

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

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

Immunology
MLE – M1

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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-1</u>		<u>Specimen IM-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	250	250	-
ASI	-	1	1	-
Beckman Coulter ICON Mono - waived	-	8	8	-
BioStar Acceava Mono Test	-	5	5	-
BioStar Acceava Mono-whole bld	-	8	8	-
Cardinal Health SP Brand	-	4	4	-
Cardinal Health SP Brand - waived	-	6	6	-
Fisher HealthCare Sure-Vue	-	9	9	-
Genzyme OSOM	-	11	11	-
Genzyme OSOM (waived)	-	87	87	-
Henry Schein OneStep+ - waived	-	10	10	-
Inverness (Wampole) Clearview	-	10	10	-
Inverness Clearview Mono Plus II	-	12	12	-
Inverness Signify Mono Test	-	1	1	-
LifeSign Status	-	1	1	-
LifeSign Status - waived	-	24	24	-
McKesson Medi-Lab Performance - waived	-	2	2	-
Meridian ImmunoCard STAT!	-	1	1	-
Other Moderate method	-	6	6	-
Other Waived method	-	16	16	-
Polymedco Poly stat	-	3	3	-
Polymedco Poly stat - waived	-	7	7	-
Quidel QuickVue+	-	2	2	-
Quidel QuickVue+ - waived	-	1	1	-
Remel SeraTest	-	1	1	-
Seradyn	-	10	10	-
Wampole ColorCard	-	1	1	-
Wampole Mono-Plus II	-	3	3	-

Infectious Mononucleosis – cont'd

<u>Method</u>	Specimen IM-3		Specimen IM-4		Specimen IM- 5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	124	1	1	124	125	-
ASI	1	-	-	1	1	-
Beckman Coulter ICON Mono - waived	8	-	-	8	8	-
BioStar Acceava Mono Test	4	-	-	4	4	-
BioStar Acceava Mono-whole bld	3	-	-	3	3	-
Cardinal Health SP Brand	4	-	-	4	4	-
Cardinal Health SP Brand - waived	1	-	-	1	1	-
Fisher HealthCare Sure-Vue	7	-	-	7	7	-
Genzyme OSOM	10	-	-	10	10	-
Genzyme OSOM (waived)	34	1	1	34	35	-
Henry Schein OneStep+ - waived	3	-	-	3	3	-
Inverness (Wampole) Clearview	7	-	-	7	7	-
Inverness Clearview Mono Plus II	4	-	-	4	4	-
LifeSign Status	1	-	-	1	1	-
LifeSign Status - waived	4	-	-	4	4	-
McKesson Medi-Lab Performance - waived	1	-	-	1	1	-
Meridian ImmunoCard STAT!	1	-	-	1	1	-
Other Moderate method	5	-	-	5	5	-
Other Waived method	3	-	-	3	3	-
Polymedco Poly stat	3	-	-	3	3	-
Polymedco Poly stat - waived	4	-	-	4	4	-
Quidel QuickVue+	2	-	-	2	2	-
Remel SeraTest	1	-	-	1	1	-
Seradyn	10	-	-	10	10	-
Wampole ColorCard	1	-	-	1	1	-
Wampole Mono-Plus II	2	-	-	2	2	-

Rheumatoid Factor—Qualitative

<u>Method</u>	<u>Specimen RF-1</u>		<u>Specimen RF-2</u>		<u>Specimen RF-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	75	-	1	74	75	-
ASI	4	-	-	4	4	-
Beckman Synchron	1	-	-	1	1	-
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	1	-	-	1	1	-
Fisher HealthCare Sure-Vue	9	-	-	9	9	-
Immunostics Inc.	7	-	-	7	7	-
JAS Diagnostics, Inc.	1	-	-	1	1	-
Remel SeraTest	16	-	-	16	16	-
Seradyn	3	-	-	3	3	-
Siemens Dimension/AR/ES/RxL/Xpand	1	-	-	1	1	-
Stanbio Laboratory	1	-	-	1	1	-
TheraTest	4	-	-	4	4	-
Wampole ColorCard	7	-	-	7	7	-
Wampole Rheumatex	8	-	-	8	8	-
Wampole Rheumaton	3	-	1	2	3	-

<u>Method</u>	<u>Specimen RF-4</u>		<u>Specimen RF-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	75	75	-
ASI	-	4	4	-
Beckman Synchron	-	1	1	-
Beckman Synchron LX / Pro / DxC	-	1	1	-
Biokit Rheumajet	-	3	3	-
Cardinal Health SP Brand	-	1	1	-
Diagnostic Technology	-	3	3	-
Diamedix	-	1	1	-
Fisher HealthCare Sure-Vue	-	9	9	-
Immunostics Inc.	-	7	7	-
JAS Diagnostics, Inc.	-	1	1	-
Remel SeraTest	-	16	16	-
Seradyn	-	3	3	-
Siemens Dimension/AR/ES/RxL/Xpand	-	1	1	-
Stanbio Laboratory	-	1	1	-
TheraTest	-	4	4	-
Wampole ColorCard	-	7	7	-
Wampole Rheumatex	-	8	8	-
Wampole Rheumaton	-	3	3	-

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-1											
ALL METHODS	-	6	3	1	3	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	4	-	-	1	-	-	-	-	-	-
Remel SeraTest	-	2	1	-	1	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	1	-	-	-	-	-
Wampole Rheumatex	-	-	-	-	1	-	-	-	-	-	-
Specimen RF-3											
ALL METHODS	4	3	2	3	1	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	3	1	-	-	1	-	-	-	-	-	-
Remel SeraTest	1	2	-	1	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	1	-	-	-	-	-
Wampole Rheumatex	-	-	-	1	-	-	-	-	-	-	-
Specimen RF-5											
ALL METHODS	5	2	1	2	2	1	1	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	3	1	-	-	1	-	-	-	-	-	-
Remel SeraTest	2	-	1	1	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	1	-	-	-	-	-
Wampole Rheumatex	-	-	-	-	-	-	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-1						
All Method	18	187.2	80.1	42.8	190	0 - 428
Specimen RF-2						
All Method	18	9.4	8.2	87.4	6	0 - 35
Specimen RF-3						
All Method	18	111.5	41.3	37.0	131	0 - 236
Specimen RF-4						
All Method	18	9.2	8.3	90.9	5	0 - 35
Specimen RF-5						
All Method	18	111.6	41.9	37.5	130	0 - 238

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<u>Specimen AS-1</u>		<u>Specimen AS-2</u>		<u>Specimen AS-3</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-4</u>		<u>Specimen AS-5</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-1						
All Method	12	106.0	20.3	19.2	104	44 - 168
Specimen IMP-2						
All Method	12	141.5	9.4	6.7	141	113 - 170
Specimen IMP-3						
All Method	12	57.0	9.5	16.7	59	28 - 86
Specimen IMP-4						
All Method	12	39.9	4.2	10.4	41	27 - 53
Specimen IMP-5						
All Method	12	148.7	9.3	6.2	151	120 - 177

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-1						
All Method	12	21.2	3.5	16.5	22	10 - 32
Specimen IMP-2						
All Method	12	29.1	3.3	11.5	29	19 - 40
Specimen IMP-3						
All Method	12	12.8	1.5	12.1	13	8 - 18
Specimen IMP-4						
All Method	12	9.0	1.7	19.0	9	3 - 15
Specimen IMP-5						
All Method	12	31.3	2.5	7.9	32	23 - 39

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	<u>Specimen AN-1</u>		<u>Specimen AN-2</u>		<u>Specimen AN-3</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-4</u>		<u>Specimen AN-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	1	-	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-1</u>		<u>Specimen CR-2</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-1						
mg/dL - units						
All Chemistry Reagents	24	0.225	0.203	90.3	0.20	0.00 - 0.84
mg/L - units						
All Chemistry Reagents	10	1.310	1.770	135.1	0.24	0.00 - 6.62
Specimen CR-2						
mg/dL - units						
All Chemistry Reagents	24	1.441	0.274	19.0	1.50	0.62 - 2.27
mg/L - units						
All Chemistry Reagents	11	14.561	2.030	13.9	14.42	8.46 - 20.66

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-1						
All Method	48	11.826	0.770	6.5	11.73	9.51 - 14.14
Specimen HCR-2						
All Method	51	0.917	0.232	25.4	0.91	0.21 - 1.62

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

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

<u>Method</u>	<u>Specimen AE-4</u>		<u>Specimen AE-5</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
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>
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Specimen AE-2

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

Specimen AE-3

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

Specimen AE-4

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

Anti-dsDNA

<u>Method</u>	<u>Specimen AE-1</u>		<u>Specimen AE-2</u>		<u>Specimen AE-3</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	6	3	9	-
Immuno Concepts	-	1	1	-	1	-
INOVA Diagnostics	-	1	1	-	1	-
Kallestad	-	2	-	2	2	-
TheraTest	-	3	2	1	3	-
Wampole	-	1	1	-	1	-
Zeus	-	1	1	-	1	-

<u>Method</u>	<u>Specimen AE-4</u>		<u>Specimen AE-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	1	8
Immuno Concepts	1	-	1	-
INOVA Diagnostics	1	-	-	1
Kallestad	2	-	-	2
TheraTest	3	-	-	3
Wampole	1	-	-	1
Zeus	1	-	-	1

Specimen AE-2 is an ungraded challenge due to lack of 80% participant consensus.

Anti-RNP

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	3	4	-	-	4
INOVA Diagnostics	-	2	2	-	-	2
TheraTest	1	-	1	-	-	1
Zeus	-	1	1	-	-	1

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	-	4
INOVA Diagnostics	-	2	-	2
TheraTest	-	1	-	1
Zeus	-	1	-	1

Specimen AE-1 is an ungraded challenge due to lack of 80% participant consensus.

Anti-RNP/Sm

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	5	-	6
Diamedix	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	1	2	-	3
Wampole	-	1	-	1

Anti-SSA

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	-	8
Diamedix	1	-	-	1
INOVA Diagnostics	2	-	-	2
TheraTest	3	-	-	3
Wampole	1	-	-	1
Zeus	1	-	-	1

Anti-SSB

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	7	-	8
Diamedix	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	3	-	3
Wampole	-	1	-	1
Zeus	1	-	-	1

Anti-SSA/SSB

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	1	2	-	2	-
Immuno Concepts	-	1	1	-	1	-
TheraTest	1	-	1	-	1	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	-	2
Immuno Concepts	1	-	-	1
TheraTest	1	-	-	1

Specimen AE-1 is an ungraded challenge due to lack of 80% participant consensus.

Anti-Sm

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	5	3	-	8
Diamedix	-	1	-	1	-	1
INOVA Diagnostics	-	2	1	1	-	2
TheraTest	-	3	3	-	-	3
Wampole	-	1	-	1	-	1
Zeus	-	1	1	-	-	1

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8
Diamedix	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	3	-	3
Wampole	-	1	-	1
Zeus	-	1	-	1

Specimen AE-2 is an ungraded challenge due to lack of 80% participant consensus.

Rubella—Qualitative

<u>Method</u>	Specimen RU-1		Specimen RU-2		Specimen RU-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	1	5	1	5
Bayer ADVIA Centaur	2	-	1	1	1	1
bioMerieux Vidas, Mini Vidas	3	-	-	3	-	3

<u>Method</u>	Specimen RU-4		Specimen RU-5	
	<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	3	-	3	-

Rubella—Quantitative (IU/mL)

Only one lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values for specimens RU-1 through RU-5 are: 49.3 IU/mL, 0.0 IU/mL, 0.0 IU/mL, 24.0 IU/mL and 115.0 IU/mL, respectively.

Anti-HIV

<u>Method</u>	Specimen HIV-1		Specimen HIV-2	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	31	31	-
Inverness Clearview Complete HIV 1/2	-	6	6	-
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	14	14	-
Other Moderate method	-	2	2	-
Other Waived method	-	5	5	-

<u>Method</u>	Specimen HIV-3		Specimen HIV-4		Specimen HIV-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Positive</u>
ALL METHODS	2	-	-	2	2	-
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-1						
All Method	8	657.4	107.4	16.3	718	335 - 980
Specimen AL-2						
All Method	8	409.3	47.0	11.5	434	268 - 551
Specimen AL-3						
All Method	8	22.3	4.1	18.3	20	10 - 35
Specimen AL-4						
All Method	8	21.9	3.8	17.5	20	10 - 34
Specimen AL-5						
All Method	8	55.1	10.1	18.4	52	24 - 86

Allergen Specific IgE Antibodies

Specimen AL-1

<u>Method</u>	House Dust Mite Allergen CLASS RESULT								Cat Epithelium Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	1	15	1	3	-	-	-	1	-	9	2	7	-	-
Hitachi CLA-1	-	-	1	5	-	3	-	-	-	-	-	-	1	7	-	-
Phadia ImmunoCAP Rapid	-	-	-	5	-	-	-	-	-	-	-	5	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	4	1	-	-	-	-	1	-	4	-	-	-	-
	Alternaria alternate Allergen CLASS RESULT								Peanut 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	6	-	-	-	-	-	-	-	4	-	6	-	-
Hitachi CLA-1	-	3	3	3	-	-	-	-	-	-	-	-	-	6	-	-
Phadia ImmunoCAP Rapid	-	-	1	3	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	1	-	4	-	-	-	-	-	-	-	-	4	-	-	-	-
	Cow's Milk 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	6	2	1	-	-	-	-	2	11	7	-	-	-	-
Hitachi CLA-1	-	-	2	2	1	-	-	-	-	1	4	4	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	-	-	-	-	-	-	-	4	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	1	3	-	-	-	-	-	-	1	3	1	-	-	-	-
	English Plantain Allergen CLASS RESULT															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	5	3	4	-	-	-	-	-								
Hitachi CLA-1	3	2	4	-	-	-	-	-								
Phadia UniCap 100 (KU/L)	1	1	-	-	-	-	-	-								

English Plantain Allergen is an ungraded challenge due to lack of 80% participant consensus.

Allergen Specific IgE Antibodies (cont'd)

Specimen AL-2

<u>Method</u>	Dog Dander 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	-	-	-	9	2	6	-	-	-	-	-	10	1	3	-	-
Hitachi CLA-1	-	-	-	1	1	6	-	-	-	-	-	1	1	3	-	-
Phadia ImmunoCAP Rapid	-	-	-	5	-	-	-	-	-	-	-	5	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	3	1	-	-	-	-	-	-	4	-	-	-	-

	Meadow Fescue Allergen CLASS RESULT								Alternaria alternate 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	5	10	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	1	2	2	4	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	-	-	-	-	-	-	-	-	4	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	1	3	1	-	-	-	-

	House Dust Mite Allergen CLASS RESULT								Peanut Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	1	8	7	4	-	-	-	-	-	4	-	5	-	-
Hitachi CLA-1	-	-	1	3	2	3	-	-	-	-	-	-	-	5	-	-
Phadia ImmunoCAP Rapid	-	-	-	5	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	4	1	-	-	-	-	-	4	-	-	-	-

	White Oak Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	1	3	11	2	-	-	-
Hitachi CLA-1	-	1	3	3	1	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	4	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	4	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-1						
All Method	14	210.1	11.2	5.3	212	176 - 244
Specimen IMP-2						
All Method	14	467.5	39.0	8.3	463	350 - 585
Specimen IMP-3						
All Method	14	119.8	10.0	8.4	119	89 - 150
Specimen IMP-4						
All Method	14	82.4	6.7	8.2	82	62 - 103
Specimen IMP-5						
All Method	14	224.4	13.0	5.8	226	185 - 264

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-1						
All Method	14	907.7	49.9	5.5	920	680 - 1135
Specimen IMP-2						
All Method	14	1019.1	61.3	6.0	1020	764 - 1274
Specimen IMP-3						
All Method	14	519.0	29.3	5.6	524	389 - 649
Specimen IMP-4						
All Method	13	350.5	11.2	3.2	347	262 - 439
Specimen IMP-5						
All Method	14	1802.7	143.2	7.9	1866	1352 - 2254

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-1						
All Method	14	101.4	10.9	10.8	107	68 - 135
Specimen IMP-2						
All Method	14	110.8	11.1	10.0	113	77 - 145
Specimen IMP-3						
All Method	14	55.6	6.3	11.4	58	36 - 75
Specimen IMP-4						
All Method	14	37.9	3.2	8.4	39	28 - 48
Specimen IMP-5						
All Method	14	133.1	29.2	21.9	150	45 - 221

Syphilis Serology—Qualitative: VDRL Slide

<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
Fisher HealthCare Sure-Vue	1	-	1	-	-	1

<u>Method</u>	<u>Specimen SY-4</u>		<u>Specimen SY-5</u>	
	<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: Treponema pallidum antibodies (TPA)

<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
DPC Immulite 2000/2500	1	-	1	-	-	1

<u>Method</u>	<u>Specimen SY-4</u>		<u>Specimen SY-5</u>	
	<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>	<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	27	-	27	-	-	27
ASI	9	-	9	-	-	9
Becton Dickinson	12	-	12	-	-	12
Fisher HealthCare Sure-Vue	3	-	3	-	-	3
Thermo Fisher Accutex	1	-	1	-	-	1
Wampole Impact RPR	1	-	1	-	-	1

<u>Method</u>	<u>Specimen SY-4</u>		<u>Specimen SY-5</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	27	-	-	27
ASI	9	-	-	9
Becton Dickinson	12	-	-	12
Fisher HealthCare Sure-Vue	3	-	-	3
Thermo Fisher Accutex	1	-	-	1
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-1							
ALL METHODS	-	-	8	5	1	-	-
ASI	-	-	3	3	-	-	-
Becton Dickinson	-	-	4	2	1	-	-
Specimen SY-2							
ALL METHODS	1	4	7	-	-	1	-
ASI	1	2	3	-	-	-	-
Becton Dickinson	-	2	4	-	-	1	-
Specimen SY-4							
ALL METHODS	-	1	6	6	-	-	-
ASI	-	1	4	1	-	-	-
Becton Dickinson	-	-	2	5	-	-	-

H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-1</u>		<u>Specimen HP-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	127	126	4
Alfa Scientific Instant-View	-	2	2	-
Beckman Coulter ICON HP	-	10	8	2
bioMerieux Vidas, Mini Vidas	-	1	1	-
Cardinal Health SP Brand	1	9	10	-
Consult Diagnostics	-	15	14	1
DPC Immulite 2000/2500	-	1	1	-
Fisher HealthCare Sure-Vue	-	5	5	-
Henry Schein OneStep+ - waived	-	6	6	-
Inverness (Wampole) Clearview	2	9	11	-
LifeSign Status	-	1	1	-
McKesson Medi-Lab Performance - waived	-	8	7	1
Polymedco Poly stat	-	6	6	-
PSS Select Diagnostics	-	3	3	-
Quidel QuickVue	-	48	48	-
SDI Biomed, Inc.	-	1	1	-

Lyme Disease Serology

<u>Method</u>	<u>Specimen LY-1</u>		<u>Specimen LY-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	3	3	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
Immunostics Inc.	-	1	1	-

Mycoplasma Antibody

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

Specimens VM-1 and VM-2 are ungraded challenges due to lack of 80% participant consensus.

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	-	8	-	8
Bayer ADVIA Centaur - Total	1	-	-	1	-	1
Inverness Clearview Complete HIV 1/2	1	-	-	1	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	4	-	-	4	-	4
Orasure OraQuick Advance Rapid HIV-1/2 - waived	2	-	-	2	-	2

<u>Method</u>	Specimen VM-4		Specimen VM-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8
Bayer ADVIA Centaur - Total	-	1	-	1
Inverness Clearview Complete HIV 1/2	-	1	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	4	-	4
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	2	-	2

Viral Markers – HAV

<u>Method</u>	<u>Specimen VM-1</u>		<u>Specimen VM-2</u>		<u>Specimen VM-3</u>	
	<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>	<u>Specimen VM-4</u>		<u>Specimen VM-5</u>	
	<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	-

Specimens VM-2, VM-3 and VM-5 are ungraded challenges due to lack of 80% participant consensus.

Viral Markers – HBeAg

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

Viral Markers – HBsAb

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

<u>Method</u>	<u>Specimen VM-4</u>		<u>Specimen VM-5</u>	
	<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-1 is an ungraded challenge due to lack of 80% participant consensus.

Viral Markers – HBsAg

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

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

Viral Markers – HCV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<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-4		Specimen VM-5	
	<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

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