

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

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

Immunology
MLE-M2

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2012 Evaluation Criteria

The evaluation criteria used in the 2012 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)	\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	1	257	255	3
ASI	-	1	1	-
Beckman Coulter ICON Mono - waived	-	8	8	-
BioStar Acceava Mono Test	-	3	3	-
BioStar Acceava Mono-whole bld	-	7	7	-
Cardinal Health SP Brand	-	1	1	-
Cardinal Health SP Brand - waived	1	10	10	1
Fisher HealthCare Sure-Vue	-	8	8	-
Genzyme OSOM	-	13	13	-
Genzyme OSOM (waived)	-	96	96	-
Henry Schein OneStep+ - waived	-	11	11	-
Inverness (Wampole) Clearview	-	14	14	-
Inverness Clearview Mono Plus II	-	9	9	-
Inverness Signify Mono Test	-	1	1	-
LifeSign Status - waived	-	15	15	-
McKesson Medi-Lab Performance - waived	-	7	7	-
Meridian ImmunoCard STAT!	-	1	1	-
Other Moderate method	-	6	6	-
Other Waived method	-	18	18	-
Polymedco Poly stat	-	1	1	-
Polymedco Poly stat - waived	-	6	6	-
Quidel QuickVue+	-	1	1	-
Quidel QuickVue+ - waived	-	13	11	2
Seradyn	-	4	4	-
Wampole ColorCard	-	1	1	-
Wampole Mono-Plus II	-	2	2	-

Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-8</u>		<u>Specimen IM-9</u>		<u>Specimen IM-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	113	1	1	113	113	1
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	1	-	-	1	1	-
Cardinal Health SP Brand - waived	4	-	-	4	4	-
Fisher HealthCare Sure-Vue	8	-	-	8	8	-
Genzyme OSOM	11	-	-	11	11	-
Genzyme OSOM (waived)	33	1	1	33	33	1
Henry Schein OneStep+ - waived	4	-	-	4	4	-
Inverness (Wampole) Clearview	8	-	-	8	8	-
Inverness Clearview Mono Plus II	3	-	-	3	3	-
LifeSign Status - waived	2	-	-	2	2	-
McKesson Medi-Lab Performance - waived	1	-	-	1	1	-
Meridian ImmunoCard STAT!	1	-	-	1	1	-
Other Moderate method	6	-	-	6	6	-
Other Waived method	2	-	-	2	2	-
Polymedco Poly stat	1	-	-	1	1	-
Polymedco Poly stat - waived	4	-	-	4	4	-
Quidel QuickVue+	1	-	-	1	1	-
Quidel QuickVue+ - waived	3	-	-	3	3	-
Seradyn	4	-	-	4	4	-
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	-	65	65	-	65	-
Abbott Architect	-	1	1	-	1	-
ASI	-	7	7	-	7	-
Beckman Synchron	-	1	1	-	1	-
Biokit Rheumajet	-	9	9	-	9	-
Diamedix	-	1	1	-	1	-
Fisher HealthCare Sure-Vue	-	7	7	-	7	-
Immunostics Inc.	-	4	4	-	4	-
JAS Diagnostics, Inc.	-	1	1	-	1	-
Remel SeraTest	-	7	7	-	7	-
Seradyn	-	1	1	-	1	-
Siemens Dimension/AR/ES/RxL/Xpand	-	1	1	-	1	-
Stanbio Laboratory	-	2	2	-	2	-
Teco Diagnostics	-	5	5	-	5	-
TheraTest	-	3	3	-	3	-
Wampole ColorCard	-	8	8	-	8	-
Wampole Rheumatex	-	6	6	-	6	-
Wampole Rheumaton	-	1	1	-	1	-

<u>Method</u>	Specimen RF-9		Specimen RF-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	65	-	65
Abbott Architect	-	1	-	1
ASI	-	7	-	7
Beckman Synchron	-	1	-	1
Biokit Rheumajet	-	9	-	9
Diamedix	-	1	-	1
Fisher HealthCare Sure-Vue	-	7	-	7
Immunostics Inc.	-	4	-	4
JAS Diagnostics, Inc.	-	1	-	1
Remel SeraTest	-	7	-	7
Seradyn	-	1	-	1
Siemens Dimension/AR/ES/RxL/Xpand	-	1	-	1
Stanbio Laboratory	-	2	-	2
Teco Diagnostics	-	5	-	5
TheraTest	-	3	-	3
Wampole ColorCard	-	8	-	8
Wampole Rheumatex	-	6	-	6
Wampole Rheumaton	-	1	-	1

Rheumatoid Factor—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>2/4</u>	<u>8/10</u>	<u>16/20</u>	<u>32/40</u>	<u>64/80</u>	<u>128/160</u>	<u>256/320</u>	<u>512/640</u>	<u>1024/1280</u>	<u>2048/2560</u>	<u>>2560</u>
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Specimen RF-7

ALL METHODS	1	6	1	1	2	-	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	3	-	-	-	-	-	-	-	-	-
Remel SeraTest	-	2	-	-	1	-	-	-	-	-	-
Wampole ColorCard	-	1	-	-	1	-	-	-	-	-	-

Specimen RF-8

ALL METHODS	-	2	6	1	1	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	2	-	-	-	-	-	-	-	-
Remel SeraTest	-	-	2	-	-	1	-	-	-	-	-
Wampole ColorCard	-	-	1	-	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	19	4.0	4.0	99.0	2	0 - 16
Specimen RF-7						
All Method	17	60.6	12.3	20.3	59	23 - 98
Specimen RF-8						
All Method	19	110.2	45.7	41.5	101	0 - 248
Specimen RF-9						
All Method	18	4.4	3.8	87.4	3	0 - 16
Specimen RF-10						
All Method	19	4.3	4.0	91.7	2	0 - 17

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
ASI	-	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	-		
ASI	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	21	115.4	15.0	13.0	118	70 - 161
Specimen IMP-7						
All Method	21	119.2	16.9	14.1	123	68 - 170
Specimen IMP-8						
All Method	21	125.0	20.6	16.5	134	63 - 187
Specimen IMP-9						
All Method	21	60.3	9.0	14.9	64	33 - 88
Specimen IMP-10						
All Method	21	125.5	18.4	14.7	131	70 - 181

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	21	20.3	2.3	11.3	20	13 - 28
Specimen IMP-7						
All Method	21	21.4	1.8	8.2	21	16 - 27
Specimen IMP-8						
All Method	21	24.8	2.6	10.4	25	17 - 33
Specimen IMP-9						
All Method	21	12.5	1.3	10.4	13	8 - 17
Specimen IMP-10						
All Method	21	24.4	2.7	11.3	24	16 - 33

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	6	-	6	-	-	6
Diagnostic Technology	4	-	4	-	-	4
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	6	-	-	6
Diagnostic Technology	4	-	-	4
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	18	-	18	-
ASI	2	-	2	-
Biokit Rheumajet	1	-	1	-
Fisher HealthCare Sure-Vue	8	-	8	-
Siemens Dimension/AR/ES/RxL/Xpand	1	-	1	-
Teco Diagnostics	5	-	5	-
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	25	3.432	0.379	11.0	3.50	2.29 - 4.57
mg/L - units						
All Immunology Methods	11	33.441	6.410	19.2	34.49	14.21 - 52.67
Specimen CR-4						
mg/dL - units						
All Immunology Methods	25	1.610	0.331	20.6	1.60	0.61 - 2.61
mg/L - units						
All Immunology Methods	11	15.911	4.072	25.6	16.30	3.69 - 28.13

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	51	2.899	0.522	18.0	2.78	1.33 - 4.47
Siemens Dimension High Sensi CRP	10	2.780	1.430	51.5	3.51	0.00 - 7.08

Specimen HCR-4

All Method	50	12.715	1.120	8.8	12.66	9.35 - 16.08
Siemens Dimension High Sensi CRP	10	10.811	3.828	35.4	12.15	0.00 - 22.30

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	1	14	2	-	16
Immuno Concepts	4	1	5	-	-	5
INOVA Diagnostics	3	-	3	-	-	3
Kallestad	1	-	1	-	-	1
TheraTest	4	-	3	1	-	4
Wampole	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	-	16	15	1
Immuno Concepts	-	5	5	-
INOVA Diagnostics	-	3	2	1
Kallestad	-	1	1	-
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>
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Specimen AE-6

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

Specimen AE-7

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

Specimen AE-10

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

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	-	11	-	11	-	11
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	-	1	-	1
Kallestad	-	2	-	2	-	2
TheraTest	-	5	-	5	-	5
Wampole	-	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	-	11	11	-
Immuno Concepts	-	1	1	-
INOVA Diagnostics	-	1	1	-
Kallestad	-	2	2	-
TheraTest	-	5	5	-
Wampole	-	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	-	2	1	-	3
INOVA Diagnostics	2	-	2	-	-	2

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

Specimens AE-7 and AE-10 are ungraded challenges due to less than 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	8	-	7	1	-	8
Diamedix	1	-	1	-	-	1
Immuno Concepts	1	-	-	1	-	1
TheraTest	5	-	5	-	-	5
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	-	8	7	1
Diamedix	-	1	1	-
Immuno Concepts	-	1	-	1
TheraTest	-	5	5	-
Wampole	-	1	1	-

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	10	-	6	4	-	10
Diamedix	1	-	1	-	-	1
INOVA Diagnostics	2	-	-	2	-	2
TheraTest	5	-	5	-	-	5
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	-	10	9	-
Diamedix	-	1	1	-
INOVA Diagnostics	-	2	1	-
TheraTest	-	5	5	-
Wampole	-	1	1	-

Specimen AE-7 is an ungraded challenge due to less than 80% participant consensus.

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	3	-	10	-	10
Diamedix	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
TheraTest	5	-	-	5	-	5
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	-	10	7	2
Diamedix	-	1	-	1
INOVA Diagnostics	-	2	-	1
TheraTest	-	5	5	-
Wampole	-	1	1	-

Specimens AE-6 and AE-10 are ungraded challenges due to less than 80% participant consensus.

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	-	1	1	-	2
Immuno Concepts	2	-	1	1	-	2

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

Specimens AE-7 and A-10 are ungraded challenges due to less than 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	8	2	-	10	-	10
Diamedix	1	-	-	1	-	1
INOVA Diagnostics	2	-	-	2	-	2
TheraTest	4	1	-	5	-	5
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	-	10	-	9
Diamedix	-	1	-	1
INOVA Diagnostics	-	2	-	1
TheraTest	-	5	-	5
Wampole	-	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	8	-	8	-	-	8
Bayer ADVIA Centaur	2	-	2	-	-	2
Biokit	1	-	1	-	-	1
bioMerieux Vidas, Mini Vidas	3	-	3	-	-	3
DiaSorin	2	-	2	-	-	2

<u>Method</u>	Specimen RU-9		Specimen RU-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	1	7
Bayer ADVIA Centaur	2	-	-	2
Biokit	1	-	1	-
bioMerieux Vidas, Mini Vidas	3	-	-	3
DiaSorin	2	-	-	2

Rubella—Quantitative (IU/mL)

Two labs reported results for Rubella – Quantitative (IU/mL). The vendor assay values for specimens RU-6 through RU-10 are: 27 IU/mL, 102 IU/mL, 0 IU/mL, 27 IU/mL and 0 IU/mL, respectively.

Anti-HIV

<u>Method</u>	<u>Specimen HIV-6</u>		<u>Specimen HIV-7</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	40	-	-	40
Abbott Architect	1	-	-	1
BD LINK 2	1	-	-	1
Inverness Clearview Complete HIV 1/2	13	-	-	13
Orasure OraQuick Advance Rapid HIV-1/2 - waived	19	-	-	19
Other Moderate method	1	-	-	1
Other Waived method	5	-	-	5

<u>Method</u>	<u>Specimen HIV-8</u>		<u>Specimen HIV-9</u>		<u>Specimen HIV-10</u>	
	<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	1	-	-	1	1	-
Inverness Clearview Complete HIV 1/2	3	-	-	3	3	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	2	-	-	2	2	-
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-6						
All Method	7	967.1	138.7	14.3	940	551 - 1384
Specimen AL-7						
All Method	8	116.3	12.2	10.5	117	79 - 153
Specimen AL-8						
All Method	8	22.3	3.7	16.6	20	11 - 34
Specimen AL-9						
All Method	8	23.0	4.2	18.4	21	10 - 36
Specimen AL-10						
All Method	8	60.9	8.1	13.4	58	36 - 86

Allergen Specific IgE Antibodies

Specimen AL-6

<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	-	-	-	10	1	5	-	-	1	-	-	9	2	3	-	-
DPC Immulite 2000/2500	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	3	-	5	-	-	1	-	-	1	2	3	-	-
Phadia ImmunoCAP Rapid	-	-	-	2	-	-	-	-	-	-	-	2	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Timothy Grass Allergen CLASS RESULT							Perennial Rye Allergen CLASS RESULT								
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	1	1	1	7	-	-	1	-	1	-	1	3	-	-
DPC Immulite 2000/2500	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	5	-	-	1	-	-	-	-	2	-	-
Phadia ImmunoCAP Rapid	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-

Perennial Rye Allergen is an ungraded challenge due to less than 80% participant consensus.

	Maple (Box Elder) 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	3	6	5	-	-	-	-	-	1	-	4	8	-	-	-	-
DPC Immulite 2000/2500	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
DPC-Standard Microplate	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	2	4	3	-	-	-	-	-	-	-	3	4	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-

	Peanut Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	3	-	3	-	-
DPC Immulite 2000/2500	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	3	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-7

Method	Sweet Vernal Grass Allergen								Bermuda Grass Allergen							
	CLASS RESULT								CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	-	-	-	-	-	-	3	2	11	-	-	1	-	-
DPC Immulite 2000/2500	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	1	-	-	-	-	-	-	-	3	2	4	-	-	-	-	-
Phadia ImmunoCAP Rapid	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
	Dog Dander Allergen								Cat Epithelium Allergen							
	CLASS RESULT								CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	-	7	4	2	-	-	1	-	-	7	5	1	-	-
DPC Immulite 2000/2500	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	1	-	-	2	3	2	-	-	1	-	-	1	4	1	-	-
Phadia ImmunoCAP Rapid	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-
	Common (Short) Ragweed Allergen								House Dust Mite Allergen							
	CLASS RESULT								CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	4	2	6	1	-	-	-	-	-	-	2	8	1	4	-	-
DPC Immulite 2000/2500	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	4	2	1	-	-	-	-	-	-	-	2	2	-	4	-	-
Phadia ImmunoCAP Rapid	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-
	Cow's Milk Allergen															
	CLASS RESULT															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	1	-	-	7	-	-	-	-								
DPC Immulite 2000/2500	-	-	-	1	-	-	-	-								
DPC-Standard Microplate	-	-	-	1	-	-	-	-								
Hitachi CLA-1	1	-	-	3	-	-	-	-								
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-6						
All Method	21	164.8	13.9	8.4	166	123 - 207
Specimen IMP-7						
All Method	21	180.4	10.2	5.7	183	149 - 212
Specimen IMP-8						
All Method	21	209.9	10.1	4.8	211	179 - 241
Specimen IMP-9						
All Method	21	106.6	6.4	6.0	106	87 - 126
Specimen IMP-10						
All Method	21	520.1	59.5	11.4	525	341 - 699

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	21	1917.5	120.6	6.3	1949	1438 - 2397
Specimen IMP-7						
All Method	21	1896.5	125.8	6.6	1920	1422 - 2371
Specimen IMP-8						
All Method	21	990.5	58.7	5.9	994	742 - 1239
Specimen IMP-9						
All Method	21	516.8	44.2	8.6	516	387 - 646
Specimen IMP-10						
All Method	21	980.4	53.2	5.4	993	735 - 1226

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	21	401.4	44.1	11.0	414	269 - 534
Specimen IMP-7						
All Method	21	85.9	9.3	10.8	84	57 - 114
Specimen IMP-8						
All Method	21	98.7	11.7	11.8	97	63 - 134
Specimen IMP-9						
All Method	21	51.3	4.4	8.6	51	38 - 65
Specimen IMP-10						
All Method	21	109.7	21.0	19.2	98	46 - 173

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>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	1	-	1
Fisher HealthCare Sure-Vue	-	1	-	1

Syphilis Serology—Qualitative: Treponema pallidum antibodies

<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	-
DPC Immulite 2000/2500	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	-	1	-	1
DPC Immulite 2000/2500	-	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	27	-	-	27	27	-
ASI	11	-	-	11	11	-
Becton Dickinson	11	-	-	11	11	-
Cardinal Health SP Brand	1	-	-	1	1	-
Fisher HealthCare Sure-View	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	1	26	-	27
ASI	1	10	-	11
Becton Dickinson	-	11	-	11
Cardinal Health SP Brand	-	1	-	1
Fisher HealthCare Sure-View	-	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-6								
ALL METHODS	-	4	7	1	-	-	-	-
ASI	-	3	3	-	-	-	-	-
Becton Dickinson	-	1	4	1	-	-	-	-
Specimen SY-8								
ALL METHODS	-	2	9	1	-	-	-	-
ASI	-	1	4	1	-	-	-	-
Becton Dickinson	-	1	5	-	-	-	-	-

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	3	119	119	3
Alfa Scientific Instant-View	-	3	3	-
Beckman Coulter ICON HP	-	9	9	-
Biokit Rheumagen	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
Cardinal Health SP Brand	-	8	8	-
Consult Diagnostics	-	15	14	1
DPC Immulite 2000/2500	-	1	1	-
Fisher HealthCare Sure-Vue	-	4	4	-
Henry Schein OneStep+ - waived	-	6	6	-
Inverness (Wampole) Clearview	-	14	14	-
McKesson Medi-Lab Performance - waived	2	7	7	2
Polymedco Poly stat	-	3	3	-
PSS Select Diagnostics	-	2	2	-
Quidel QuickVue	1	43	44	-
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	1	4	5	-
DiaSorin	-	2	2	-

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	3	-	-	3
Meridian ImmunoCard	3	-	-	3

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	1	1	1	1	1	1
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	-	2	-	2
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	-	1	-	1

Specimens VM-6, VM-7 and VM-8 are ungraded challenges due to less than 80% participant consensus.

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	-	8	-	8	-	8
Abbott Architect - Total	-	1	-	1	-	1
Bayer ADVIA Centaur - Total	-	2	-	2	-	2
Inverness Clearview HIV1/2 STAT-PAK	-	1	-	1	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	3	-	3	-	3
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	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	8	-	-	8
Abbott Architect - Total	1	-	-	1
Bayer ADVIA Centaur - Total	2	-	-	2
Inverness Clearview HIV1/2 STAT-PAK	1	-	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	3	-	-	3
Orasure OraQuick Advance Rapid HIV-1/2 - waived	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	1	3	1	2	1	3
Abbott Architect - IgM	-	1	-	1	-	1
Bayer ADVIA Centaur - IgM	-	1	-	-	-	1
Bayer ADVIA Centaur - Total	1	1	1	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	1	3
Abbott Architect - IgM	-	1	-	1
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	-	2	1	1

Specimens VM-6, VM-7 and VM-8 are ungraded challenges due to less than 80% participant consensus.

Viral Markers – HBeAg

The vendor assay for specimens VM-6 through VM-10 is: Positive, Negative, 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	-	5	5	-	5	-
Abbott Architect - Total	-	1	1	-	1	-
Bayer ADVIA Centaur - Total	-	4	4	-	4	-

<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
Abbott Architect - Total	1	-	-	1
Bayer ADVIA Centaur - Total	4	-	-	4

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 Architect	1	-	1	-	-	1
Abbott Architect - Total	1	-	1	-	-	1
Bayer ADVIA Centaur - Total	2	-	2	-	-	2
DPC Immulite 2000/2500	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	-	6	-	6
Abbott Architect	-	1	-	1
Abbott Architect - Total	-	1	-	1
Bayer ADVIA Centaur - Total	-	2	-	2
DPC Immulite 2000/2500	-	1	-	1
VITROS ECI - Total	-	1	-	1

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	-	5	-	5	-	5
Abbott Architect - Total	-	2	-	2	-	2
Bayer ADVIA Centaur - Total	-	3	-	3	-	3

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

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