

**MEDICAL LABORATORY**

**EVALUATION**

**PARTICIPANT SUMMARY**

**2 • 0 • 2 • 0**

Immunology  
2020 MLE-M2

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-6</u>		<u>Specimen IM-7</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	114	-	115
Alere Clearview - moderate	-	1	-	1
Alere Clearview - waived	-	6	-	6
Alere Clearview Mono Plus II - moderate	-	1	-	1
Alere Clearview Mono Plus II - waived	-	2	-	2
BioStar Acceava Mono Test	-	2	-	2
BioStar Acceava Mono-whole bld	-	3	-	3
Cardinal Health SP Brand - waived	-	2	-	2
Clarity Diagnostics	-	1	-	1
Consult Diagnostics - moderate	-	9	-	9
Consult Diagnostics - waived	-	11	-	11
Fisher HealthCare Sure-Vue	-	2	-	2
Henry Schein OneStep+ - moderate	-	1	-	1
Henry Schein OneStep+ - waived	-	10	-	10
LifeSign Status - waived	-	6	-	6
Other Moderate method	-	1	-	1
Other Waived method	-	9	-	9
Quidel QuickVue+	-	1	-	1
Quidel QuickVue+ - waived	-	2	-	2
Sekisui OSOM	-	4	-	4
Sekisui OSOM (waived)	1	40	-	41

## Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-8</u>		<u>Specimen IM-9</u>		<u>Specimen IM-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	26	-	26	-	-	26
Alere Clearview - moderate	1	-	1	-	-	1
Alere Clearview Mono Plus II - moderate	1	-	1	-	-	1
BioStar Acceava Mono Test	1	-	1	-	-	1
BioStar Acceava Mono-whole bld	1	-	1	-	-	1
Consult Diagnostics - moderate	3	-	3	-	-	3
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	1	-	1	-	-	1
Sekisui OSOM	4	-	4	-	-	4
Sekisui OSOM (waived)	2	-	2	-	-	2

## Rheumatoid Factor—Qualitative

<b><u>Method</u></b>	<b>Specimen RF-6</b>		<b>Specimen RF-7</b>		<b>Specimen RF-8</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	23	-	23	-	-	23
ASI	5	-	5	-	-	5
Beckman AU	1	-	1	-	-	1
Biokit Rheumajet	2	-	2	-	-	2
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

<b><u>Method</u></b>	<b>Specimen RF-9</b>		<b>Specimen RF-10</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	1	22	20	3
ASI	-	5	5	-
Beckman AU	-	1	1	-
Biokit Rheumajet	-	2	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>&gt;2560</u>
<b>Specimen RF-6</b>												
ALL METHODS	-	-	2	2	-	1	-	-	-	-	-	-
Beckman AU	-	-	-	2	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	1	-	-	-	-	-	-	-	-
<b>Specimen RF-7</b>												
ALL METHODS	-	-	3	2	-	-	-	-	-	-	-	-
Beckman AU	-	-	-	2	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	3	-	-	-	-	-	-	-	-	-
<b>Specimen RF-8</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	2	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	3	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen RF-9</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	2	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	3	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen RF-10</b>												
ALL METHODS	-	-	3	2	-	-	-	-	-	-	-	-
Beckman AU	-	-	-	2	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	3	-	-	-	-	-	-	-	-	-

## 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>
<b>Specimen RF-6</b>						
All Method	16	117.4	15.9	13.5	117	69 - 166
Beckman AU	10	117.8	18.7	15.8	115	61 - 174
<b>Specimen RF-7</b>						
All Method	16	66.4	11.0	16.6	66	33 - 100
Beckman AU	10	66.5	13.0	19.5	63	27 - 106
<b>Specimen RF-8</b>						
All Method	16	6.3	4.5	71.4	1	0 - 20
Beckman AU	10	5.0	4.5	90.3	4	0 - 19
<b>Specimen RF-9</b>						
All Method	16	6.0	4.6	77.2	1	0 - 20
Beckman AU	10	4.7	4.6	99.3	4	0 - 19
<b>Specimen RF-10</b>						
All Method	16	66.5	10.3	15.5	66	35 - 98
Beckman AU	10	66.5	12.1	18.2	64	30 - 103

## Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<b>Specimen AS-6</b>		<b>Specimen AS-7</b>		<b>Specimen AS-8</b>	
	<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>	<b>Specimen AS-9</b>		<b>Specimen AS-10</b>			
	<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>
<b>Specimen IMP-6</b>						
All Method	16	48.2	1.5	3.1	49	43 - 53
Beckman AU	10	47.7	1.5	3.2	47	43 - 53
<b>Specimen IMP-7</b>						
All Method	16	122.0	4.6	3.7	122	108 - 136
Beckman AU	10	120.7	4.6	3.8	122	106 - 135
<b>Specimen IMP-8</b>						
All Method	16	120.0	4.3	3.6	120	107 - 133
Beckman AU	10	119.0	5.0	4.2	120	104 - 134
<b>Specimen IMP-9</b>						
All Method	16	118.1	3.3	2.8	119	108 - 129
Beckman AU	10	117.3	3.4	2.9	119	106 - 128
<b>Specimen IMP-10</b>						
All Method	16	118.9	5.1	4.3	118	103 - 135
Beckman AU	10	116.2	2.8	2.4	118	107 - 125

## 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>
<b>Specimen IMP-6</b>						
All Method	16	7.8	0.8	10.7	8	5 - 11
Beckman AU	10	7.8	1.0	12.6	8	4 - 11
<b>Specimen IMP-7</b>						
All Method	12	20.4	1.4	7.0	20	16 - 25
Beckman AU	6	20.7	1.6	7.9	21	15 - 26
<b>Specimen IMP-8</b>						
All Method	16	19.9	1.4	6.9	20	15 - 24
Beckman AU	10	20.0	1.4	7.1	20	15 - 25
<b>Specimen IMP-9</b>						
All Method	16	20.3	1.4	7.0	20	16 - 25
Beckman AU	10	20.7	1.6	7.9	21	15 - 26
<b>Specimen IMP-10</b>						
All Method	16	20.0	1.4	7.1	20	15 - 25
Beckman AU	10	20.0	1.7	8.4	20	14 - 26

## 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>
<b>Specimen IMP-6</b>						
All Method	16	76.4	4.9	6.4	77	61 - 92
Beckman AU	10	79.3	2.5	3.2	79	71 - 87
<b>Specimen IMP-7</b>						
All Method	16	193.4	4.9	2.5	191	178 - 209
Beckman AU	10	192.0	4.6	2.4	191	178 - 206
<b>Specimen IMP-8</b>						
All Method	16	192.6	5.8	3.0	192	175 - 211
Beckman AU	10	192.3	6.5	3.4	192	172 - 212
<b>Specimen IMP-9</b>						
All Method	16	454.0	20.1	4.4	456	393 - 515
Beckman AU	10	441.3	13.1	3.0	437	402 - 481
<b>Specimen IMP-10</b>						
All Method	16	196.8	5.4	2.8	197	180 - 214
Beckman AU	10	196.0	4.6	2.3	197	182 - 210

## 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>
<b>Specimen IMP-6</b>						
All Method	16	349.4	21.7	6.2	341	262 - 437
Beckman AU	10	350.7	29.9	8.5	337	263 - 439
<b>Specimen IMP-7</b>						
All Method	16	919.0	29.7	3.2	913	689 - 1149
Beckman AU	10	921.7	41.7	4.5	913	691 - 1153
<b>Specimen IMP-8</b>						
All Method	16	909.8	29.5	3.2	918	682 - 1138
Beckman AU	10	910.7	39.5	4.3	918	683 - 1139
<b>Specimen IMP-9</b>						
All Method	16	873.8	51.5	5.9	865	655 - 1093
Beckman AU	10	878.0	72.4	8.2	859	658 - 1098
<b>Specimen IMP-10</b>						
All Method	16	1880.8	127.2	6.8	1924	1410 - 2351
Beckman AU	10	1849.3	169.1	9.1	1786	1386 - 2312

**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>
<b>Specimen IMP-6</b>						
All Method	16	30.8	3.0	9.8	31	21 - 40
Beckman AU	10	32.7	2.1	6.4	32	26 - 39
<b>Specimen IMP-7</b>						
All Method	16	375.4	26.4	7.0	364	296 - 455
Beckman AU	10	356.7	7.0	2.0	356	335 - 378
<b>Specimen IMP-8</b>						
All Method	16	77.8	2.9	3.7	78	69 - 87
Beckman AU	10	78.3	3.8	4.8	80	66 - 90
<b>Specimen IMP-9</b>						
All Method	16	75.2	4.4	5.8	75	62 - 89
Beckman AU	10	76.7	5.1	6.7	78	61 - 93
<b>Specimen IMP-10</b>						
All Method	16	79.4	3.8	4.8	79	67 - 91
Beckman AU	10	80.3	5.0	6.3	81	65 - 96

**C-Reactive Protein—Qualitative, Regular**

<u>Method</u>	<u>Specimen CR-3</u>		<u>Specimen CR-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5	-
Siemens Dimension	5	-	5	-

**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>
<b>Specimen CR-3</b>						
mg/dL - units						
All Immunology Methods	17	1.260	0.166	13.2	1.21	0.76 - 1.76
mg/L - units						
All Immunology Methods	12	12.781	2.365	18.5	12.08	5.68 - 19.88
<b>Specimen CR-4</b>						
mg/dL - units						
All Immunology Methods	17	2.699	0.367	13.6	2.78	1.59 - 3.81
mg/L - units						
All Immunology Methods	12	27.554	4.077	14.8	26.25	15.32 - 39.79

**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>
<b>Specimen HCR-3</b>						
All Method	19	10.347	0.589	5.7	10.20	8.57 - 12.12

**Specimen HCR-4**

All Method	19	2.858	0.734	25.7	2.72	0.65 - 5.06
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**Antinuclear Antibody (ANA) - Qualitative**

<u>Method</u>	<u>Specimen AE-6</u>		<u>Specimen AE-7</u>		<u>Specimen AE-8</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	13	11	2	13	-
ASI	-	2	-	2	2	-
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-9</u>		<u>Specimen AE-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	13	11	2
ASI	-	2	-	2
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>&gt;640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
<b>Specimen AE-6</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen AE-7</b>												
ALL METHODS	-	-	-	-	-	-	-	4	-	-	-	1
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	-	-	-	1
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
<b>Specimen AE-8</b>												
ALL METHODS	-	-	-	-	-	-	-	2	2	-	1	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	-	1	-	1	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
<b>Specimen AE-9</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen AE-10</b>												
ALL METHODS	-	-	-	-	-	-	1	-	-	3	-	1
Bio-Rad	-	-	-	-	-	-	-	-	-	1	-	-
Immuno Concepts	-	-	-	-	-	-	1	-	-	-	-	1
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-	-

**Anti-dsDNA**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8	3	5
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	1	-	1	1	-
Phadia EliA	-	1	-	1	-	1
TheraTest	-	5	-	5	2	3

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	5	-	5

**Anti-RNP**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	1	1	1	1
Immuno Concepts	-	1	1	-	1	-
Phadia EliA	-	1	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	2	-
Immuno Concepts	-	1	1	-
Phadia EliA	-	1	1	-

## Anti-RNP/Sm

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	6	1	6	1
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	1	1	-	1	-
TheraTest	-	5	5	-	5	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	7	-
GenBio ImmunoDOT Panel 1	-	1	1	-
Immuno Concepts	-	1	1	-
TheraTest	-	5	5	-

## Anti-SSA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	7	-	-	7
Immuno Concepts	-	1	1	-	-	1
Phadia EliA	-	1	1	-	-	1
TheraTest	-	5	5	-	-	5

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	5	-	5



**Anti-SSB**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	6	1	-	7
Immuno Concepts	-	1	1	-	-	1
Phadia EliA	-	1	1	-	-	1
TheraTest	-	5	4	1	-	5

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<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-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	1	1	-	-	1
GenBio ImmunoDOT Panel 1	-	1	1	-	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1

**Anti-Sm**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7	-	7
Immuno Concepts	-	1	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	-	5	-	5	-	5

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	1	6
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	5	1	4

## Rubella—Qualitative

<u>Method</u>	Specimen RU-6		Specimen RU-7		Specimen RU-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	2	-	-	2
Siemens ADVIA Centaur	-	2	2	-	-	2

<u>Method</u>	Specimen RU-9		Specimen RU-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	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-6 through RU-10 are: <10.0 IU/mL, 69.6 IU/mL, <10.0 IU/mL, 69.6 IU/mL, and 43.2 IU/mL, respectively.

## Anti-HIV

<u>Method</u>	Specimen HIV-6		Specimen HIV-7	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	59	60	-
Alere Clearview HIV1/2 STAT-PAK	-	2	2	-
Alere Determine HIV - moderate	-	2	2	-
Alere Determine HIV - waived	-	17	17	-
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	-	10	11	-
Other Waived method	-	3	3	-

<u>Method</u>	Specimen HIV-8		Specimen HIV-9		Specimen HIV-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5	5	-
Alere Determine HIV - moderate	5	-	-	5	5	-

# Allergen Specific IgE Antibodies

## Specimen AL-6

### Method

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

Common (Short) Ragweed (w1) Allergen CLASS RESULT								Russian Thistle (w11) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	-	1	3	-	-	-	-	-	-	1	1	-	-	-	-
-	-	1	1	-	-	-	-	-	-	-	1	-	-	-	-
-	-	-	2	-	-	-	-	-	-	1	-	-	-	-	-

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

Silver Birch Tree (t3) Allergen CLASS RESULT								Grey Alder (t2) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	-	-	3	1	-	-	-	-	-	-	1	-	-	-	-
-	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-
-	-	-	2	-	-	-	-	-	-	-	1	-	-	-	-

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

Bermuda Grass (g2) Allergen CLASS RESULT								Mouse Urine Protein (e72) 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	-	-	-	-	-	-	-	-	-	-	-	-

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

Egg White (f1) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6
-	-	-	2	-	2	-	-
-	-	-	-	-	2	-	-
-	-	-	2	-	-	-	-

# Allergen Specific IgE Antibodies

## Specimen AL-7

<u>Method</u>	Bahia Grass (g17) Allergen								Meadow, Kentucky Blue, June Grass (g8) Allergens							
	<i>CLASS RESULT</i>								<i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	2	-	-	-	-	-	-	-	2	-	1	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	-	-	-	-	-	-	-	2	-	-	-	-
<u>Method</u>	Penicillium chrysogenum (m1) Allergen								Alternaria alternata (m6) Allergen							
	<i>CLASS RESULT</i>								<i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	2	-	-	-	-	-	-	-	-	-	3	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	2	-	-	-	-	-	-	-	-	-	2	-	-	-	-
<u>Method</u>	Hazelnut (f17) Allergen								Lobster (f80) Allergen							
	<i>CLASS RESULT</i>								<i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	2	-	-	-	-	-	-	-	2	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	-	-	-	-	-	-	-	2	-	-	-	-
<u>Method</u>	Walnut (f256) Allergen															
	<i>CLASS RESULT</i>															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	-	-	-	2	-	-	-	-								
Hitachi CLA-1	-	-	-	-	-	-	-	-								
Phadia ImmunoCAP System (KU/L)	-	-	-	2	-	-	-	-								

**Total IgE—Quantitative (U/mL)**

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen AL-6</b>						
All Method	5	183.0	19.5	10.6	176	124 - 242
<b>Specimen AL-7</b>						
All Method	5	382.7	15.8	4.1	379	335 - 431
<b>Specimen AL-8</b>						
All Method	5	9.3	2.3	24.7	8	2 - 17
<b>Specimen AL-9</b>						
All Method	5	9.7	2.9	29.9	8	1 - 19
<b>Specimen AL-10</b>						
All Method	5	8.0	0.1	0.0	8	7 - 9

### Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	-	1	1	-
Serodia	1	-	-	1	1	-

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	1	1	-
Serodia	-	1	1	-

### Syphilis Serology—Qualitative: Treponema pallidum antibodies

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	9	-	-	9	9	-
Abbott Architect	1	-	-	1	1	-
diagnostics direct Syphilis Health						
Check	6	-	-	6	6	-
Siemens ADVIA Centaur	2	-	-	2	2	-

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	9	9	-
Abbott Architect	-	1	1	-
diagnostics direct Syphilis Health				
Check	-	6	6	-
Siemens ADVIA Centaur	-	2	2	-

### Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	14	-	-	14	14	-
ASI	6	-	-	6	6	-
Becton Dickinson	5	-	-	5	5	-
Fisher HealthCare Sure-Vue	3	-	-	3	3	-

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	14	14	-
ASI	-	6	6	-
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:&gt;64</u>
<b>Specimen SY-6</b>									
ALL METHODS	-	-	-	2	5	-	-	-	-
ASI	-	-	-	1	2	-	-	-	-
Becton Dickinson	-	-	-	1	3	-	-	-	-
<b>Specimen SY-7</b>									
ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
<b>Specimen SY-8</b>									
ALL METHODS	-	-	2	5	-	-	-	-	-
ASI	-	-	1	2	-	-	-	-	-
Becton Dickinson	-	-	1	3	-	-	-	-	-
<b>Specimen SY-9</b>									
ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
<b>Specimen SY-10</b>									
ALL METHODS	-	-	-	3	3	1	-	-	-
ASI	-	-	-	1	1	1	-	-	-
Becton Dickinson	-	-	-	2	2	-	-	-	-

## H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-3</u>		<u>Specimen HP-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	34	-	1	33
Alere Clearview - moderate	3	-	-	3
Alfa Scientific Instant-View	1	-	-	1
Consult Diagnostics - moderate	6	-	1	5
Consult Diagnostics - waived	4	-	-	4
Henry Schein OneStep+ - waived	8	-	-	8
McKesson Medi-Lab Performance - waived	1	-	-	1
NDC Pro Advantage	1	-	-	1
Polymedco Poly stat	1	-	-	1
Quidel QuickVue	9	-	-	-

## Mycoplasma Antibody

<u>Method</u>	<u>Specimen MY-3</u>		<u>Specimen MY-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	-	6
Meridian ImmunoCard	6	-	-	6



**Viral Markers – Anti-HBc (IgM)**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	3	-	-	-	3	-	-	3	-
Abbott Architect	2	-	-	-	2	-	-	2	-
VITROS 5600	1	-	-	-	1	-	-	1	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	3	-	-	3	-
Abbott Architect	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-

**Viral Markers – Anti-HBc (Total/IgG)**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	1	-	-	-	1	-	-	1	-
Abbott Architect	1	-	-	-	1	-	-	1	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	1	-	-	-	1	-
Abbott Architect	1	-	-	-	1	-

## Viral Markers – Anti-HIV

<u>Method</u>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<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	-
bioLytical Labs INSTI									
HIV - moderate	-	1	-	-	1	-	-	1	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	-	3	-	-	3	-	-	3	-
Siemens ADVIA									
Centaur	-	1	-	-	1	-	-	1	-

  

<u>Method</u>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<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	-	-
bioLytical Labs INSTI						
HIV - moderate	-	1	-	1	-	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	-	3	-	3	-	-
Siemens ADVIA						
Centaur	-	1	-	1	-	-

## Viral Markers – Anti-HAV (IgM)

<u>Method</u>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<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>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<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-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	3	-	1	2	-	3	-	-
Abbott Architect	-	2	-	1	1	-	2	-	-
Siemens ADVIA									
Centaur	-	1	-	-	1	-	1	-	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	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-6 through VM-10 are: Negative, Negative, Negative, Negative, and Negative, respectively.

**Viral Markers – Anti-HBs**

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	3	-	-	3	-	3	-	-
Abbott Architect	-	2	-	-	2	-	2	-	-
Siemens ADVIA									
Centaur	-	1	-	-	1	-	1	-	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	3	-	3	-	-
Abbott Architect	-	2	-	2	-	-
Siemens ADVIA						
Centaur	-	1	-	1	-	-

## Viral Markers – HBsAg

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	6	-	-	-	6	-	-	6	-
Abbott Architect	3	-	-	-	3	-	-	3	-
Siemens ADVIA									
Centaur	2	-	-	-	2	-	-	2	-
VITROS 5600	1	-	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	6	-	-	-	6	-
Abbott Architect	3	-	-	-	3	-
Siemens ADVIA						
Centaur	2	-	-	-	2	-
VITROS 5600	1	-	-	-	1	-

## Viral Markers – Anti-HCV

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	8	-	-	9	-	-	9	-
Abbott Architect	-	3	-	-	3	-	-	3	-
OraSure OraQuick									
HCV	-	2	-	-	2	-	-	2	-
Roche cobas e 411	1	-	-	-	1	-	-	1	-
Siemens ADVIA									
Centaur	-	2	-	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	9	-	-	-	9	-
Abbott Architect	3	-	-	-	3	-
OraSure OraQuick						
HCV	2	-	-	-	2	-
Roche cobas e 411	1	-	-	-	1	-
Siemens ADVIA						
Centaur	2	-	-	-	2	-
VITROS 5600	1	-	-	-	1	-

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