

**MEDICAL LABORATORY**

**EVALUATION**

**PARTICIPANT SUMMARY**

**2 • 0 • 0 • 8**



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

**Immunology**  
**MLE – M3**

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## 2008 Evaluation Criteria

The evaluation criteria used in the 2008 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
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
Viral Markers	80% Participant Consensus
Tear Lactoferrin	80% Participant Consensus
Tear IgE	80% Participant Consensus

### Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each peer group consisting of 5 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
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>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	263	34	2	295
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	-	5	-	5
BioStar Acceava Mono Test	2	-	-	2
BioStar Acceava Mono-whole bld	13	-	1	12
Cardinal Health SP Brand	4	1	-	5
Cardinal Health SP Brand - waived	12	5	-	17
Fisher HealthCare Sure-Vue	9	-	1	8
Genzyme OSOM	23	-	-	23
Genzyme OSOM (waived)	100	-	-	100
Genzyme Signify Mono - waived	1	-	-	1
Henry Schein OneStep+ - waived	6	-	-	6
Immunostics - IMMUNO/IM	-	1	-	1
Instant Technologies i Screen-WB	1	-	-	1
Inverness (Wampole) Clearview	17	1	-	18
Inverness ClearviewMono-plusII	5	1	-	6
Inverness Signify Mono Test	-	1	-	1
LifeSign Status	1	1	-	2
LifeSign Status - waived	11	10	-	21
McKesson Medi-Lab Performance - waived	2	-	-	2
Other Waived method	6	-	-	6
Polymedco Poly stat	4	2	-	6
Polymedco Poly stat - waived	11	1	-	12
Quidel QuickVue+	2	2	-	4
Quidel QuickVue+ - waived	2	1	-	3
Seradyn	21	-	-	21
Wampole Mono-Plus II	3	-	-	3
Wampole Mono-Plus II (whole blood)	1	-	-	1

<u>Method</u>	<u>Specimen IM-13</u>		<u>Specimen IM-14</u>		<u>Specimen IM-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	180	160	20	161	19
ASI	-	1	1	-	1	-
Beckman Coulter ICON Mono - waived	-	5	-	5	-	5
BioStar Acceava Mono Test	-	2	2	-	2	-
Cardinal Health SP Brand	-	4	3	1	4	-
Cardinal Health SP Brand - waived	-	6	5	1	5	1
Fisher HealthCare Sure-Vue	-	8	8	-	8	-
Genzyme OSOM	-	22	22	-	22	-
Genzyme OSOM (waived)	-	49	49	-	47	2
Henry Schein OneStep+ - waived	-	3	3	-	3	-
Immunostics - IMMUNO/IM	-	1	-	1	-	1
Inverness (Wampole) Clearview	-	13	13	-	13	-
Inverness ClearviewMono-plusII	-	6	5	1	6	-
LifeSign Status	-	1	-	1	1	-

## Infectious Mononucleosis (cont'd)

<u>Method</u>	<u>Specimen IM-13</u>		<u>Specimen IM-14</u>		<u>Specimen IM-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
LifeSign Status - waived	-	4	2	2	2	2
McKesson Medi-Lab Performance - waived	-	1	1	-	1	-
Other Waived method	-	3	2	1	3	-
Polymedco Poly stat	-	6	6	-	4	2
Polymedco Poly stat - waived	-	7	5	2	6	1
Quidel QuickVue+	-	4	2	2	2	2
Quidel QuickVue+ - waived	-	1	-	1	1	-
Seradyn	-	22	22	-	22	-
Wampole Mono-Plus II	-	3	3	-	3	-
Wampole Mono-Plus II (whole blood)	-	1	1	-	1	-

## Rheumatoid Factor—Qualitative

<u>Method</u>	<u>Specimen RF-11</u>		<u>Specimen RF-12</u>		<u>Specimen RF-13</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	86	-	1	85	86	-
ASI	4	-	-	4	4	-
Beckman Synchron	3	-	-	3	3	-
Becton Dickinson	1	-	-	1	1	-
Biokit Rheumajet	7	-	-	7	7	-
Diamedix	2	-	-	2	2	-
Fisher HealthCare Sure-Vue	6	-	-	6	6	-
Immunostics Inc.	8	-	-	8	8	-
J&S Medical Assoc. Accutex	1	-	-	1	1	-
JAS Diagnostics, Inc.	1	-	-	1	1	-
Roche Hitachi 902, 911, 912, 914, 917	1	-	-	1	1	-
Seradyn	33	-	-	33	33	-
Stanbio	2	-	-	2	2	-
Wampole ColorCard	3	-	1	2	3	-
Wampole Rheumatex	6	-	-	6	6	-
Wampole Rheumaton	4	-	-	4	4	-

**Rheumatoid Factor—Qualitative (cont'd)**

<u>Method</u>	<b>Specimen RF-14</b>		<b>Specimen RF-15</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	86	-	86
ASI	-	4	-	4
Beckman Synchron	-	3	-	3
Becton Dickinson	-	1	-	1
Biokit Rheumajet	-	7	-	7
Diamedix	-	2	-	2
Fisher HealthCare Sure-View	-	6	-	6
Immunostics Inc.	-	8	-	8
J&S Medical Assoc. Accutex	-	1	-	1
JAS Diagnostics, Inc.	-	1	-	1
Roche Hitachi 902, 911, 912, 914, 917	-	1	-	1
Seradyn	-	33	-	33
Stanbio	-	2	-	2
Wampole ColorCard	-	3	-	3
Wampole Rheumatex	-	6	-	6
Wampole Rheumaton	-	4	-	4

**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	1	8	8	3	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	3	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	-	3	-	-	-	-	-	-	-	-
Seradyn	1	4	4	-	-	1	-	-	-	-	-
Wampole Rheumatex	-	-	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>
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### Specimen RF-14

ALL METHODS	4	11	3	1	1	1	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	1	2	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	1	-	-	-	-	-	-	-	-
Seradyn	3	6	-	-	-	1	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

<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>
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### Specimen RF-15

ALL METHODS	1	14	2	3	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	3	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	3	-	-	-	-	-	-	-	-	-
Seradyn	1	7	-	1	-	1	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

## Rheumatoid Factor—Quantitative (IU)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
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### Specimen RF-11

All Beckman Instruments	6	20.0	0.0	0.0	20
All Method	12	5.8	6.5	112.3	10
Beckman Synchron	5	20.0	0.0	0.0	20

### Specimen RF-12

All Beckman Instruments	6	243.0	10.2	4.2	248
All Method	12	166.0	72.8	43.8	150
Beckman Synchron	5	241.4	10.5	4.4	243

### Specimen RF-13

All Beckman Instruments	6	20.0	0.0	0.0	20
All Method	12	6.2	6.6	107.1	10
Beckman Synchron	5	20.0	0.0	0.0	20

**Rheumatoid Factor—Quantitative (IU) (cont'd)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
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**Specimen RF-14**

All Beckman Instruments	6	132.0	8.1	6.1	136
All Method	12	97.6	52.4	53.7	87
Beckman Synchron	5	132.8	8.8	6.6	136

**Specimen RF-15**

All Beckman Instruments	6	132.7	8.6	6.5	136
All Method	12	97.2	51.8	53.4	84
Beckman Synchron	5	132.0	9.4	7.1	132

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

<u>Method</u>	<b>Specimen AS-11</b>		<b>Specimen AS-12</b>		<b>Specimen AS-13</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	1	-	1	1	-
Immunostics Inc.	-	1	-	1	1	-

<u>Method</u>	<b>Specimen AS-14</b>		<b>Specimen AS-15</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	1	-	1	-
Immunostics Inc.	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>
<b>Specimen COM-11</b>					
All Method	14	228.9	31.0	13.5	231
DiaSorin	5	232.6	46.1	19.8	211
<b>Specimen COM-12</b>					
All Method	14	160.3	15.5	9.7	164
DiaSorin	5	152.0	18.1	11.9	150
<b>Specimen COM-13</b>					
All Method	14	89.6	7.4	8.3	91
DiaSorin	5	84.2	7.4	8.8	84
<b>Specimen COM-14</b>					
All Method	14	257.9	75.3	29.2	282
DiaSorin	5	255.8	60.9	23.8	263
<b>Specimen COM-15</b>					
All Method	13	19.0	10.2	53.9	15
DiaSorin	4	-	-	-	37

**Complement C4 (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
<b>Specimen COM-11</b>					
All Method	14	73.9	13.8	18.7	70
DiaSorin	5	68.2	4.3	6.3	69
<b>Specimen COM-12</b>					
All Method	14	54.2	11.6	21.4	51
DiaSorin	5	48.2	4.8	9.9	49
<b>Specimen COM-13</b>					
All Method	14	29.9	4.8	16.2	29
DiaSorin	5	29.0	5.2	18.1	27
<b>Specimen COM-14</b>					
All Method	14	81.5	27.8	34.1	80
DiaSorin	5	75.4	10.2	13.5	76
<b>Specimen COM-15</b>					
All Method	14	5.5	1.7	31.7	5
DiaSorin	5	6.0	1.6	26.4	6

**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>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	2	8	10	-	2	8
Diagnostic Technology	2	4	6	-	2	4
Seradyn Seratest SLE	-	1	1	-	-	1
Stanbio	-	1	1	-	-	1
Wampole	-	1	1	-	-	1

<u>Method</u>	<u>Specimen AN-14</u>		<u>Specimen AN-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	10	-	2	8
Diagnostic Technology	6	-	2	4
Seradyn Seratest SLE	1	-	-	1
Stanbio	1	-	-	1
Wampole	1	-	-	1

**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>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	17	1	-	18	-	18
Diamedix	1	-	-	1	-	1
GenBio ImmunoDOT	1	-	-	1	-	1
Immuno Concepts	5	-	-	5	-	5
INOVA Diagnostics	2	1	-	3	-	3
Kallestad	3	-	-	3	-	3
Zeus	2	-	-	2	-	2

<u>Method</u>	<u>Specimen AE-14</u>		<u>Specimen AE-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	18	-	-	18
Diamedix	1	-	-	1
GenBio ImmunoDOT	1	-	-	1
Immuno Concepts	5	-	-	5
INOVA Diagnostics	3	-	-	3
Kallestad	3	-	-	3
Zeus	2	-	-	2

## 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>≥640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
<b>Specimen AE-12</b>											
ALL METHODS	-	-	1	-	2	1	1	-	-	-	-
Immuno Concepts	-	-	1	-	1	-	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-
Kallestad	-	-	-	-	1	-	-	-	-	-	-
<b>Specimen AE-13</b>											
ALL METHODS	-	-	1	1	1	1	1	-	-	-	-
Immuno Concepts	-	-	1	-	1	1	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-
Kallestad	-	-	-	1	-	-	-	-	-	-	-
<b>Specimen AE-15</b>											
ALL METHODS	-	-	-	1	-	1	1	-	1	1	-
Immuno Concepts	-	-	-	1	-	-	1	-	1	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-
Kallestad	-	-	-	-	-	1	-	-	-	-	-

## C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-5</u>		<u>Specimen CR-6</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	1	8	9	-
ASI	-	2	2	-
Dade Dimension/AR/ES/RxL/Xpand	1	-	1	-
Fisher HealthCare Sure-View	-	1	1	-
Immunostics Inc.	-	1	1	-
Stanbio	-	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>
<b>Specimen CR-5</b>					
All Method mg/dL - units	37	5.619	6.235	111.0	1.53
Beckman Synchron	5	1.160	0.114	9.8	1.20
Roche Integra	5	1.504	0.122	8.1	1.48
All Immunology Methods mg/L - units	23	1.290	0.281	21.8	1.30
All Immunology Methods	13	13.284	4.113	31.0	14.77

**Specimen CR-6**

All Method mg/dL - units	34	0.480	0.898	187.2	0.20
Beckman Synchron	5	0.380	0.084	22.0	0.40
Roche Integra	5	0.026	0.042	162.3	0.01
All Immunology Methods mg/L - units	23	0.247	0.204	82.8	0.20
All Immunology Methods	12	1.320	1.865	141.3	0.30

**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>
<b>Specimen HCR-5</b>					
All Method mg/dL - units	61	1.845	0.887	48.1	2.09
All Immunology Methods mg/L - units	10	0.215	0.043	20.0	0.21
DPC Immulite/1000	8	2.058	0.350	17.0	2.09
EQual CRPultra WR	5	1.944	0.289	14.9	2.11
Roche Integra hsCRP	8	2.170	0.139	6.4	2.20
All Immunology Methods	48	2.098	0.418	19.9	2.11

**Specimen HCR-6**

All Method mg/dL - units	62	8.130	3.559	43.8	9.56
All Immunology Methods mg/L - units	10	0.899	0.077	8.5	0.87
DPC Immulite/1000	8	8.648	2.773	32.1	9.60
EQual CRPultra WR	5	9.786	0.565	5.8	10.10
Roche Integra hsCRP	8	10.069	0.548	5.4	10.40
All Immunology Methods	49	9.833	0.864	8.8	9.75

**Rubella—Qualitative**

<u>Method</u>	<b>Specimen RU-11</b>		<b>Specimen RU-12</b>		<b>Specimen RU-13</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	4	1	-	5	5	-
Abbott AxSYM	1	-	-	1	1	-
Seradyn	-	1	-	1	1	-
Wampole Impact	1	-	-	1	1	-
Wampole Rubella - Plus	2	-	-	2	2	-
	<b>Specimen RU-14</b>		<b>Specimen RU-15</b>			
ALL METHODS	-	5	-	5		
Abbott AxSYM	-	1	-	1		
Seradyn	-	1	-	1		
Wampole Impact	-	1	-	1		
Wampole Rubella - Plus	-	2	-	2		

**Rubella—Quantitative (IU/mL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
<b>Specimen RU-11</b>					
All Methods	4	-	-	-	1.7
<b>Specimen RU-12</b>					
All Methods	4	-	-	-	119.0
<b>Specimen RU-13</b>					
All Methods	4	-	-	-	1.5
<b>Specimen RU-14</b>					
All Methods	4	-	-	-	26.7
<b>Specimen RU-15</b>					
All Methods	4	-	-	-	24.8

**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>Specimen AL-11</b>					
All Method	10	90.7	15.1	16.6	90
<b>Specimen AL-12</b>					
All Method	10	165.3	11.6	7.0	164
<b>Specimen AL-13</b>					
All Method	10	45.4	9.8	21.7	42
<b>Specimen AL-14</b>					
All Method	10	45.9	9.6	20.9	43
<b>Specimen AL-15</b>					
All Method	10	18.0	2.9	16.1	18

**Allergen Specific IgE Antibodies**

**Specimen AL-11**

	<b>Peanut (Arachis hyogaea) Allergen</b>							<b>Egg White Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
ALL METHODS	1	-	5	1	1	-	-	2	2	2	-	-	-	-
Hitachi CLA-1	1	-	1	-	1	-	-	1	-	1	-	-	-	-
Hycor EIA	-	-	-	1	-	-	-	-	-	1	-	-	-	-
Phadia CAP (% ref)	-	-	1	-	-	-	-	-	1	-	-	-	-	-
Phadia UniCap (% ref)	-	-	1	-	-	-	-	-	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-	-	-	-	-	-	-

	<b>Common Ragweed Allergen</b>							<b>Timothy Grass Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
ALL METHODS	2	1	7	-	-	-	-	-	-	-	-	5	3	-
Hitachi CLA-1	2	1	1	-	-	-	-	-	-	-	-	3	-	-
Hycor EIA	-	-	1	-	-	-	-	-	-	-	-	1	-	-
Phadia CAP (% ref)	-	-	1	-	-	-	-	-	-	-	-	-	1	-
Phadia UniCap 100 (% ref)	-	-	2	-	-	-	-	-	-	-	-	-	2	-
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-	-	-	-	1	-	-

	<b>Perennial Rye Allergen</b>							<b>House Dust Mite Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
ALL METHODS	-	-	-	-	2	2	-	-	-	3	4	2	-	-
Hitachi CLA-1	-	-	-	-	1	-	-	-	-	1	1	2	-	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Phadia CAP (% ref)	-	-	-	-	-	1	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	1	-	-	-	-	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	-	1	-	-	-	-

	<b>Cat Epithelium Allergen</b>						
	<b>CLASS RESULT</b>						
	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
ALL METHODS	-	-	5	3	2	-	-
Hitachi CLA-1	-	-	-	2	2	-	-
Hycor EIA	-	-	-	1	-	-	-
Phadia CAP (% ref)	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	2	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-

**Allergen Specific IgE Antibodies (cont'd)**

**Specimen AL-12**

	<b>Cow's Milk Allergen</b>							<b>Peanut (Arachis hyogaea) Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
ALL METHODS	-	4	2	1	-	-	-	-	1	4	1	2	-	-
Hitachi CLA-1	-	-	1	1	-	-	-	-	1	-	-	2	-	-
Hycor EIA	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Phadia CAP (% ref)	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	1	-	-	-	-	-	-	-	1	-	-	-	-
	<b>White Oak Allergen</b>							<b>Maple (Box Elder) Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
ALL METHODS	2	1	7	1	-	-	-	8	1	-	-	-	-	-
Hitachi CLA-1	2	1	2	-	-	-	-	4	-	-	-	-	-	-
Hycor EIA	-	-	-	1	-	-	-	1	-	-	-	-	-	-
Phadia CAP (% ref)	-	-	1	-	-	-	-	1	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	2	-	-	-	-	1	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	1	-	-	-	-	-	-
	<b>Common Ragweed Allergen</b>							<b>House Dust Mite Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
ALL METHODS	1	-	7	2	-	-	-	-	-	2	3	4	-	-
Hitachi CLA-1	1	-	2	1	-	-	-	-	-	-	-	4	-	-
Hycor EIA	-	-	1	-	-	-	-	-	-	1	-	-	-	-
Phadia CAP (% ref)	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	1	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-	-	1	-	-	-	-
	<b>Dog Dander Allergen</b>													
	<b>CLASS RESULT</b>													
	<b>0/1</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>							
ALL METHODS	-	1	6	-	-	-	-							
Hitachi CLA-1	-	1	3	-	-	-	-							
Hycor EIA	-	-	-	-	-	-	-							
Phadia CAP (% ref)	-	-	1	-	-	-	-							
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-							
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-							

**IgA (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
<b>Specimen IP-11</b>					
All Method	16	523.9	66.6	12.7	533
Roche Integra	6	504.5	29.1	5.8	525
<b>Specimen IP-12</b>					
All Method	16	368.6	43.2	11.7	365
Roche Integra	6	346.5	17.6	5.1	356
<b>Specimen IP-13</b>					
All Method	16	202.6	21.1	10.4	200
Roche Integra	6	189.5	10.5	5.5	194
<b>Specimen IP-14</b>					
All Method	15	631.5	156.2	24.7	646
Roche Integra	5	605.2	43.4	7.2	581
<b>Specimen IP-15</b>					
All Method	15	37.9	9.7	25.6	37
Roche Integra	6	34.2	8.1	23.7	33
<b>IgG (mg/dL)</b>					
<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
<b>Specimen IP-11</b>					
All Method	15	2359.3	258.3	10.9	2334
Roche Integra	6	2309.2	75.3	3.3	2328
<b>Specimen IP-12</b>					
All Method	16	1606.2	121.3	7.6	1609
Roche Integra	6	1615.3	52.1	3.2	1609
<b>Specimen IP-13</b>					
All Method	16	898.2	63.5	7.1	898
Roche Integra	6	903.3	21.0	2.3	916
<b>Specimen IP-14</b>					
All Method	14	2955.1	381.4	12.9	2877
Roche Integra	5	2796.4	149.9	5.4	2777
<b>Specimen IP-15</b>					
All Method	12	176.2	30.6	17.4	183
Roche Integra	5	157.4	6.7	4.2	160

**IgM (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
<b>Specimen IP-11</b>					
All Method	15	354.1	37.3	10.5	360
Roche Integra	6	349.5	28.2	8.1	356
<b>Specimen IP-12</b>					
All Method	16	259.2	32.6	12.6	264
Roche Integra	6	239.5	14.8	6.2	239
<b>Specimen IP-13</b>					
All Method	16	146.8	18.2	12.4	144
Roche Integra	6	136.2	8.0	5.9	135
<b>Specimen IP-14</b>					
All Method	14	417.3	82.2	19.7	435
Roche Integra	5	422.4	30.9	7.3	427
<b>Specimen IP-15</b>					
All Method	p	26.5	4.8	18.0	25
Roche Integra	6	23.7	2.3	9.5	23

**Syphilis Serology—Qualitative: MHA-TP**

<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	-
	<u>Specimen SY-14</u>		<u>Specimen SY-15</u>			
ALL METHODS	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	-	40	40	-	38	2
ASI	-	12	12	-	10	2
Becton Dickinson	-	18	18	-	18	-
Fisher HealthCare Sure-Vue	-	4	4	-	4	-
J&S Medical Assoc. Accutex	-	1	1	-	1	-
New Horizons	-	1	1	-	1	-
Wampole Impact RPR	-	2	2	-	2	-

  

	<b>Specimen SY-14</b>		<b>Specimen SY-15</b>	
ALL METHODS	39	1	-	40
ASI	12	-	-	12
Becton Dickinson	18	-	-	18
Fisher HealthCare Sure-Vue	3	1	-	4
J&S Medical Assoc. Accutex	1	-	-	1
New Horizons	1	-	-	1
Wampole Impact RPR	2	-	-	2

## 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>
<b>Specimen SY-12</b>							
ALL METHODS	-	2	13	1	-	-	-
ASI	-	2	4	-	-	-	-
Becton Dickinson	-	-	7	1	-	-	-
Fisher HealthCare Sure-Vue	-	-	1	-	-	-	-

### Specimen SY-13

ALL METHODS	2	13	1	-	-	-	-
ASI	2	4	-	-	-	-	-
Becton Dickinson	-	7	1	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	-	-	-	-	-

### Specimen SY-14

ALL METHODS	-	1	13	1	-	-	-
ASI	-	1	5	-	-	-	-
Becton Dickinson	-	-	7	1	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-

## H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-5</u>		<u>Specimen HP-6</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	152	2	11	144
BD LINK 2	1	-	-	1
Beckman Coulter FlexSure	1	-	-	1
Beckman Coulter ICON HP	10	-	1	9
bioMerieux Vitek, Mini Vidas	2	-	-	2
BioStar Acceava H. pylori	1	-	-	1
Cardinal Health SP Brand	11	-	1	10
DPC Immulite/1000	1	-	-	1
Fisher HealthCare Sure-Vue	4	-	1	3
Instant Technologies i Screen	12	-	-	12
Inverness (Wampole) Clearview	12	1	6	7
LifeSign Status	1	-	-	1
McKesson Medi-Lab Performance - waived	4	-	-	4
Polymedco Poly stat	16	-	1	15
PSS Select Diagnostics	9	-	-	9
Quidel QuickVue	59	1	-	61

## Lyme Disease Serology

<u>Method</u>	Specimen LY-5		Specimen LY-6	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	7	-	-	7
bioMerieux Vitek, Mini Vidas	2	-	-	2
Diamedix	1	-	-	1
DiaSorin	1	-	-	1
Immunostics Inc.	1	-	-	1
Wampole	1	-	-	1
Wampole Impact	1	-	-	1

## Mycoplasma Antibody

<u>Method</u>	Specimen MY-5		Specimen MY-6	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	-	-	1

## Viral Markers – Anti-HBc

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	3	3	-	2	1
Abbott AxSYM - IgM	-	1	1	-	1	-
Bayer ADVIA Centaur - IgM	-	1	1	-	1	-
Bayer ADVIA Centaur - Total	-	1	1	-	-	1

  

	Specimen VM-14		Specimen VM-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	3	-	2	1
Abbott AxSYM - IgM	1	-	1	-
Bayer ADVIA Centaur - IgM	1	-	1	-
Bayer ADVIA Centaur - Total	1	-	-	1

## Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	8	-	8	-	-	8
Orasure OraQuick Advance Rapid HIV-1/2	5	-	5	-	-	5
Other IgG Method	1	-	1	-	-	1
Other Total Method	2	-	2	-	-	2

  

	Specimen VM-14		Specimen VM-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	8	-	1	7
Orasure OraQuick Advance Rapid HIV-1/2	5	-	-	5
Other IgG Method	1	-	-	1
Other Total Method	2	-	1	1

**Viral Markers – HAV**

<u>Method</u>	<b>Specimen VM-11</b>		<b>Specimen VM-12</b>		<b>Specimen VM-13</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	3	-	3	-	2	1
Abbott AxSYM - IgM	1	-	1	-	1	-
Bayer ADVIA Centaur - IgM	1	-	1	-	1	-
Bayer ADVIA Centaur - Total	1	-	1	-	-	1
	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>			
ALL METHODS	2	1	2	1		
Abbott AxSYM - IgM	1	-	1	-		
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>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	4	-	4	-	-	4
Abbott AxSYM - Total	1	-	1	-	-	1
Bayer ADVIA Centaur - Total	2	-	2	-	-	2
Roche Elecsys - Total	1	-	1	-	-	1
	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>			
ALL METHODS	-	4	-	4		
Abbott AxSYM - Total	-	1	-	1		
Bayer ADVIA Centaur - Total	-	2	-	2		
Roche Elecsys - Total	-	1	-	1		

## Viral Markers – HBsAg

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	6	6	-	6	-
Abbott AxSYM	-	1	1	-	1	-
Abbott AxSYM - Total	-	1	1	-	1	-
Bayer ADVIA Centaur - Total	-	1	1	-	1	-
Other IgM Method	-	1	1	-	1	-
Roche Elecsys - Total	-	2	2	-	2	-
	Specimen VM-14		Specimen VM-15			
ALL METHODS	4	2	6	-		
Abbott AxSYM	-	1	1	-		
Abbott AxSYM - Total	-	1	1	-		
Bayer ADVIA Centaur - Total	1	-	1	-		
Other IgM Method	1	-	1	-		
Roche Elecsys - Total	2	-	2	-		

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

## Viral Markers – HCV

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	4	-	4	-	4	-
Abbott AxSYM	1	-	1	-	1	-
Abbott AxSYM - IgG	1	-	1	-	1	-
Bayer ADVIA Centaur - Total	2	-	2	-	2	-
	Specimen VM-14		Specimen VM-15			
ALL METHODS	-	4	4	-		
Abbott AxSYM	-	1	1	-		
Abbott AxSYM - IgG	-	1	1	-		
Bayer ADVIA Centaur - Total	-	2	2	-		

**Tear Lactoferrin**

<u>Method</u>	<u>Labs</u>	<u>&lt;0.9 mg/mL</u>	<u>&gt;1.0 mg/mL</u>
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**Specimen TLF-5**

Touch Scientific	12	-	12
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**Specimen TLF-6**

Touch Scientific	11	9	2
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**Tear IgE**

<u>Method</u>	<u>Labs</u>	<u>&lt;79 ng/mL</u>	<u>&gt;80 ng/mL</u>
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**Specimen TIG-11**

Touch Scientific	10	10	-
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**Specimen TIG-12**

Touch Scientific	10	2	8
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**Specimen TIG-13**

Touch Scientific	10	1	9
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**Specimen TIG-14**

Touch Scientific	10	2	8
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**Specimen TIG-15**

Touch Scientific	9	9	-
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**Medical Laboratory Evaluation**

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