

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

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Immunology
2020 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/semi-quantitative procedures, evaluation is based on participant or referee consensus. A minimum percentage of participants must receive a passing score or the challenge is not evaluated due to lack of consensus. These percentages are listed below.

Anti-dsDNA	80% Participant Consensus
Anti-HIV	80% Participant Consensus
Antinuclear Antibody (ANA)	80% Participant Consensus
Anti-RNP	80% Participant Consensus
Anti-RNP/Sm	80% Participant Consensus
Anti-Sm	80% Participant Consensus
Anti-SSA	80% Participant Consensus
Anti-SSA/SSB	80% Participant Consensus
Anti-SSB	80% Participant Consensus
Anti-Streptolysin O (ASO)	80% Participant Consensus
C-Reactive Protein	80% Participant Consensus
Diagnostic Allergy	80% Participant Consensus
H. <i>pylori</i> Antibody Detection	80% Participant Consensus
Infectious Mononucleosis	80% Participant Consensus
Mycoplasma Antibody	80% Participant Consensus
Rheumatoid Factor	80% Participant Consensus
Rubella Antibody	80% Participant Consensus
Syphilis Serology	80% Participant Consensus
Viral Markers	80% Participant Consensus

Semi-Quantitative

Antinuclear Antibody (ANA) Titer	80% Participant Consensus
Anti-Streptolysin O (ASO) Titer	80% Participant Consensus
Rheumatoid Factor (Titer)	80% Participant Consensus
RPR Titer	80% Participant Consensus
VDRL Titer	80% Participant Consensus

Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each peer group consisting of 10 or more laboratories. Acceptable performance is established based on a target value \pm the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on page 37 under the heading "Acceptable Ranges for Quantitative Results."

Complement C3	\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 3 SD
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	121	2	122	1
Alere Clearview - moderate	1	-	1	-
Alere Clearview - waived	6	-	6	-
Alere Clearview Mono Plus II - moderate	1	-	1	-
Alere Clearview Mono Plus II - waived	3	-	3	-
Beckman Coulter ICON Mono - waived	-	1	1	-
BioStar Acceava Mono Test	2	-	2	-
BioStar Acceava Mono-whole bld	3	-	3	-
Cardinal Health SP Brand	1	-	1	-
Cardinal Health SP Brand - waived	4	-	4	-
Clarity Diagnostics	1	-	1	-
Consult Diagnostics - moderate	6	-	6	-
Consult Diagnostics - waived	14	-	14	-
Fisher HealthCare Sure-Vue	2	-	2	-
Henry Schein OneStep+ - moderate	1	-	1	-
Henry Schein OneStep+ - waived	12	-	12	-
LifeSign Status - waived	6	-	6	-
Other Moderate method	1	-	1	-
Other Waived method	7	-	7	-
Quidel QuickVue+	1	-	1	-
Quidel QuickVue+ - waived	2	1	2	1
Sekisui OSOM	4	-	4	-
Sekisui OSOM (waived)	43	-	43	-

Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-13</u>		<u>Specimen IM-14</u>		<u>Specimen IM-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	27	1	-	28	1	27
Alere Clearview - moderate	1	-	-	1	-	1
Alere Clearview Mono Plus II - moderate	1	-	-	1	-	1
Alere Clearview Mono Plus II - waived	1	-	-	1	-	1
Beckman Coulter ICON Mono - waived	-	1	-	1	1	-
BioStar Aceava Mono Test	1	-	-	1	-	1
BioStar Aceava Mono-whole bld	1	-	-	1	-	1
Consult Diagnostics - moderate	2	-	-	2	-	2
Consult Diagnostics - waived	4	-	-	4	-	4
Fisher HealthCare Sure-Vue	1	-	-	1	-	1
Henry Schein OneStep+ - moderate	1	-	-	1	-	1
Henry Schein OneStep+ - waived	1	-	-	1	-	1
LifeSign Status - waived	1	-	-	1	-	1
Other Moderate method	1	-	-	1	-	1
Other Waived method	2	-	-	2	-	2
Quidel QuickVue+	1	-	-	1	-	1
Quidel QuickVue+ - waived	2	-	-	2	-	2
Sekisui OSOM	4	-	-	4	-	4
Sekisui OSOM (waived)	2	-	-	2	-	2

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	1	20	21	-	1	20
ASI	1	3	4	-	1	3
Beckman AU	-	1	1	-	-	1
Biokit Rheumajet	-	1	1	-	-	1
Fisher HealthCare Sure-Vue	-	3	3	-	-	3
Phadia EliA	-	1	1	-	-	1
Stanbio Laboratory	-	1	1	-	-	1
TheraTest	-	5	5	-	-	5
Wampole ColorCard	-	4	4	-	-	4
Wampole Rheumatex	-	1	1	-	-	1

<u>Method</u>	Specimen RF-14		Specimen RF-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	19	21	-
ASI	1	3	4	-
Beckman AU	-	1	1	-
Biokit Rheumajet	-	1	1	-
Fisher HealthCare Sure-Vue	-	3	3	-
Phadia EliA	-	1	1	-
Stanbio Laboratory	-	1	1	-
TheraTest	-	5	5	-
Wampole ColorCard	-	4	4	-
Wampole Rheumatex	1	-	1	-

Rheumatoid Factor—Semi-Quantitative (Titer)

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>2/4</u>	<u>8/10</u>	<u>16/20</u>	<u>32/40</u>	<u>64/80</u>	<u>128/160</u>	<u>256/320</u>	<u>512/640</u>	<u>1024/1280</u>	<u>2048/2560</u>	<u>>2560</u>
Specimen RF-11												
ALL METHODS	3	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-12												
ALL METHODS	-	-	1	1	-	1	-	-	-	-	-	-
Beckman AU	-	-	-	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	1	1	-	-	-	-	-	-	-	-
Specimen RF-13												
ALL METHODS	3	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-14												
ALL METHODS	3	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-15												
ALL METHODS	-	-	1	-	1	1	-	-	-	-	-	-
Beckman AU	-	-	-	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	1	-	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	12	9.7	2.3	23.7	10	2 - 17
Beckman AU	5	9.7	2.9	29.7	10	1 - 19
Specimen RF-12						
All Method	12	127.0	20.9	16.5	128	64 - 190
Beckman AU	5	127.8	26.4	20.6	126	48 - 208
Specimen RF-13						
All Method	12	9.9	2.2	22.3	10	3 - 17
Beckman AU	5	9.8	2.8	28.3	10	1 - 19
Specimen RF-14						
All Method	12	10.1	2.4	23.4	10	3 - 18
Beckman AU	5	10.2	2.9	28.8	10	1 - 19
Specimen RF-15						
All Method	12	78.2	13.5	17.2	79	37 - 119
Beckman AU	5	78.7	17.0	21.6	78	27 - 130

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	Specimen AS-11		Specimen AS-12		Specimen AS-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	-	2	-	2
ASI	2	-	-	2	-	2
<u>Method</u>	Specimen AS-14		Specimen AS-15			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	2	-	2	-		
ASI	2	-	2	-		

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	17	197.7	6.1	3.1	198	179 - 216
Beckman AU	10	195.0	4.6	2.4	196	181 - 209
Specimen IMP-12						
All Method	17	31.2	3.4	10.8	31	21 - 42
Beckman AU	10	30.9	1.5	4.7	31	26 - 36
Specimen IMP-13						
All Method	17	118.5	3.7	3.1	118	107 - 130
Beckman AU	10	119.0	3.8	3.2	118	107 - 131
Specimen IMP-14						
All Method	17	117.5	3.5	3.0	119	107 - 129
Beckman AU	10	118.1	2.4	2.0	119	110 - 126
Specimen IMP-15						
All Method	17	18.0	2.6	14.3	17	10 - 26
Beckman AU	10	17.6	2.3	13.1	16	10 - 25

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	17	32.7	2.5	7.7	34	25 - 41
Beckman AU	10	33.7	2.1	6.1	34	27 - 40
Specimen IMP-12						
All Method	17	5.5	2.1	37.3	5	0 - 12
Beckman AU	10	6.0	1.9	31.9	5	0 - 12
Specimen IMP-13						
All Method	17	19.5	1.8	9.0	19	14 - 25
Beckman AU	10	20.0	1.6	8.2	20	15 - 25
Specimen IMP-14						
All Method	17	20.1	1.9	9.3	20	14 - 26
Beckman AU	10	20.9	1.8	8.5	21	15 - 27
Specimen IMP-15						
All Method	17	5.2	2.4	46.3	5	0 - 13
Beckman AU	10	5.6	2.4	42.5	5	0 - 13

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>
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Specimen IMP-11

All Method	17	320.1	12.1	3.8	318	283 - 357
Beckman AU	10	314.3	7.5	2.4	318	291 - 337

Specimen IMP-12

All Method	17	46.6	3.0	6.4	47	37 - 56
Beckman AU	10	48.3	2.5	5.2	47	40 - 56

Specimen IMP-13

All Method	17	198.6	4.9	2.5	196	183 - 214
Beckman AU	10	198.3	4.8	2.4	198	183 - 213

Specimen IMP-14

All Method	17	455.3	14.4	3.2	454	411 - 499
Beckman AU	10	450.3	17.3	3.8	449	398 - 503

Specimen IMP-15

All Method	17	21.3	2.7	12.8	23	13 - 30
Beckman AU	10	23.0	0.8	3.5	23	20 - 26

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>
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Specimen IMP-11

All Method	17	1491.9	113.3	7.6	1443	1118 - 1865
Beckman AU	10	1477.8	138.3	9.4	1422	1108 - 1848

Specimen IMP-12

All Method	17	211.1	33.0	15.6	198	158 - 264
Beckman AU	10	195.5	23.2	11.9	192	146 - 245

Specimen IMP-13

All Method	17	1872.3	124.5	6.7	1826	1404 - 2341
Beckman AU	10	1842.5	122.7	6.7	1801	1381 - 2304

Specimen IMP-14

All Method	17	851.9	33.5	3.9	846	638 - 1065
Beckman AU	10	850.0	45.9	5.4	839	637 - 1063

Specimen IMP-15

All Method	17	122.4	67.4	55.1	109	91 - 154
Beckman AU	10	88.5	16.0	18.1	88	66 - 111

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	17	130.6	8.2	6.3	128	105 - 156
Beckman AU	10	126.8	6.8	5.4	124	106 - 148
Specimen IMP-12						
All Method	17	21.6	2.1	10.0	22	15 - 29
Beckman AU	10	22.0	0.8	3.7	22	19 - 25
Specimen IMP-13						
All Method	17	80.7	2.8	3.5	81	72 - 90
Beckman AU	10	80.0	1.8	2.3	80	74 - 86
Specimen IMP-14						
All Method	17	79.6	5.0	6.3	79	64 - 95
Beckman AU	10	76.0	2.6	3.4	76	68 - 84
Specimen IMP-15						
All Method	17	16.4	5.3	32.6	15	0 - 33
Beckman AU	10	17.0	3.6	20.9	18	6 - 28

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	-	4	4	-
Siemens Dimension	-	4	4	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CR-5						
mg/dL - units						
All Immunology Methods	17	0.144	0.136	94.6	0.10	0.00 - 0.56
mg/L - units						
All Immunology Methods	11	1.811	2.131	117.7	0.90	0.00 - 8.21
Specimen CR-6						
mg/dL - units						
All Immunology Methods	17	6.989	0.686	9.8	7.18	4.93 - 9.05
mg/L - units						
All Immunology Methods	11	69.185	5.728	8.3	66.00	52.00 - 86.37

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen HCR-5						
All Method	20	2.688	1.093	40.7	2.70	0.00 - 5.97
Specimen HCR-6						
All Method	19	0.976	0.392	40.2	1.00	0.00 - 2.16

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	-	12	-	12	-	12
ASI	-	1	-	1	-	1
Bio-Rad	-	1	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	2	-	2	-	2
INOVA Diagnostics	-	2	-	2	-	2
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	12	-	11	1
ASI	1	-	-	1
Bio-Rad	1	-	1	-
GenBio ImmunoDOT Panel 1	1	-	1	-
Immuno Concepts	2	-	2	-
INOVA Diagnostics	2	-	2	-
TheraTest	5	-	5	-

Antinuclear Antibody (ANA)—Semi-Quantitative (Titer)

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>8/</u> <u>10</u>	<u>16/</u> <u>20</u>	<u>32/</u> <u>40</u>	<u>64/</u> <u>80</u>	<u>128/</u> <u>160</u>	<u>256/</u> <u>320</u>	<u>512/</u> <u>640</u>	<u>>640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
Specimen AE-11												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-12												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-13												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-14												
ALL METHODS	-	-	-	-	-	-	-	1	1	1	-	1
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	-	1	-	-	1
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-15												
ALL METHODS	-	-	-	-	-	-	-	-	2	1	-	1
Bio-Rad	-	-	-	-	-	-	-	-	1	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	-	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	-	8	-	8	-	8
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	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	4	4	-	8
GenBio ImmunoDOT Panel 1	1	-	-	1
Immuno Concepts	1	-	-	1
Phadia EliA	-	1	-	1
TheraTest	2	3	-	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	-	2	-	2	-	2
Immuno Concepts	-	1	-	1	-	1
Phadia EliA	-	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	2	-
Immuno Concepts	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	-	7	-	7	-	7
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
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	7	-	7	-
GenBio ImmunoDOT Panel 1	1	-	1	-
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	-	7	-	7	-	7
Immuno Concepts	-	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	-	7	-	7
Immuno Concepts	-	1	-	1
Phadia EliA	-	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
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	-	7	-	7
Immuno Concepts	-	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
GenBio ImmunoDOT Panel 1	-	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
GenBio ImmunoDOT Panel 1	-	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	-	7	-	7
Immuno Concepts	-	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	-	7	2	5
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	5	2	3

Rubella—Qualitative

<u>Method</u>	<u>Specimen RU-11</u>		<u>Specimen RU-12</u>		<u>Specimen RU-13</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	-	2	-	2
Siemens ADVIA Centaur	2	-	-	2	-	2

<u>Method</u>	<u>Specimen RU-14</u>		<u>Specimen RU-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	2	-
Siemens ADVIA Centaur	-	2	2	-

Rubella—Quantitative (IU/mL)

One lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values on a Beckman Access 2 for specimens RU-11 through RU-15 are: 21.3 IU/mL, 0.1 IU/mL, 0.1 IU/mL, 0.1 IU/mL, and 40.1 IU/mL, respectively.

Anti-HIV

<u>Method</u>	<u>Specimen HIV-11</u>		<u>Specimen HIV-12</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	59	2	1	60
Alere Clearview HIV1/2 STAT-PAK	2	-	-	2
Alere Determine HIV - moderate	2	-	-	2
Alere Determine HIV - waived	14	-	-	14
bioLytical Labs INSTI HIV - moderate	2	-	-	2
bioLytical Labs INSTI HIV - waived	12	-	-	12
Chembio HIV 1/2 Assay - waived	11	-	-	11
Orasure OraQuick Advance Rapid HIV-1/2 - waived	14	1	-	15
Other Waived method	2	1	1	2

<u>Method</u>	<u>Specimen HIV-13</u>		<u>Specimen HIV-14</u>		<u>Specimen HIV-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5	5	-
bioLytical Labs INSTI HIV - moderate	-	5	-	5	5	-

Allergen Specific IgE Antibodies

Specimen AL-11

Method

ALL METHODS
Hitachi CLA-1
Phadia ImmunoCAP System (KU/L)

Apple (f49) Allergen CLASS RESULT								Dog Dander (e5) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	-	1	1	1	1	-	-	-	-	-	1	2	-	-	-
-	-	1	1	-	1	-	-	-	-	-	-	1	-	-	-
-	-	-	1	1	-	-	-	-	-	-	1	1	-	-	-

ALL METHODS
Hitachi CLA-1
Phadia ImmunoCAP System (KU/L)

House Dust Mite (D. farinae) (d2) Allergen CLASS RESULT								Peanut (f13) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	-	-	1	1	2	-	-	-	-	-	-	2	1	-	-
-	-	-	-	-	2	-	-	-	-	-	-	-	1	-	-
-	-	-	1	1	-	-	-	-	-	-	-	2	-	-	-

ALL METHODS
Hitachi CLA-1
Phadia ImmunoCAP System (KU/L)

Sheep Sorrel (w18) 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
-	-	2	2	-	-	-	-	-	-	-	-	1	1	-	-
-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-
-	-	1	1	-	-	-	-	-	-	-	-	1	1	-	-

ALL METHODS
Hitachi CLA-1
Phadia ImmunoCAP System (KU/L)

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

Allergen Specific IgE Antibodies

Specimen AL-12

<u>Method</u>	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	-	-	-	1	1	-	-	-	-	-	-	-	1	1	1	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	1	-	-	-	-	-	-	-	1	1	-	-	-
	Cow Milk (f2) Allergen								Crab (f23) 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	1	-	-	-	-	-	-	1	1	-	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	-	-	-	-	-	-	-	-	1	1	-	-	-
	Honey Bee Venom (i1) Allergen								Aspergillus fumigatus (m3) 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	-	-	-	-	-	-	-	-	2	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	1	1	-	-	-	-	-	-	-	-	1	1	-	-	-	-
	Sweet Vernal Grass (g1) Allergen																
	CLASS RESULT																
	0	0/1	1	2	3	4	5	6									
ALL METHODS	-	-	-	-	-	1	1	-									
Hitachi CLA-1	-	-	-	-	-	-	-	-									
Phadia ImmunoCAP System (KU/L)	-	-	-	-	-	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-11						
All Method	5	406.7	24.4	6.0	416	333 - 480
Specimen AL-12						
All Method	5	231.0	4.0	1.7	231	219 - 243
Specimen AL-13						
All Method	5	7.7	0.6	7.5	8	5 - 10
Specimen AL-14						
All Method	5	75.3	7.2	9.6	79	53 - 98
Specimen AL-15						
All Method	5	7.3	0.6	7.9	7	5 - 10

Syphilis Serology—Qualitative: MHA-TP

<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	-	1	1	-	1	-
Serodia	-	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	1	-	-	1
Serodia	1	-	-	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	-	10	10	-	10	-
Abbott Architect	-	1	1	-	1	-
diagnostics direct Syphilis Health Check	-	7	7	-	7	-
Siemens ADVIA Centaur	-	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	10	-	-	10
Abbott Architect	1	-	-	1
diagnostics direct Syphilis Health Check	7	-	-	7
Siemens ADVIA Centaur	2	-	-	2

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	-	5	5	-	5	-
Becton Dickinson	-	5	5	-	5	-
Fisher HealthCare Sure-Vue	-	3	3	-	3	-

<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	5	-	-	5
Becton Dickinson	5	-	-	5
Fisher HealthCare Sure-Vue	3	-	-	3

Syphilis Serology—Semi-Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>N/A (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>
Specimen SY-11									
ALL METHODS	6	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
Specimen SY-12									
ALL METHODS	-	-	-	1	5	-	-	-	-
ASI	-	-	-	1	1	-	-	-	-
Becton Dickinson	-	-	-	-	4	-	-	-	-
Specimen SY-13									
ALL METHODS	-	-	1	5	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	-	4	-	-	-	-	-
Specimen SY-14									
ALL METHODS	-	-	1	5	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	-	4	-	-	-	-	-
Specimen SY-15									
ALL METHODS	6	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-

H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-5</u>		<u>Specimen HP-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	35	37	-
Alere Clearview - moderate	-	3	3	-
Alfa Scientific Instant-View	-	1	1	-
Beckman Coulter ICON HP	-	1	1	-
Consult Diagnostics - moderate	1	5	6	-
Consult Diagnostics - waived	1	4	5	-
Henry Schein OneStep+ - waived	-	8	8	-
McKesson Medi-Lab Performance - waived	-	1	1	-
NDC Pro Advantage	-	2	2	-
Polymedco Poly stat	-	1	1	-
Quidel QuickVue	-	9	9	-

Mycoplasma Antibody

<u>Method</u>	<u>Specimen MY-5</u>		<u>Specimen MY-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	9	-
Meridian ImmunoCard	-	9	9	-

Viral Markers – Anti-HBc (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	-	3	-	-	3	-	-	3	-
Abbott Architect	-	2	-	-	2	-	-	2	-
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	1	1	1	-	3	-
Abbott Architect	1	-	1	-	2	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HBc (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	-	1	-	1	-	-	-	1	-
Abbott Architect	-	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	1	-	-	1	-	-
Abbott Architect	1	-	-	1	-	-

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	-	5	-	-	5	-	5	-	-
Abbott Architect	-	2	-	-	2	-	2	-	-
bioLytical Labs INSTI									
HIV - moderate	-	1	-	-	1	-	1	-	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	-	1	-	-	1	-	1	-	-
Siemens ADVIA									
Centaur	-	1	-	-	1	-	1	-	-

<u>Method</u>	Specimen VM-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	-
Abbott Architect	-	2	-	-	2	-
bioLytical Labs INSTI						
HIV - moderate	-	1	-	-	1	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	-	1	-	-	1	-
Siemens ADVIA						
Centaur	-	1	-	-	1	-

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	-	3	-	-	3	-	-	3	-
Abbott Architect	-	2	-	-	2	-	-	2	-
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	-	3	-	3	-	-
Abbott Architect	-	2	-	2	-	-
VITROS 5600	-	1	-	1	-	-

Viral Markers – Anti-HAV (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	3	-	-	-	3	-	3	-	-
Abbott Architect	2	-	-	-	2	-	2	-	-
Siemens ADVIA									
Centaur	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	3	-	-	3	-	-
Abbott Architect	2	-	-	2	-	-
Siemens ADVIA						
Centaur	1	-	-	1	-	-

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>	<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	-	-	-	3	-	3	-	-
Abbott Architect	2	-	-	-	2	-	2	-	-
Siemens ADVIA									
Centaur	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	-	3	-	-	3	-
Abbott Architect	-	2	-	-	2	-
Siemens ADVIA						
Centaur	-	1	-	-	1	-

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	-	5	-	5	-	-	-	5	-
Abbott Architect	-	2	-	2	-	-	-	2	-
Siemens ADVIA									
Centaur	-	2	-	2	-	-	-	2	-
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	5	-	-	2	2	1
Abbott Architect	2	-	-	1	1	-
Siemens ADVIA						
Centaur	2	-	-	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	-	6	-	1	5	-	-	6	-
Abbott Architect	-	1	-	-	1	-	-	1	-
OraSure OraQuick									
HCV	-	1	-	-	1	-	-	1	-
Roche cobas e 411	-	1	-	1	-	-	-	1	-
Siemens ADVIA									
Centaur	-	2	-	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-	-	1	-

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

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