

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

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Immunology
2017 MLE-M3

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
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	185	6	4	187
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	1	-	11
BioStar Aceava Mono Test	2	-	-	2
BioStar Aceava Mono-whole bld	3	1	1	3
BTNX Rapid Response – moderate	1	-	-	1
Cardinal Health SP Brand	1	-	-	1
Cardinal Health SP Brand - waived	8	-	-	8
Consult Diagnostics	22	-	-	22
Fisher HealthCare Sure-Vue	7	-	-	7
Henry Schein OneStep+ - waived	13	-	-	13
LifeSign Status - waived	6	2	1	7
McKesson Medi-Lab Performance - waived	2	-	-	2
Other Moderate method	4	-	-	4
Other Waived method	17	-	1	16
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	12	1	-	13
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	53	1	1	53
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	57	1	57	1	-	58
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	11	-	11	-	-	11
BioStar Aceava Mono-whole bld	2	-	2	-	-	2
BTNX Rapid Response – moderate	1	-	1	-	-	1
Cardinal Health SP Brand	1	-	1	-	-	1
Cardinal Health SP Brand - waived	1	-	1	-	-	1
Consult Diagnostics	5	-	5	-	-	5
Fisher HealthCare Sure-Vue	3	-	2	1	-	3
Henry Schein OneStep+ - waived	4	-	4	-	-	4
LifeSign Status - waived	1	-	1	-	-	1
McKesson Medi-Lab Performance - waived	1	-	1	-	-	1
Other Moderate method	4	-	4	-	-	4
Other Waived method	2	-	2	-	-	2
Quidel QuickVue+	1	-	1	-	-	1
Quidel QuickVue+ - waived	2	1	3	-	-	3
Sekisui OSOM	4	-	4	-	-	4
Sekisui OSOM (waived)	7	-	7	-	-	7
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	-	38	1	37	38	-
Abbott Architect	-	1	-	1	1	-
ASI	-	10	-	10	10	-
Biokit Rheumajet	-	4	-	4	4	-
Diamedix	-	1	-	1	1	-
Fisher HealthCare Sure-View	-	4	-	4	4	-
Immunostics Inc.	-	2	-	2	2	-
INOVA Diagnostics	-	1	-	1	1	-
TheraTest	-	4	-	4	4	-
Wampole ColorCard	-	7	1	6	7	-
Wampole Rheumatex	-	4	-	4	4	-

<u>Method</u>	Specimen RF-14		Specimen RF-15	
	<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	-	4	4	-
Diamedix	-	1	1	-
Fisher HealthCare Sure-View	-	4	4	-
Immunostics Inc.	-	2	2	-
INOVA Diagnostics	-	1	1	-
TheraTest	-	4	4	-
Wampole ColorCard	-	7	7	-
Wampole Rheumatex	-	4	4	-

Rheumatoid Factor—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-11												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	1	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-12												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	1	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-13												
ALL METHODS	-	-	-	2	-	-	2	-	-	-	-	-
ASI	-	-	-	-	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	2	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	-	1	-	-	-	-	-
Specimen RF-14												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	1	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-15												
ALL METHODS	-	-	-	2	1	-	-	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	19	6.4	4.4	68.5	5	0 - 16
Specimen RF-12						
All Method	19	6.3	4.6	72.6	6	0 - 16
Specimen RF-13						
All Method	19	186.7	42.8	22.9	185	101 - 273
Specimen RF-14						
All Method	19	6.6	4.2	63.8	6	0 - 15
Specimen RF-15						
All Method	19	185.0	41.8	22.6	185	101 - 269

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
<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-	-		

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	14	118.1	5.9	5.0	119	100 - 136
Specimen IMP-12						
All Method	14	91.9	4.5	4.8	92	78 - 106
Specimen IMP-13						
All Method	14	141.3	6.3	4.4	144	122 - 161
Specimen IMP-14						
All Method	14	88.4	4.9	5.6	89	73 - 104
Specimen IMP-15						
All Method	14	38.4	3.2	8.3	39	28 - 48

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	14	23.7	1.6	6.9	23	18 - 29
Specimen IMP-12						
All Method	14	18.4	1.3	7.3	19	14 - 23
Specimen IMP-13						
All Method	14	28.6	2.1	7.4	29	22 - 35
Specimen IMP-14						
All Method	14	17.2	1.1	6.5	18	13 - 21
Specimen IMP-15						
All Method	14	7.5	0.8	10.1	8	5 - 10

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	171.5	13.8	8.1	172	130 - 213
Specimen IMP-12						
All Method	11	134.4	11.5	8.6	132	99 - 169
Specimen IMP-13						
All Method	11	517.3	33.9	6.6	499	415 - 620
Specimen IMP-14						
All Method	11	138.9	10.2	7.3	134	108 - 170
Specimen IMP-15						
All Method	11	54.5	4.4	8.0	55	41 - 68

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	872.5	66.4	7.6	875	654 - 1091
Specimen IMP-12						
All Method	11	669.8	59.7	8.9	655	502 - 838
Specimen IMP-13						
All Method	11	1012.3	77.0	7.6	987	759 - 1266
Specimen IMP-14						
All Method	11	1914.5	144.1	7.5	1880	1435 - 2394
Specimen IMP-15						
All Method	11	250.3	22.7	9.1	262	187 - 313

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	77.5	10.0	12.9	73	47 - 108
Specimen IMP-12						
All Method	11	463.8	111.7	24.1	477	128 - 800
Specimen IMP-13						
All Method	11	95.7	12.1	12.7	92	59 - 133
Specimen IMP-14						
All Method	11	61.2	13.1	21.4	56	21 - 101
Specimen IMP-15						
All Method	11	23.5	4.5	19.2	25	9 - 38

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-5</u>		<u>Specimen CR-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	-	11
Beckman Synchron	8	-	-	8
Fisher HealthCare Sure-Vue	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-5						
mg/dL - units						
All Immunology Methods	20	1.708	0.248	14.5	1.74	0.96 - 2.46
mg/L - units						
All Immunology Methods	17	16.536	3.673	22.2	15.50	5.51 - 27.56
Specimen CR-6						
mg/dL - units						
All Immunology Methods	20	0.206	0.172	83.5	0.20	0.00 - 0.73
mg/L - units						
All Immunology Methods	17	2.320	2.281	98.3	2.00	0.00 - 9.17

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	29	0.649	0.245	37.8	0.70	0.00 - 1.39
Specimen HCR-6						
All Method	28	2.497	0.427	17.1	2.49	1.21 - 3.78

Antinuclear Antibody (ANA) - Qualitative

<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	3	11	13	1	13	1
ASI	-	2	2	-	2	-
Bio-Rad	-	1	1	-	1	-
Immuno Concepts	-	4	4	-	4	-
INOVA Diagnostics	-	2	2	-	2	-
Teco Diagnostics	-	1	-	1	-	1
TheraTest	3	1	4	-	4	-

<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	2	12	11	3
ASI	-	2	-	2
Bio-Rad	-	1	1	-
Immuno Concepts	-	4	4	-
INOVA Diagnostics	-	2	2	-
Teco Diagnostics	-	1	-	1
TheraTest	2	2	4	-

Antinuclear Antibody (ANA)—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-11												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-12												
ALL METHODS	-	-	-	-	-	3	2	-	-	-	-	-
Bio-Rad	-	-	-	-	-	1	-	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	2	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-	-
Specimen AE-13												
ALL METHODS	-	-	-	1	-	1	2	1	-	-	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	1	-	-	2	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-	-
Specimen AE-14												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-15												
ALL METHODS	-	-	1	-	-	2	2	-	-	-	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	1	-	-	1	1	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-	-

Anti-dsDNA

<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	-	7	1	6	-	7
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	-	5	1	4	-	5

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	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	-	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-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	1	6	7	-	-	7
Immuno Concepts	1	-	1	-	-	1
INOVA Diagnostics	-	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	-	7	7	-
Immuno Concepts	-	1	1	-
INOVA Diagnostics	-	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	1	-	7	-	7
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	-	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	1	6	1
Immuno Concepts	1	-	1	-
INOVA Diagnostics	-	1	-	1
TheraTest	5	-	5	-

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	-	7	-	7	-	7
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	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	-	7	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	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	-	7	4	3	-	7
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	1	-	-	1
TheraTest	-	5	3	2	-	5

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	7	-
Immuno Concepts	-	1	1	-
INOVA Diagnostics	-	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	5	-	-	5	-	5
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	1
DiaSorin	1	-	-	1	-	1
INOVA Diagnostics	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	-	5	5	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
DiaSorin	-	1	1	-
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: 19.0 IU/mL, <10.0 IU/mL, <10.0 IU/mL, <10.0 IU/mL, and 31.7 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	58	1	-	59
Alere Clearview Complete HIV 1/2	5	-	-	5
Alere Clearview HIV1/2 STAT-PAK	4	-	-	4
Alere Determine HIV 1/2 Ag/Ab Combo	2	-	-	2
BD LINK 2	1	-	-	1
Chembio HIV 1/2 Assay - moderate	1	-	-	1
Chembio HIV 1/2 Assay - waived	5	-	-	5
Orasure OraQuick Advance Rapid HIV-1/2 - waived	21	1	-	22
Other Waived method	9	-	-	9

<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	-	5	-	5	5	-
Chembio HIV 1/2 Assay - moderate	-	5	-	5	5	-

Allergen Specific IgE Antibodies

Specimen AL-11

Method

	Peanut (f13) 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	-	-	-	2	-	2	-	-	-	-	-	1	2	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-	-	-	1	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Olive (t9) Allergen							Common (Short) Ragweed (w1) 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	-	-	-	-	-	-	-	-	-	3	1	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-

	House Dust Mite (D. farinae) (d2) 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	-	-	-	3	2	-	-	-	-	-	-	4	-	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Meadow, Kentucky Blue, June Grass (g8) Allergens							
	CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	-	2	1	2
DPC-Standard Microplate	-	-	-	-	-	-	-	1
Hitachi CLA-1	-	-	-	-	-	1	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	1
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	1	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	1	-	-

Allergen Specific IgE Antibodies

Specimen AL-12

<u>Method</u>	Wheat (f4) Allergen								Soybean (f14) 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	3	-	-	-	-	-	1	2	1	-	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	1	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	House Dust Mite (D. pteronyssinus) (d1) Allergen								Cat Epithelium (e1) Allergen							
	CLASS RESULT								CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	3	1	-	-	-	-	-	-	4	1	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
	Timothy Grass (g6) Allergen								Meadow Fescue (g4) 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	-	-	-	-	-	-	-	1	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	1	-	-	-	-	-	-	-	1	-
	Alternaria alternata (m6) Allergen															
	CLASS RESULT															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	1	1	3	-	-	-	-	-								
DPC-Standard Microplate	-	-	1	-	-	-	-	-								
Hitachi CLA-1	1	-	-	-	-	-	-	-								
Hycor RAST (Ru/mL)	-	-	1	-	-	-	-	-								
Phadia UniCap 100 (% ref)	-	1	-	-	-	-	-	-								
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-								

Total IgE—Quantitative (U/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen AL-11						
All Method	5	367.5	35.3	9.6	382	261 - 474
Specimen AL-12						
All Method	5	469.0	65.3	13.9	493	272 - 666
Specimen AL-13						
All Method	5	18.3	1.7	9.4	19	13 - 24
Specimen AL-14						
All Method	5	18.5	2.1	11.3	19	12 - 25
Specimen AL-15						
All Method	5	66.5	3.7	5.6	68	55 - 78

VDRL Slide

<u>Method</u>	Specimen SY-11			Specimen SY-12		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	-	-	-	1
<u>Method</u>	Specimen SY-13			Specimen SY-14		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	-	-	-	1
<u>Method</u>	Specimen SY-15					
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>			
ALL METHODS	1	-	-			

Syphilis Serology—Qualitative: Treponema pallidum antibodies

<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	11	-	-	11	11	-
diagnostics direct Syphilis Health Check	9	-	-	9	9	-
INOVA Diagnostics	1	-	-	1	1	-
Siemens ADVIA Centaur	1	-	-	1	1	-

<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	-	11	11	-
diagnostics direct Syphilis Health Check	-	9	9	-
INOVA Diagnostics	-	1	1	-
Siemens ADVIA Centaur	-	1	1	-

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-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	13	-	-	13	13	-
ASI	3	-	-	3	3	-
Becton Dickinson	5	-	-	5	5	-
Fisher HealthCare Sure-Vue	3	-	-	3	3	-
Wampole Impact RPR	1	-	-	1	1	-

<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	-	13	13	-
ASI	-	3	3	-
Becton Dickinson	-	5	5	-
Fisher HealthCare Sure-Vue	-	3	3	-
Wampole Impact RPR	-	1	1	-

Syphilis Serology—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-11

ALL METHODS	-	-	-	2	3	1	-	-	-
ASI	-	-	-	2	-	-	-	-	-
Becton Dickinson	-	-	-	-	3	1	-	-	-

Specimen SY-12

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

Specimen SY-13

ALL METHODS	-	-	3	3	-	-	-	-	-
ASI	-	-	2	-	-	-	-	-	-
Becton Dickinson	-	-	1	3	-	-	-	-	-

Specimen SY-14

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

Specimen SY-15

ALL METHODS	-	-	4	2	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	3	1	-	-	-	-	-

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	64	64	1
Alere Clearview - moderate	-	4	4	-
Alfa Scientific Instant-View	-	1	1	-
Beckman Coulter ICON HP	-	1	1	-
Cardinal Health SP Brand	-	1	1	-
Consult Diagnostics	-	19	19	-
Fisher HealthCare Sure-View	-	2	2	-
Henry Schein OneStep+ - waived	-	11	11	-
Immunostics Inc.	-	1	1	-
McKesson Medi-Lab Performance - waived	-	3	3	-
Quidel QuickVue	1	19	19	1
Sekisui OSOM	-	1	1	-

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	-	2	2	-
Meridian ImmunoCard	-	2	2	-

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	3	-	1	-	4	-	-	4	-
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	-	4	-	-	4	-
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	2	-	-	-	2	-	-	2	-
Siemens ADVIA									
Centaur	2	-	-	-	2	-	-	2	-

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

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	-	7	-	-	7	-	7	-	-
Abbott Architect	-	3	-	-	3	-	3	-	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	-	1	-	-	1	-	1	-	-
Siemens ADVIA									
Centaur	-	2	-	-	2	-	2	-	-

<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	-	7	-	-	7	-
Abbott Architect	-	3	-	-	3	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	-	1	-	-	1	-
Siemens ADVIA						
Centaur	-	2	-	-	2	-

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	-	4	-	-	4	-	-	4	-
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	-	4	-	-	4	-
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	-	3	-	3	-	-	3	-	-
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	-	3	-	3	-	-
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, Negative, 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	-	-
Siemens ADVIA									
Centaur	-	5	-	5	-	-	5	-	-

<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	-	-	-	5	-
Siemens ADVIA						
Centaur	5	-	-	-	5	-

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	4	1	1	-	6	-	-	6	-
Abbott Architect	2	-	-	-	2	-	-	2	-
Siemens ADVIA									
Centaur	2	-	1	-	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	2	3	1	6	-	-
Abbott Architect	2	-	-	2	-	-
Siemens ADVIA						
Centaur	-	2	1	3	-	-
VITROS 5600	-	1	-	1	-	-

Specimen VM-14 is an ungraded challenge due to lack of consensus.

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	-	9	-	-	9	-	-	9	-
Abbott Architect	-	2	-	-	2	-	-	2	-
OraSure OraQuick									
HCV	-	1	-	-	1	-	-	1	-
Siemens ADVIA									
Centaur	-	5	-	-	5	-	-	5	-
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	9	-	-	-	9	-
Abbott Architect	2	-	-	-	2	-
OraSure OraQuick						
HCV	1	-	-	-	1	-
Siemens ADVIA						
Centaur	5	-	-	-	5	-
VITROS 5600	1	-	-	-	1	-

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