

**MEDICAL LABORATORY**

**EVALUATION**

**PARTICIPANT SUMMARY**

**2 • 0 • 2 • 1**

Immunology  
2021 MLE-M1

ACP | Medical Laboratory  
Evaluation 

Total Commitment to Education and Service  
Provided by ACP, Inc.

# Table of Contents

<b>Evaluation Criteria</b> .....	<b>3</b>
<b>Immunology</b>	
<b>Infectious Mononucleosis</b> .....	<b>4</b>
<b>Rheumatoid Factor</b> .....	<b>6</b>
Qualitative .....	6
Semi-Quantitative (Titer).....	7
Quantitative (IU) .....	8
<b>Anti-Streptolysin O (ASO)</b> .....	<b>8</b>
<b>Complement C3</b> .....	<b>9</b>
<b>Complement C4</b> .....	<b>10</b>
<b>IgA</b> .....	<b>11</b>
<b>IgG</b> .....	<b>11</b>
<b>IgM</b> .....	<b>12</b>
<b>C-Reactive Protein, Regular</b> .....	<b>12</b>
Qualitative .....	12
Quantitative .....	12
<b>C-Reactive Protein, High Sensitivity</b> .....	<b>13</b>
<b>Antinuclear Antibody</b> .....	<b>13</b>
Qualitative .....	13
Semi-Quantitative (Titer).....	14
<b>Anti-dsDNA</b> .....	<b>15</b>
<b>Anti-RNP</b> .....	<b>15</b>
<b>Anti-RNP/Sm</b> .....	<b>16</b>
<b>Anti-SSA</b> .....	<b>16</b>
<b>Anti-SSB</b> .....	<b>17</b>
<b>Anti-SSA/SSB</b> .....	<b>17</b>
<b>Anti-Sm</b> .....	<b>17</b>
<b>Rubella</b> .....	<b>18</b>
Qualitative .....	18
Quantitative .....	18
<b>Anti-HIV</b> .....	<b>18</b>
<b>Allergen Specific IgE Antibodies</b> .....	<b>19</b>
<b>Total IgE</b> .....	<b>21</b>
<b>Syphilis Serology</b> .....	<b>22</b>
Qualitative: MHA-TP .....	22
Qualitative: Treponema pallidum antibodies .....	22
Qualitative: RPR .....	22
Semi-Quantitative: RPR (Titer) .....	23
<b>H. pylori Antibody Detection</b> .....	<b>24</b>
<b>Mycoplasma Antibody</b> .....	<b>24</b>
<b>SARS-CoV-2 Serology</b> .....	<b>24</b>
<b>Viral Markers</b> .....	<b>25</b>
Anti-HBc (IgM) .....	25
Anti-HBc (Total/IgG) .....	25
Anti-HIV .....	26
Anti-HAV (IgM) .....	26
Anti-HAV (Total/IgG).....	27
HBeAg .....	27
Anti-HBs .....	27
HBsAg .....	28
Anti-HCV .....	28

## 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
SARS-CoV-2 Serology	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	$\pm$ 30% or 2 SD*
High Sensitivity C-Reactive Protein	$\pm$ 30% or 1 mg/L*
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

\*Whichever is greater

## Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-1</u>		<u>Specimen IM-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	119	1	-	120
Alere Clearview - moderate	1	-	-	1
Alere Clearview - waived	5	-	-	5
Alere Clearview Mono Plus II - moderate	1	-	-	1
Alere Clearview Mono Plus II - waived	3	-	-	3
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	4	-	-	4
Consult Diagnostics - waived	13	-	-	13
Fisher HealthCare Sure-Vue	2	-	-	2
Henry Schein OneStep+ - moderate	1	-	-	1
Henry Schein OneStep+ - waived	12	1	-	13
LifeSign Status - waived	6	-	-	6
Other Moderate method	1	-	-	1
Other Waived method	7	-	-	7
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	3	-	-	3
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	44	-	-	44

**Infectious Mononucleosis**

<u>Method</u>	<b>Specimen IM-3</b>		<b>Specimen IM-4</b>		<b>Specimen IM-5</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	27	-	27	-	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
BioStar Aceava Mono Test	-	1	-	1	-	1
Consult Diagnostics - moderate	-	1	-	1	-	1
Consult Diagnostics - waived	-	5	-	5	-	5
Fisher HealthCare Sure-Vue	-	1	-	1	-	1
Henry Schein OneStep+ - moderate	-	1	-	1	-	1
Henry Schein OneStep+ - waived	-	2	-	2	-	2
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

<b><u>Method</u></b>	<b>Specimen RF-1</b>		<b>Specimen RF-2</b>		<b>Specimen RF-3</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	-	19	19	-	19	-
ASI	-	4	4	-	4	-
Biokit Rheumajet	-	1	1	-	1	-
Fisher HealthCare Sure-View	-	3	3	-	3	-
Stanbio Laboratory	-	4	4	-	4	-
TheraTest	-	5	5	-	5	-
Wampole ColorCard	-	1	1	-	1	-
Wampole Rheumatex	-	1	1	-	1	-

<b><u>Method</u></b>	<b>Specimen RF-4</b>		<b>Specimen RF-5</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	19	-	-	19
ASI	4	-	-	4
Biokit Rheumajet	1	-	-	1
Fisher HealthCare Sure-View	3	-	-	3
Stanbio Laboratory	4	-	-	4
TheraTest	5	-	-	5
Wampole ColorCard	1	-	-	1
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-1</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen RF-2</b>												
ALL METHODS	-	-	2	3	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	1	-	-	-	-	-	-	-	-
<b>Specimen RF-3</b>												
ALL METHODS	-	-	2	3	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	1	-	-	-	-	-	-	-	-
<b>Specimen RF-4</b>												
ALL METHODS	-	2	3	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	1	-	-	-	-	-	-	-	-	-
<b>Specimen RF-5</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
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-1</b>						
All Method	14	7.3	2.6	35.4	6	0 - 16
Beckman AU	8	6.7	2.7	39.9	6	0 - 15
<b>Specimen RF-2</b>						
All Method	14	114.1	4.2	3.7	117	101 - 127
Beckman AU	8	116.2	3.7	3.1	118	105 - 128
<b>Specimen RF-3</b>						
All Method	14	113.7	2.7	2.4	113	105 - 122
Beckman AU	8	114.5	2.9	2.6	115	105 - 124
<b>Specimen RF-4</b>						
All Method	14	61.0	1.4	2.3	61	56 - 66
Beckman AU	8	61.2	1.6	2.6	61	56 - 66
<b>Specimen RF-5</b>						
All Method	14	7.4	2.5	33.0	6	0 - 15
Beckman AU	8	7.0	2.4	33.8	6	0 - 15

## Anti-Streptolysin O (ASO)—Qualitative

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



**Complement C3 (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen IMP-1</b>						
All Method	14	150.7	6.1	4.1	152	132 - 170
Beckman AU	6	149.8	6.0	4.0	149	131 - 168
<b>Specimen IMP-2</b>						
All Method	14	48.9	5.1	10.5	49	33 - 65
Beckman AU	6	51.0	5.3	10.4	50	35 - 67
<b>Specimen IMP-3</b>						
All Method	14	127.1	6.0	4.7	127	109 - 146
Beckman AU	6	127.5	4.7	3.7	127	113 - 142
<b>Specimen IMP-4</b>						
All Method	14	151.6	6.8	4.5	150	131 - 173
Beckman AU	6	149.7	4.8	3.2	148	135 - 165
<b>Specimen IMP-5</b>						
All Method	14	147.1	6.8	4.6	145	126 - 168
Beckman AU	6	145.7	6.0	4.1	145	127 - 164

## 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-1</b>						
All Method	14	25.7	2.2	8.4	26	19 - 33
Beckman AU	6	26.7	1.8	6.6	28	21 - 32
<b>Specimen IMP-2</b>						
All Method	14	7.5	0.8	11.3	8	4 - 11
Beckman AU	6	7.8	0.8	9.6	8	5 - 11
<b>Specimen IMP-3</b>						
All Method	14	20.7	1.5	7.2	21	16 - 26
Beckman AU	6	21.3	1.2	5.7	22	17 - 25
<b>Specimen IMP-4</b>						
All Method	14	25.4	2.9	11.3	26	16 - 35
Beckman AU	6	26.2	1.8	7.0	27	20 - 32
<b>Specimen IMP-5</b>						
All Method	14	23.9	2.1	8.7	25	17 - 31
Beckman AU	6	24.3	2.2	8.9	25	17 - 31

**IgA (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
------------------------	-------------	-------------	-----------	-----------	---------------	--------------

**Specimen IMP-1**

All Method	12	518.7	11.7	2.3	517	483 - 554
Beckman AU	5	511.0	6.6	1.3	510	491 - 531

**Specimen IMP-2**

All Method	12	74.8	4.8	6.4	74	60 - 90
Beckman AU	5	78.7	3.2	4.1	80	69 - 89

**Specimen IMP-3**

All Method	12	197.2	8.4	4.3	196	171 - 223
Beckman AU	5	196.7	1.5	0.8	197	192 - 202

**Specimen IMP-4**

All Method	12	241.8	12.5	5.2	242	204 - 280
Beckman AU	5	244.3	7.4	3.0	247	222 - 267

**Specimen IMP-5**

All Method	12	233.7	9.3	4.0	232	205 - 262
Beckman AU	5	233.7	3.8	1.6	232	222 - 246

**IgG (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
------------------------	-------------	-------------	-----------	-----------	---------------	--------------

**Specimen IMP-1**

All Method	12	1083.0	31.4	2.9	1083	812 - 1354
Beckman AU	5	1071.7	22.0	2.1	1073	803 - 1340

**Specimen IMP-2**

All Method	12	335.0	21.8	6.5	336	251 - 419
Beckman AU	5	336.0	23.5	7.0	325	252 - 420

**Specimen IMP-3**

All Method	12	949.0	31.4	3.3	950	711 - 1187
Beckman AU	5	951.7	16.6	1.7	954	713 - 1190

**Specimen IMP-4**

All Method	12	1156.2	52.2	4.5	1152	867 - 1446
Beckman AU	5	1145.3	53.4	4.7	1138	858 - 1432

**Specimen IMP-5**

All Method	12	1979.0	159.2	8.0	2026	1484 - 2474
Beckman AU	5	1878.7	160.7	8.6	1822	1409 - 2349

**IgM (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
------------------------	-------------	-------------	-----------	-----------	---------------	--------------

**Specimen IMP-1**

All Method	12	104.5	7.5	7.2	105	81 - 128
Beckman AU	5	98.0	2.6	2.7	97	90 - 106

**Specimen IMP-2**

All Method	12	31.2	2.2	7.2	31	24 - 38
Beckman AU	5	31.3	0.6	1.8	31	29 - 34

**Specimen IMP-3**

All Method	12	85.5	5.4	6.4	84	69 - 102
Beckman AU	5	83.0	1.7	2.1	82	77 - 89

**Specimen IMP-4**

All Method	12	350.0	22.5	6.4	347	282 - 418
Beckman AU	5	337.3	12.5	3.7	337	299 - 375

**Specimen IMP-5**

All Method	12	100.5	6.4	6.4	99	81 - 120
Beckman AU	5	97.3	2.1	2.1	98	91 - 104

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

<u>Method</u>	<u>Specimen CR-1</u>		<u>Specimen CR-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	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-1**

mg/dL - units						
Beckman AU	6	0.183	0.172	93.9	0.15	0.00 - 0.53
Siemens Dimension	6	0.173	0.065	37.7	0.20	0.04 - 0.31
All Immunology Methods	17	0.163	0.131	80.5	0.20	0.00 - 0.43
mg/L - units						
All Immunology Methods	13	2.015	1.986	98.5	1.40	0.00 - 5.99

**Specimen CR-2**

mg/dL - units						
Beckman AU	6	6.332	0.293	4.6	6.37	4.43 - 8.24
Siemens Dimension	6	6.852	0.497	7.3	6.95	4.79 - 8.91
All Immunology Methods	17	6.382	0.575	9.0	6.40	4.46 - 8.30
mg/L - units						
All Immunology Methods	13	64.107	6.580	10.3	62.35	44.87 - 83.34

**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-1</b>						
All Method	22	3.170	0.376	11.9	3.03	2.17 - 4.18
Beckman AU	8	3.381	0.741	21.9	3.01	2.36 - 4.40

**Specimen HCR-2**

All Method	23	11.981	1.157	9.7	11.82	8.38 - 15.58
Beckman AU	8	12.460	1.351	10.8	11.82	8.72 - 16.20

**Antinuclear Antibody (ANA) - Qualitative**

<u>Method</u>	<u>Specimen AE-1</u>		<u>Specimen AE-2</u>		<u>Specimen AE-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	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-4</u>		<u>Specimen AE-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	1	-	12
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>&gt;640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
<b>Specimen AE-1</b>												
ALL METHODS	-	-	-	-	-	1	2	1	-	1	-	-
Bio-Rad	-	-	-	-	-	-	-	-	-	1	-	-
Immuno Concepts	-	-	-	-	-	1	1	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	1	-	-	-	-
<b>Specimen AE-2</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	2	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen AE-3</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	2	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen AE-4</b>												
ALL METHODS	-	-	-	-	-	-	3	2	-	-	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	1	-	-	-	-
<b>Specimen AE-5</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	2	-	-	-	-	-	-	-	-	-	-	-

## Anti-dsDNA

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

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

## Anti-RNP

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

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

## Anti-RNP/Sm

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	5	-	6
GenBio ImmunoDOT Panel 1	1	-	-	1
TheraTest	-	5	-	5

## Anti-SSA

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	-	6	-	6
Phadia EliA	-	1	-	1	-	1
TheraTest	-	5	-	5	-	5

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



## Anti-SSB

<u>Method</u>	<u>Specimen AE-1</u>		<u>Specimen AE-2</u>		<u>Specimen AE-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	-	6	-	6
Phadia EliA	-	1	-	1	-	1
TheraTest	-	5	-	5	-	5

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

## Anti-SSA/SSB

<u>Method</u>	<u>Specimen AE-1</u>		<u>Specimen AE-2</u>		<u>Specimen AE-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	1	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1

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

## Anti-Sm

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

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

## Rubella—Qualitative

<u>Method</u>	<u>Specimen RU-1</u>		<u>Specimen RU-2</u>		<u>Specimen RU-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5	5	-
Siemens ADVIA Centaur	-	5	-	5	5	-

<u>Method</u>	<u>Specimen RU-4</u>		<u>Specimen RU-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5
Siemens ADVIA Centaur	5	-	-	5

## 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-1 through RU-5 are: <10.0 IU/mL, <10.0 IU/mL, 37.7 IU/mL, 19.4 IU/mL, and <10.0 IU/mL, respectively.

## Anti-HIV

<u>Method</u>	<u>Specimen HIV-1</u>		<u>Specimen HIV-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	68	1	2	67
Alere Clearview HIV1/2 STAT-PAK	2	-	-	2
Alere Determine HIV - moderate	2	-	-	2
Alere Determine HIV - waived	16	-	1	15
bioLytical Labs INSTI HIV - moderate	2	-	-	2
bioLytical Labs INSTI HIV - waived	14	-	-	14
Chembio HIV 1/2 Assay - waived	17	-	-	17
Orasure OraQuick Advance Rapid HIV-1/2 - waived	12	1	1	12
Other Waived method	3	-	-	3

<u>Method</u>	<u>Specimen HIV-3</u>		<u>Specimen HIV-4</u>		<u>Specimen HIV-5</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-1

**Method**

	Timothy Grass (g6) Allergen								Bermuda Grass (g2) 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	-	-	-	-	1	2	-	-	1	-	-	2	2	-	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-	1	-	-	1	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	2	1	-	-	-	-	-	1	2	-	-	-

	Silver Birch Tree (t3) Allergen								Maple (Box Elder) (t1) 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	1	-	2	2	-	-	-	-	1	-	2	2	-	-	-	-
Hitachi CLA-1	1	-	1	-	-	-	-	-	1	-	1	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	2	-	-	-	-	-	-	1	2	-	-	-	-

	Dog Dander (e5) Allergen								English Plantain (w9) 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	1	-	-	2	1	1	-	-	1	-	2	2	-	-	-	-
Hitachi CLA-1	1	-	-	-	-	1	-	-	1	-	1	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	1	-	-	-	-	-	1	2	-	-	-	-

	Common (Short) Ragweed (w1) Allergen							
	<i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	-	2	2	-	-	-
Hitachi CLA-1	1	-	-	1	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	2	-	-	-

## Allergen Specific IgE Antibodies

### Specimen AL-2

<b><u>Method</u></b>	<b>Sweet Vernal Grass (g1) Allergen</b>								<b>Meadow Fescue (g4) Allergen</b>							
	<b>CLASS RESULT</b>								<b>CLASS RESULT</b>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	2	1	-	-	-	-	-	2	1	-	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	2	-	-	-	-	-	-	2	1	-	-	-
	<b>Cat Epithelium (e1) Allergen</b>								<b>Mouse Urine Protein (e72) Allergen</b>							
	<b>CLASS RESULT</b>								<b>CLASS RESULT</b>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	1	1	2	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	2	-	-	-	-	-	-	-	-	-	-	-
	<b>House Dust Mite (D. pteronyssinus) (d1) Allergen</b>								<b>Cow Milk (f2) Allergen</b>							
	<b>CLASS RESULT</b>								<b>CLASS RESULT</b>							
	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	2	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-	-	-	-	-	-	2	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	2	-	-	-	-	-	-	2	1	-	-	-
	<b>Peanut (f13) Allergen</b>															
	<b>CLASS RESULT</b>															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	-	-	-	-	2	3	-	-								
Hitachi CLA-1	-	-	-	-	-	2	-	-								
Phadia ImmunoCAP System (KU/L)	-	-	-	-	2	1	-	-								

**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-1</b>						
All Method	5	177.7	9.3	5.2	182	149 - 206
<b>Specimen AL-2</b>						
All Method	5	204.0	8.9	4.4	207	177 - 231
<b>Specimen AL-3</b>						
All Method	5	6.7	0.6	8.7	7	4 - 9
<b>Specimen AL-4</b>						
All Method	5	77.0	6.0	7.8	77	59 - 95
<b>Specimen AL-5</b>						
All Method	5	17.0	1.7	10.2	18	11 - 23

### Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	-	1	1	-
Serodia	1	-	-	1	1	-

<u>Method</u>	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	-	1
Serodia	1	-	-	1

### Syphilis Serology—Qualitative: Treponema pallidum antibodies

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	9	-	-	9	9	-
Abbott Architect	1	-	-	1	1	-
diagnostics direct Syphilis Health						
Check	6	-	-	6	6	-
Siemens ADVIA	2	-	-	2	2	-

<u>Method</u>	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	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-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	13	-	-	13	13	-
ASI	5	-	-	5	5	-
Becton Dickinson	5	-	-	5	5	-
Fisher HealthCare Sure-Vue	3	-	-	3	3	-

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

## H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-1</u>		<u>Specimen HP-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	33	34	-
Alere Clearview - moderate	-	2	2	-
Alfa Scientific Instant-View	-	1	1	-
Consult Diagnostics - moderate	-	5	5	-
Consult Diagnostics - waived	-	6	6	-
Henry Schein OneStep+ - waived	-	8	8	-
McKesson Medi-Lab Performance - waived	-	2	2	-
NDC Pro Advantage	-	1	1	-
Polymedco Poly stat	-	1	1	-
Quidel QuickVue	1	7	8	-

## Mycoplasma Antibody

<u>Method</u>	<u>Specimen MY-1</u>		<u>Specimen MY-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	1	4
Meridian ImmunoCard	5	-	1	4

## SARS-CoV-2 Serology

<u>Method</u>	<u>Specimen SAB-1</u>		<u>Specimen SAB-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	17	-
Abbott Architect	-	4	4	-
Beckman ACCESS / 2 / DxI	-	3	3	-
Healgen Scientific	-	2	2	-
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas e 411	-	3	3	-
Roche Elecsys	-	1	1	-
Siemens ADVIA	-	1	1	-
VITROS Eci	-	1	1	-



### Viral Markers – Anti-HBc (IgM)

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	5	-	1	3	1	1	4	-
Abbott Alinity	-	1	-	1	-	-	1	-	-
Abbott Architect	-	2	-	-	1	1	-	2	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	5	-	3	1	1
Abbott Alinity	-	1	-	1	-	-
Abbott Architect	-	2	-	1	-	1
Siemens ADVIA	-	1	-	1	-	-
VITROS 5600	-	1	-	-	1	-

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

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	3	-	3	-	-	3	-	-
Abbott Alinity	-	1	-	1	-	-	1	-	-
Abbott Architect	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-	1	-	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	3	-	3	-	-
Abbott Alinity	-	1	-	1	-	-
Abbott Architect	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-

## Viral Markers – Anti-HIV

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	7	-	-	7	-	-	7	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	2	-	-	2	-	-	2	-
bioLytical Labs INSTI									
HIV - moderate	-	1	-	-	1	-	-	1	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	-	2	-	-	2	-	-	2	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	7	-	-	-	7	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	2	-	-	-	2	-
bioLytical Labs INSTI						
HIV - moderate	1	-	-	-	1	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	2	-	-	-	2	-
Siemens ADVIA	1	-	-	-	1	-

## Viral Markers – Anti-HAV (IgM)

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	5	-	-	5	-	-	5	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	5	-	-	5	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-

### Viral Markers – Anti-HAV (Total/IgG)

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

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

### Viral Markers – HBeAg

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

### Viral Markers – Anti-HBs

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	-	-	-	5	-	1	4	-
Abbott Alinity	1	-	-	-	1	-	-	1	-
Abbott Architect	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	1	-	-	-	1	-	1	-	-
Siemens ADVIA	1	-	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	-	-	-	5	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	2	-	-	-	2	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Siemens ADVIA	1	-	-	-	1	-

## Viral Markers – HBsAg

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	7	-	7	-	-	5	1	1
Abbott Alinity	-	1	-	1	-	-	1	-	-
Abbott Architect	-	2	-	2	-	-	1	1	-
Roche cobas 6000 / e 601	-	1	-	1	-	-	1	-	-
Siemens ADVIA	-	2	-	2	-	-	2	-	-
VITROS 5600	-	1	-	1	-	-	-	-	1

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	7	-	7	-	-
Abbott Alinity	-	1	-	1	-	-
Abbott Architect	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Siemens ADVIA	-	2	-	2	-	-
VITROS 5600	-	1	-	1	-	-

## Viral Markers – Anti-HCV

<u>Method</u>	<u>Specimen VM-1</u>			<u>Specimen VM-2</u>			<u>Specimen VM-3</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	11	-	-	2	9	-	-	11	-
Abbott Alinity	1	-	-	-	1	-	-	1	-
Abbott Architect	2	-	-	-	2	-	-	2	-
OraSure OraQuick HCV	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	1	-	-	1	-	-	-	1	-
Roche cobas e 411	1	-	-	1	-	-	-	1	-
Siemens ADVIA	3	-	-	-	3	-	-	3	-
VITROS 5600	1	-	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	11	-	2	9	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	-	2	-	-	2	-
OraSure OraQuick HCV	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Roche cobas e 411	-	1	-	1	-	-
Siemens ADVIA	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-

## Medical Laboratory Evaluation

25 Massachusetts Ave NW Ste 700  
Washington, DC 20001-7401

800-338-2746 • 202-261-4500 • Fax: 202-835-0440  
[www.acponline.org/mle](http://www.acponline.org/mle)