

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 3



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

Immunology
MLE-M3

Table of Contents

Evaluation Criteria.....	3
Immunology	
Infectious Mononucleosis	4
Rheumatoid Factor.....	6
Qualitative	6
Quantitative (Titer).....	7
Quantitative (IU)	8
Anti-Streptolysin O (ASO).....	8
Qualitative	8
Complement C3.....	9
Complement C4.....	9
Antinuclear Antibody (ANA [AN-11 – AN-15])	10
Qualitative	10
C-Reactive Protein, Regular	10
Qualitative	10
Quantitative	10
C-Reactive Protein, High Sensitivity.....	11
Quantitative	11
Antinuclear Antibody (ANA [AE-11 – AE-15]).....	11
Qualitative	11
Quantitative (Titer).....	12
Anti-dsDNA.....	12
Anti-RNP	13
Anti-RNP/Sm.....	13
Anti-SSA	14
Anti-SSB	14
Anti-SSA/SSB	15
Anti-Sm	15
Rubella.....	16
Qualitative	16
Quantitative	16
Anti-HIV.....	17
Total IgE.....	17
Quantitative	17
Allergen Specific IgE Antibodies	18
IgA.....	20
IgG.....	20
IgM.....	21
Syphilis Serology	22
Qualitative: VDRL	22
Qualitative: Treponema pallidum antibodies	22
Qualitative: RPR.....	22
Quantitative: RPR (Titer)	23
H. pylori Antibody Detection	23
Lyme Disease Serology	24
Mycoplasma Antibody	24
Viral Markers	24
Anti-HBc	24
Anti-HIV.....	25
HAV.....	25
HBeAg.....	26
HBsAb.....	26
HBsAg.....	26
HCV	27

Evaluation Criteria

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

Qualitative

For qualitative 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)	± 2 SD
Rheumatoid Factor (Titer)	Not Evaluated
Anti-Streptolysin O (ASO) Titer	Not Evaluated
Complement C3	± 3 SD
Complement C4	± 3 SD
Antinuclear Antibody (ANA) Titer	Not Evaluated
C-Reactive Protein	± 3 SD
High Sensitivity C-Reactive Protein	± 3 SD
Rubella (International Units)	± 3 SD
Total IgE	± 3 SD
Total IgA	± 3 SD
Total IgG	$\pm 25\%$
Total IgM	± 3 SD

Infectious Mononucleosis

<u>Method</u>	Specimen IM-11		Specimen IM-12	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	231	1	1	231
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	9	-	-	9
BioStar Acceava Mono Test	2	-	-	2
BioStar Acceava Mono-whole bld	6	-	-	6
Cardinal Health SP Brand - waived	6	-	-	6
Consult Diagnostics	2	1	1	2
Fisher HealthCare Sure-Vue	10	-	-	10
Genzyme OSOM	7	-	-	7
Genzyme OSOM (waived)	79	-	-	79
Henry Schein OneStep+ - waived	12	-	-	12
Inverness (Wampole) Clearview	7	-	-	7
Inverness Clearview Mono Plus II	10	-	-	10
Inverness Signify Mono Test	2	-	-	2
LifeSign Status	1	-	-	1
LifeSign Status - waived	8	-	-	8
McKesson Medi-Lab Performance - waived	10	-	-	10
Meridian ImmunoCard STAT!	1	-	-	1
Other Moderate method	9	-	-	9
Other Waived method	30	-	-	30
Polymedco Poly stat - waived	2	-	-	2
Quidel QuickVue+	2	-	-	2
Quidel QuickVue+ - waived	11	-	-	11
Seradyn	1	-	-	1
Wampole ColorCard	1	-	-	1
Wampole Mono-Plus II	2	-	-	2

Infectious Mononucleosis

<u>Method</u>	Specimen IM-13		Specimen IM-14		Specimen IM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	93	1	-	94	93	1
ASI	1	-	-	1	1	-
Beckman Coulter ICON Mono - waived	9	-	-	9	9	-
BioStar Acceava Mono Test	1	-	-	1	1	-
BioStar Acceava Mono-whole bld	1	-	-	1	1	-
Cardinal Health SP Brand - waived	1	-	-	1	1	-
Consult Diagnostics	2	-	-	2	2	-
Fisher HealthCare Sure-Vue	5	-	-	5	5	-
Genzyme OSOM	7	-	-	7	7	-
Genzyme OSOM (waived)	30	1	-	31	31	-
Henry Schein OneStep+ - waived	4	-	-	4	4	-
Inverness (Wampole) Clearview	5	-	-	5	4	1
Inverness Clearview Mono Plus II	3	-	-	3	3	-
LifeSign Status	1	-	-	1	1	-
LifeSign Status - waived	2	-	-	2	2	-
Meridian ImmunoCard STAT!	1	-	-	1	1	-
Other Moderate method	9	-	-	9	9	-
Other Waived method	4	-	-	4	4	-
Quidel QuickVue+	2	-	-	2	2	-
Quidel QuickVue+ - waived	2	-	-	2	2	-
Seradyn	1	-	-	1	1	-
Wampole ColorCard	1	-	-	1	1	-
Wampole Mono-Plus II	1	-	-	1	1	-

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-11		Specimen RF-12		Specimen RF-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	60	2	58	60	-
Abbott Architect	-	1	-	1	1	-
ASI	-	8	-	8	8	-
Biokit Rheumajet	-	11	-	11	11	-
Diamedix	-	2	-	2	2	-
Fisher HealthCare Sure-View	-	7	1	6	7	-
Immunostics Inc.	-	5	-	5	5	-
JAS Diagnostics, Inc.	-	1	-	1	1	-
Remel SeraTest	-	1	-	1	1	-
Teco Diagnostics	-	4	-	4	4	-
TheraTest	-	4	-	4	4	-
Wampole ColorCard	-	10	-	10	10	-
Wampole Rheumatex	-	4	1	3	4	-

<u>Method</u>	Specimen RF-14		Specimen RF-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	60	-	58	2
Abbott Architect	1	-	1	-
ASI	8	-	8	-
Biokit Rheumajet	11	-	11	-
Diamedix	2	-	1	1
Fisher HealthCare Sure-View	7	-	6	1
Immunostics Inc.	5	-	5	-
JAS Diagnostics, Inc.	1	-	1	-
Remel SeraTest	1	-	1	-
Teco Diagnostics	4	-	4	-
TheraTest	4	-	4	-
Wampole ColorCard	10	-	10	-
Wampole Rheumatex	4	-	4	-

Rheumatoid Factor—Quantitative (Titer)

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

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

Specimen RF-13

ALL METHODS	1	5	1	-	2	-	-	-	-	-	-
ASI	-	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	1	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	4	-	-	1	-	-	-	-	-	-
Remel SeraTest	-	-	-	-	1	-	-	-	-	-	-
Wampole ColorCard	-	-	1	-	-	-	-	-	-	-	-

Specimen RF-14

ALL METHODS	-	3	3	1	2	-	-	-	-	-	-
ASI	-	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	2	2	-	1	-	-	-	-	-	-
Remel SeraTest	-	-	-	-	1	-	-	-	-	-	-
Wampole ColorCard	-	-	-	1	-	-	-	-	-	-	-

Specimen RF-15

ALL METHODS	1	5	1	-	1	-	-	-	-	-	-
ASI	-	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	1	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	4	-	-	-	-	-	-	-	-	-
Remel SeraTest	-	-	-	-	1	-	-	-	-	-	-
Wampole ColorCard	-	-	1	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen RF-11						
All Method	17	3.6	4.6	125.3	2	0 - 13
Specimen RF-12						
All Method	16	3.9	4.7	120.6	2	0 - 14
Specimen RF-13						
All Method	16	66.6	10.9	16.4	61	44 - 89
Specimen RF-14						
All Method	16	119.9	15.3	12.8	115	89 - 151
Specimen RF-15						
All Method	15	67.5	10.6	15.7	61	46 - 89

Anti-Streptolysin O (ASO)—Qualitative

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

Complement C3 (mg/dL)

<u><i>Specimen/Method</i></u>	<u><i>Labs</i></u>	<u><i>Mean</i></u>	<u><i>SD</i></u>	<u><i>CV</i></u>	<u><i>Median</i></u>	<u><i>Range</i></u>
Specimen IMP-11						
All Method	15	86.5	4.8	5.5	87	72 - 101
Specimen IMP-12						
All Method	15	233.3	12.3	5.3	233	196 - 271
Specimen IMP-13						
All Method	15	177.3	10.7	6.0	178	145 - 210
Specimen IMP-14						
All Method	15	230.4	10.2	4.4	228	199 - 261
Specimen IMP-15						
All Method	15	175.7	10.5	5.9	177	144 - 208

Complement C4 (mg/dL)

<u><i>Specimen/Method</i></u>	<u><i>Labs</i></u>	<u><i>Mean</i></u>	<u><i>SD</i></u>	<u><i>CV</i></u>	<u><i>Median</i></u>	<u><i>Range</i></u>
Specimen IMP-11						
All Method	15	14.8	2.1	14.3	14	8 - 22
Specimen IMP-12						
All Method	15	39.9	3.4	8.6	39	29 - 51
Specimen IMP-13						
All Method	15	30.6	2.2	7.1	30	24 - 38
Specimen IMP-14						
All Method	15	39.1	3.4	8.8	38	28 - 50
Specimen IMP-15						
All Method	15	30.8	2.1	6.9	31	24 - 38

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	5	-
ASI	-	2	-	2	2	-
Diagnostic Technology	-	2	-	2	2	-
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	5	-	-	5
ASI	2	-	-	2
Diagnostic Technology	2	-	-	2
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	-	16	16	-
Biokit Rheumajet	-	1	1	-
Fisher HealthCare Sure-Vue	-	8	8	-
Immunostics Inc.	-	1	1	-
Siemens Dimension/AR/ES/RxL/Xpand	-	1	1	-
Teco Diagnostics	-	4	4	-
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>
Specimen CR-5						
mg/dL - units						
Siemens						
Dimension/AR/ES/RxL/Xpand	11	0.132	0.096	72.5	0.20	0.00 - 0.42
All Immunology Methods	23	0.172	0.169	98.3	0.20	0.00 - 0.69
mg/L - units						
All Immunology Methods	10	1.793	2.031	113.3	1.05	0.00 - 7.89
Specimen CR-6						
mg/dL - units						
Siemens						
Dimension/AR/ES/RxL/Xpand	11	1.530	0.110	7.2	1.50	1.20 - 1.86
All Immunology Methods	24	1.585	0.385	24.3	1.53	0.42 - 2.75
mg/L - units						
All Immunology Methods	10	16.969	5.097	30.0	15.64	1.67 - 32.26

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>
Specimen HCR-5						
All Method	45	13.832	1.175	8.5	13.87	10.30 - 17.36
Siemens Dimension High Sensi CRP	10	13.067	0.612	4.7	12.88	11.23 - 14.91

Specimen HCR-6

All Method	46	0.770	0.241	31.3	0.80	0.04 - 1.50
Siemens Dimension High Sensi CRP	10	1.057	0.390	36.9	1.04	0.00 - 2.23

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	2	7	10	-	17
Diamedix	2	-	-	2	-	2
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1
Immuno Concepts	4	-	3	1	-	4
INOVA Diagnostics	2	1	-	3	-	3
Kallestad	2	-	1	1	-	2
TheraTest	4	-	3	1	-	4
Wampole	-	1	-	1	-	1

Specimen AE-12 is an ungraded challenge due to less than 80% referee consensus.

<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	-	17	17	-
Diamedix	-	2	2	-
GenBio ImmunoDOT Panel 1	-	1	1	-
Immuno Concepts	-	4	4	-
INOVA Diagnostics	-	3	3	-
Kallestad	-	2	2	-
TheraTest	-	4	4	-
Wampole	-	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>
------------------------	------------------	-------------------	-------------------	-------------------	---------------------	---------------------	---------------------	----------------	-----------------------	-----------------------	--------------

Specimen AE-11

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

Specimen AE-12

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

Specimen AE-15

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

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	-	11	-	11	-	11
Diamedix	-	3	-	3	-	3
Kallestad	-	2	-	2	-	2
TheraTest	-	5	-	5	-	5
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	-	11	10	1
Diamedix	-	3	3	-
Kallestad	-	2	2	-
TheraTest	-	5	5	-
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	3	-	-	3	-	3
INOVA Diagnostics	2	-	-	2	-	2

<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

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	2	-	10	-	10
Diamedix	2	1	-	3	-	3
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
TheraTest	5	-	-	5	-	5
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	-	10	1	9
Diamedix	-	3	-	3
GenBio ImmunoDOT Panel 1	-	1	-	1
TheraTest	-	5	1	4
Wampole	-	1	-	1

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	11	-	-	11	1	10
Diamedix	4	-	-	4	1	3
INOVA Diagnostics	1	-	-	1	-	1
TheraTest	5	-	-	5	-	5
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	-	11	11	-
Diamedix	-	4	4	-
INOVA Diagnostics	-	1	1	-
TheraTest	-	5	5	-
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	7	4	-	11	-	11
Diamedix	-	4	-	4	-	4
INOVA Diagnostics	1	-	-	1	-	1
TheraTest	5	-	-	5	-	5
Wampole	1	-	-	1	-	1

Specimen AE-11 is an ungraded challenge due to a lack of referee group.

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	11	11	-
Diamedix	-	4	4	-
INOVA Diagnostics	-	1	1	-
TheraTest	-	5	5	-
Wampole	-	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	-	1
GenBio ImmunoDOT Panel 1	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	-
GenBio ImmunoDOT Panel 1	-	1	1	-

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	-	11	-	11	-	11
Diamedix	-	4	-	4	-	4
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	-	5	-	5	-	5
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	-	11	-	11
Diamedix	-	4	-	4
INOVA Diagnostics	-	1	-	1
TheraTest	-	5	-	5
Wampole	-	1	-	1

Rubella—Qualitative

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	6	-	6	-
Bayer ADVIA Centaur	-	2	2	-	2	-
bioMerieux Vidas, Mini Vidas	-	2	2	-	2	-
DiaSorin	-	2	2	-	2	-

<u>Method</u>	Specimen RU-14		Specimen RU-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	-	6
Bayer ADVIA Centaur	2	-	-	2
bioMerieux Vidas, Mini Vidas	2	-	-	2
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: 0 IU/mL, 36 IU/mL, 20 IU/mL, 86 IU/mL and 0 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	2	39	39	2
Abbott Architect	-	1	1	-
Inverness Clearview Complete HIV 1/2	-	13	13	-
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	4	4	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	1	14	14	1
Other Moderate method	-	1	1	-
Other Waived method	1	6	6	1

<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	6	-	6	-	-	6
Abbott Architect	1	-	1	-	-	1
Inverness Clearview Complete HIV 1/2	3	-	3	-	-	3
Orasure OraQuick Advance Rapid HIV-1/2 - waived	1	-	1	-	-	1
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>
Specimen AL-11						
All Method	5	253.2	27.0	10.7	250	172 - 335
Specimen AL-12						
All Method	5	215.0	27.3	12.7	206	133 - 297
Specimen AL-13						
All Method	5	24.2	5.5	22.7	23	7 - 41
Specimen AL-14						
All Method	5	22.2	5.5	24.8	23	5 - 39
Specimen AL-15						
All Method	5	49.8	10.2	20.5	51	19 - 81

Allergen Specific IgE Antibodies

Specimen AL-11

Method

	House Dust Mite 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	-	-	-	6	-	1	-	-	-	-	-	4	1	2	-	-
Hitachi CLA-1	-	-	-	2	-	1	-	-	-	-	-	1	1	2	-	-
Phadia ImmunoCAP Rapid	-	-	-	2	-	-	-	-	-	-	-	2	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Peanut Allergen CLASS RESULT								Bermuda 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	3	-	-	-	-	9	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	3	-	-	-	-	5	-	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	-	-	1	-	-	-	-	-

	Meadow Fescue Allergen CLASS RESULT								White Oak Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	7	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	4	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-

	English Plantain Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	2	3	1	-	-	-	-	-
Hitachi CLA-1	2	2	1	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-12

<u>Method</u>	Cat Epithelium Allergen CLASS RESULT								Egg White Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	4	2	2	-	-	-	-	1	-	1	-	-	-
Hitachi CLA-1	-	-	-	-	2	2	-	-	-	-	-	-	1	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-

Egg White Allergen is an ungraded challenge due to less than 80% participant consensus.

	Cow's Milk Allergen CLASS RESULT								Cocksfoot Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	2	-	3	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	3	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-

	Timothy Grass Allergen CLASS RESULT								Silver Birch Tree Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	3	-	3	-	-	1	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	3	-	-	1	-	-	-	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-

Silver Birch Tree Allergen is an ungraded challenge due to less than 80% participant consensus.

	Common (Short) Ragweed Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	2	4	1	-	-	-	-	-
Hitachi CLA-1	2	2	-	-	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	1	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	1	-	-	-	-	-	-

IgA (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-11						
All Method	14	495.7	50.8	10.3	503	343 - 649
Specimen IMP-12						
All Method	14	321.9	19.0	5.9	327	264 - 379
Specimen IMP-13						
All Method	14	255.0	12.1	4.7	259	218 - 292
Specimen IMP-14						
All Method	14	310.6	21.2	6.8	317	246 - 375
Specimen IMP-15						
All Method	14	254.7	15.9	6.2	258	206 - 303

IgG (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-11						
All Method	14	833.4	28.5	3.4	836	625 - 1042
Specimen IMP-12						
All Method	14	1596.1	93.6	5.9	1614	1197 - 1996
Specimen IMP-13						
All Method	14	1244.8	50.0	4.0	1261	933 - 1556
Specimen IMP-14						
All Method	14	1847.1	88.9	4.8	1866	1385 - 2309
Specimen IMP-15						
All Method	14	1248.9	34.2	2.7	1251	936 - 1562

IgM (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-11						
All Method	14	433.8	61.4	14.2	432	249 - 619
Specimen IMP-12						
All Method	14	391.4	42.7	10.9	389	263 - 520
Specimen IMP-13						
All Method	14	118.6	10.7	9.0	116	86 - 151
Specimen IMP-14						
All Method	14	395.9	47.1	11.9	392	254 - 538
Specimen IMP-15						
All Method	14	121.2	12.7	10.5	117	83 - 160

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-11			Specimen SY-12			Specimen SY-13		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	-	2	-	1	1	2	-	-
ASI	-	-	1	-	1	-	1	-	-

<u>Method</u>	Specimen SY-14			Specimen SY-15		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	1	2	-	-
ASI	-	-	1	1	-	-

Specimens SY-11 and SY-14 are ungraded challenges due to less than 80% participant consensus.

Syphilis Serology—Qualitative: Treponema pallidum antibodies

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<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>	Specimen SY-14		Specimen SY-15	
	<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>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	23	1	22	23	-
ASI	-	9	1	8	9	-
Becton Dickinson	-	11	-	11	11	-
Fisher HealthCare Sure-Vue	-	2	-	2	2	-
Wampole Impact RPR	-	1	-	1	1	-

<u>Method</u>	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	20	3	23	-
ASI	6	3	9	-
Becton Dickinson	11	-	11	-
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>>64</u>
Specimen SY-13								
ALL METHODS	4	7	1	-	-	-	-	-
ASI	3	3	-	-	-	-	-	-
Becton Dickinson	1	4	1	-	-	-	-	-
Specimen SY-14								
ALL METHODS	8	2	-	-	-	-	-	-
ASI	4	-	-	-	-	-	-	-
Becton Dickinson	4	2	-	-	-	-	-	-
Specimen SY-15								
ALL METHODS	2	9	1	-	-	-	-	-
ASI	2	3	1	-	-	-	-	-
Becton Dickinson	-	6	-	-	-	-	-	-

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	96	1	-	97
Alfa Scientific Instant-View	2	-	-	2
Beckman Coulter ICON HP	2	-	-	2
Cardinal Health SP Brand	7	-	-	7
Consult Diagnostics	15	-	-	15
Fisher HealthCare Sure-View	3	-	-	3
Henry Schein OneStep+ - waived	8	-	-	8
Inverness (Wampole) Clearview	10	-	-	10
McKesson Medi-Lab Performance - waived	10	-	-	10
Other Waived method	1	-	-	1
Polymedco Poly stat	2	1	-	3
PSS Select Diagnostics	1	-	-	1
Quidel QuickVue	34	-	-	34
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	-	1	1	-
Meridian ImmunoCard	-	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	2	4	-	-	4
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	3	1	4	-
Bayer ADVIA Centaur – IgM	1	-	1	-
Bayer ADVIA Centaur – Total	1	-	1	-

Specimen VM-14 is an ungraded challenge due to less than 80% consensus.

Viral Markers – Anti-HIV

<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	-	9	6	3	9	-
Bayer ADVIA Centaur – Total	-	3	3	-	3	-
Inverness Clearview HIV1/2 STAT-PAK	-	1	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 – moderate	-	4	3	1	4	-
Orasure OraQuick Advance Rapid HIV-1/2 – waived	-	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	3	6	3	6
Bayer ADVIA Centaur - Total	3	-	3	-
Inverness Clearview HIV1/2 STAT-PAK	-	1	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	4	-	4
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	1	-	1

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

Viral Markers – HAV

<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	1	1
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	2	-	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, Positive, Negative, Positive, and Positive, 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	2	-	-	2	-	2
Bayer ADVIA Centaur - Total	3	-	-	3	-	3

<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	-	2	-	2
Bayer ADVIA Centaur - Total	-	3	-	3

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	1	4	5	-	5	-
Abbott Architect – Total	-	1	1	-	1	-
Bayer ADVIA Centaur – Total	-	2	2	-	2	-
Other IgG Method	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	5	-	5	-
Abbott Architect - Total	1	-	1	-
Bayer ADVIA Centaur - Total	2	-	2	-
Other IgG Method	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	7	-	-	7	-	7
Abbott Architect - Total	2	-	-	2	-	2
Bayer ADVIA Centaur - Total	3	-	-	3	-	3
OraSure OraQuick HCV	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	-	7	7	-
Abbott Architect - Total	-	2	2	-
Bayer ADVIA Centaur - Total	-	3	3	-
OraSure OraQuick HCV	-	2	2	-

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