

**MEDICAL LABORATORY**

**EVALUATION**

**PARTICIPANT SUMMARY**

**2 • 0 • 1 • 2**



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

**Immunology  
MLE-M3**

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## 2012 Evaluation Criteria

The evaluation criteria used in the 2012 MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

### Qualitative

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

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 page 37 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	-	267	266	1
ASI	-	2	2	-
Beckman Coulter ICON Mono - waived	-	8	8	-
BioStar Acceava Mono Test	-	3	3	-
BioStar Acceava Mono-whole bld	-	7	7	-
Cardinal Health SP Brand	-	2	2	-
Cardinal Health SP Brand - waived	-	9	9	-
Consult Diagnostics	-	2	2	-
Fisher HealthCare Sure-Vue	-	7	7	-
Genzyme OSOM	-	10	10	-
Genzyme OSOM (waived)	-	107	107	-
Henry Schein OneStep+ - waived	-	11	11	-
Inverness (Wampole) Clearview	-	13	13	-
Inverness Clearview Mono Plus II	-	11	11	-
Inverness Signify Mono Test	-	2	2	-
LifeSign Status - waived	-	15	15	-
McKesson Medi-Lab Performance - waived	-	7	7	-
Meridian ImmunoCard STAT!	-	1	1	-
Other Moderate method	-	7	7	-
Other Waived method	-	21	19	1
Polymedco Poly stat	-	1	1	-
Polymedco Poly stat - waived	-	4	4	-
Quidel QuickVue+	-	2	2	-
Quidel QuickVue+ - waived	-	9	9	-
Seradyn	-	3	3	-
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	111	-	111	-	-	111
ASI	2	-	2	-	-	2
Beckman Coulter ICON Mono - waived	8	-	8	-	-	8
BioStar Acceava Mono Test	3	-	3	-	-	3
BioStar Acceava Mono-whole bld	2	-	2	-	-	2
Cardinal Health SP Brand	2	-	2	-	-	2
Cardinal Health SP Brand - waived	2	-	2	-	-	2
Fisher HealthCare Sure-Vue	6	-	6	-	-	6
Genzyme OSOM	9	-	9	-	-	9
Genzyme OSOM (waived)	35	-	35	-	-	35
Henry Schein OneStep+ - waived	4	-	4	-	-	4
Inverness (Wampole) Clearview	7	-	7	-	-	7
Inverness Clearview Mono Plus II	4	-	4	-	-	4
LifeSign Status - waived	2	-	2	-	-	2
McKesson Medi-Lab Performance - waived	1	-	1	-	-	1
Meridian ImmunoCard STAT!	1	-	1	-	-	1
Other Moderate method	7	-	7	-	-	7
Other Waived method	4	-	4	-	-	4
Polymedco Poly stat	1	-	1	-	-	1
Polymedco Poly stat - waived	2	-	2	-	-	2
Quidel QuickVue+	2	-	2	-	-	2
Quidel QuickVue+ - waived	2	-	2	-	-	2
Seradyn	3	-	3	-	-	3
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	-	66	67	-	-	67
Abbott Architect	-	1	1	-	-	1
ASI	-	10	10	-	-	10
Beckman Synchron	-	1	1	-	-	1
Biokit Rheumajet	-	12	12	-	-	12
Diamedix	-	2	2	-	-	2
Fisher HealthCare Sure-Vue	-	7	7	-	-	7
Immunostics Inc.	-	4	4	-	-	4
JAS Diagnostics, Inc.	-	1	1	-	-	1
Remel SeraTest	-	3	4	-	-	4
Stanbio Laboratory	-	1	1	-	-	1
Teco Diagnostics	-	6	6	-	-	6
TheraTest	-	3	3	-	-	3
Wampole ColorCard	-	9	9	-	-	9
Wampole Rheumatex	-	4	4	-	-	4
Wampole Rheumaton	-	1	1	-	-	1

<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	67	-	67	-
Abbott Architect	1	-	1	-
ASI	10	-	10	-
Beckman Synchron	1	-	1	-
Biokit Rheumajet	12	-	12	-
Diamedix	2	-	2	-
Fisher HealthCare Sure-Vue	7	-	7	-
Immunostics Inc.	4	-	4	-
JAS Diagnostics, Inc.	1	-	1	-
Remel SeraTest	4	-	4	-
Stanbio Laboratory	1	-	1	-
Teco Diagnostics	6	-	6	-
TheraTest	3	-	3	-
Wampole ColorCard	9	-	9	-
Wampole Rheumatex	4	-	4	-
Wampole Rheumaton	1	-	1	-

## 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-12</b>											
ALL METHODS	-	2	6	1	1	1	1	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	1	1	1	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	2	-	-	-	-	-	-	-	-
Remel SeraTest	-	-	1	-	-	-	1	-	-	-	-
Wampole ColorCard	-	-	1	-	-	-	-	-	-	-	-
<b>Specimen RF-14</b>											
ALL METHODS	2	3	5	-	1	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	1	2	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	2	-	-	-	-	-	-	-	-	-
Remel SeraTest	-	-	1	-	-	1	-	-	-	-	-
Wampole ColorCard	-	-	1	-	-	-	-	-	-	-	-
<b>Specimen RF-15</b>											
ALL METHODS	2	5	2	1	1	1	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	1	1	1	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	3	-	-	-	-	-	-	-	-	-
Remel SeraTest	-	1	-	-	-	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	18	4.7	4.5	95.8	2	0 - 19
<b>Specimen RF-12</b>						
All Method	15	114.5	5.7	5.0	113	97 - 132
<b>Specimen RF-13</b>						
All Method	18	4.5	4.5	100.9	3	0 - 19
<b>Specimen RF-14</b>						
All Method	16	71.7	10.1	14.1	69	41 - 102
<b>Specimen RF-15</b>						
All Method	16	71.8	11.1	15.5	69	38 - 106

**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	13	123.1	14.3	11.6	128	80 - 167
<b>Specimen IMP-12</b>						
All Method	14	58.7	7.3	12.4	61	36 - 81
<b>Specimen IMP-13</b>						
All Method	14	126.4	13.5	10.7	128	85 - 167
<b>Specimen IMP-14</b>						
All Method	14	149.2	16.1	10.8	156	101 - 198
<b>Specimen IMP-15</b>						
All Method	14	57.3	7.8	13.7	61	33 - 81

**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	15	21.7	4.4	20.0	23	8 - 35
<b>Specimen IMP-12</b>						
All Method	14	11.9	1.3	10.9	12	7 - 16
<b>Specimen IMP-13</b>						
All Method	15	22.7	4.4	19.1	22	9 - 36
<b>Specimen IMP-14</b>						
All Method	14	23.9	1.4	5.8	24	19 - 29
<b>Specimen IMP-15</b>						
All Method	15	11.1	0.9	8.0	11	8 - 14

**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	-	5	5	-	4	1
ASI	-	1	1	-	-	1
Diagnostic Technology	-	3	3	-	3	-
Teco Diagnostics	-	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	-	5	4	1
ASI	-	1	-	1
Diagnostic Technology	-	3	3	-
Teco Diagnostics	-	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	1	18	17	1
ASI	-	2	2	-
Biokit Rheumajet	-	1	1	-
Fisher HealthCare Sure-Vue	-	8	8	-
Siemens Dimension/AR/ES/RxL/Xpand	-	1	1	-
Teco Diagnostics	1	4	4	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	27	0.191	0.172	90.2	0.20	0.00 - 0.71
mg/L - units						
All Immunology Methods	11	2.895	2.251	77.8	3.58	0.00 - 9.65
<b>Specimen CR-6</b>						
mg/dL - units						
All Immunology Methods	27	1.576	0.366	23.2	1.60	0.47 - 2.68
mg/L - units						
All Immunology Methods	11	18.102	5.364	29.6	16.54	2.00 - 34.20

**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	50	14.506	1.099	7.6	14.64	11.20 - 17.81
Siemens Dimension High Sensi CRP	10	13.876	1.009	7.3	14.15	10.85 - 16.91

**Specimen HCR-6**

All Method	50	0.945	0.189	20.0	0.90	0.37 - 1.52
Siemens Dimension High Sensi CRP	10	1.129	0.229	20.3	1.24	0.44 - 1.82

**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	12	4	-	16	-	16
Immuno Concepts	4	1	-	5	-	5
INOVA Diagnostics	2	1	-	3	-	3
Kallestad	2	-	-	2	-	2
TheraTest	3	1	-	4	-	4
Wampole	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	16	-	16	-
Immuno Concepts	5	-	5	-
INOVA Diagnostics	3	-	3	-
Kallestad	2	-	2	-
TheraTest	4	-	4	-
Wampole	1	-	1	-

Specimen AE-11 is an ungraded challenge due to less than 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	-	-	-	-	-	1	2	2	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	2	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-
Kallestad	-	-	-	-	-	-	1	-	-	-	-

### Specimen AE-14

ALL METHODS	-	-	-	-	-	3	1	1	-	-	-
Immuno Concepts	-	-	-	-	-	2	-	1	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-
Kallestad	-	-	-	-	-	1	-	-	-	-	-

### Specimen AE-15

ALL METHODS	-	-	-	-	1	1	1	2	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	2	-	-	-
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	-	10	-	10	-	10
Diamedix	-	1	-	1	-	1
Immuno Concepts	-	1	-	1	-	1
Kallestad	-	2	-	2	-	2
TheraTest	-	4	-	4	-	4
Wampole	-	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	1	-	10
Diamedix	1	-	-	1
Immuno Concepts	1	-	-	1
Kallestad	2	-	-	2
TheraTest	4	-	-	4
Wampole	-	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	-	2	-	2
INOVA Diagnostics	-	1	-	1	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	1	1	1
INOVA Diagnostics	1	-	1	-

Specimens AE-14 and AE-15 are ungraded challenges due to less than 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	-	8	-	8	-	8
Diamedix	-	2	-	2	-	2
TheraTest	-	4	-	4	-	4
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	5	3	7	1
Diamedix	-	2	2	-
TheraTest	4	-	4	-
Wampole	1	-	1	-

Specimen AE-14 is an ungraded challenge due to less than 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	-	9	-	9	-	9
Diamedix	-	2	-	2	-	2
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	-	4	-	4	-	4
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	9	-	9	-
Diamedix	2	-	2	-
INOVA Diagnostics	1	-	1	-
TheraTest	4	-	4	-
Wampole	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	-	9	-	9	-	9
Diamedix	-	2	-	2	-	2
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	-	4	-	4	-	4
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	-	9	-	9
Diamedix	-	2	-	2
INOVA Diagnostics	-	1	-	1
TheraTest	-	4	-	4
Wampole	-	1	-	1

## Anti-SSA/SSB

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

## Anti-Sm

<u>Method</u>	<b>Specimen AE-11</b>		<b>Specimen AE-12</b>		<b>Specimen AE-13</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9	-	9
Diamedix	-	2	-	2	-	2
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	-	4	-	4	-	4
Wampole	-	1	-	1	-	1

  

<u>Method</u>	<b>Specimen AE-14</b>		<b>Specimen AE-15</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9
Diamedix	-	2	-	2
INOVA Diagnostics	-	1	-	1
TheraTest	-	4	-	4
Wampole	-	1	-	1

## Rubella—Qualitative

<u>Method</u>	<u>Specimen RU-11</u>		<u>Specimen RU-12</u>		<u>Specimen RU-13</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	-	8	-	8
Bayer ADVIA Centaur	2	-	-	2	-	2
bioMerieux Vidas, Mini Vidas	3	-	-	3	-	3
DiaSorin	2	-	-	2	-	2

<u>Method</u>	<u>Specimen RU-14</u>		<u>Specimen RU-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8	-
Bayer ADVIA Centaur	2	-	2	-
bioMerieux Vidas, Mini Vidas	3	-	3	-
DiaSorin	2	-	2	-

## Rubella—Quantitative (IU/mL)

Two labs reported results for Rubella – Quantitative (IU/mL). The vendor assay values for specimens RU-11 through RU-15 are: 46 IU/mL, 0 IU/mL, 0 IU/mL, 26 IU/mL and 99 IU/mL, respectively.



**Anti-HIV**

<u>Method</u>	<b>Specimen HIV-11</b>		<b>Specimen HIV-12</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	41	41	-
Abbott Architect	-	1	1	-
BD LINK 2	-	1	1	-
Inverness Clearview Complete HIV 1/2	-	13	13	-
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	3	3	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	16	16	-
Other Moderate method	-	1	1	-
Other Waived method	-	6	6	-

<u>Method</u>	<b>Specimen HIV-13</b>		<b>Specimen HIV-14</b>		<b>Specimen HIV-15</b>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	-	7	7	-
Abbott Architect	1	-	-	1	1	-
Inverness Clearview Complete HIV 1/2	3	-	-	3	3	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	2	-	-	2	2	-
Other Moderate method	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	6	192.0	16.1	8.4	189	143 - 241
<b>Specimen AL-12</b>						
All Method	6	205.7	14.5	7.0	201	162 - 250
<b>Specimen AL-13</b>						
All Method	7	24.0	4.6	19.2	23	10 - 38
<b>Specimen AL-14</b>						
All Method	6	61.3	8.5	13.9	58	35 - 87
<b>Specimen AL-15</b>						
All Method	7	24.0	3.7	15.6	23	12 - 36

## Allergen Specific IgE Antibodies

### Specimen AL-11

<u>Method</u>	Aspergillus fumigatus Allergen CLASS RESULT							Meadow Fescue 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	3	-	-	-	-	-	1	-	-	-	-	-	-
DPC Immulite 2000/2500	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	1	3	3	-	-	-	-	-	1	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-

Meadow Fescue Allergen is an ungraded challenge due to lack of comparison group.

	Timothy Grass Allergen CLASS RESULT							Cow's Milk Allergen CLASS RESULT								
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	1	3	2	3	-	-	-	-	-	3	1	3	-	-
DPC Immulite 2000/2500	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	1	-	-	3	-	-	-	-	-	-	1	3	-	-
Phadia ImmunoCAP Rapid	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	1	-	-	-	-	-	-	1	-	-	-	-

	Wheat 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	5	-	-	-	-	-	1	8	4	-	-	-	-
DPC Immulite 2000/2500	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	-	-	1	3	-	-	-	-	-	1	5	-	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	2	-	-	-	-

	Russian Thistle Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	1	1	2	-	-	-	-	-
DPC Immulite 2000/2500	-	-	1	-	-	-	-	-
Hitachi CLA-1	1	1	1	-	-	-	-	-

Russian Thistle Allergen is an ungraded challenge due to less than 80% participant consensus.

**Allergen Specific IgE Antibodies**

**Specimen AL-12**

<u>Method</u>	<b>Maple (Box Elder) Allergen</b>								<b>Silver Birch Tree 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	4	2	-	-	-	-	-	1	1	-	2	-	-	-
DPC Immulite 2000/2500	-	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-
DPC-Standard Microplate	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	2	3	1	-	-	-	-	-	1	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-

<u>Method</u>	<b>Meadow, Kentucky Blue, June Grass Allergens</b>								<b>Sweet Vernal Grass 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	-	4	3	-	-	-	-	-	-	-	-	-	-
DPC Immulite 2000/2500	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	1	1	-	-	-	-	-	-	-	-	-	-

<u>Method</u>	<b>Cocksfoot Allergen</b>								<b>Alternaria alternata 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	9	-	-	-	-
DPC Immulite 2000/2500	-	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	3	4	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-

Cocksfoot Allergen is an ungraded challenge due to lack of comparison group.

<u>Method</u>	<b>Russian Thistle Allergen</b>							
	<b>CLASS RESULT</b>							
	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	3	-	-	-	-	-
DPC Immulite 2000/2500	-	-	1	-	-	-	-	-
Hitachi CLA-1	1	-	2	-	-	-	-	-

Russian Thistle Allergen is an ungraded challenge due to less than 80% participant consensus.

**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	13	199.0	7.7	3.9	199	175 - 223
<b>Specimen IMP-12</b>						
All Method	13	96.4	10.1	10.5	99	66 - 127
<b>Specimen IMP-13</b>						
All Method	13	581.4	43.7	7.5	570	450 - 713
<b>Specimen IMP-14</b>						
All Method	13	216.2	7.9	3.7	213	192 - 240
<b>Specimen IMP-15</b>						
All Method	13	94.7	6.3	6.6	95	75 - 114

**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	12	931.7	40.7	4.4	931	698 - 1165
<b>Specimen IMP-12</b>						
All Method	12	446.0	20.1	4.5	449	334 - 558
<b>Specimen IMP-13</b>						
All Method	12	909.5	40.3	4.4	914	682 - 1137
<b>Specimen IMP-14</b>						
All Method	12	2136.9	68.2	3.2	2128	1602 - 2672
<b>Specimen IMP-15</b>						
All Method	12	442.8	18.3	4.1	441	332 - 554

**IgM (mg/dL)**

<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 IMP-11</b>						
All Method	13	92.8	9.1	9.8	92	65 - 121
<b>Specimen IMP-12</b>						
All Method	13	46.0	3.7	8.1	46	34 - 58
<b>Specimen IMP-13</b>						
All Method	13	95.2	11.4	11.9	92	61 - 130
<b>Specimen IMP-14</b>						
All Method	13	279.5	26.6	9.5	283	199 - 360
<b>Specimen IMP-15</b>						
All Method	13	45.5	3.5	7.7	45	35 - 56

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

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

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

**Syphilis Serology—Qualitative: RPR**

<b><u>Method</u></b>	<b>Specimen SY-11</b>		<b>Specimen SY-12</b>		<b>Specimen SY-13</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
ALL METHODS	27	-	27	-	1	26
ASI	11	-	11	-	1	10
Becton Dickinson	11	-	11	-	-	11
Cardinal Health SP Brand	1	-	1	-	-	1
Fisher HealthCare Sure-View	3	-	3	-	-	3
Wampole Impact RPR	1	-	1	-	-	1

<b><u>Method</u></b>	<b>Specimen SY-14</b>		<b>Specimen SY-15</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
ALL METHODS	27	-	1	26
ASI	11	-	-	11
Becton Dickinson	11	-	-	11
Cardinal Health SP Brand	1	-	-	1
Fisher HealthCare Sure-View	3	-	-	3
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	-	3	8	2	-	-	-	-
ASI	-	2	4	1	-	-	-	-
Becton Dickinson	-	1	4	1	-	-	-	-
<b>Specimen SY-12</b>								
ALL METHODS	2	7	4	-	-	-	-	-
ASI	1	4	2	-	-	-	-	-
Becton Dickinson	1	3	2	-	-	-	-	-
<b>Specimen SY-14</b>								
ALL METHODS	-	5	7	1	-	-	-	-
ASI	-	4	3	-	-	-	-	-
Becton Dickinson	-	1	4	1	-	-	-	-

**H. pylori Antibody Detection**

<u>Method</u>	<u>Specimen HP-5</u>		<u>Specimen HP-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	130	-	1	129
Alfa Scientific Instant-View	3	-	-	3
Beckman Coulter ICON HP	9	-	-	9
bioMerieux Vidas, Mini Vidas	1	-	-	1
Cardinal Health SP Brand	8	-	-	8
Consult Diagnostics	17	-	-	17
DPC Immulite 2000/2500	1	-	-	1
Fisher HealthCare Sure-View	4	-	-	4
Henry Schein OneStep+ - waived	6	-	-	6
Inverness (Wampole) Clearview	12	-	-	12
McKesson Medi-Lab Performance - waived	10	-	-	10
Polymedco Poly stat	3	-	-	3
PSS Select Diagnostics	1	-	-	1
Quidel QuickVue	51	-	1	50
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	5	-	-	5
bioMerieux Vidas, Mini Vidas	1	-	-	1
DiaSorin	2	-	-	2

## Mycoplasma Antibody

<u>Method</u>	Specimen MY-5		Specimen MY-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	2	-
Meridian ImmunoCard	-	1	1	-
Meridian ImmunoCard STAT! (whole blood)	-	1	1	-

## Viral Markers – Anti-HBc

<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	-	2	1	1	-	2
Bayer ADVIA Centaur - IgM	-	1	-	1	-	1
Bayer ADVIA Centaur - Total	-	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	1	1	1	1
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	1	-	1	-

Specimens VM-12, VM-14 and VM-15 are ungraded challenges due to less than 80% participant consensus.



**Viral Markers – Anti-HIV**

<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	10	-	-	10	-	10
Abbott Architect - Total	1	-	-	1	-	1
Bayer ADVIA Centaur - Total	1	-	-	1	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	4	-	-	4	-	4
Orasure OraQuick Advance Rapid HIV-1/2 - waived	2	-	-	2	-	2
Other IgG Method	1	-	-	1	-	1
Other Waived method	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	-	10	-	10
Abbott Architect - Total	-	1	-	1
Bayer ADVIA Centaur - Total	-	1	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	4	-	4
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	2	-	2
Other IgG Method	-	1	-	1
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	-	3	-	3	1	2
Abbott Architect - IgM	-	1	-	1	-	1
Bayer ADVIA Centaur - IgM	-	1	-	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	-	3	-	3
Abbott Architect - IgM	-	1	-	1
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	-	1	-	1

Specimens VM-13 is an ungraded challenges due to less than 80% participant consensus.

**Viral Markers – HBeAg**

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

**Viral Markers – HBsAb**

<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	5	-	5	-	-	5
Abbott Architect - Total	1	-	1	-	-	1
Bayer ADVIA Centaur - Total	4	-	4	-	-	4

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5
Abbott Architect - Total	1	-	-	1
Bayer ADVIA Centaur - Total	4	-	-	4

**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 Architect	-	1	1	-	-	1
Abbott Architect - Total	-	1	1	-	-	1
Bayer ADVIA Centaur - Total	-	2	2	-	-	2
Other IgG Method	-	1	1	-	-	1
VITROS ECI - Total	-	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	-	6	6	-
Abbott Architect	-	1	1	-
Abbott Architect - Total	-	1	1	-
Bayer ADVIA Centaur - Total	-	2	2	-
Other IgG Method	-	1	1	-
VITROS ECI - Total	-	1	1	-

## 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	-	6	-	6	6	-
Abbott Architect - Total	-	2	-	2	2	-
Bayer ADVIA Centaur - 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 Architect - Total	-	2	-	2
Bayer ADVIA Centaur - Total	-	2	-	2

## Medical Laboratory Evaluation

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