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
Immuno Concepts	-	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	-	8	2	6	-	8
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	1	-	-	1
Phadia ELIA	-	1	1	-	-	1
TheraTest	-	5	-	5	-	5

<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
Phadia ELIA	-	1	-	1
TheraTest	-	5	-	5

Specimen AE-7 is an 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	6	-	-	6	-	6
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	1
DiaSorin	2	-	-	2	-	2
Roche cobas e 411	1	-	-	1	-	1
Siemens ADVIA Centaur	2	-	-	2	-	2

<u>Method</u>	Specimen RU-9		Specimen RU-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	6	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
DiaSorin	-	2	2	-
Roche cobas e 411	-	1	1	-
Siemens ADVIA Centaur	-	2	2	-

Rubella—Quantitative (IU/mL)

One lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values for specimens RU-6 through RU-10 are: 23.2 IU/mL, 0.1 IU/mL, 0.1 IU/mL, 0.1 IU/mL and 33.3 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	61	2	61	2
Alere Clearview Complete HIV 1/2	6	-	6	-
Alere Clearview HIV1/2 STAT-PAK	8	1	8	1
BD LINK 2	1	-	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	21	-	21	-
Other Waived method	13	-	13	-
Trinity Biotech Uni-Gold - waived	11	-	11	-

<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 Clearview HIV1/2 STAT-PAK	5	-	-	5	-	5

Allergen Specific IgE Antibodies

Specimen AL-6

Method

	House Dust Mite (<i>D. pteronyssinus</i>) (d1) Allergen <i>CLASS RESULT</i>								Dog Dander (e5) 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	-	-	-	3	2	1	-	-	-	-	1	1	2	2	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	1	2	1	-	-	-	-	1	-	2	2	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Wheat (f4) Allergen <i>CLASS RESULT</i>								Bermuda Grass (g2) 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	2	1	-	-	-	-	-	-	1	4	1	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	1	-	1	-	-	-	-	-	-	1	2	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-

	Meadow Fescue (g4) Allergen <i>CLASS RESULT</i>								Common (Short) Ragweed (w1) 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	-	2	2	1	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	1	-	-	2	1	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-

	Russian Thistle (w11) Allergen <i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	1	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	1	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-7

Method

ALL METHODS
DPC-Standard Microplate
Hitachi CLA-1
Phadia UniCap 100 (% ref)

House Dust Mite (D. farinae) (d2) Allergen CLASS RESULT								Cat Epithelium (e1) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	-	-	3	-	2	-	-	-	-	-	-	1	2	3	-
-	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-
-	-	-	1	-	2	-	-	-	-	-	-	-	1	3	-
-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-

ALL METHODS
DPC-Standard Microplate
Hitachi CLA-1
Phadia UniCap 100 (% ref)

Bahia Grass (g17) Allergen CLASS RESULT								Timothy Grass (g6) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	-	-	1	3	1	-	-	-	-	-	-	-	1	3	-
-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	2	1	-	-	-	-	-	-	-	3	-	-
-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-

ALL METHODS
DPC-Standard Microplate
Hitachi CLA-1
Phadia UniCap 100 (% ref)

Maple (Box Elder) (t1) Allergen CLASS RESULT								White Oak (t7) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	-	4	1	-	-	-	-	-	-	-	-	2	3	-	-
-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
-	-	2	1	-	-	-	-	-	-	-	-	1	3	-	-
-	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-

ALL METHODS
DPC-Standard Microplate
Hitachi CLA-1
Phadia UniCap 100 (% ref)

Sheep Sorrel (w18) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6
-	-	1	2	2	1	-	-
-	-	-	1	-	-	-	-
-	-	1	-	2	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-6						
All Method	5	468.0	13.5	2.9	467	427 - 509
Specimen AL-7						
All Method	5	657.0	40.0	6.1	659	536 - 778
Specimen AL-8						
All Method	5	21.0	2.0	9.5	21	15 - 27
Specimen AL-9						
All Method	5	21.7	0.6	2.7	22	19 - 24
Specimen AL-10						
All Method	5	21.3	2.1	9.8	22	15 - 28

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	-	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	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	-	17	17	-	-	17
ASI	-	5	5	-	-	5
Becton Dickinson	-	7	7	-	-	7
Fisher HealthCare Sure-Vue	-	3	3	-	-	3
Wampole Impact RPR	-	2	2	-	-	2

<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	5	-	5	-
Becton Dickinson	7	-	7	-
Fisher HealthCare Sure-Vue	3	-	3	-
Wampole Impact RPR	2	-	2	-

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</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>	<u>N/A</u> <u>(Neg)</u>
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Specimen SY-6

ALL METHODS	-	-	-	-	-	-	-	-	8
ASI	-	-	-	-	-	-	-	-	3
Becton Dickinson	-	-	-	-	-	-	-	-	4
Wampole Impact RPR	-	-	-	-	-	-	-	-	1

Specimen SY-7

ALL METHODS	-	4	3	-	-	-	-	-	-
ASI	-	1	1	-	-	-	-	-	-
Becton Dickinson	-	2	2	-	-	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-	-	-

Specimen SY-8

ALL METHODS	-	-	-	-	-	-	-	-	8
ASI	-	-	-	-	-	-	-	-	3
Becton Dickinson	-	-	-	-	-	-	-	-	4
Wampole Impact RPR	-	-	-	-	-	-	-	-	1

Specimen SY-9

ALL METHODS	-	4	3	-	-	-	-	-	-
ASI	-	1	1	-	-	-	-	-	-
Becton Dickinson	-	2	2	-	-	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-	-	-

Specimen SY-10

ALL METHODS	-	-	6	1	-	-	-	-	1
ASI	-	-	2	-	-	-	-	-	1
Becton Dickinson	-	-	3	1	-	-	-	-	-
Wampole Impact RPR	-	-	1	-	-	-	-	-	-

Syphilis Serology—Qualitative: diagnostics direct Syphilis Health Check Treponema pallidum antibodies

<u>Method</u>	Specimen SHC-6		Specimen SHC-7		Specimen SHC-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
diagnostics direct Syphilis Health Check	-	8	8	-	-	8

<u>Method</u>	Specimen SHC-9		Specimen SHC-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
diagnostics direct Syphilis Health Check	8	-	8	-

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	74	1	-	75
Alere Clearview - moderate	6	-	-	6
Alfa Scientific Instant-View	1	-	-	1
Beckman Coulter ICON HP	1	-	-	1
Cardinal Health SP Brand	3	-	-	3
Cardinal Health SP Brand - waived	1	-	-	1
Consult Diagnostics	19	-	-	19
Fisher HealthCare Sure-View	2	-	-	2
Henry Schein OneStep+ - waived	10	-	-	10
Immunostics Inc.	1	-	-	1
McKesson Medi-Lab Performance - waived	2	1	-	3
PSS Select Diagnostics	1	-	-	1
Quidel QuickVue	24	-	-	24
SDI Biomed, Inc.	1	-	-	1

Lyme Disease Serology

<u>Method</u>	Specimen LY-3		Specimen LY-4	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	2	-
DiaSorin	-	2	2	-

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	3	-	-	3
Meridian ImmunoCard	3	-	-	3

Viral Markers – Anti-HBc (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	-	6	-	4	-	2	-	6	-
Abbott Architect	-	2	-	1	-	1	-	2	-
Siemens ADVIA									
Centaur	-	3	-	3	-	-	-	3	-
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	-	2	-	-	2	-
Siemens ADVIA						
Centaur	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total/IgG)

<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	-	-	1	4	-
Abbott Architect	-	1	-	1	-	-	-	1	-
Roche cobas e 411	-	1	-	1	-	-	1	-	-
Siemens ADVIA									
Centaur	-	3	-	3	-	-	-	3	-

<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	1	-	-	-	1	-
Roche cobas e 411	1	-	-	-	1	-
Siemens ADVIA						
Centaur	3	-	-	-	3	-

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	-	9	-	-	9	-	-	9	-
Abbott Architect	-	5	-	-	5	-	-	5	-
Siemens ADVIA	-	3	-	-	3	-	-	3	-

<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	9	-	-	1	8	-
Abbott Architect	5	-	-	-	5	-
Siemens ADVIA	3	-	-	1	2	-

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	6	-	-	-	6	-	-	6	-
Abbott Architect	2	-	-	-	2	-	-	2	-
Siemens ADVIA	3	-	-	-	3	-	-	3	-
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	-	2	-	-	2	-
Siemens ADVIA	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

<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	1	-	-	-	1	-	-	1	-
Siemens ADVIA	4	-	-	-	4	-	-	4	-

<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	1	-	-	1	-	-
Siemens ADVIA	4	-	-	4	-	-

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

<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	2	-	-	2	-	-
Siemens ADVIA						
Centaur	3	-	-	3	-	-

Viral Markers – HBsAg

<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	-	10	-	10	-	-	-	10	-
Abbott Architect	-	3	-	3	-	-	-	3	-
Roche cobas e 411	-	1	-	1	-	-	-	1	-
Siemens ADVIA									
Centaur	-	4	-	4	-	-	-	4	-
Siemens									
Immulin/1000	-	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	-	10	-	-	10	-
Abbott Architect	-	3	-	-	3	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA						
Centaur	-	4	-	-	4	-
Siemens						
Immulin/1000	-	1	-	-	1	-
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	2	11	-	2	11	-	13	-	-
Abbott Architect	-	4	-	-	4	-	4	-	-
OraSure OraQuick									
HCV	-	1	-	-	1	-	1	-	-
Roche cobas e 411	2	-	-	2	-	-	2	-	-
Siemens ADVIA									
Centaur	-	5	-	-	5	-	5	-	-
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	-	13	-	13	-	-
Abbott Architect	-	4	-	4	-	-
OraSure OraQuick						
HCV	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-
Siemens ADVIA						
Centaur	-	5	-	5	-	-
VITROS 5600	-	1	-	1	-	-

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