

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 1



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

Immunology
MLE – M2

Table of Contents

2011 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-6 – AN-10])	10
Qualitative	10
C-Reactive Protein, Regular	10
Qualitative	10
Quantitative	10
C-Reactive Protein, High Sensitivity	11
Quantitative	11
Antinuclear Antibody (ANA [AE-6 – AE-10])	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	21
Qualitative: VDRL.....	21
Qualitative: RPR.....	22
Quantitative: RPR (Titer)	22
H. pylori Antibody Detection	23
Lyme Disease Serology	23
Mycoplasma Antibody	23
Viral Markers	24
Anti-HBc	24
Anti-HIV.....	24
HAV.....	25
HBeAg.....	25
HBsAb.....	25
HBsAg.....	26
HCV	26

2011 Evaluation Criteria

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

Qualitative

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

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

Quantitative

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

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

Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-6</u>		<u>Specimen IM-7</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	255	5	4	256
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	8	-	-	8
BioStar Acceava Mono Test	3	-	-	3
BioStar Acceava Mono-whole bld	9	-	-	9
Cardinal Health SP Brand	5	-	-	5
Cardinal Health SP Brand - waived	6	-	-	6
Fisher HealthCare Sure-Vue	8	-	-	8
Genzyme OSOM	12	-	-	12
Genzyme OSOM (waived)	91	2	1	92
Henry Schein OneStep+ - waived	11	-	-	11
Inverness (Wampole) Clearview	11	1	-	12
Inverness Clearview Mono Plus II	8	1	-	9
Inverness Signify Mono Test	4	-	-	4
LifeSign Status - waived	21	-	2	19
McKesson Medi-Lab Performance - waived	4	-	-	4
Meridian ImmunoCard STAT!	1	-	-	1
Other Moderate method	5	1	1	5
Other Waived method	14	-	-	14
Polymedco Poly stat	3	-	-	3
Polymedco Poly stat - waived	6	-	-	6
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	7	-	-	7
Seradyn	11	-	-	11
Wampole ColorCard	1	-	-	1
Wampole Mono-Plus II	3	-	-	3

Infectious Mononucleosis

<u>Method</u>	Specimen IM-8		Specimen IM-9		Specimen IM- 10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	126	-	125	1	1	125
ASI	1	-	1	-	-	1
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	5	-	5	-	-	5
Fisher HealthCare Sure-Vue	7	-	7	-	-	7
Genzyme OSOM	11	-	11	-	-	11
Genzyme OSOM (waived)	35	-	34	1	1	34
Henry Schein OneStep+ - waived	3	-	3	-	-	3
Inverness (Wampole) Clearview	8	-	8	-	-	8
Inverness Clearview Mono Plus II	4	-	4	-	-	4
LifeSign Status - waived	4	-	4	-	-	4
McKesson Medi-Lab Performance - waived	2	-	2	-	-	2
Meridian ImmunoCard STAT!	1	-	1	-	-	1
Other Moderate method	6	-	6	-	-	6
Other Waived method	3	-	3	-	-	3
Polymedco Poly stat	3	-	3	-	-	3
Polymedco Poly stat - waived	4	-	4	-	-	4
Quidel QuickVue+	1	-	1	-	-	1
Quidel QuickVue+ - waived	2	-	2	-	-	2
Seradyn	11	-	11	-	-	11
Wampole ColorCard	1	-	1	-	-	1
Wampole Mono-Plus II	1	-	1	-	-	1

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-6		Specimen RF-7		Specimen RF-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	73	73	-	-	73
Abbott Architect	-	1	1	-	-	1
ASI	-	4	4	-	-	4
Beckman Synchron LX / Pro / DxC	-	1	1	-	-	1
Biokit Rheumajet	-	3	3	-	-	3
Cardinal Health SP Brand	-	1	1	-	-	1
Diagnostic Technology	-	3	3	-	-	3
Diamedix	-	2	2	-	-	2
Fisher HealthCare Sure-Vue	-	9	9	-	-	9
Immunostics Inc.	-	6	6	-	-	6
JAS Diagnostics, Inc.	-	1	1	-	-	1
Remel SeraTest	-	18	18	-	-	18
Seradyn	-	3	3	-	-	3
Stanbio Laboratory	-	1	1	-	-	1
TheraTest	-	3	3	-	-	3
Wampole ColorCard	-	6	6	-	-	6
Wampole Rheumatex	-	7	7	-	-	7
Wampole Rheumaton	-	4	4	-	-	4

<u>Method</u>	Specimen RF-9		Specimen RF-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	73	73	-
Abbott Architect	-	1	1	-
ASI	-	4	4	-
Beckman Synchron LX / Pro / DxC	-	1	1	-
Biokit Rheumajet	-	3	3	-
Cardinal Health SP Brand	-	1	1	-
Diagnostic Technology	-	3	3	-
Diamedix	-	2	2	-
Fisher HealthCare Sure-Vue	-	9	9	-
Immunostics Inc.	-	6	6	-
JAS Diagnostics, Inc.	-	1	1	-
Remel SeraTest	-	18	18	-
Seradyn	-	3	3	-
Stanbio Laboratory	-	1	1	-
TheraTest	-	3	3	-
Wampole ColorCard	-	6	6	-
Wampole Rheumatex	-	7	7	-
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>>2560</u>
Specimen RF-7											
ALL METHODS	-	7	-	2	1	2	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	4	-	-	-	1	-	-	-	-	-
Remel SeraTest	-	2	-	-	1	-	-	-	-	-	-
Seradyn	-	1	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	1	-	-	-	-	-
Specimen RF-10											
ALL METHODS	-	1	6	2	-	3	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	1	3	-	-	1	-	-	-	-	-
Remel SeraTest	-	-	1	1	-	1	-	-	-	-	-
Seradyn	-	-	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>
Specimen RF-6						
All Method	20	8.4	7.2	86.6	8	0 - 31
Specimen RF-7						
All Method	19	98.9	33.1	33.4	77	0 - 199
Specimen RF-8						
All Method	20	8.1	7.5	92.1	9	0 - 31
Specimen RF-9						
All Method	20	8.2	7.5	91.4	10	0 - 31
Specimen RF-10						
All Method	18	153.7	63.5	41.3	120	0 - 345

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<u>Specimen AS-6</u>		<u>Specimen AS-7</u>		<u>Specimen AS-8</u>	
	<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	-	1
<u>Method</u>	<u>Specimen AS-9</u>		<u>Specimen AS-10</u>			
	<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>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-6						
All Method	14	117.4	16.9	14.4	128	66 - 169
Specimen IMP-7						
All Method	14	115.6	16.2	14.0	125	66 - 165
Specimen IMP-8						
All Method	14	117.0	17.6	15.1	127	64 - 170
Specimen IMP-9						
All Method	14	128.9	16.2	12.5	137	80 - 178
Specimen IMP-10						
All Method	14	86.2	9.5	11.1	86	57 - 115

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>
Specimen IMP-6						
All Method	14	24.0	1.8	7.3	24	18 - 30
Specimen IMP-7						
All Method	14	23.6	1.3	5.4	24	19 - 28
Specimen IMP-8						
All Method	14	24.1	1.9	7.9	24	18 - 30
Specimen IMP-9						
All Method	14	24.4	1.5	6.2	25	19 - 29
Specimen IMP-10						
All Method	14	17.0	3.8	22.4	16	5 - 29

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	<u>Specimen AN-6</u>		<u>Specimen AN-7</u>		<u>Specimen AN-8</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7	7	-
Alpha Scientific Medical, Inc.	-	1	-	1	1	-
Diagnostic Technology	-	5	-	5	5	-
Wampole	-	1	-	1	1	-

<u>Method</u>	<u>Specimen AN-9</u>		<u>Specimen AN-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	-	7
Alpha Scientific Medical, Inc.	1	-	-	1
Diagnostic Technology	5	-	-	5
Wampole	1	-	-	1

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-3</u>		<u>Specimen CR-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	-	16
ASI	1	-	-	1
Biokit Rheumajet	1	-	-	1
Diagnostic Technology	3	-	-	3
Fisher HealthCare Sure-Vue	8	-	-	8
Immunostics Inc.	1	-	-	1
Siemens Dimension/AR/ES/RxL/Xpand	1	-	-	1
Wampole	1	-	-	1

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CR-3						
mg/dL - units						
All Immunology Methods	23	3.255	0.350	10.8	3.38	2.20 - 4.31
mg/L - units						
All Immunology Methods	12	32.904	3.927	11.9	33.60	21.12 - 44.69
Specimen CR-4						
mg/dL - units						
All Immunology Methods	23	0.189	0.166	88.0	0.20	0.00 - 0.69
mg/L - units						
All Immunology Methods	13	1.452	1.900	130.8	0.24	0.00 - 7.16

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-3						
All Method	49	0.792	0.133	16.8	0.80	0.39 - 1.20
Specimen HCR-4						
All Method	49	14.160	1.020	7.2	14.30	11.10 - 17.22

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

<u>Method</u>	<u>Specimen AE-6</u>		<u>Specimen AE-7</u>		<u>Specimen AE-8</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	15	10	5	14	1
Immuno Concepts	-	5	4	1	4	1
INOVA Diagnostics	-	2	2	-	2	-
Kallestad	-	2	2	-	2	-
TheraTest	-	3	2	1	3	-
Wampole	-	1	-	1	1	-
Zeus	-	1	-	1	1	-

<u>Method</u>	<u>Specimen AE-9</u>		<u>Specimen AE-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	-	-	15
Immuno Concepts	5	-	-	5
INOVA Diagnostics	2	-	-	2
Kallestad	2	-	-	2
TheraTest	3	-	-	3
Wampole	1	-	-	1
Zeus	1	-	-	1

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

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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Specimen AE-7

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

Specimen AE-8

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

Specimen AE-9

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

Anti-dsDNA

<u>Method</u>	<u>Specimen AE-6</u>		<u>Specimen AE-7</u>		<u>Specimen AE-8</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8	8	-
Immuno Concepts	-	1	-	1	1	-
INOVA Diagnostics	-	1	-	1	1	-
Kallestad	-	2	-	2	2	-
TheraTest	-	2	-	2	2	-
Wampole	-	1	-	1	1	-
Zeus	-	1	-	1	1	-

<u>Method</u>	<u>Specimen AE-9</u>		<u>Specimen AE-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	7	-	8
Immuno Concepts	1	-	-	1
INOVA Diagnostics	-	1	-	1
Kallestad	-	2	-	2
TheraTest	-	2	-	2
Wampole	-	1	-	1
Zeus	-	1	-	1

Anti-RNP

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	3	1	2	2	1
INOVA Diagnostics	-	2	1	1	2	-
Zeus	-	1	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	-	-	3
INOVA Diagnostics	2	-	-	2
Zeus	1	-	-	1

Specimens AE-7 and AE-8 are ungraded challenges due to lack of 80% participant consensus.

Anti-RNP/Sm

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	2	3	3	2
Diamedix	-	1	-	1	-	1
Immuno Concepts	-	1	-	1	1	-
TheraTest	-	2	2	-	2	-
Wampole	-	1	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5
Diamedix	1	-	-	1
Immuno Concepts	1	-	-	1
TheraTest	2	-	-	2
Wampole	1	-	-	1

Specimens AE-7 and AE-8 are ungraded challenges due to lack of 80% participant consensus.

Anti-SSA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7	7	-
Diamedix	-	1	-	1	1	-
INOVA Diagnostics	-	2	-	2	2	-
TheraTest	-	2	-	2	2	-
Wampole	-	1	-	1	1	-
Zeus	-	1	-	1	1	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	6	-	7
Diamedix	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	2	-	2
Wampole	-	1	-	1
Zeus	1	-	-	1

Anti-SSB

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7	7	-
Diamedix	-	1	-	1	1	-
INOVA Diagnostics	-	2	-	2	2	-
TheraTest	-	2	-	2	2	-
Wampole	-	1	-	1	1	-
Zeus	-	1	-	1	1	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
Diamedix	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	2	-	2
Wampole	-	1	-	1
Zeus	-	1	-	1

Anti-SSA/SSB

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	-	2	1	1
Immuno Concepts	-	1	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	-	2
Immuno Concepts	-	1	-	1

Specimens AE-8 is an ungraded challenge due to lack of 80% participant consensus.

Anti-Sm

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7	1	6
Diamedix	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
TheraTest	-	2	-	2	-	2
Wampole	-	1	-	1	-	1
Zeus	-	1	-	1	1	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
Diamedix	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	2	-	2
Wampole	-	1	-	1
Zeus	-	1	-	1

Rubella—Qualitative

<u>Method</u>	Specimen RU-6		Specimen RU-7		Specimen RU-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	7	-	7	-
Bayer ADVIA Centaur	-	2	2	-	2	-
bioMerieux Vidas, Mini Vidas	-	3	3	-	3	-
DiaSorin	-	1	1	-	1	-

<u>Method</u>	Specimen RU-9		Specimen RU-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	-	7
Bayer ADVIA Centaur	2	-	-	2
bioMerieux Vidas, Mini Vidas	3	-	-	3
DiaSorin	1	-	-	1

Rubella—Quantitative (IU/mL)

Only one lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values for specimens RU-6 through RU-10 are: 0.0 IU/mL, 21.0 IU/mL, 118.0 IU/mL, 34.0 IU/mL and 0.0 IU/mL, respectively.

Anti-HIV

<u>Method</u>	Specimen HIV-6		Specimen HIV-7	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	36	36	-
Inverness Clearview Complete HIV 1/2	-	11	11	-
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	4	4	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	15	15	-
Other Waived method	-	6	6	-

<u>Method</u>	Specimen HIV-8		Specimen HIV-9		Specimen HIV-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	-	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	1	-	-	1	1	-

Total IgE—Quantitative (U/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen AL-6						
All Method	9	247.9	45.9	18.5	235	110 - 386
Specimen AL-7						
All Method	9	395.6	69.3	17.5	413	187 - 604
Specimen AL-8						
All Method	9	24.8	5.2	21.0	23	9 - 41
Specimen AL-9						
All Method	9	56.9	10.0	17.5	55	26 - 87
Specimen AL-10						
All Method	9	25.0	4.9	19.7	23	10 - 40

Allergen Specific IgE Antibodies

Specimen AL-6

Method

	House Dust Mite Allergen <i>CLASS RESULT</i>								Cat Epithelium Allergen <i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	3	3	12	1	1	-	-	-	-	2	13	2	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	3	2	3	1	1	-	-	-	-	1	4	2	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	4	-	-	-	-	-	-	-	4	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	3	-	-	-	-	-	-	1	3	-	-	-	-
	Common (Short) Ragweed Allergen <i>CLASS RESULT</i>								Sheep Sorrel Allergen <i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	1	4	12	1	-	-	-	1	1	11	-	-	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	-	1	4	4	-	-	-	-	1	1	8	-	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	3	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	3	1	-	-	-	-	-	2	-	-	-	-	-
	Bermuda Grass Allergen <i>CLASS RESULT</i>								Silver Birch Tree Allergen <i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	2	16	-	-	-	-	-	-	3	2	1	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	-	2	7	-	-	-	-	-	-	3	-	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	3	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	4	-	-	-	-	-	-	-	1	-	-	-	-
	Maple (Box Elder) Allergen <i>CLASS RESULT</i>															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	2	4	6	2	-	-	-	-								
DPC-Standard Microplate	-	-	1	-	-	-	-	-								
Hitachi CLA-1	2	4	4	-	-	-	-	-								
Phadia UniCap 100 (KU/L)	-	-	1	2	-	-	-	-								

Allergen Specific IgE Antibodies

Specimen AL-7

<u>Method</u>	House Dust Mite Allergen CLASS RESULT								Timothy Grass Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	4	10	1	5	-	-	-	-	-	5	3	5	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	4	1	-	5	-	-	-	-	-	-	-	5	-	-
Phadia ImmunoCAP Rapid	-	-	-	4	-	-	-	-	-	-	-	4	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	3	1	-	-	-	-	-	-	1	3	-	-	-
	Meadow, Kentucky Blue, June Grass Allergens CLASS RESULT								Alternaria alternata Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	4	3	-	-	1	-	13	5	-	-	-	-
DPC-Standard Microplate	-	-	-	-	1	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	8	2	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	-	-	-	-	-	-	-	-	3	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	2	1	-	-	1	-	3	-	-	-	-	-
	White Oak Allergen CLASS RESULT								Dog Dander Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	8	9	-	-	-	-	-	1	7	8	-	-	-	-
Hitachi CLA-1	-	-	6	2	-	-	-	-	-	-	3	5	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	1	3	-	-	-	-	-	-	2	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	3	-	-	-	-	-	1	1	2	-	-	-	-
	English Plantain Allergen CLASS RESULT															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	3	6	4	-	-	-	-	-								
DPC-Standard Microplate	1	-	-	-	-	-	-	-								
Hitachi CLA-1	2	6	2	-	-	-	-	-								
Phadia UniCap 100 (KU/L)	-	-	2	-	-	-	-	-								

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-6						
All Method	14	211.2	9.0	4.2	211	184 - 239
Specimen IMP-7						
All Method	14	206.7	20.4	9.9	196	145 - 268
Specimen IMP-8						
All Method	14	212.8	7.6	3.6	212	189 - 236
Specimen IMP-9						
All Method	14	195.6	21.7	11.1	184	130 - 261
Specimen IMP-10						
All Method	14	773.1	120.2	15.6	764	412 - 1134

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-6						
All Method	14	965.4	45.6	4.7	983	724 - 1207
Specimen IMP-7						
All Method	14	920.6	42.8	4.6	934	690 - 1151
Specimen IMP-8						
All Method	14	957.6	37.5	3.9	971	718 - 1198
Specimen IMP-9						
All Method	14	1957.2	104.5	5.3	1988	1467 - 2447
Specimen IMP-10						
All Method	14	973.5	55.8	5.7	993	730 - 1217

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-6						
All Method	14	101.1	13.0	12.9	107	61 - 141
Specimen IMP-7						
All Method	14	344.6	46.5	13.5	361	205 - 485
Specimen IMP-8						
All Method	14	100.8	13.3	13.2	105	60 - 141
Specimen IMP-9						
All Method	12	409.5	18.5	4.5	413	354 - 465
Specimen IMP-10						
All Method	14	427.0	57.7	13.5	433	253 - 601

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	1	1	-	1	-
Fisher HealthCare Sure-Vue	-	1	1	-	1	-

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Wk. Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	-	1
Fisher HealthCare Sure-Vue	1	-	-	1

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	22	22	-	21	1
ASI	-	10	10	-	9	1
Becton Dickinson	-	8	8	-	8	-
DPC Immulite 2000/2500	-	1	1	-	1	-
Fisher HealthCare Sure-Vue	-	2	2	-	2	-
Wampole Impact RPR	-	1	1	-	1	-

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	22	-	-	22
ASI	10	-	-	10
Becton Dickinson	8	-	-	8
DPC Immulite 2000/2500	1	-	-	1
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>
Specimen SY-7							
ALL METHODS	-	1	8	-	-	-	-
ASI	-	1	5	-	-	-	-
Becton Dickinson	-	-	3	-	-	-	-
Specimen SY-8							
ALL METHODS	3	6	-	-	-	-	-
ASI	3	3	-	-	-	-	-
Becton Dickinson	-	3	-	-	-	-	-
Specimen SY-9							
ALL METHODS	-	1	7	1	-	-	-
ASI	-	1	4	1	-	-	-
Becton Dickinson	-	-	3	-	-	-	-

H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-3</u>		<u>Specimen HP-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	128	4	9	123
Alfa Scientific Instant-View	2	-	-	2
Beckman Coulter ICON HP	9	1	-	10
bioMerieux Vidas, Mini Vidas	1	-	-	1
Cardinal Health SP Brand	9	1	2	8
Consult Diagnostics	15	-	2	13
DPC Immulite 2000/2500	1	-	-	1
Fisher HealthCare Sure-View	5	-	1	4
Henry Schein OneStep+ - waived	5	-	-	5
Inverness (Wampole) Clearview	11	1	4	8
LifeSign Status	1	-	-	1
McKesson Medi-Lab Performance - waived	8	1	-	9
Polymedco Poly stat	5	-	-	5
PSS Select Diagnostics	3	-	-	3
Quidel QuickVue	50	-	-	50
SDI Biomed, Inc.	1	-	-	1

Lyme Disease Serology

<u>Method</u>	<u>Specimen LY-3</u>		<u>Specimen LY-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	4	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
DiaSorin	-	1	1	-
Immunostics Inc.	-	1	1	-

Mycoplasma Antibody

<u>Method</u>	<u>Specimen MY-3</u>		<u>Specimen MY-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	2	-
Meridian ImmunoCard	-	1	1	-
Remel ELISA	-	1	1	-

Viral Markers – Anti-HBc

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	3	3	-	-	3
Bayer ADVIA Centaur - IgM	-	1	1	-	-	1
Bayer ADVIA Centaur - Total	-	1	1	-	-	1
VITROS Eci - Total	-	1	1	-	-	1

<u>Method</u>	Specimen VM-9		Specimen VM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	3	-	3
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	-	1	-	1
VITROS Eci - Total	-	1	-	1

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5	5	-
Bayer ADVIA Centaur - Total	-	1	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	3	-	3	3	-
Other Waived method	-	1	-	1	1	-

<u>Method</u>	Specimen VM-9		Specimen VM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5
Bayer ADVIA Centaur - Total	-	1	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	3	-	3
Other Waived method	-	1	-	1

Viral Markers – HAV

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	-	2	-	2
Bayer ADVIA Centaur - IgM	-	1	-	1	-	1
Bayer ADVIA Centaur - Total	-	1	-	1	-	1

<u>Method</u>	Specimen VM-9		Specimen VM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	1	2	-
Bayer ADVIA Centaur - IgM	-	1	1	-
Bayer ADVIA Centaur - Total	1	-	1	-

Specimen VM-9 is an ungraded challenge due to lack of 80% participant consensus.

Viral Markers – HBeAg

The vendor assay for specimens VM-6 through VM-10 is: Negative, Positive, Negative, Negative and Negative, respectively.

Viral Markers – HBsAb

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	-	-	4	1	3
Abbott AxSYM - Total	1	-	-	1	-	1
Bayer ADVIA Centaur - Total	2	-	-	2	1	1
VITROS Eci - Total	1	-	-	1	-	1

<u>Method</u>	Specimen VM-9		Specimen VM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	-	4
Abbott AxSYM - Total	-	1	-	1
Bayer ADVIA Centaur - Total	-	2	-	2
VITROS Eci - Total	-	1	-	1

Specimen VM-8 is an ungraded challenge due to lack of 80% participant consensus.

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	6	-	-	6
Abbott AxSYM - Total	-	1	1	-	-	1
Bayer ADVIA Centaur - Total	-	2	2	-	-	2
Other IgG Method	-	1	1	-	-	1
VITROS ECI - Total	-	2	2	-	-	2

<u>Method</u>	Specimen VM-9		Specimen VM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	4	-	6
Abbott AxSYM - Total	1	-	-	1
Bayer ADVIA Centaur - Total	-	2	-	2
Other IgG Method	1	-	-	1
VITROS ECI - Total	-	2	-	2

Specimen VM-9 is an ungraded challenge due to lack of 80% participant consensus.

Viral Markers – HCV

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	-	4	-	4
Abbott AxSYM - Total	-	1	-	1	-	1
Bayer ADVIA Centaur - Total	-	2	-	2	-	2
VITROS ECI - IgG	-	1	-	1	-	1

<u>Method</u>	Specimen VM-9		Specimen VM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	-	-	4
Abbott AxSYM - Total	1	-	-	1
Bayer ADVIA Centaur - Total	2	-	-	2
VITROS ECI - IgG	1	-	-	1

Medical Laboratory Evaluation

25 Massachusetts Ave NW Ste 700

Washington, DC 20001-7401

800-338-2746 • 202-261-4500 • Fax: 202-835-0440

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