

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 6

Immunology
2016 MLE-M3

ACP | Medical Laboratory
Evaluation 

Total Commitment to Education and Service
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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-11</u>		<u>Specimen IM-12</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	195	2	1	196
Alere Clearview - moderate	3	-	-	3
Alere Clearview - waived	5	-	-	5
Alere Clearview Mono Plus II - moderate	1	-	-	1
Alere Clearview Mono Plus II - waived	6	1	-	7
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	9	-	-	9
BioStar Aceava Mono Test	3	-	-	3
BioStar Aceava Mono-whole bld	4	-	-	4
Cardinal Health SP Brand - waived	9	-	-	9
Consult Diagnostics	24	-	-	24
Fisher HealthCare Sure-View	10	-	-	10
Henry Schein OneStep+ - waived	14	-	-	14
Immunostics Inc.	1	-	-	1
LifeSign Status - waived	4	-	-	4
McKesson Medi-Lab Performance - waived	2	-	-	2
Other Moderate method	5	-	-	5
Other Waived method	13	-	-	13
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	13	-	-	13
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	59	1	1	59
Seradyn	1	-	-	1
Wampole ColorCard	1	-	-	1

Infectious Mononucleosis

<u>Method</u>	Specimen IM-13		Specimen IM-14		Specimen IM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	64	-	64	-	-	64
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 Aceava Mono-whole bld	2	-	2	-	-	2
Cardinal Health SP Brand - waived	2	-	2	-	-	2
Consult Diagnostics	9	-	9	-	-	9
Fisher HealthCare Sure-View	5	-	5	-	-	5
Henry Schein OneStep+ - waived	5	-	5	-	-	5
LifeSign Status - waived	1	-	1	-	-	1
Other Moderate method	5	-	5	-	-	5
Other Waived method	1	-	1	-	-	1
Quidel QuickVue+	1	-	1	-	-	1
Quidel QuickVue+ - waived	2	-	2	-	-	2
Sekisui OSOM	4	-	4	-	-	4
Sekisui OSOM (waived)	10	-	10	-	-	10
Seradyn	1	-	1	-	-	1
Wampole ColorCard	1	-	1	-	-	1

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-11		Specimen RF-12		Specimen RF-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	-	30	9	39	-
Abbott Architect	1	-	1	-	1	-
ASI	10	-	10	-	10	-
Biokit Rheumajet	5	-	5	-	5	-
Diamedix	1	-	1	-	1	-
Fisher HealthCare Sure-View	3	-	3	-	3	-
Immunostics Inc.	2	-	1	1	2	-
Siemens RapiTex	1	-	1	-	1	-
TheraTest	4	-	4	-	4	-
Wampole ColorCard	8	-	2	6	8	-
Wampole Rheumatex	4	-	2	2	4	-

Specimen RF-12 is graded to 80% referee consensus.

<u>Method</u>	Specimen RF-14		Specimen RF-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	37	38	1
Abbott Architect	-	1	1	-
ASI	1	9	10	-
Biokit Rheumajet	-	5	5	-
Diamedix	-	1	1	-
Fisher HealthCare Sure-View	-	3	3	-
Immunostics Inc.	-	2	2	-
Teco Diagnostics	-	1	1	-
TheraTest	-	4	4	-
Wampole ColorCard	1	7	7	1
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-11												
ALL METHODS	-	-	1	2	-	-	1	-	-	-	-	-
ASI	-	-	-	-	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	1	1	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	1	-	-	-	-	-	-	-	-
Specimen RF-12												
ALL METHODS	1	-	1	-	-	1	-	-	-	-	-	1
ASI	-	-	-	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	-	1	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	-	-	-	-	-	-	1
Specimen RF-13												
ALL METHODS	-	2	1	-	-	-	1	-	-	-	-	-
ASI	-	-	-	-	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	1	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	1	-	-	-	-	-	-	-	-	-	-
Specimen RF-14												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
ASI	-	-	-	-	-	-	-	-	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-	2
Wampole ColorCard	-	-	-	-	-	-	-	-	-	-	-	1
Specimen RF-15												
ALL METHODS	-	1	2	-	-	-	1	-	-	-	-	-
ASI	-	-	-	-	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-
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-11						
All Method	23	201.5	58.7	29.1	211	84 - 319
Specimen RF-12						
All Method	22	54.9	17.3	31.6	49	20 - 90
Specimen RF-13						
All Method	23	138.8	40.2	28.9	124	58 - 220
Specimen RF-14						
All Method	23	7.7	3.2	42.2	8	1 - 15
Specimen RF-15						
All Method	23	137.6	37.6	27.3	125	62 - 213

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<u>Specimen AS-11</u>		<u>Specimen AS-12</u>		<u>Specimen AS-13</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-14</u>		<u>Specimen AS-15</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-11						
All Method	13	129.5	4.4	3.4	129	116 - 143
Specimen IMP-12						
All Method	13	154.7	5.8	3.7	153	137 - 173
Specimen IMP-13						
All Method	13	141.7	5.1	3.6	141	126 - 158
Specimen IMP-14						
All Method	13	142.2	6.3	4.4	141	123 - 161
Specimen IMP-15						
All Method	13	58.5	1.7	2.8	58	53 - 64

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-11						
All Method	13	25.6	1.6	6.1	25	20 - 31
Specimen IMP-12						
All Method	13	32.5	2.3	7.2	33	25 - 40
Specimen IMP-13						
All Method	13	28.3	1.8	6.2	28	23 - 34
Specimen IMP-14						
All Method	13	28.3	1.8	6.2	28	23 - 34
Specimen IMP-15						
All Method	13	11.1	1.0	8.6	11	8 - 14

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-11						
All Method	11	182.7	9.1	5.0	182	155 - 210
Specimen IMP-12						
All Method	11	527.3	27.3	5.2	532	445 - 610
Specimen IMP-13						
All Method	11	207.6	10.8	5.2	206	175 - 240
Specimen IMP-14						
All Method	11	205.8	11.0	5.3	204	172 - 239
Specimen IMP-15						
All Method	11	84.2	5.7	6.8	83	66 - 102

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-11						
All Method	11	927.8	72.2	7.8	931	695 - 1160
Specimen IMP-12						
All Method	11	999.0	66.0	6.6	1013	749 - 1249
Specimen IMP-13						
All Method	11	1046.2	67.4	6.4	1046	784 - 1308
Specimen IMP-14						
All Method	11	1046.3	61.6	5.9	1031	784 - 1308
Specimen IMP-15						
All Method	11	438.9	27.7	6.3	431	329 - 549

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-11						
All Method	11	492.7	39.3	8.0	505	374 - 611
Specimen IMP-12						
All Method	11	481.8	33.6	7.0	489	381 - 583
Specimen IMP-13						
All Method	11	95.5	7.2	7.6	93	73 - 118
Specimen IMP-14						
All Method	11	95.7	6.8	7.1	93	75 - 117
Specimen IMP-15						
All Method	11	47.3	3.6	7.5	46	36 - 58

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	Specimen AN-11		Specimen AN-12		Specimen AN-13	
	<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	-
Wampole	-	1	1	-	1	-

<u>Method</u>	Specimen AN-14		Specimen AN-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	5	-
ASI	-	3	3	-
Diagnostic Technology	-	1	1	-
Wampole	-	1	1	-

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	Specimen CR-5		Specimen CR-6	
	<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	-
Teco Diagnostics	-	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-5						
mg/dL - units						
All Immunology Methods	26	0.167	0.168	100.7	0.10	0.00 - 0.68
mg/L - units						
All Immunology Methods	15	1.617	2.021	125.0	0.30	0.00 - 7.69
Specimen CR-6						
mg/dL - units						
All Immunology Methods	26	3.054	0.458	15.0	3.09	1.67 - 4.43
mg/L - units						
All Immunology Methods	15	29.327	6.493	22.1	26.09	9.84 - 48.81

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-5						
All Method	38	13.094	1.327	10.1	13.17	9.11 - 17.08
Beckman AU	10	13.046	1.125	8.6	13.20	9.66 - 16.43
Specimen HCR-6						
All Method	38	2.568	0.458	17.8	2.42	1.19 - 3.95
Beckman AU	10	2.670	0.820	30.7	2.41	0.20 - 5.14

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

<u>Method</u>	<u>Specimen AE-11</u>		<u>Specimen AE-12</u>		<u>Specimen AE-13</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	10	11	-	8	3
Immuno Concepts	-	4	4	-	3	1
INOVA Diagnostics	-	3	3	-	1	2
Phadia Elia	-	1	1	-	1	-
TheraTest	-	2	2	-	2	-

Specimen AE-13 is graded to 80% referee consensus.

<u>Method</u>	<u>Specimen AE-14</u>		<u>Specimen AE-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	10	11	-
Immuno Concepts	-	4	4	-
INOVA Diagnostics	-	3	3	-
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-11												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
Immuno Concepts	-	-	-	-	-	-	-	-	-	-	-	3
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	1
Specimen AE-12												
ALL METHODS	-	-	-	-	-	1	2	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	2	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-	-
Specimen AE-13												
ALL METHODS	-	-	-	-	-	2	-	1	-	-	-	1
Immuno Concepts	-	-	-	-	-	2	-	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	1
Specimen AE-14												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
Immuno Concepts	-	-	-	-	-	-	-	-	-	-	-	3
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	1
Specimen AE-15												
ALL METHODS	-	-	-	-	-	3	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	2	-	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-	-

Anti-dsDNA

<u>Method</u>	<u>Specimen AE-11</u>		<u>Specimen AE-12</u>		<u>Specimen AE-13</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
TheraTest	-	5	-	5	-	5

<u>Method</u>	<u>Specimen AE-14</u>		<u>Specimen AE-15</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
TheraTest	-	5	-	5

Anti-RNP

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	3	-	3	1	2
Immuno Concepts	-	1	-	1	1	-
INOVA Diagnostics	-	1	-	1	-	1
Phadia Elia	-	1	-	1	-	1

Specimen AE-13 is an ungraded challenge due to less than 80% consensus.

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<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-11		Specimen AE-12		Specimen AE-13	
	<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-14		Specimen AE-15	
	<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-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	2	8	-	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-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	2	-	8
Immuno Concepts	1	-	-	1
INOVA Diagnostics	-	1	-	1
Phadia ELIA	-	1	-	1
TheraTest	5	-	-	5

Specimens AE-11 and AE-14 are ungraded challenges due to less than 80% consensus.

Anti-SSB

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<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	-	5

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<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-11		Specimen AE-12		Specimen AE-13	
	<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-14		Specimen AE-15	
	<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-11		Specimen AE-12		Specimen AE-13	
	<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
TheraTest	-	5	-	5	-	5

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<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	-

Rubella—Qualitative

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<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-14		Specimen RU-15	
	<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-11 through RU-15 are: <10 IU/mL, 29.2 IU/mL, 29.2 IU/mL, <10 IU/mL and 19.8 IU/mL, respectively.

Anti-HIV

<u>Method</u>	Specimen HIV-11		Specimen HIV-12	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	63	-	-	62
Alere Clearview Complete HIV 1/2	8	-	-	8
Alere Clearview HIV1/2 STAT-PAK	8	-	-	8
Alere Determine HIV 1/2 Ag/Ab Combo	1	-	-	1
BD LINK 2	1	-	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	1	-	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - waived	22	-	-	21
Other Waived method	7	-	-	7
Trinity Biotech Uni-Gold - waived	15	-	-	15

<u>Method</u>	Specimen HIV-13		Specimen HIV-14		Specimen HIV-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	-	6	6	-
Alere Clearview HIV1/2 STAT-PAK	-	6	-	6	6	-

Allergen Specific IgE Antibodies

Specimen AL-11

Method

Mouse Urine Protein (e72) 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
-	-	-	-	-	-	-	-	-	-	-	-	1	2	2	-	-
-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
-	-	-	-	-	-	-	-	-	-	-	-	-	1	2	-	-
-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-

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

Cockroach - German (i6) Allergen CLASS RESULT									Wheat (f4) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6		0	0/1	1	2	3	4	5	6
-	-	2	-	-	-	-	-	-	-	-	-	3	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
-	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-
-	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-

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

Apple (f49) Allergen CLASS RESULT									Maple (Box Elder) (t1) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6		0	0/1	1	2	3	4	5	6
-	-	1	-	-	-	-	-	-	-	3	2	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
-	-	1	-	-	-	-	-	-	-	2	1	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-

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

Olive (t9) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6

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

Allergen Specific IgE Antibodies

Specimen AL-12

<u>Method</u>	Bermuda Grass (g2) 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
ALL METHODS	-	-	1	2	2	-	-	-	-	-	-	-	-	4	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	1	-	2	-	-	-	-	-	-	-	-	3	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-
<u>Method</u>	Silver Birch Tree (t3) 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
ALL METHODS	-	-	-	1	1	-	-	-	-	-	1	1	-	2	-	-
DPC-Standard Microplate	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	1	-	-	2	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
<u>Method</u>	Alternaria alternata (m6) Allergen CLASS RESULT								Cod Fish (f3) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	1	-	4	-	-	-	-	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	1	-	2	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
<u>Method</u>	Hazelnut (f17) Allergen CLASS RESULT															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	-	-	-	-	-	-	-	-								
DPC-Standard Microplate	-	-	-	-	-	-	-	-								
Hitachi CLA-1	-	-	-	-	-	-	-	-								
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-								

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-11						
All Method	5	122.0	10.6	8.7	118	90 - 154
Specimen AL-12						
All Method	5	480.3	31.4	6.5	491	386 - 575
Specimen AL-13						
All Method	5	24.3	1.5	6.3	24	19 - 29
Specimen AL-14						
All Method	5	24.3	2.5	10.3	24	16 - 32
Specimen AL-15						
All Method	5	25.0	1.7	6.9	24	19 - 31

Syphilis Serology—Qualitative: Treponema pallidum antibodies

<u>Method</u>	<u>Specimen SY-11</u>		<u>Specimen SY-12</u>		<u>Specimen SY-13</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	2	-	-	2	2	-
Abbott Architect	1	-	-	1	1	-
Siemens ADVIA Centaur	1	-	-	1	1	-

<u>Method</u>	<u>Specimen SY-14</u>		<u>Specimen SY-15</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	2	2	-
Abbott Architect	-	1	1	-
Siemens ADVIA Centaur	-	1	1	-

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<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-View	3	-	-	3	3	-
Wampole Impact RPR	2	-	-	2	2	-

<u>Method</u>	Specimen SY-14		Specimen SY-15	
	<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-View	-	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-11

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

Specimen SY-12

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

Specimen SY-13

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

Specimen SY-14

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

Specimen SY-15

ALL METHODS	1	1	5	-	-	-	-	-	-
ASI	1	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	4	-	-	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-	-	-

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

<u>Method</u>	Specimen SHC-11		Specimen SHC-12		Specimen SHC-13	
	<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	10	-	5	5	10	-

<u>Method</u>	Specimen SHC-14		Specimen SHC-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
diagnostics direct Syphilis Health Check	5	5	10	-

H. pylori Antibody Detection

<u>Method</u>	Specimen HP-5		Specimen HP-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	70	69	2
Alere Clearview - moderate	-	6	6	-
Alfa Scientific Instant-View	-	1	1	-
Cardinal Health SP Brand	-	3	3	-
Consult Diagnostics	-	20	20	-
Fisher HealthCare Sure-Vue	-	2	2	-
Henry Schein OneStep+ - waived	-	11	10	1
Immunostics Inc.	-	1	1	-
McKesson Medi-Lab Performance - waived	1	1	1	1
Quidel QuickVue	-	23	23	-
SDI Biomed, Inc.	-	1	1	-

Lyme Disease Serology

<u>Method</u>	Specimen LY-5		Specimen LY-6	
	<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-5		Specimen MY-6	
	<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>	<u>Specimen VM-11</u>			<u>Specimen VM-12</u>			<u>Specimen VM-13</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	1	-	-	6	-	-	6	-
Abbott Architect	2	-	-	-	2	-	-	2	-
Siemens ADVIA									
Centaur	3	-	-	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-14</u>			<u>Specimen VM-15</u>		
	<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>	<u>Specimen VM-11</u>			<u>Specimen VM-12</u>			<u>Specimen VM-13</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	-
Roche cobas e 411	1	-	-	-	1	-	-	1	-
Siemens ADVIA									
Centaur	3	-	-	-	3	-	-	3	-

<u>Method</u>	<u>Specimen VM-14</u>			<u>Specimen VM-15</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	-	-	1	4	-
Abbott Architect	1	-	-	-	1	-
Roche cobas e 411	1	-	-	1	-	-
Siemens ADVIA						
Centaur	3	-	-	-	3	-

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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 Determine HIV 1/2 Ag/Ab Combo	-	1	-	-	1	-	1	-	-
Siemens ADVIA Centaur	-	3	-	-	3	-	3	-	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<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 Determine HIV 1/2 Ag/Ab Combo	-	1	-	-	1	-
Siemens ADVIA Centaur	-	3	-	-	3	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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 Centaur	-	3	-	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<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-HAV (Total/IgG)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	-	1	-	1	-	-	1	-	-
Siemens ADVIA									
Centaur	-	3	-	3	-	-	3	-	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	4	-	-	-	4	-
Abbott Architect	1	-	-	-	1	-
Siemens ADVIA						
Centaur	3	-	-	-	3	-

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-11 through VM-15 are: Negative, Negative, Negative, Positive and Negative, respectively.

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	5	-	2	3	-
Abbott Architect	-	2	-	1	-	-
Siemens ADVIA						
Centaur	-	3	-	1	3	-

Specimen VM-15 is an ungraded challenge due to less than 80% consensus.

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	-	1	-	9	1	-	10	-
Abbott Architect	3	-	-	-	3	-	-	3	-
Roche cobas e 411	1	-	-	-	1	-	-	1	-
Siemens ADVIA Centaur Siemens	4	-	-	-	4	-	-	4	-
Immulate/1000	1	-	-	-	1	-	-	1	-
VITROS 5600	-	-	1	-	-	1	-	1	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	10	-	-	8	1	1
Abbott Architect	3	-	-	3	-	-
Roche cobas e 411	1	-	-	1	-	-
Siemens ADVIA Centaur Siemens	4	-	-	4	-	-
Immulate/1000	1	-	-	-	1	-
VITROS 5600	1	-	-	-	-	1

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	-	14	-	-	14	-	-	14	-
Abbott Architect	-	5	-	-	5	-	-	5	-
OraSure OraQuick HCV	-	1	-	-	1	-	-	1	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-	-	2	-
VITROS 5600	-	4	-	-	4	-	-	4	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	14	-	14	-	-
Abbott Architect	-	5	-	5	-	-
OraSure OraQuick HCV	-	1	-	1	-	-
Roche cobas e 411	-	1	-	1	-	-
Siemens ADVIA Centaur	-	2	-	2	-	-
VITROS 5600	-	4	-	4	-	-

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