

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 6

Immunology
2016 MLE-M1

ACP | Medical Laboratory
Evaluation 

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	\pm 3 SD
Complement C4	\pm 3 SD
C-Reactive Protein	\pm 3 SD
High Sensitivity C-Reactive Protein	\pm 3 SD
Rheumatoid Factor (International Units)	\pm 2 SD
Rheumatoid Factor (Titer)	Not Evaluated
Rubella (International Units)	\pm 3 SD
Total IgA	\pm 3 SD
Total IgE	\pm 3 SD
Total IgG	\pm 25%
Total IgM	\pm 3 SD

Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-1</u>		<u>Specimen IM-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	179	180	1
Alere Clearview - moderate	-	3	3	-
Alere Clearview - waived	-	8	8	-
Alere Clearview Mono Plus II - moderate	-	2	2	-
Alere Clearview Mono Plus II - waived	-	3	3	-
ASI	-	1	1	-
Beckman Coulter ICON Mono - waived	-	10	10	-
BioStar Acceava Mono Test	-	2	2	-
BioStar Acceava Mono-whole bld	-	4	4	-
Cardinal Health SP Brand - waived	-	8	8	-
Consult Diagnostics	-	23	23	-
Fisher HealthCare Sure-Vue	-	10	10	-
Henry Schein OneStep+ - waived	-	15	15	-
LifeSign Status - waived	1	3	4	-
McKesson Medi-Lab Performance - waived	1	3	3	1
Other Moderate method	-	6	6	-
Other Waived method	-	8	8	-
Quidel QuickVue+ - waived	-	10	10	-
Sekisui OSOM	-	5	5	-
Sekisui OSOM (waived)	-	51	51	-
Wampole ColorCard	-	1	1	-

Infectious Mononucleosis

<u>Method</u>	Specimen IM-3		Specimen IM-4		Specimen IM-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	63	63	-	62	1
Alere Clearview - moderate	-	1	1	-	1	-
Alere Clearview Mono Plus II - moderate	-	2	2	-	2	-
Alere Clearview Mono Plus II - waived	-	1	1	-	1	-
ASI	-	1	1	-	1	-
Beckman Coulter ICON Mono - waived	-	10	10	-	10	-
BioStar Aceava Mono-whole bld	-	2	2	-	2	-
Cardinal Health SP Brand - waived	-	1	1	-	1	-
Consult Diagnostics	-	8	8	-	8	-
Fisher HealthCare Sure-Vue	-	5	5	-	5	-
Henry Schein OneStep+ - waived	-	5	5	-	5	-
LifeSign Status - waived	-	1	1	-	1	-
Other Moderate method	-	6	6	-	6	-
Other Waived method	-	2	2	-	2	-
Quidel QuickVue+ - waived	-	2	2	-	2	-
Sekisui OSOM	-	3	3	-	3	-
Sekisui OSOM (waived)	-	10	10	-	10	-
Wampole ColorCard	-	1	1	-	-	1

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-1		Specimen RF-2		Specimen RF-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	38	38	-	-	38
Abbott Architect	-	1	1	-	-	1
ASI	-	10	10	-	-	10
Biokit Rheumajet	-	3	3	-	-	3
Diamedix	-	1	1	-	-	1
Fisher HealthCare Sure-Vue	-	4	4	-	-	4
Immunostics Inc.	-	1	1	-	-	1
Teco Diagnostics	-	1	1	-	-	1
TheraTest	-	4	4	-	-	4
Wampole ColorCard	-	7	7	-	-	7
Wampole Rheumatex	-	4	4	-	-	4

<u>Method</u>	Specimen RF-4		Specimen RF-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	38	38	-
Abbott Architect	-	1	1	-
ASI	-	10	10	-
Biokit Rheumajet	-	3	3	-
Diamedix	-	1	1	-
Fisher HealthCare Sure-Vue	-	4	4	-
Immunostics Inc.	-	1	1	-
Teco Diagnostics	-	1	1	-
TheraTest	-	4	4	-
Wampole ColorCard	-	7	7	-
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-1												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
ASI	-	-	-	-	-	-	-	-	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-	2
Wampole ColorCard	-	-	-	-	-	-	-	-	-	-	-	1
Specimen RF-2												
ALL METHODS	1	2	-	-	-	1	-	-	-	-	-	-
ASI	-	-	-	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	1	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	1	-	-	-	-	-	-	-	-	-	-
Specimen RF-3												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
ASI	-	-	-	-	-	-	-	-	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-	2
Wampole ColorCard	-	-	-	-	-	-	-	-	-	-	-	1
Specimen RF-4												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
ASI	-	-	-	-	-	-	-	-	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-	2
Wampole ColorCard	-	-	-	-	-	-	-	-	-	-	-	1
Specimen RF-5												
ALL METHODS	-	1	2	-	-	-	1	-	-	-	-	-
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-1						
All Method	20	4.0	3.9	98.3	4	0 - 12
Specimen RF-2						
All Method	20	55.9	2.9	5.2	56	50 - 62
Specimen RF-3						
All Method	20	4.1	3.9	93.9	4	0 - 12
Specimen RF-4						
All Method	20	4.2	4.1	97.7	4	0 - 13
Specimen RF-5						
All Method	21	155.7	46.2	29.7	137	63 - 249

Anti-Streptolysin O (ASO)—Qualitative

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

Complement C3 (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-1						
All Method	12	97.6	17.9	18.3	91	44 - 152
Specimen IMP-2						
All Method	12	86.8	16.2	18.6	81	38 - 136
Specimen IMP-3						
All Method	12	91.8	14.4	15.6	88	48 - 135
Specimen IMP-4						
All Method	10	63.7	11.6	18.1	63	29 - 99
Specimen IMP-5						
All Method	12	123.3	18.2	14.8	120	68 - 178

Complement C4 (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-1						
All Method	12	20.8	1.5	7.3	21	16 - 26
Specimen IMP-2						
All Method	12	19.5	1.2	6.0	20	15 - 24
Specimen IMP-3						
All Method	12	18.3	0.9	4.8	18	15 - 21
Specimen IMP-4						
All Method	10	14.0	2.2	15.8	13	7 - 21
Specimen IMP-5						
All Method	12	25.8	3.2	12.2	25	16 - 36

IgA (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-1						
All Method	9	157.6	10.6	6.7	156	125 - 190
Specimen IMP-2						
All Method	9	551.1	25.7	4.7	548	474 - 629
Specimen IMP-3						
All Method	9	133.4	8.6	6.4	133	107 - 160
Specimen IMP-4						
All Method	8	177.0	14.4	8.2	177	133 - 221
Specimen IMP-5						
All Method	9	218.8	21.2	9.7	214	155 - 283

IgG (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-1						
All Method	9	1996.4	103.1	5.2	1981	1497 - 2496
Specimen IMP-2						
All Method	9	942.7	43.1	4.6	935	707 - 1179
Specimen IMP-3						
All Method	9	2173.9	149.0	6.9	2120	1630 - 2718
Specimen IMP-4						
All Method	8	804.9	41.5	5.2	807	603 - 1007
Specimen IMP-5						
All Method	9	935.0	38.5	4.1	934	701 - 1169

IgM (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-1						
All Method	9	69.7	6.2	9.0	68	50 - 89
Specimen IMP-2						
All Method	8	606.8	49.4	8.1	614	458 - 756
Specimen IMP-3						
All Method	8	605.1	96.8	16.0	640	314 - 896
Specimen IMP-4						
All Method	7	654.1	79.8	12.2	673	414 - 894
Specimen IMP-5						
All Method	9	99.9	20.4	20.4	86	38 - 161

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	<u>Specimen AN-1</u>		<u>Specimen AN-2</u>		<u>Specimen AN-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5	5	-
ASI	3	-	-	3	3	-
Diagnostic Technology	1	-	-	1	1	-
Teco Diagnostics	1	-	-	1	1	-

<u>Method</u>	<u>Specimen AN-4</u>		<u>Specimen AN-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	5	-
ASI	-	3	3	-
Diagnostic Technology	-	1	1	-
Teco Diagnostics	-	1	1	-

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-1</u>		<u>Specimen CR-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	-	12
ASI	1	-	-	1
Fisher HealthCare Sure-Vue	8	-	-	8
Siemens Dimension/AR/ES/RxL/Xpand	2	-	-	2
Wampole	1	-	-	1

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CR-1						
mg/dL - units						
All Immunology Methods	24	2.779	0.477	17.2	2.66	1.34 - 4.22
mg/L - units						
All Immunology Methods	13	26.822	4.647	17.3	25.90	12.88 - 40.77
Specimen CR-2						
mg/dL - units						
All Immunology Methods	23	0.147	0.143	96.8	0.10	0.00 - 0.58
mg/L - units						
All Immunology Methods	13	1.481	1.899	128.3	0.30	0.00 - 7.18

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen HCR-1						
All Method	38	1.019	0.349	34.2	1.00	0.00 - 2.07
Specimen HCR-2						
All Method	37	12.799	1.072	8.4	12.91	9.58 - 16.02

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

<u>Method</u>	<u>Specimen AE-1</u>		<u>Specimen AE-2</u>		<u>Specimen AE-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	2	-	11	10	1
Diamedix	-	1	-	1	1	-
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-
Immuno Concepts	3	-	-	3	2	1
INOVA Diagnostics	2	-	-	2	2	-
TheraTest	2	-	-	1	1	-

<u>Method</u>	<u>Specimen AE-4</u>		<u>Specimen AE-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	-	11
Diamedix	1	-	-	1
GenBio ImmunoDOT Panel 1	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>
Specimen AE-1												
ALL METHODS	-	-	-	-	-	-	-	3	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	2	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
Specimen AE-2												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	3
Immuno Concepts	-	-	-	-	-	-	-	-	-	-	-	2
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	1
Specimen AE-3												
ALL METHODS	-	-	-	-	-	-	-	3	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	2	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
Specimen AE-4												
ALL METHODS	-	-	-	-	-	-	1	1	1	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	-	1	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
Specimen AE-5												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	3
Immuno Concepts	-	-	-	-	-	-	-	-	-	-	-	2
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	1

Anti-dsDNA

<u>Method</u>	<u>Specimen AE-1</u>		<u>Specimen AE-2</u>		<u>Specimen AE-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8	8	-
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-
INOVA Diagnostics	-	1	-	1	1	-
Phadia EliA	-	1	-	1	1	-
TheraTest	-	5	-	5	5	-

<u>Method</u>	<u>Specimen AE-4</u>		<u>Specimen AE-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8
GenBio ImmunoDOT Panel 1	-	1	-	1
INOVA Diagnostics	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	5	-	5

Anti-RNP

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	-	2
INOVA Diagnostics	-	1	-	1
Phadia Elia	-	1	-	1

Anti-RNP/Sm

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7	6	1
Diamedix	-	1	-	1	1	-
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
TheraTest	-	5	-	5	5	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
Diamedix	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1
TheraTest	-	5	-	5

Anti-SSA

<u>Method</u>	<u>Specimen AE-1</u>		<u>Specimen AE-2</u>		<u>Specimen AE-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	1	1	6	7	-
INOVA Diagnostics	-	-	-	1	1	-
Phadia ELIA	-	1	-	1	1	-
TheraTest	5	-	1	4	5	-

<u>Method</u>	<u>Specimen AE-4</u>		<u>Specimen AE-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	-	7
INOVA Diagnostics	1	-	-	1
Phadia ELIA	1	-	-	1
TheraTest	5	-	-	5

Anti-SSB

<u>Method</u>	<u>Specimen AE-1</u>		<u>Specimen AE-2</u>		<u>Specimen AE-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7	7	-
INOVA Diagnostics	-	1	-	1	1	-
Phadia ELIA	-	1	-	1	1	-
TheraTest	-	5	-	5	5	-

<u>Method</u>	<u>Specimen AE-4</u>		<u>Specimen AE-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	-	7
INOVA Diagnostics	1	-	-	1
Phadia ELIA	1	-	-	1
TheraTest	5	-	-	5

Anti-SSA/SSB

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

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

Anti-Sm

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7	1	5
INOVA Diagnostics	-	1	-	1	1	-
Phadia EliA	-	1	-	1	-	5
TheraTest	-	5	-	5	1	5

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
INOVA Diagnostics	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	5	-	5

Rubella—Qualitative

<u>Method</u>	Specimen RU-1		Specimen RU-2		Specimen RU-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	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-4		Specimen RU-5	
	<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-1 through RU-5 are: 0 IU/mL, 28 IU/mL, 119 IU/mL, 0.1 IU/mL and 43 IU/mL, respectively.

Anti-HIV

<u>Method</u>	Specimen HIV-1		Specimen HIV-2	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	57	57	1
Alere Clearview Complete HIV 1/2	-	8	8	-
Alere Clearview HIV1/2 STAT-PAK	-	3	3	-
Alere Determine HIV 1/2 Ag/Ab Combo	-	1	1	-
BD LINK 2	-	2	2	-
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	21	22	-
Other Waived method	-	8	8	-
Trinity Biotech Uni-Gold - waived	-	13	12	1

<u>Method</u>	Specimen HIV-3		Specimen HIV-4		Specimen HIV-5	
	<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 1/2 Ag/Ab Combo	-	5	5	-	5	-

Allergen Specific IgE Antibodies

Specimen AL-1

Method	Common (Short) Ragweed (w1) Allergen								English Plantain (w9) Allergen							
	CLASS RESULT								CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	1	2	-	-	-	-	-	-	4	1	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	2	-	-	-	-	-	-	2	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Peanut (f13) Allergen								Dog Dander (e5) 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	3	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	3	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-

	Orchard Grass (g3) Allergen								White Oak (t7) Allergen							
	CLASS RESULT								CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	1	2	1	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	2	1	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-

	Maple (Box Elder) (t1) Allergen							
	CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	3	2	-	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-
Hitachi CLA-1	-	-	1	2	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-2

<u>Method</u>	Natural Latex (k82) Allergen								House Dust Mite (D. pteronyssinus) (d1) Allergen							
	CLASS RESULT								CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	1	-	-	-	-	-	-	-	-	-	2	2	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-
Phadia UniCap 100 (% ref)	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-
	Cat Epithelium (e1) Allergen								Timothy Grass (g6) 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	3	-	-	-	-	-	-	-	4	-	-
DPC-Standard Microplate	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	3	-	-	-	-	-	-	-	3	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-
	Meadow, Kentucky Blue, June Grass (g8) Allergens								Silver Birch Tree (t3) 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	-	-	-	1	2	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	1	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	1	-	-	-	-	-	1	-	-	-	-
	Walnut Tree Pollen (t10) Allergen															
	CLASS RESULT															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	-	-	-	2	-	-	-	-								
DPC-Standard Microplate	-	-	-	-	-	-	-	-								
Hitachi CLA-1	-	-	-	1	-	-	-	-								
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-								

Total IgE—Quantitative (U/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen AL-1						
All Method	5	712.5	37.5	5.3	713	600 - 825
Specimen AL-2						
All Method	5	668.0	67.9	10.2	668	464 - 872
Specimen AL-3						
All Method	5	37.0	4.2	11.5	37	24 - 50
Specimen AL-4						
All Method	5	21.5	0.7	3.3	22	19 - 24
Specimen AL-5						
All Method	5	21.0	1.4	6.7	21	16 - 26

VDRL Slide

<u>Method</u>	Specimen SY-1			Specimen SY-2		
	<i>Reactive</i>	<i>Weakly Reactive</i>	<u>Non-Reactive</u>	<i>Reactive</i>	<i>Weakly Reactive</i>	<u>Non-Reactive</u>
ALL METHODS	-	-	1	-	-	1
ASI	-	-	1	-	-	1

<u>Method</u>	Specimen SY-3			Specimen SY-4		
	<i>Reactive</i>	<i>Weakly Reactive</i>	<u>Non-Reactive</u>	<i>Reactive</i>	<i>Weakly Reactive</i>	<u>Non-Reactive</u>
ALL METHODS	-	-	1	1	-	-
ASI	-	-	1	1	-	-

<u>Method</u>	Specimen SY-5		
	<i>Reactive</i>	<i>Weakly Reactive</i>	<u>Non-Reactive</u>
ALL METHODS	1	-	-
ASI	1	-	-

Syphilis Serology—Qualitative: Treponema pallidum antibodies

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<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-4		Specimen SY-5	
	<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-1		Specimen SY-2		Specimen SY-3	
	<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	15	-	16
ASI	-	4	1	3	-	4
Becton Dickinson	-	7	-	7	-	7
Fisher HealthCare Sure-Vue	-	3	-	3	-	3
Wampole Impact RPR	-	2	-	2	-	2

<u>Method</u>	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	16	-	16	-
ASI	4	-	4	-
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 (Neg)</u>
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Specimen SY-1

ALL METHODS	-	-	-	-	-	-	-	-	7
ASI	-	-	-	-	-	-	-	-	2
Becton Dickinson	-	-	-	-	-	-	-	-	4
Wampole Impact RPR	-	-	-	-	-	-	-	-	1

Specimen SY-2

ALL METHODS	-	-	-	-	-	-	-	-	7
ASI	-	-	-	-	-	-	-	-	2
Becton Dickinson	-	-	-	-	-	-	-	-	4
Wampole Impact RPR	-	-	-	-	-	-	-	-	1

Specimen SY-3

ALL METHODS	-	-	-	-	-	-	-	-	7
ASI	-	-	-	-	-	-	-	-	2
Becton Dickinson	-	-	-	-	-	-	-	-	4
Wampole Impact RPR	-	-	-	-	-	-	-	-	1

Specimen SY-4

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

Specimen SY-5

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

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

<u>Method</u>	Specimen SHC-1		Specimen SHC-2		Specimen SHC-3	
	<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	-	7	7	-	7	-

<u>Method</u>	Specimen SHC-4		Specimen SHC-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
diagnostics direct Syphilis Health Check	-	7	7	-

H. pylori Antibody Detection

<u>Method</u>	Specimen HP-1		Specimen HP-2	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	70	71	-
Alere Clearview - moderate	1	4	5	-
Alfa Scientific Instant-View	-	1	1	-
Beckman Coulter ICON HP	-	1	1	-
Cardinal Health SP Brand	-	3	3	-
Consult Diagnostics	-	19	19	-
Fisher HealthCare Sure-Vue	-	2	2	-
Henry Schein OneStep+ - waived	-	12	12	-
Immunostics Inc.	-	1	1	-
McKesson Medi-Lab Performance - waived	-	3	3	-
PSS Select Diagnostics	-	1	1	-
Quidel QuickVue	-	20	20	-
SDI Biomed, Inc.	-	1	1	-
Sekisui OSOM	-	1	1	-

Lyme Disease Serology

<u>Method</u>	Specimen LY-1		Specimen LY-2	
	<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-1		Specimen MY-2	
	<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-1			Specimen VM-2			Specimen VM-3		
	<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	2	-	3	-	-	-	3	-
Abbott Architect	-	1	-	1	-	-	-	1	-
Siemens ADVIA									
Centaur	1	1	-	2	-	-	-	2	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<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	-	2	-	-	2	-

Specimen VM-1 is not graded due to less than 80% participant consensus.

Viral Markers – Anti-HBc (Total/IgG)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	2	-	-	2	-	-	-	2	-
Roche cobas e 411	1	-	-	1	-	-	1	-	-
Siemens ADVIA									
Centaur	2	-	-	2	-	-	-	2	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<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	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA						
Centaur	-	2	-	-	2	-

Viral Markers – Anti-HIV

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>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	-	4	-	-	4	-	-	4	-
Alere Clearview									
HIV1/2 STAT-PAK	-	2	-	-	2	-	-	2	-
Siemens ADVIA									
Centaur	-	3	-	-	3	-	-	3	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	9	-	9	-	-
Abbott Architect	-	4	-	4	-	-
Alere Clearview						
HIV1/2 STAT-PAK	-	2	-	2	-	-
Siemens ADVIA						
Centaur	-	3	-	3	-	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>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-4</u>			<u>Specimen VM-5</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 – Anti-HAV (Total/IgG)

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	4	1	-	-	5	-	-	5	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Siemens ADVIA									
Centaur	4	-	-	-	4	-	-	4	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	1	-	5	-	-
Abbott Architect	1	-	-	1	-	-
Siemens ADVIA						
Centaur	3	1	-	4	-	-

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-1 through VM-5 are: Positive, Negative, Negative, Negative and Negative, respectively.

Viral Markers – Anti-HBs

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>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									
Centaur	-	4	-	-	4	-	4	-	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</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	1	-	-	1	-	-
Siemens ADVIA						
Centaur	4	-	-	4	-	-

Viral Markers – HBsAg

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>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	-
Roche cobas e 411	1	-	-	1	-	-	-	1	-
Siemens ADVIA									
Centaur	3	-	-	3	-	-	-	3	-
Siemens									
Immulinite/1000	1	-	-	1	-	-	-	1	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<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	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA						
Centaur	-	3	-	-	3	-
Siemens						
Immulinite/1000	-	1	-	-	1	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	-	11	-	2	7	2	11	-	-
Abbott Architect	-	4	-	-	2	2	4	-	-
OraSure OraQuick									
HCV	-	1	-	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-	2	-	-
Siemens ADVIA									
Centaur	-	4	-	-	4	-	4	-	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	10	-	-	11	-
Abbott Architect	-	4	-	-	4	-
OraSure OraQuick						
HCV	-	1	-	-	1	-
Roche cobas e 411	-	2	-	-	2	-
Siemens ADVIA						
Centaur	1	3	-	-	4	-

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