

**MEDICAL LABORATORY**

**EVALUATION**

**PARTICIPANT SUMMARY**

**2 • 0 • 1 • 1**



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

**Immunology**  
**MLE – M3**

# Table of Contents

<b>2011 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
Quantitative (Titer).....	7
Quantitative (IU) .....	8
<b>Anti-Streptolysin O (ASO)</b> .....	<b>8</b>
Qualitative .....	8
<b>Complement C3</b> .....	<b>9</b>
<b>Complement C4</b> .....	<b>9</b>
<b>Antinuclear Antibody (ANA [AN-11 – AN-15])</b> .....	<b>10</b>
Qualitative .....	10
<b>C-Reactive Protein, Regular</b> .....	<b>10</b>
Qualitative .....	10
Quantitative .....	10
<b>C-Reactive Protein, High Sensitivity</b> .....	<b>11</b>
Quantitative .....	11
<b>Antinuclear Antibody (ANA [AE-11 – AE-15])</b> .....	<b>11</b>
Qualitative .....	11
Quantitative (Titer).....	12
<b>Anti-dsDNA</b> .....	<b>12</b>
<b>Anti-RNP</b> .....	<b>13</b>
<b>Anti-RNP/Sm</b> .....	<b>13</b>
<b>Anti-SSA</b> .....	<b>14</b>
<b>Anti-SSB</b> .....	<b>14</b>
<b>Anti-SSA/SSB</b> .....	<b>15</b>
<b>Anti-Sm</b> .....	<b>15</b>
<b>Rubella</b> .....	<b>16</b>
Qualitative .....	16
Quantitative .....	16
<b>Anti-HIV</b> .....	<b>17</b>
<b>Total IgE</b> .....	<b>17</b>
Quantitative .....	17
<b>Allergen Specific IgE Antibodies</b> .....	<b>18</b>
<b>IgA</b> .....	<b>20</b>
<b>IgG</b> .....	<b>20</b>
<b>IgM</b> .....	<b>21</b>
<b>Syphilis Serology</b> .....	<b>21</b>
Qualitative: VDRL.....	21
Quantitative: Treponema pallidum antibodies .....	21
Qualitative: RPR.....	22
Quantitative: RPR (Titer) .....	22
<b>H. pylori Antibody Detection</b> .....	<b>23</b>
<b>Lyme Disease Serology</b> .....	<b>23</b>
<b>Mycoplasma Antibody</b> .....	<b>23</b>
<b>Viral Markers</b> .....	<b>24</b>
Anti-HBc .....	24
Anti-HIV.....	24
HAV.....	25
HBeAg.....	25
HBsAb.....	25
HBsAg.....	26
HCV .....	26

## 2011 Evaluation Criteria

The evaluation criteria used in the 2011 MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

### Qualitative

For qualitative procedures, evaluation is based on participant 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.

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

### Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each peer group consisting of 10 or more laboratories. Acceptable performance is established based on a target value  $\pm$  the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on pages 39-40 under the heading "Acceptable Ranges for Quantitative Results."

Rheumatoid Factor (International Units)	$\pm$ 3 SD
Rheumatoid Factor (Titer)	Not Evaluated
Anti-Streptolysin O (ASO) Titer	Not Evaluated
Complement C3	$\pm$ 3 SD
Complement C4	$\pm$ 3 SD
Antinuclear Antibody (ANA) Titer	Not Evaluated
C-Reactive Protein	$\pm$ 3 SD
High Sensitivity C-Reactive Protein	$\pm$ 3 SD
Rubella (International Units)	$\pm$ 3 SD
Total IgE	$\pm$ 3 SD
Total IgA	$\pm$ 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	1	261	260	2
ASI	-	1	1	-
Beckman Coulter ICON Mono - waived	1	7	8	-
BioStar Acceava Mono Test	-	3	3	-
BioStar Acceava Mono-whole bld	-	10	10	-
Cardinal Health SP Brand	-	3	3	-
Cardinal Health SP Brand - waived	-	6	6	-
Consult Diagnostics	-	1	1	-
Fisher HealthCare Sure-Vue	-	7	7	-
Genzyme OSOM	-	13	13	-
Genzyme OSOM (waived)	-	93	92	1
Henry Schein OneStep+ - waived	-	13	13	-
Immunostics Inc.	-	1	1	-
Instant Technologies i Screen	-	1	1	-
Inverness (Wampole) Clearview	-	14	14	-
Inverness Clearview Mono Plus II	-	12	12	-
Inverness Signify Mono Test	-	2	2	-
LifeSign Status - waived	-	17	17	-
McKesson Medi-Lab Performance - waived	-	5	5	-
Meridian ImmunoCard STAT!	-	1	1	-
Other Moderate method	-	5	5	-
Other Waived method	-	14	13	1
Polymedco Poly stat	-	3	3	-
Polymedco Poly stat - waived	-	5	5	-
Quidel QuickVue+	-	1	1	-
Quidel QuickVue+ - waived	-	9	9	-
Seradyn	-	10	10	-
Wampole ColorCard	-	1	1	-
Wampole Mono-Plus II	-	2	2	-

**Infectious Mononucleosis**

<b><u>Method</u></b>	<b>Specimen IM-13</b>		<b>Specimen IM-14</b>		<b>Specimen IM- 15</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	122	-	1	121	121	1
ASI	1	-	-	1	1	-
Beckman Coulter ICON Mono - waived	8	-	-	8	8	-
BioStar Acceava Mono Test	3	-	-	3	3	-
BioStar Acceava Mono-whole bld	3	-	-	3	3	-
Cardinal Health SP Brand	2	-	-	2	2	-
Cardinal Health SP Brand - waived	1	-	-	1	1	-
Consult Diagnostics	1	-	-	1	1	-
Fisher HealthCare Sure-Vue	6	-	-	6	6	-
Genzyme OSOM	11	-	-	11	11	-
Genzyme OSOM (waived)	31	-	1	30	30	1
Henry Schein OneStep+ - waived	4	-	-	4	4	-
Instant Technologies i Screen	1	-	-	1	1	-
Inverness (Wampole) Clearview	7	-	-	7	7	-
Inverness Clearview Mono Plus II	5	-	-	5	5	-
LifeSign Status - waived	4	-	-	4	4	-
McKesson Medi-Lab Performance - waived	2	-	-	2	2	-
Meridian ImmunoCard STAT!	1	-	-	1	1	-
Other Moderate method	5	-	-	5	5	-
Other Waived method	3	-	-	3	3	-
Polymedco Poly stat	3	-	-	3	3	-
Polymedco Poly stat - waived	3	-	-	3	3	-
Quidel QuickVue+	1	-	-	1	1	-
Quidel QuickVue+ - waived	3	-	-	3	3	-
Seradyn	10	-	-	10	10	-
Wampole ColorCard	1	-	-	1	1	-
Wampole Mono-Plus II	1	-	-	1	1	-

**Rheumatoid Factor—Qualitative**

<b><u>Method</u></b>	<b>Specimen RF-11</b>		<b>Specimen RF-12</b>		<b>Specimen RF-13</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	74	-	74	-	-	74
Abbott Architect	1	-	1	-	-	1
ASI	5	-	5	-	-	5
Biokit Rheumajet	3	-	3	-	-	3
Cardinal Health SP Brand	1	-	1	-	-	1
Diamedix	2	-	2	-	-	2
Fisher HealthCare Sure-Vue	9	-	9	-	-	9
Immunostics Inc.	6	-	6	-	-	6
Olympus AU	2	-	2	-	-	2
Remel SeraTest	16	-	16	-	-	16
Seradyn	2	-	2	-	-	2
Stanbio Laboratory	1	-	1	-	-	1
Teco Diagnostics	4	-	4	-	-	4
TheraTest	2	-	2	-	-	2
Wampole ColorCard	10	-	10	-	-	10
Wampole Rheumatex	7	-	7	-	-	7

<b><u>Method</u></b>	<b>Specimen RF-14</b>		<b>Specimen RF-15</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	74	-	-	74
Abbott Architect	1	-	-	1
ASI	5	-	-	5
Biokit Rheumajet	3	-	-	3
Cardinal Health SP Brand	1	-	-	1
Diamedix	2	-	-	2
Fisher HealthCare Sure-Vue	9	-	-	9
Immunostics Inc.	6	-	-	6
Olympus AU	2	-	-	2
Remel SeraTest	16	-	-	16
Seradyn	2	-	-	2
Stanbio Laboratory	1	-	-	1
Teco Diagnostics	4	-	-	4
TheraTest	2	-	-	2
Wampole ColorCard	10	-	-	10
Wampole Rheumatex	7	-	-	7

## Rheumatoid Factor—Quantitative (Titer)

This portion is not evaluated. Results reported are as follows:

<u>Specimen/Method</u>	<u>2/ 4</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>&gt;2560</u>
<b>Specimen RF-11</b>											
ALL METHODS	-	8	-	1	1	2	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	4	-	-	-	1	-	-	-	-	-
Remel SeraTest	-	3	-	-	1	-	-	-	-	-	-
Wampole ColorCard	-	1	-	-	-	-	-	-	-	-	-
<b>Specimen RF-12</b>											
ALL METHODS	-	2	6	1	-	3	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	4	-	-	1	-	-	-	-	-
Remel SeraTest	-	2	1	-	-	1	-	-	-	-	-
Wampole ColorCard	-	-	1	-	-	-	-	-	-	-	-
<b>Specimen RF-14</b>											
ALL METHODS	1	7	-	1	2	1	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	4	-	-	1	-	-	-	-	-	-
Remel SeraTest	1	2	-	-	1	-	-	-	-	-	-
Wampole ColorCard	-	1	-	-	-	-	-	-	-	-	-

**Rheumatoid Factor—Quantitative (IU)**

<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-11</b>						
All Method	16	61.7	11.1	18.0	60	28 - 96
<b>Specimen RF-12</b>						
All Method	16	102.1	8.9	8.7	100	75 - 129
<b>Specimen RF-13</b>						
All Method	18	5.5	5.2	94.4	5	0 - 22
<b>Specimen RF-14</b>						
All Method	17	69.2	24.6	35.5	59	0 - 143
<b>Specimen RF-15</b>						
All Method	18	5.4	5.3	98.0	5	0 - 22

**Anti-Streptolysin O (ASO)—Qualitative**

<u>Method</u>	<u>Specimen AS-11</u>		<u>Specimen AS-12</u>		<u>Specimen AS-13</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	-	-	1	1	-
ASI	1	-	-	1	1	-
<u>Method</u>	<u>Specimen AS-14</u>		<u>Specimen AS-15</u>			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	1	-	1		
ASI	-	1	-	1		



**Complement C3 (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen IMP-11</b>						
All Method	14	133.9	13.1	9.8	138	94 - 174
<b>Specimen IMP-12</b>						
All Method	14	64.3	5.8	9.1	67	46 - 82
<b>Specimen IMP-13</b>						
All Method	14	128.9	12.9	10.0	133	90 - 168
<b>Specimen IMP-14</b>						
All Method	14	137.4	16.5	12.0	140	87 - 187
<b>Specimen IMP-15</b>						
All Method	14	126.9	12.9	10.2	130	88 - 166

**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-11</b>						
All Method	14	22.4	1.7	7.6	23	17 - 28
<b>Specimen IMP-12</b>						
All Method	15	13.1	1.7	13.1	13	7 - 19
<b>Specimen IMP-13</b>						
All Method	15	22.2	2.4	10.8	23	15 - 30
<b>Specimen IMP-14</b>						
All Method	15	26.7	2.8	10.7	27	18 - 36
<b>Specimen IMP-15</b>						
All Method	15	24.2	2.5	10.3	24	16 - 32

### Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	<u>Specimen AN-11</u>		<u>Specimen AN-12</u>		<u>Specimen AN-13</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	7	-	-	7
Alpha Scientific Medical, Inc.	-	1	1	-	-	1
Diagnostic Technology	-	5	5	-	-	5
Wampole	-	1	1	-	-	1

<u>Method</u>	<u>Specimen AN-14</u>		<u>Specimen AN-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7	-
Alpha Scientific Medical, Inc.	1	-	1	-
Diagnostic Technology	5	-	5	-
Wampole	1	-	1	-

### 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	17	-	-	17
ASI	1	-	-	1
Biokit Rheumajet	1	-	-	1
Fisher HealthCare Sure-Vue	7	-	-	7
Gamma	1	-	-	1
Immunostics Inc.	4	-	-	4
Siemens Dimension/AR/ES/RxL/Xpand	1	-	-	1
Wampole	1	-	-	1

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen CR-5</b>						
mg/dL - units						
All Immunology Methods	28	3.178	0.532	16.7	3.20	1.58 - 4.78
mg/L - units						
All Immunology Methods	11	31.315	6.493	20.7	32.44	11.83 - 50.80
<b>Specimen CR-6</b>						
mg/dL - units						
All Immunology Methods	29	0.213	0.187	87.8	0.20	0.00 - 0.78
mg/L - units						
All Immunology Methods	10	1.349	1.741	129.1	0.39	0.00 - 6.58

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen HCR-5</b>						
All Method	56	3.019	0.494	16.4	3.00	1.53 - 4.50
<b>Specimen HCR-6</b>						
All Method	55	14.439	1.459	10.1	14.17	10.06 - 18.82

**Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods**

<u>Method</u>	<u>Specimen AE-11</u>		<u>Specimen AE-12</u>		<u>Specimen AE-13</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	-	14	1	-	15
Immuno Concepts	5	-	4	1	-	5
INOVA Diagnostics	2	-	2	-	-	2
Kallestad	2	-	2	-	-	2
TheraTest	3	-	3	-	-	3
Wampole	1	-	1	-	-	1
Zeus	1	-	1	-	-	1

<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	-	15	15	-
Immuno Concepts	-	5	5	-
INOVA Diagnostics	-	2	2	-
Kallestad	-	2	2	-
TheraTest	-	3	3	-
Wampole	-	1	1	-
Zeus	-	1	1	-

Specimen AE-7 is an ungraded challenge due to lack of 80% referee consensus.

## Antinuclear Antibody (ANA)—Quantitative (Titer)

This portion is not evaluated. Titers reported are as follows:

<u>Specimen/Method</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>&gt;640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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### Specimen AE-11

ALL METHODS	-	-	-	-	2	-	1	1	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	1	-	-	-
INOVA Diagnostics	-	-	-	-	1	-	-	-	-	-	-
Kallestad	-	-	-	-	1	-	-	-	-	-	-

### Specimen AE-12

ALL METHODS	-	-	-	-	-	2	1	1	-	-	-
Immuno Concepts	-	-	-	-	-	1	-	1	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-
Kallestad	-	-	-	-	-	1	-	-	-	-	-

### Specimen AE-15

ALL METHODS	-	-	-	1	-	-	2	1	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	1	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-
Kallestad	-	-	-	1	-	-	-	-	-	-	-

## Anti-dsDNA

<u>Method</u>	<u>Specimen AE-11</u>		<u>Specimen AE-12</u>		<u>Specimen AE-13</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	-	9	-	9
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	1	-	-	1	-	1
Kallestad	2	-	-	2	-	2
TheraTest	3	-	-	3	-	3
Wampole	1	-	-	1	-	1
Zeus	1	-	-	1	-	1

<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	-	9	-	9
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
Kallestad	-	2	-	2
TheraTest	-	3	-	3
Wampole	-	1	-	1
Zeus	-	1	-	1

**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	1	2	1	-	3
INOVA Diagnostics	2	-	2	-	-	2
Zeus	-	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	-	3	3	-
INOVA Diagnostics	-	2	2	-
Zeus	-	1	1	-

Specimens AE-11 and AE-12 are ungraded challenges due to lack of 80% participant consensus.

**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	3	3	1	5	-	6
Diamedix	-	1	-	1	-	1
Immuno Concepts	-	1	1	-	-	1
TheraTest	3	-	-	3	-	3
Wampole	-	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	5	6	-
Diamedix	-	1	1	-
Immuno Concepts	-	1	1	-
TheraTest	1	2	3	-
Wampole	-	1	1	-

Specimen AE-11 an ungraded challenge due to lack of 80% participant consensus.

**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	8	-	8	-	-	8
Diamedix	1	-	1	-	-	1
INOVA Diagnostics	2	-	2	-	-	2
TheraTest	3	-	3	-	-	3
Wampole	1	-	1	-	-	1
Zeus	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	-	8	1	7
Diamedix	-	1	1	-
INOVA Diagnostics	-	2	-	2
TheraTest	-	3	-	3
Wampole	-	1	-	1
Zeus	-	1	-	1

**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	1	8	-	-	8
Diamedix	-	1	1	-	-	1
INOVA Diagnostics	2	-	2	-	-	2
TheraTest	3	-	3	-	-	3
Wampole	1	-	1	-	-	1
Zeus	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	-	8	-	8
Diamedix	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	3	-	3
Wampole	-	1	-	1
Zeus	-	1	-	1

**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	2	-	-	2
Immuno Concepts	-	1	1	-	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	1	1
Immuno Concepts	-	1	1	-

Specimens AE-11 and AE-15 are ungraded challenges due to lack of 80% participant consensus.

**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	1	7	-	8	-	8
Diamedix	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
TheraTest	-	3	-	3	-	3
Wampole	-	1	-	1	-	1
Zeus	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	-	8	-	8
Diamedix	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	3	-	3
Wampole	-	1	-	1
Zeus	-	1	-	1

**Rubella—Qualitative**

<u>Method</u>	<b>Specimen RU-11</b>		<b>Specimen RU-12</b>		<b>Specimen RU-13</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7	-	-	7
Bayer ADVIA Centaur	2	-	2	-	-	2
bioMerieux Vidas, Mini Vidas	3	-	3	-	-	3
DiaSorin	1	-	1	-	-	1

<u>Method</u>	<b>Specimen RU-14</b>		<b>Specimen RU-15</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	7	-
Bayer ADVIA Centaur	-	2	2	-
bioMerieux Vidas, Mini Vidas	-	3	3	-
DiaSorin	-	1	1	-

**Rubella—Quantitative (IU/mL)**

Only one lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values for specimens RU- through RU- are: 103 IU/mL, 20 IU/mL, 0 IU/mL, 0 IU/mL and 37 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	35	-	-	35
Inverness Clearview Complete HIV 1/2	13	-	-	13
Orasure OraQuick Advance Rapid HIV-1/2 - waived	17	-	-	17
Other Waived method	5	-	-	5

<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	-
Inverness Clearview Complete HIV 1/2	4	-	-	4	4	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	1	-	-	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>
<b>Specimen AL-11</b>						
All Method	7	95.6	4.8	5.0	96	81 - 110
<b>Specimen AL-12</b>						
All Method	7	210.7	17.0	8.1	209	159 - 262
<b>Specimen AL-13</b>						
All Method	8	54.4	8.3	15.3	50	29 - 80
<b>Specimen AL-14</b>						
All Method	8	22.0	2.9	13.1	20	13 - 31
<b>Specimen AL-15</b>						
All Method	7	54.6	7.6	14.0	51	31 - 78

# Allergen Specific IgE Antibodies

## Specimen AL-11

### Method

	Cat Epithelium Allergen CLASS RESULT								Dog Dander Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	8	3	7	-	-	-	1	8	10	-	-	-	-
DPC Immulite 2000/2500	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	1	7	-	-	-	1	4	5	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	4	-	-	-	-	-	-	2	2	-	-	-	-
Phadia Unicap 100	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	1	-	-	-	-	-	-	3	-	-	-	-

	Bermuda Grass Allergen CLASS RESULT								Timothy Grass Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	1	10	4	4	-	-	-	-	-	2	2	6	-	-
DPC Immulite 2000/2500	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	3	3	4	-	-	-	-	-	-	-	5	-	-
Phadia ImmunoCAP Rapid	-	-	1	2	-	-	-	-	-	-	-	2	-	-	-	-
Phadia Unicap 100	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	1	-	-	-	-	-	-	-	2	1	-	-

	English Plantain Allergen CLASS RESULT								Russian Thistle Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	7	7	-	-	-	-	-	-	2	4	-	-	-	-
DPC Immulite 2000/2500	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	1	-	7	3	-	-	-	-	-	-	2	4	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-

	White Oak Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	2	9	2	-	-	-
Hitachi CLA-1	-	-	2	4	1	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	2	-	-	-	-
Phadia Unicap 100	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	1	-	-	-

# Allergen Specific IgE Antibodies

## Specimen AL-12

<u>Method</u>	House Dust Mite Allergen CLASS RESULT								Common (Short) Ragweed Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	3	1	9	-	5	-	-	-	-	-	3	9	5	-	-
DPC Immulite 2000/2500	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	3	1	-	-	5	-	-	-	-	-	-	3	4	-	-
Phadia ImmunoCAP Rapid	-	-	-	4	-	-	-	-	-	-	-	3	1	-	-	-
Phadia Unicap 100	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	3	-	-	-	-	-	-	-	-	2	1	-	-
	Silver Birch Tree Allergen CLASS RESULT								Maple (Box Elder) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	3	1	-	-	-	3	1	8	2	-	-	-	-
Hitachi CLA-1	-	-	-	2	-	-	-	-	2	1	7	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	1	2	-	-	-	-
	Meadow Fescue Allergen CLASS RESULT								Sweet Vernal Grass Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
	English Plantain Allergen CLASS RESULT															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	-	2	15	2	-	-	-	-								
Hitachi CLA-1	-	2	9	-	-	-	-	-								
Phadia ImmunoCAP Rapid	-	-	1	2	-	-	-	-								
Phadia Unicap 100	-	-	1	-	-	-	-	-								
Phadia UniCap 100 (KU/L)	-	-	3	-	-	-	-	-								

**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-11</b>						
All Method	14	191.0	18.3	9.6	189	135 - 247
<b>Specimen IMP-12</b>						
All Method	15	104.5	4.9	4.7	105	89 - 120
<b>Specimen IMP-13</b>						
All Method	15	188.5	8.2	4.4	189	163 - 214
<b>Specimen IMP-14</b>						
All Method	15	210.1	9.4	4.5	211	181 - 239
<b>Specimen IMP-15</b>						
All Method	14	473.1	35.2	7.4	473	367 - 579

**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-11</b>						
All Method	14	2091.6	106.7	5.1	2113	1568 - 2615
<b>Specimen IMP-12</b>						
All Method	14	453.1	27.8	6.1	455	339 - 567
<b>Specimen IMP-13</b>						
All Method	14	2039.9	126.8	6.2	2114	1529 - 2550
<b>Specimen IMP-14</b>						
All Method	14	932.7	52.1	5.6	952	699 - 1166
<b>Specimen IMP-15</b>						
All Method	15	929.5	55.5	6.0	929	697 - 1162

**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-11</b>						
All Method	15	412.3	46.2	11.2	412	273 - 551
<b>Specimen IMP-12</b>						
All Method	15	46.6	5.9	12.6	46	28 - 65
<b>Specimen IMP-13</b>						
All Method	15	89.6	8.1	9.0	87	65 - 114
<b>Specimen IMP-14</b>						
All Method	15	98.2	12.5	12.7	95	60 - 136
<b>Specimen IMP-15</b>						
All Method	15	97.7	13.4	13.7	94	57 - 138

**Syphilis Serology—Qualitative: VDRL Slide**

<u>Method</u>	<u>Specimen SY-11</u>		<u>Specimen SY-12</u>		<u>Specimen SY-13</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	-	1	1	-
Fisher HealthCare Sure-Vue	1	-	-	1	1	-

  

<u>Method</u>	<u>Specimen SY-14</u>		<u>Specimen SY-15</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Wk. Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	1	-	1
Fisher HealthCare Sure-Vue	-	1	-	1

**Syphilis Serology—Qualitative: Treponema pallidum antibodies**

<u>Method</u>	<u>Specimen SY-11</u>		<u>Specimen SY-12</u>		<u>Specimen SY-13</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	-	1	1	-
DPC Immulite 2000/2500	1	-	-	1	1	-

  

<u>Method</u>	<u>Specimen SY-14</u>		<u>Specimen SY-15</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	1	-	1
DPC Immulite 2000/2500	-	1	-	1

**Syphilis Serology—Qualitative: RPR**

<u>Method</u>	<b>Specimen SY-11</b>		<b>Specimen SY-12</b>		<b>Specimen SY-13</b>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	26	-	-	26	26	-
ASI	10	-	-	10	10	-
Becton Dickinson	13	-	-	13	13	-
Fisher HealthCare Sure-Vue	2	-	-	2	2	-
Wampole Impact RPR	1	-	-	1	1	-

  

<u>Method</u>	<b>Specimen SY-14</b>		<b>Specimen SY-15</b>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	26	-	26
ASI	-	10	-	10
Becton Dickinson	-	13	-	13
Fisher HealthCare Sure-Vue	-	2	-	2
Wampole Impact RPR	-	1	-	1

**Syphilis Serology—Quantitative: RPR (Titer)**

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>&gt;64</u>
<b>Specimen SY-11</b>								
ALL METHODS	-	1	10	2	-	-	-	-
ASI	-	1	3	2	-	-	-	-
Becton Dickinson	-	-	7	-	-	-	-	-
<b>Specimen SY-13</b>								
ALL METHODS	1	-	8	4	-	-	-	-
ASI	1	-	2	3	-	-	-	-
Becton Dickinson	-	-	6	1	-	-	-	-

## H. pylori Antibody Detection

<u>Method</u>	Specimen HP-5		Specimen HP-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	124	2	-	126
Alfa Scientific Instant-View	2	-	-	2
Beckman Coulter ICON HP	9	-	-	9
bioMerieux Vidas, Mini Vidas	1	-	-	1
BioStar Acceava H. pylori	1	-	-	1
Cardinal Health SP Brand	10	-	-	10
Consult Diagnostics	15	-	-	15
Fisher HealthCare Sure-Vue	5	-	-	5
Henry Schein OneStep+ - waived	5	-	-	5
Inverness (Wampole) Clearview	12	2	-	14
McKesson Medi-Lab Performance - waived	10	-	-	10
Polymedco Poly stat	6	-	-	6
PSS Select Diagnostics	5	-	-	5
Quidel QuickVue	41	-	-	41
SDI Biomed, Inc.	1	-	-	1

## Lyme Disease Serology

<u>Method</u>	Specimen LY-5		Specimen LY-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	-	-	4
DiaSorin	1	-	-	1
Immunostics Inc.	1	-	-	1

## Mycoplasma Antibody

<u>Method</u>	Specimen MY-5		Specimen MY-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	1	1
Meridian ImmunoCard	-	1	1	-
Remel ELISA	-	1	-	1

Specimen MY-6 is an ungraded challenge due to lack of 80% participant consensus.

**Viral Markers – Anti-HBc**

<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>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	3	3	-	-	3
Bayer ADVIA Centaur – IgM	-	1	1	-	-	1
Bayer ADVIA Centaur – Total	-	1	1	-	-	1
VITROS ECI – Total	-	1	1	-	-	1

<u>Method</u>	<u>Specimen VM-14</u>		<u>Specimen VM-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	2	2	1
Bayer ADVIA Centaur – IgM	-	1	-	1
Bayer ADVIA Centaur – Total	-	1	1	-
VITROS ECI – Total	1	-	1	-

Specimen VM-14 is an ungraded challenge due to lack of 80% participant consensus.

**Viral Markers – Anti-HIV**

<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>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	10	-	10	-	10
Bayer ADVIA Centaur - Total	-	2	-	2	-	2
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	4	-	4	-	4
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	3	-	3	-	3
Other Waived method	-	1	-	1	-	1

<u>Method</u>	<u>Specimen VM-14</u>		<u>Specimen VM-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	-	-	10
Bayer ADVIA Centaur - Total	2	-	-	2
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	4	-	-	4
Orasure OraQuick Advance Rapid HIV-1/2 - waived	3	-	-	3
Other Waived method	1	-	-	1



**Viral Markers – HAV**

<u>Method</u>	<b>Specimen VM-11</b>		<b>Specimen VM-12</b>		<b>Specimen VM-13</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	1	-	2	1	-
Bayer ADVIA Centaur - IgM	-	1	-	1	-	-
Bayer ADVIA Centaur - Total	1	-	-	1	1	-

<u>Method</u>	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	-	2
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	-	1	-	1

**Viral Markers – HBeAg**

The vendor assay for specimens VM-11 through VM-15 is: Negative, Negative, Negative, Negative and Negative, respectively.

**Viral Markers – HBsAb**

<u>Method</u>	<b>Specimen VM-11</b>		<b>Specimen VM-12</b>		<b>Specimen VM-13</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	-	4	4	-
Abbott AxSYM - Total	-	1	-	1	1	-
Bayer ADVIA Centaur - Total	-	2	-	2	2	-
VITROS ECI - Total	-	1	-	1	1	-

<u>Method</u>	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	4	-
Abbott AxSYM - Total	-	1	1	-
Bayer ADVIA Centaur - Total	-	2	2	-
VITROS ECI - Total	-	1	1	-

**Viral Markers – HBsAg**

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	6	-	-	6
Abbott AxSYM - Total	-	1	1	-	-	1
Bayer ADVIA Centaur - Total	-	2	2	-	-	2
DPC Immulite 2000/2500	-	1	1	-	-	1
VITROS ECI - Total	-	2	2	-	-	2

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	-	6
Abbott AxSYM - Total	-	1	-	1
Bayer ADVIA Centaur - Total	-	2	-	2
DPC Immulite 2000/2500	-	1	-	1
VITROS ECI - Total	-	2	-	2

**Viral Markers – HCV**

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	-	-	4	-	4
Abbott AxSYM - Total	1	-	-	1	-	1
Bayer ADVIA Centaur - Total	2	-	-	2	-	2
VITROS ECI - IgG	1	-	-	1	-	1

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	-	4
Abbott AxSYM - Total	-	1	-	1
Bayer ADVIA Centaur - Total	-	2	-	2
VITROS ECI - IgG	-	1	-	1

**Medical Laboratory Evaluation**

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