

# MEDICAL LABORATORY EVALUATION

## PARTICIPANT SUMMARY

2 • 0 • 0 • 8



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

Immunology  
MLE – M1

# Table of Contents

<b>2008 Evaluation Criteria</b> .....	<b>3</b>
<b>Immunology</b>	
<b>Infectious Mononucleosis</b> .....	<b>4</b>
<b>Rheumatoid Factor</b> .....	<b>5</b>
Qualitative .....	5
Quantitative (Titer) .....	6
Quantitative (IU) .....	7
<b>Anti-Streptolysin O (ASO)</b> .....	<b>8</b>
Qualitative .....	8
Quantitative .....	8
<b>Complement C3</b> .....	<b>9</b>
<b>Complement C4</b> .....	<b>9</b>
<b>Antinuclear Antibody (ANA [AN-1 – AN-5])</b> .....	<b>10</b>
Qualitative .....	10
<b>Antinuclear Antibody (ANA [AE-1 – AE-5])</b> .....	<b>10</b>
Qualitative .....	10
Quantitative (Titer) .....	11
<b>C-Reactive Protein, Regular</b> .....	<b>11</b>
Qualitative .....	11
Quantitative .....	12
<b>C-Reactive Protein, High Sensitivity</b> .....	<b>12</b>
Quantitative .....	12
<b>Rubella</b> .....	<b>13</b>
Qualitative .....	13
Quantitative .....	13
<b>Total IgE</b> .....	<b>14</b>
Quantitative .....	14
<b>Allergen Specific IgE Antibodies</b> .....	<b>15</b>
<b>IgA</b> .....	<b>17</b>
<b>IgG</b> .....	<b>17</b>
<b>IgM</b> .....	<b>18</b>
<b>Syphilis Serology</b> .....	<b>18</b>
Qualitative: VDRL Slide .....	18
Qualitative: MHA-TP .....	18
Qualitative: RPR .....	18
Quantitative: RPR (Titer) .....	20
<b>H. pylori Antibody Detection</b> .....	<b>20</b>
<b>Lyme Disease Serology</b> .....	<b>21</b>
<b>Mycoplasma Antibody</b> .....	<b>21</b>
<b>Viral Markers</b> .....	<b>21</b>
Anti-HBc .....	21
Anti-HIV .....	21
HAV .....	22
HBeAg .....	22
HBsAb .....	22
HBsAg .....	22
HCV .....	23
<b>Tear Lactoferrin</b> .....	<b>23</b>
<b>Tear IgE</b> .....	<b>23</b>

## 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>	<b>Specimen IM-1</b>		<b>Specimen IM-2</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	304	304	-
ASI	-	1	1	-
Beckman Coulter ICON Mono - waived	-	1	1	-
BioStar Acceava Mono Test	-	5	5	-
BioStar Acceava Mono-whole bld	-	12	12	-
Cardinal Health SP Brand	-	6	6	-
Cardinal Health SP Brand - waived	-	14	14	-
Fisher HealthCare Sure-Vue	-	8	8	-
Genzyme OSOM	-	17	17	-
Genzyme OSOM (waived)	-	59	59	-
Henry Schein OneStep+ - waived	-	2	2	-
Immunostics - IMMUNO/IM	-	1	1	-
Instant Technologies i Screen-WB	-	6	6	-
Inverness (Wampole) Clearview	-	21	21	-
Inverness ClearviewMono-plusII	-	14	14	-
Inverness Signify Mono Test	-	7	7	-
LifeSign Status	-	2	2	-
LifeSign Status - waived	-	14	14	-
McKesson Medi-Lab Performance - waived	-	7	7	-
Polymedco Poly stat	-	3	3	-
Polymedco Poly stat - waived	-	16	16	-
Quidel QuickVue+	-	37	37	-
Quidel QuickVue+ - waived	-	13	13	-
Seradyn	-	24	24	-
Seradyn Color Q (whole blood)	-	1	1	-
Wampole ColorCard	-	1	1	-
Wampole Mono-Plus II	-	2	2	-
Wampole Mono-Plus II (whole blood)	-	2	2	-
Wampole Mono-Test	-	1	1	-

<u>Method</u>	<b>Specimen IM-3</b>		<b>Specimen IM-4</b>		<b>Specimen IM-5</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	184	-	184	184	-
ASI	-	1	-	1	1	-
Beckman Coulter ICON Mono - waived	-	1	-	1	1	-
BioStar Acceava Mono Test	-	2	-	2	2	-
BioStar Acceava Mono-whole bld	-	2	-	2	2	-
Cardinal Health SP Brand	-	5	-	5	5	-
Cardinal Health SP Brand - waived	-	4	-	4	4	-
Fisher HealthCare Sure-Vue	-	8	-	8	8	-
Genzyme OSOM	-	16	-	16	16	-
Genzyme OSOM (waived)	-	27	-	27	27	-
Immunostics - IMMUNO/IM	-	1	-	1	1	-
Instant Technologies i Screen-WB	-	1	-	1	1	-
Inverness (Wampole) Clearview	-	18	-	18	18	-
Inverness ClearviewMono-plusII	-	9	-	9	9	-

## Infectious Mononucleosis (cont'd)

<u>Method</u>	<u>Specimen IM-3</u>		<u>Specimen IM-4</u>		<u>Specimen IM-5</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
Inverness Signify Mono Test	-	4	-	4	4	-
LifeSign Status	-	1	-	1	1	-
LifeSign Status - waived	-	5	-	5	5	-
McKesson Medi-Lab Performance - waived	-	4	-	4	4	-
Polymedco Poly stat	-	3	-	3	3	-
Polymedco Poly stat - waived	-	8	-	8	8	-
Quidel QuickVue+	-	31	-	31	31	-
Quidel QuickVue+ - waived	-	1	-	1	1	-
Seradyn	-	24	-	24	24	-
Seradyn Color Q (whole blood)	-	1	-	1	1	-
Wampole Mono-Plus II	-	2	-	2	2	-
Wampole Mono-Plus II (whole blood)	-	1	-	1	1	-
Wampole Mono-Test	-	1	-	1	1	-

## Rheumatoid Factor—Qualitative

<u>Method</u>	<u>Specimen RF-1</u>		<u>Specimen RF-2</u>		<u>Specimen RF-3</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	93	-	92	1	-	93
ASI	4	-	4	-	-	4
Beckman Synchron	3	-	3	-	-	3
Becton Dickinson	1	-	1	-	-	1
Behring RapiTex - Plate method	1	-	1	-	-	1
Biokit Rheumajet	5	-	5	-	-	5
BMH 902, 911, 912, 914, 917	1	-	1	-	-	1
Diamedix	2	-	2	-	-	2
Fisher HealthCare Sure-Vue	8	-	8	-	-	8
Immunostics Inc.	9	-	9	-	-	9
J&S Medical Assoc. Accutex	1	-	1	-	-	1
JAS Diagnostics, Inc.	1	-	1	-	-	1
Pulse Scientific	1	-	1	-	-	1
Roche Integra	1	-	1	-	-	1
Seradyn	30	-	30	-	-	30
Stanbio	1	-	1	-	-	1
Sterling Diagnostics, Inc.	1	-	1	-	-	1
Wampole ColorCard	4	-	4	-	-	4
Wampole Rheumatex	7	-	7	-	-	7
Wampole Rheumaton	8	-	7	1	-	8

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

<b><u>Method</u></b>	<b>Specimen RF-4</b>		<b>Specimen RF-5</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
ALL METHODS	1	92	93	-
ASI	-	4	4	-
Beckman Synchron	-	3	3	-
Becton Dickinson	-	1	1	-
Behring RapiTex - Plate method	-	1	1	-
Biokit Rheumajet	-	5	5	-
BMH 902, 911, 912, 914, 917	-	1	1	-
Diamedix	-	2	2	-
Fisher HealthCare Sure-View	-	8	8	-
Immunostics Inc.	-	9	9	-
J&S Medical Assoc. Accutex	-	1	1	-
JAS Diagnostics, Inc.	-	1	1	-
Pulse Scientific	-	1	1	-
Roche Integra	-	1	1	-
Seradyn	-	30	30	-
Stanbio	-	1	1	-
Sterling Diagnostics, Inc.	-	1	1	-
Wampole ColorCard	-	4	4	-
Wampole Rheumatex	-	7	7	-
Wampole Rheumaton	1	7	8	-

**Rheumatoid Factor—Quantitative (Titer)**

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

<b><u>Specimen/Method</u></b>	<b><u>2/4</u></b>	<b><u>8/10</u></b>	<b><u>16/20</u></b>	<b><u>32/40</u></b>	<b><u>64/80</u></b>	<b><u>128/160</u></b>	<b><u>256/320</u></b>	<b><u>512/640</u></b>	<b><u>1024/1280</u></b>	<b><u>2048/2560</u></b>	<b><u>&gt;2560</u></b>
-------------------------------	-------------------	--------------------	---------------------	---------------------	---------------------	-----------------------	-----------------------	-----------------------	-------------------------	-------------------------	------------------------

**Specimen RF-3**

ALL METHODS	3	10	5	4	-	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	1	2	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	1	3	-	-	-	-	-	-	-	-	-
Immunostics Inc.	-	-	-	1	-	-	-	-	-	-	-
Seradyn	-	5	2	-	-	1	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

### 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>
------------------------	-----------------	------------------	-------------------	-------------------	-------------------	---------------------	---------------------	---------------------	-----------------------	-----------------------	-----------------

#### Specimen RF-4

ALL METHODS	2	10	7	2	1	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	3	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-View	1	3	-	-	-	-	-	-	-	-	-
Immunostics Inc.	-	-	1	-	-	-	-	-	-	-	-
Seradyn	-	4	3	-	-	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>	<u>Low Value</u>	<u>High Value</u>
------------------------	-------------	-------------	-----------	-----------	---------------	------------------	-------------------

#### Specimen RF-1

All Beckman Instruments	6	20.0	0.0	0.0	20	20	20
All Method	14	5.4	6.1	112.8	10	0.0	20
Beckman Synchron	5	20.0	0.0	0.0	20	20	20

#### Specimen RF-2

All Beckman Instruments	6	20.0	0.0	0.0	20	20	20
All Method	14	5.2	5.9	112.9	10	0.0	20
Beckman Synchron	5	20.0	0.0	0.0	20	20	20

#### Specimen RF-3

All Beckman Instruments	121.5	19.0	15.7	133	87	136	121.5
All Method	87.2	61.6	70.6	71	14	254	87.2
Beckman Synchron	123.4	20.6	16.7	133	87	136	123.4

## 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>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen RF-4</b>							
All Beckman Instruments	6	121.3	16.6	13.7	130	91	136
All Method	14	88.3	61.6	69.8	76	12	260
Beckman Synchron	5	122.8	18.1	14.8	130	91	136

### Specimen RF-5

All Beckman Instruments	6	20.0	0	0	20	20	20
All Method	14	5.4	6.1	112.3	10	0	20
Beckman Synchron	5	20.0	0	0	20	20	20

## Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<u>Specimen AS-1</u>		<u>Specimen AS-2</u>		<u>Specimen AS-3</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	2	1	2	1	3	-
Behring RapiTex	-	1	-	1	1	-
Fisher HealthCare Sure-View	1	-	1	-	1	-
Immunostics Inc.	1	-	1	-	1	-

<u>Method</u>	<u>Specimen AS-4</u>		<u>Specimen AS-5</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	3	-	-	3
Behring RapiTex	1	-	-	1
Fisher HealthCare Sure-View	1	-	-	1
Immunostics Inc.	1	-	-	1

Specimen AS-1 and AS-2 are not graded due to less than 80% participant consensus.

**Complement C3 (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen COM-1</b>							
All Method	14	27.3	7.2	26.4	27	8	37
<b>Specimen COM-2</b>							
All Method	14	150.1	11.2	7.5	150	129	166
<b>Specimen COM-3</b>							
All Method	14	267.2	20.1	7.5	267	240	310
<b>Specimen COM-4</b>							
All Method	14	383.1	31.2	8.1	383	340	442
<b>Specimen COM-5</b>							
All Method	14	453.4	67.4	14.9	455	323	575

**Complement C4 (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen COM-1</b>							
All Method	14	5.0	2.0	40.0	4	2	8
<b>Specimen COM-2</b>							
All Method	14	23.1	2.1	9.2	23	20	27
<b>Specimen COM-3</b>							
All Method	14	40.1	3.7	9.3	41	35	47
<b>Specimen COM-4</b>							
All Method	14	57.5	5.3	9.3	60	50	68
<b>Specimen COM-5</b>							
All Method	14	72.5	9.5	13.1	69	57	91

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

<b><u>Method</u></b>	<b>Specimen AN-1</b>		<b>Specimen AN-2</b>		<b>Specimen AN-3</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>	<b><u>Positive</u></b>
ALL METHODS	10	-	10	-	3	7
Diagnostic Technology	7	-	7	-	3	4
Seradyn Seratest SLE	1	-	1	-	-	1
Wampole	1	-	1	-	-	1

<b><u>Method</u></b>	<b>Specimen AN-4</b>		<b>Specimen AN-5</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
ALL METHODS	3	7	10	-
Diagnostic Technology	3	4	7	-
Seradyn Seratest SLE	-	1	1	-
Wampole	-	1	1	-

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

<b><u>Method</u></b>	<b>Specimen AE-1</b>		<b>Specimen AE-2</b>		<b>Specimen AE-3</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>	<b><u>Positive</u></b>
ALL METHODS	19	-	19	-	-	19
Diamedix	1	-	1	-	-	1
GenBio ImmunoDOT	1	-	1	-	-	1
Immuno Concepts	7	-	7	-	-	7
INOVA Diagnostics	3	-	3	-	-	3
Kallestad	3	-	3	-	-	3
Zeus	1	-	1	-	-	1

<b><u>Method</u></b>	<b>Specimen AE-4</b>		<b>Specimen AE-5</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
ALL METHODS	-	19	-	19
Diamedix	-	1	-	1
GenBio ImmunoDOT	-	1	-	1
Immuno Concepts	-	7	-	7
INOVA Diagnostics	-	3	-	3
Kallestad	-	3	-	3
Zeus	-	1	-	1

## 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-3</b>											
ALL METHODS	-	-	1	-	3	4	1	-	1	-	-
Immuno Concepts	-	-	1	-	1	3	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-
Kallestad	-	-	-	-	2	-	-	-	-	-	-
<b>Specimen AE-4</b>											
ALL METHODS	-	-	-	1	3	3	2	-	-	-	-
Immuno Concepts	-	-	-	1	1	3	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-
Kallestad	-	-	-	-	2	-	-	-	-	-	-
<b>Specimen AE-5</b>											
ALL METHODS	-	-	-	1	3	4	-	-	1	-	-
Immuno Concepts	-	-	-	1	3	2	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	1	-	-
Kallestad	-	-	-	-	-	2	-	-	-	-	-

## C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-1</u>		<u>Specimen CR-2</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	1	13	14	-
ASI	-	2	2	-
BMH 902, 911, 912, 914, 917	-	1	1	-
Dade Dimension/AR/ES/RxL/Xpand	-	1	1	-
Fisher HealthCare Sure-View	-	2	2	-
Immunostics Inc.	-	3	3	-
Olympus AU	-	1	1	-
Polymedco CRP	-	1	1	-
Pulse Scientific	1	-	1	-
Roche Integra	-	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-1</b>					
All Method mg/dL - units	37	11.400	13.062	114.6	3.25
Beckman Synchron	6	2.733	0.242	8.9	2.60
Dade Dimension/AR/ES/RxL/Xpand	6	3.217	0.232	7.2	3.30
Roche Integra	5	3.226	0.129	4.0	3.25
All Immunology Methods	22	3.016	0.300	9.9	3.08
mg/L - units					
All Immunology Methods	11	31.076	2.270	7.3	31.56

**Specimen CR-2**

All Method mg/dL - units	32	0.236	0.224	95.0	0.20
Beckman Synchron	6	0.333	0.082	24.5	0.30
Dade Dimension/AR/ES/RxL/Xpand	6	0.167	0.082	49.0	0.20
Roche Integra	5	0.050	0.085	170.9	0.01
All Immunology Methods	24	0.239	0.182	76.2	0.20
mg/L - units					
All Immunology Methods	11	1.801	2.180	121.1	0.38

**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-1</b>					
All Method mg/dL - units	63	0.764	0.359	46.9	0.89
All Immunology Methods	9	0.133	0.123	92.2	0.09
mg/L - units					
DPC Immulite/1000	8	0.926	0.071	7.6	0.95
Other High Sensi. CRP method	6	0.748	0.230	30.7	0.90
Roche Integra hsCRP	8	0.866	0.082	9.4	0.90
All Immunology Methods	45	0.899	0.187	20.8	0.91

**Specimen HCR-2**

All Method mg/dL - units	63	12.553	5.413	43.1	14.57
All Immunology Methods	9	1.288	0.370	28.7	1.41
mg/L - units					
DPC Immulite/1000	8	16.712	2.292	13.7	16.30
Other High Sensi. CRP method	6	14.702	0.910	6.2	14.75
Roche Integra hsCRP	8	15.462	0.765	4.9	16.00
All Immunology Methods	46	14.830	2.434	16.4	14.78

**Rubella—Qualitative**

<u>Method</u>	<b>Specimen RU-1</b>		<b>Specimen RU-2</b>		<b>Specimen RU-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	9	-	9	-	9
Abbott AxSYM	-	2	-	2	-	2
Bayer ADVIA Centaur	-	1	-	1	-	1
bioMerieux Vitek, Mini Vidas	-	3	-	3	-	3
Seradyn	-	2	-	2	-	2
Wampole Rubella - Plus	-	1	-	1	-	1
	<b>Specimen RU-4</b>		<b>Specimen RU-5</b>			
ALL METHODS	9	-	9	-		
Abbott AxSYM	2	-	2	-		
Bayer ADVIA Centaur	1	-	1	-		
bioMerieux Vitek, Mini Vidas	3	-	3	-		
Seradyn	2	-	2	-		
Wampole Rubella - Plus	1	-	1	-		

**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-1</b>					
All Methods	4	-	-	-	121.3
<b>Specimen RU-2</b>					
All Methods	4	-	-	-	51.2
<b>Specimen RU-3</b>					
All Methods	4	-	-	-	51.8
<b>Specimen RU-4</b>					
All Methods	4	-	-	-	0.7
<b>Specimen RU-5</b>					
All Methods	4	-	-	-	1.2

**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>Low Value</u>	<u>High Value</u>
<b>Specimen AL-1</b>							
All Method	8	1416.6	460.0	32.5	1456	653	2000
<b>Specimen AL-2</b>							
All Method	10	149.2	21.5	14.4	150	106	182
<b>Specimen AL-3</b>							
All Method	9	18.2	2.9	15.9	18	14	23
<b>Specimen AL-4</b>							
All Method	9	19.0	4.1	21.4	17	16	27
<b>Specimen AL-5</b>							
All Method	8	42.9	4.5	10.6	43	38	53

## Allergen Specific IgE Antibodies

### Specimen AL-1

	Aspergillus fumigatus Allergen							Peanut (Arachis hyogaea) Allergen						
	CLASS RESULT							CLASS RESULT						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	3	7	-	1	-	-	-	-	-	4	5	-	-
Hitachi CLA-1	-	3	1	-	1	-	-	-	-	-	-	3	-	-
Hycor EIA	-	-	1	-	-	-	-	-	-	-	-	1	-	-
Phadia CAP 100	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	5	-	-	-	-	-	-	3	1	-	-

  

	White Oak Allergen							Bermuda Grass Allergen						
	CLASS RESULT							CLASS RESULT						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	11	2	-	-	-	-	11	1	1	-	-
Hitachi CLA-1	-	-	-	4	2	-	-	-	-	5	-	1	-	-
Hycor EIA	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Phadia CAP 100	-	-	-	1	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	5	-	-	-	-	-	5	-	-	-	-

  

	House Dust Mite Allergen							Cat Epithelium Allergen						
	CLASS RESULT							CLASS RESULT						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	10	2	-	-	-	-	-	7	6	-	-
Hitachi CLA-1	-	-	-	3	2	-	-	-	-	-	-	6	-	-
Hycor EIA	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Phadia CAP 100	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	5	-	-	-	-	-	-	5	-	-	-

  

	Natural Latex Allergen						
	CLASS RESULT						
	0/1	1	2	3	4	5	6
ALL METHODS	-	-	2	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-
Hycor EIA	-	-	-	-	-	-	-
Phadia CAP 100	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	-	-	-	-

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

**Specimen AL-2**

	<b>Alternaria alternate Allergen</b>							<b>Meadow, Kentucky Blue, June Grass Allergens</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	1	6	5	-	-	-	-	-	-	6	1	-	-	-
Hitachi CLA-1	1	4	-	-	-	-	-	-	-	1	-	-	-	-
Hycor EIA	-	1	-	-	-	-	-	-	-	-	1	-	-	-
Phadia CAP 100	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	1	4	-	-	-	-	-	-	-	4	-	-	-
	<b>Perennial Rye Allergen</b>							<b>Dog Dander Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	1	4	-	-	-	-	-	-	-	-	3	5	-
Hitachi CLA-1	-	1	-	-	-	-	-	-	-	-	-	5	-	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia CAP 100	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (% ref)	-	-	4	-	-	-	-	-	-	-	-	2	-	-
	<b>Cow's Milk Allergen</b>							<b>Common Ragweed Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	4	5	-	-	3	3	5	2	-	-	-
Hitachi CLA-1	-	-	-	-	3	-	-	3	3	-	-	-	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	1	-	-	-
Phadia CAP 100	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	3	1	-	-	-	-	-	4	1	-	-
	<b>Peanut (Arachis hyogaea) Allergen</b>													
	<b>CLASS RESULT</b>													
	0/1	1	2	3	4	5	6							
ALL METHODS	-	-	-	-	10	-	-							
Hitachi CLA-1	-	-	-	-	4	-	-							
Hycor EIA	-	-	-	-	1	-	-							
Phadia CAP 100	-	-	-	-	1	-	-							
Phadia UniCap 100 (% ref)	-	-	-	-	4	-	-							

**IgA (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen IP-1</b>							
All Method	14	40.7	3.3	8.2	42	33	45
Roche Integra	5	40.8	2.6	6.3	40	38	44
<b>Specimen IP-2</b>							
All Method	15	234.7	11.0	4.7	234	217	258
Roche Integra	5	231.6	6.7	2.9	233	222	240
<b>Specimen IP-3</b>							
All Method	15	415.6	26.5	6.4	415	348	471
Roche Integra	5	410.2	12.8	3.1	415	393	424
<b>Specimen IP-4</b>							
All Method	15	598.5	37.4	6.2	599	523	695
Roche Integra	5	593.6	11.6	2.0	599	578	606
<b>Specimen IP-5</b>							
All Method	15	741.5	99.5	13.4	702	622	973
Roche Integra	5	688.8	23.8	3.5	697	657	716

**IgG (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen IP-1</b>							
All Method	14	190.4	34.8	18.3	195	97	242
Roche Integra	5	192.8	6.4	3.3	191	187	201
<b>Specimen IP-2</b>							
All Method	14	1108.1	25.2	2.3	1107	1067	1148
Roche Integra	5	1099.8	15.7	1.4	1101	1076	1120
<b>Specimen IP-3</b>							
All Method	15	1940.1	159.8	8.2	1956	1490	2123
Roche Integra	5	1875.8	219.2	11.7	1946	1490	2033
<b>Specimen IP-4</b>							
All Method	15	2798.1	167.4	6.0	2854	2368	2984
Roche Integra	5	2840.8	53.1	1.9	2854	2769	2911
<b>Specimen IP-5</b>							
All Method	15	3552.3	311.4	8.8	3658	2905	3975
Roche Integra	5	3695.4	217.2	5.9	3658	3385	3975

## IgM (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen IP-1</b>							
All Method	14	17.2	4.6	26.6	16	12	25
Roche Integra	5	14.6	0.9	6.1	14	14	16
<b>Specimen IP-2</b>							
All Method	15	85.0	8.1	9.5	84	74	103
Roche Integra	5	81.2	4.4	5.4	84	74	84
<b>Specimen IP-3</b>							
All Method	15	151.1	13.5	8.9	150	132	183
Roche Integra	5	145.4	7.8	5.4	149	132	151
<b>Specimen IP-4</b>							
All Method	15	213.7	23.8	11.1	213	169	262
Roche Integra	5	207.8	10.0	4.8	213	191	215
<b>Specimen IP-5</b>							
All Method	15	272.6	40.1	14.7	268	216	346
Roche Integra	5	266.4	14.7	5.5	268	249	283

## Syphilis Serology—Qualitative: VDRL

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

Specimen SY-5 is ungraded due to the lack of 80% participant consensus.

## Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	<u>Specimen SY-1</u>		<u>Specimen SY-2</u>		<u>Specimen SY-3</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-4</u>		<u>Specimen SY-5</u>			
ALL METHODS	1	-	1	-		

**Syphilis Serology—Qualitative: RPR**

<b><u>Method</u></b>	<b>Specimen SY-1</b>		<b>Specimen SY-2</b>		<b>Specimen SY-3</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	36	9	-	45	-	45
ASI	10	3	-	13	-	13
Becton Dickinson	19	4	-	23	-	23
Fisher HealthCare Sure-View	1	1	-	2	-	2
J&S Medical Assoc. Accutex	1	-	-	1	-	1
New Horizons	1	-	-	1	-	1
Stanbio	1	-	-	1	-	1
Wampole Impact RPR	-	1	-	1	-	1

  

	<b>Specimen SY-4</b>		<b>Specimen SY-5</b>	
ALL METHODS	45	-	33	12
ASI	13	-	9	4
Becton Dickinson	23	-	18	5
Fisher HealthCare Sure-View	2	-	1	1
J&S Medical Assoc. Accutex	1	-	1	-
New Horizons	1	-	1	-
Stanbio	1	-	-	1
Wampole Impact RPR	1	-	1	-

Specimen SY-5 is graded by referee consensus.

## 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-1</b>							
ALL METHODS	12	4	-	-	-	-	-
ASI	6	1	-	-	-	-	-
Becton Dickinson	5	3	-	-	-	-	-
<b>Specimen SY-4</b>							
ALL METHODS	2	12	5	-	-	-	-
ASI	1	6	3	-	-	-	-
Becton Dickinson	-	6	2	-	-	-	-
<b>Specimen SY-5</b>							
ALL METHODS	11	3	1	-	-	-	-
ASI	5	2	-	-	-	-	-
Becton Dickinson	6	1	1	-	-	-	-

## H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-1</u>		<u>Specimen HP-2</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	10	155	160	5
Abbott Signify	-	2	2	-
BD LINK 2	-	2	2	-
Beckman Coulter FlexSure	-	2	2	-
Beckman Coulter ICON HP	2	7	9	-
bioMerieux Vitek, Mini Vidas	-	2	2	-
BioStar Acceava H. pylori	2	1	3	-
Cardinal Health SP Brand	-	6	6	-
DPC Immulite/1000	-	1	1	-
Fisher HealthCare Sure-Vue	1	5	6	-
Instant Technologies i Screen	-	16	16	-
Inverness (Wampole) Clearview	1	13	14	-
LifeSign Status	1	3	4	-
McKesson Medi-Lab Performance - waived	-	5	5	-
Meridian ImmunoCard	-	1	1	-
Polymedco Poly stat	1	16	17	-
Quidel QuickVue	1	69	66	4

## Lyme Disease Serology

<u>Method</u>	Specimen LY-1		Specimen LY-2	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	9	-	-	9
bioMerieux Vitek, Mini Vidas	2	-	-	2
Diamedix	1	-	-	1
Immunostics Inc.	1	-	-	1
Remel Rapidot	1	-	-	1
Wampole	1	-	-	1
Wampole PreVue	2	-	-	2

## Mycoplasma Antibody

<u>Method</u>	Specimen MY-1		Specimen MY-2	
	<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-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	-	2	-	2	-
<u>Method</u>	Specimen VM-4		Specimen VM-5			
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	1	2	-		

## Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	2	3	5	-	1	4
Inverness (Wampole) Clearview	1	-	1	-	-	1
Orasure OraQuick Advance Rapid HIV-1/2	1	1	2	-	1	1
Other IgG Method	-	1	1	-	-	1
Other Total Method	-	1	1	-	-	1
<u>Method</u>	Specimen VM-4		Specimen VM-5			
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	5	-	5	-		
Inverness (Wampole) Clearview	1	-	1	-		
Orasure OraQuick Advance Rapid HIV-1/2	2	-	2	-		
Other IgG Method	1	-	1	-		
Other Total Method	1	-	1	-		

Specimen VM-1 is ungraded due to the lack of 80% participant consensus.

## Viral Markers – HAV

<u>Method</u>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	-	2	-	2	-
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
All Methods	2	-	-	2		

## Viral Markers – HBeAg

The vendor assay for specimens VM-1 through VM-5 is: Negative, Negative, Positive, Negative and Negative, respectively.

## Viral Markers – HBsAb

<u>Method</u>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</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
Bayer ADVIA Centaur - IgG	1	-	1	-	1	-
Bayer ADVIA Centaur - Total	1	-	1	-	1	-
Roche Elecsys - Total	1	-	1	-	-	1
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
ALL METHODS	3	-	3	-		
Bayer ADVIA Centaur - IgG	1	-	1	-		
Bayer ADVIA Centaur - Total	1	-	1	-		
Roche Elecsys - Total	1	-	1	-		

Specimen VM-3 is ungraded due to the lack of 80% participant consensus.

## Viral Markers – HBsAg

<u>Method</u>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	5	-	5	-	1	4
Bayer ADVIA Centaur - Total	1	-	1	-	-	1
Abbott AxSYM - IgG	1	-	1	-	1	-
Roche Elecsys - Total	2	-	2	-	-	2
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
ALL METHODS	-	5	4	1		
Bayer ADVIA Centaur - Total	-	1	1	-		
Abbott AxSYM - IgG	-	1	1	-		
Roche Elecsys - Total	-	2	2	-		

## Viral Markers – HCV

<u>Method</u>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	3	3	-	3	-
Bayer ADVIA Centaur - IgG	-	1	1	-	1	-
Bayer ADVIA Centaur - Total	-	1	1	-	1	-
Abbott AxSYM - IgG	-	1	1	-	1	-
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
ALL METHODS	3	-	3	-		
Bayer ADVIA Centaur - IgG	1	-	1	-		
Bayer ADVIA Centaur - Total	1	-	1	-		
Abbott AxSYM - IgG	1	-	1	-		

## Tear Lactoferrin

<u>Method</u>	<u>Labs</u>	<u>&lt;0.9 mcg/mL</u>	<u>&gt;1.0 mcg/mL</u>
<b>Specimen TLF-1</b>			
Touch Scientific	10	7	3
<b>Specimen TLF-2</b>			
Touch Scientific	10	2	8

Specimen TLF-1 is ungraded due to the less than 80% participant consensus.

## Tear IgE

<u>Method</u>	<u>Labs</u>	<u>&lt;79 ng/mL</u>	<u>&gt;80 ng/mL</u>
<b>Specimen TIG-1</b>			
Touch Scientific	9	4	5
<b>Specimen TIG-2</b>			
Touch Scientific	9	8	1
<b>Specimen TIG-3</b>			
Touch Scientific	9	9	-
<b>Specimen TIG-4</b>			
Touch Scientific	9	3	6
<b>Specimen TIG-5</b>			
Touch Scientific	9	1	8

Specimen TIG-1 and TIG-4 are ungraded due to less than 80% participant consensus

**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)