

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

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Immunology
MLE-M3

ACP | Medical Laboratory
Evaluation 

Total Commitment to Education and Service
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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.

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

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

Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-11</u>		<u>Specimen IM-12</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	193	3	2	194
Alere Clearview - moderate	4	-	-	4
Alere Clearview - waived	2	-	-	2
Alere Clearview Mono Plus II - moderate	1	-	-	1
Alere Clearview Mono Plus II - waived	9	-	-	9
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	9	1	1	9
BioStar Aceava Mono Test	2	-	-	2
BioStar Aceava Mono-whole bld	5	-	-	5
Cardinal Health SP Brand - waived	10	-	-	10
Consult Diagnostics	18	1	-	19
Fisher HealthCare Sure-Vue	9	-	-	9
Henry Schein OneStep+ - waived	16	-	1	15
LifeSign Status - waived	7	-	-	7
McKesson Medi-Lab Performance - waived	4	-	-	4
Other Moderate method	7	-	-	7
Other Waived method	11	-	-	11
Quidel QuickVue+	3	-	-	3
Quidel QuickVue+ - waived	15	-	-	15
Sekisui OSOM	3	-	-	3
Sekisui OSOM (waived)	55	1	-	56
Seradyn	1	-	-	1
Wampole ColorCard	1	-	-	1

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	76	-	74	2	1	75
Alere Clearview - moderate	2	-	2	-	-	2
Alere Clearview Mono Plus II - moderate	1	-	1	-	-	1
Alere Clearview Mono Plus II - waived	1	-	1	-	-	1
ASI	1	-	1	-	-	1
Beckman Coulter ICON Mono - waived	10	-	9	1	1	9
BioStar Acceava Mono-whole bld	2	-	2	-	-	2
Cardinal Health SP Brand - waived	1	-	1	-	-	1
Consult Diagnostics	9	-	9	-	-	9
Fisher HealthCare Sure-View	5	-	5	-	-	5
Henry Schein OneStep+ - waived	4	-	4	-	-	4
LifeSign Status - waived	3	-	3	-	-	3
McKesson Medi-Lab Performance - waived	1	-	1	-	-	1
Other Moderate method	7	-	7	-	-	7
Other Waived method	1	-	1	-	-	1
Quidel QuickVue+	3	-	3	-	-	3
Quidel QuickVue+ - waived	2	-	2	-	-	2
Sekisui OSOM	3	-	3	-	-	3
Sekisui OSOM (waived)	18	-	17	1	-	18
Seradyn	1	-	1	-	-	1
Wampole ColorCard	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	40	-	-	40	1	39
Abbott Architect	1	-	-	1	-	1
ASI	8	-	-	8	-	8
Biokit Rheumajet	4	-	-	4	-	4
Diamedix	1	-	-	1	-	1
Fisher HealthCare Sure-View	4	-	-	4	-	4
Immunostics Inc.	2	-	-	2	-	2
Remel SeraTest	1	-	-	1	-	1
Siemens RapiTex	2	-	-	2	-	2
Teco Diagnostics	2	-	-	2	-	2
TheraTest	3	-	-	3	-	3
Wampole ColorCard	8	-	-	8	-	8
Wampole Rheumatex	4	-	-	4	1	3

<u>Method</u>	Specimen RF-14		Specimen RF-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	40	40	-
Abbott Architect	-	1	1	-
ASI	-	8	8	-
Biokit Rheumajet	-	4	4	-
Diamedix	-	1	1	-
Fisher HealthCare Sure-View	-	4	4	-
Immunostics Inc.	-	2	2	-
Remel SeraTest	-	1	1	-
Siemens RapiTex	-	2	2	-
Teco Diagnostics	-	2	2	-
TheraTest	-	3	3	-
Wampole ColorCard	-	8	8	-
Wampole Rheumatex	-	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>
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Specimen RF-11

ALL METHODS	-	2	2	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	2	1	-	-	-	-	-	-	-	-
Siemens RapiTex	-	-	1	-	-	-	-	-	-	-	-
TheraTest	-	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	1	-	-	-	-	-	-	-

Specimen RF-15

ALL METHODS	-	2	2	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	2	1	-	-	-	-	-	-	-	-
Siemens RapiTex	-	-	-	1	-	-	-	-	-	-	-
TheraTest	-	-	-	-	-	-	-	-	-	-	-
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	19	140.2	38.1	27.2	131	64 - 217
Specimen RF-12						
All Method	4.7	4.3	92.0	5	0 - 14	4.7
Specimen RF-13						
All Method	19	4.3	4.5	104.9	2	0 - 14
Specimen RF-14						
All Method	19	4.4	4.4	100.7	3	0 - 14
Specimen RF-15						
All Method	18	143.4	31.2	21.8	129	81 - 206

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<u>Specimen AS-11</u>		<u>Specimen AS-12</u>		<u>Specimen AS-13</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-14</u>		<u>Specimen AS-15</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-11						
All Method	13	123.3	13.6	11.0	120	82 - 165
Specimen IMP-12						
All Method	13	44.7	6.0	13.3	41	26 - 63
Specimen IMP-13						
All Method	12	97.9	20.3	20.7	93	37 - 159
Specimen IMP-14						
All Method	13	96.7	16.4	17.0	88	47 - 146
Specimen IMP-10						
All Method	11	17.8	4.2	23.8	16	5 - 31

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-11						
All Method	13	27.2	2.5	9.1	27	19 - 35
Specimen IMP-12						
All Method	13	9.3	1.8	18.8	9	4 - 15
Specimen IMP-13						
All Method	12	22.3	3.2	14.5	22	12 - 32
Specimen IMP-14						
All Method	13	18.9	2.7	14.2	19	10 - 27
Specimen IMP-15						
All Method	12	4.5	1.6	36.1	5	0 - 10

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	11	235.5	14.1	6.0	232	193 - 278
Specimen IMP-12						
All Method	11	91.9	8.1	8.8	91	67 - 117
Specimen IMP-13						
All Method	10	484.9	39.3	8.1	489	367 - 603
Specimen IMP-14						
All Method	10	166.9	10.9	6.5	167	134 - 200
Specimen IMP-15						
All Method	11	40.5	4.4	10.9	40	27 - 54

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	11	947.5	43.5	4.6	954	710 - 1185
Specimen IMP-12						
All Method	11	439.8	16.7	3.8	441	329 - 550
Specimen IMP-13						
All Method	11	875.0	34.9	4.0	877	656 - 1094
Specimen IMP-14						
All Method	11	2059.4	88.1	4.3	2079	1544 - 2575
Specimen IMP-15						
All Method	10	187.5	31.5	16.8	175	140 - 235

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	10	83.8	10.9	13.0	79	51 - 117
Specimen IMP-12						
All Method	10	44.1	4.6	10.5	44	30 - 58
Specimen IMP-13						
All Method	10	87.8	14.4	16.4	84	44 - 131
Specimen IMP-14						
All Method	10	81.1	11.9	14.7	78	45 - 117
Specimen IMP-15						
All Method	11	20.1	3.6	18.0	20	9 - 31

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	Specimen AN-11		Specimen AN-12		Specimen AN-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5	5	-
Diagnostic Technology	-	3	-	3	3	-
Wampole	-	2	-	2	2	-

<u>Method</u>	Specimen AN-14		Specimen AN-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5	-
Diagnostic Technology	3	-	3	-
Wampole	2	-	2	-

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	Specimen CR-5		Specimen CR-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	14	14	-
ASI	-	1	1	-
Fisher HealthCare Sure-Vue	-	8	8	-
Siemens Dimension/AR/ES/RxL/Xpand	-	2	2	-
Teco Diagnostics	-	2	2	-
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						
All Method mg/dL - units	34	0.730	1.466	200.9	0.15	0.00 - 5.13
All Immunology Methods mg/L - units	21	0.171	0.167	97.4	0.10	0.00 - 0.68
All Immunology Methods	12	1.535	2.170	141.4	0.15	0.00 - 8.05
Specimen CR-6						
All Method mg/dL - units	34	11.089	12.945	116.7	2.80	0.00 - 49.93
All Immunology Methods mg/L - units	20	2.642	0.273	10.3	2.64	1.82 - 3.47
All Immunology Methods	12	26.690	9.564	35.8	27.40	0.00 - 55.39

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	40	1.130	0.281	24.9	1.09	0.28 - 1.98
Specimen HCR-6						
All Method	40	14.151	0.930	6.6	14.20	11.36 - 16.95

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	13	-	12	1	-	13
Diamedix	2	-	2	-	-	2
GenBio ImmunoDOT Panel 1	1	-	1	-	-	1
Immuno Concepts	4	-	3	1	-	4
INOVA Diagnostics	1	-	1	-	-	1
Phadia ElIA	1	-	1	-	-	1
TheraTest	3	-	3	-	-	3

<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	1	12	9	4
Diamedix	-	2	-	2
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	1	3	3	1
INOVA Diagnostics	-	1	1	-
Phadia ElIA	-	1	1	-
TheraTest	-	3	3	-

Specimen AE-15 is an ungraded challenge due to less than 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-11

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

Specimen AE-12

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

Specimen AE-15

ALL METHODS	-	-	-	-	1	-	-	1	1	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	1	-	-
INOVA Diagnostics	-	-	-	-	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	-	9	9	-	-	9
Diamedix	-	2	2	-	-	2
GenBio ImmunoDOT Panel 1	-	1	1	-	-	1
Immuno Concepts	-	1	1	-	-	1
Phadia ELIA	-	1	1	-	-	1
TheraTest	-	-	-	-	-	-

<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	-	9	3	6
Diamedix	-	2	-	2
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	1	-
Phadia ELIA	-	1	-	1
TheraTest	-	4	2	2

Specimen AE-15 is an ungraded challenge due to less than 80% participant consensus.

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	-	2	1	1	-	2
Immuno Concepts	-	1	-	1	-	1
Phadia Elia	-	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	-	2	-	2
Immuno Concepts	-	1	-	1
Phadia Elia	-	1	-	1

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

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	5	3	-	8
Diamedix	-	2	-	2	-	2
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	1	1	-	-	1
TheraTest	-	4	4	-	-	4

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8
Diamedix	-	2	-	2
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	-	4	-	4

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

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	8	-	8	-	-	8
Diamedix	2	-	2	-	-	2
Immuno Concepts	1	-	1	-	-	1
Phadia ELIA	1	-	1	-	-	1
TheraTest	4	-	4	-	-	4

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	6	2
Diamedix	-	2	-	2
Immuno Concepts	-	1	1	-
Phadia ELIA	-	1	1	-
TheraTest	-	4	4	-

Specimen AE-15 is an ungraded challenge due to less than 80% participant consensus.

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	8	-	-	8	-	8
Diamedix	2	-	-	2	-	2
Immuno Concepts	1	-	-	1	-	1
Phadia ELIA	1	-	-	1	-	1
TheraTest	4	-	-	4	-	4

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8
Diamedix	-	2	-	2
Immuno Concepts	-	1	-	1
Phadia ELIA	-	1	-	1
TheraTest	-	4	-	4

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	1	-	2
GenBio ImmunoDOT Panel 1	1	-	1	-	-	1
Immuno Concepts	-	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	-	2	-	2
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1

Specimens AE-11 and AE-12 is an ungraded challenge due to less than 80% participant consensus.

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	-	8	1	7	-	8
Diamedix	-	2	-	2	-	2
Immuno Concepts	-	1	-	1	-	1
Phadia ELIA	-	1	1	-	-	1
TheraTest	-	4	-	4	-	4

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8
Diamedix	-	2	-	2
Immuno Concepts	-	1	-	1
Phadia ELIA	-	1	-	1
TheraTest	-	4	-	4

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
bioMerieux Vidas, Mini Vidas	-	2	2	-	-	2
DiaSorin	-	2	2	-	-	2
Siemens ADVIA Centaur	-	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	-
bioMerieux Vidas, Mini Vidas	2	-	2	-
DiaSorin	2	-	2	-
Siemens ADVIA Centaur	2	-	2	-

Rubella—Quantitative (IU/mL)

One lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values for specimens RU-11 through RU-15 are: <10 IU/ml, 88.3 IU/mL, <10 IU/ml, 22 IU/mL and 88.3IU/mL, respectively.

Anti-HIV

<u>Method</u>	Specimen HIV-11		Specimen HIV-12	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	58	58	1
Alere Clearview Complete HIV 1/2	-	7	7	-
Alere Clearview HIV1/2 STAT-PAK	-	8	8	-
Alere Determine HIV 1/2 Ag/Ab Combo	-	2	2	-
BD LINK 2	1	2	2	1
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	19	19	-
Other Waived method	-	18	18	-

<u>Method</u>	Specimen HIV-13		Specimen HIV-14		Specimen HIV-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	2	3	2	-	5
Alere Clearview Complete HIV 1/2	-	2	-	2	-	2
Alere Determine HIV 1/2 Ag/Ab Combo	3	-	3	-	-	3

Specimens HIV-13 and HIV-14 are ungraded challenges due to less than 80% participant consensus.

Allergen Specific IgE Antibodies

Specimen AL-11

Method

	Alternaria alternata 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	-	5	-	-	-	-	-	-	2	4	-	-	-	-	-
DPC Immulite 2000/2500	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	1	-	2	-	-	-	-	-	-	2	1	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-

	Meadow Fescue 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	-	-	-	-	-	-	-	-	-	1	-	3	-	-	-	-
DPC Immulite 2000/2500	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-

	White Oak Allergen CLASS RESULT								Cow's Milk 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	3	-	-	-	-	-	-	2	3	-	-	-	-
DPC Immulite 2000/2500	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-

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

Allergen Specific IgE Antibodies

Specimen AL-12

Method

	Bahia Grass Allergen CLASS RESULT							Sweet Vernal 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	2	2	-	-	-	-	-	-	-	-	-	-	-
DPC Immulite 2000/2500	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-

	Cat Epithelium 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	-	-	-	1	1	3	-	-	-	-	-	1	1	3	-	-
DPC Immulite 2000/2500	-	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-
DPC-Standard Microplate	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	-	-	1	2	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	House Dust Mite (D. pteronyssinus) 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	-	-	-	3	-	2	-	-	-	-	-	-	1	3	-	-
DPC Immulite 2000/2500	-	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	1	-	1	-	-	-	-	-	-	-	2	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-

	Wheat Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	1	3	1	-	-	-
DPC Immulite 2000/2500	-	-	-	-	1	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-
Hitachi CLA-1	-	-	-	2	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	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	308.5	6.4	2.1	309	289 - 328
Specimen AL-12						
All Method	5	571.5	17.7	3.1	572	518 - 625
Specimen AL-13						
All Method	5	49.0	4.2	8.7	49	36 - 62
Specimen AL-14						
All Method	5	22.0	4.2	19.3	22	9 - 35
Specimen AL-15						
All Method	5	22.5	2.1	9.4	23	16 - 29

Syphilis Serology—Qualitative: Treponema pallidum antibodies

<u>Method</u>	<u>Specimen SY-11</u>		<u>Specimen SY-12</u>		<u>Specimen SY-13</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	-
Siemens ADVIA Centaur	1	-	1	-	1	-

<u>Method</u>	<u>Specimen SY-14</u>		<u>Specimen SY-15</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	1	-	1
Siemens ADVIA Centaur	-	1	-	1

Syphilis Serology—Qualitative: RPR

<u>Method</u>	<u>Specimen SY-11</u>		<u>Specimen SY-12</u>		<u>Specimen SY-13</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	17	-	17	-	17	-
ASI	5	-	5	-	5	-
Becton Dickinson	7	-	7	-	7	-
Fisher HealthCare Sure-Vue	3	-	3	-	3	-
Wampole Impact RPR	2	-	2	-	2	-

<u>Method</u>	<u>Specimen SY-14</u>		<u>Specimen SY-15</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	17	-	17
ASI	-	5	-	5
Becton Dickinson	-	7	-	7
Fisher HealthCare Sure-Vue	-	3	-	3
Wampole Impact RPR	-	2	-	2

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>1:1</u>	<u>1:2</u>	<u>1:4</u>	<u>1:8</u>	<u>1:16</u>	<u>1:32</u>	<u>1:64</u>	<u>1:>64</u>
Specimen SY-11								
ALL METHODS	-	3	3	-	-	-	-	-
ASI	-	1	1	-	-	-	-	-
Becton Dickinson	-	2	2	-	-	-	-	-
Specimen SY-12								
ALL METHODS	-	5	1	-	-	-	-	-
ASI	-	2	-	-	-	-	-	-
Becton Dickinson	-	3	1	-	-	-	-	-
Specimen SY-13								
ALL METHODS	-	-	4	2	-	-	-	-
ASI	-	-	2	-	-	-	-	-
Becton Dickinson	-	-	2	2	-	-	-	-

Syphilis Serology—Qualitative: diagnostics direct Syphilis Health Check Treponema pallidum antibodies

<u>Method</u>	<u>Specimen SHC-11</u>		<u>Specimen SHC-12</u>		<u>Specimen SHC-13</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
diagnostics direct Syphilis Health Check	7	-	-	7	7	-

<u>Method</u>	<u>Specimen SHC-14</u>		<u>Specimen SHC-15</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
diagnostics direct Syphilis Health Check	-	7	7	-

H. pylori Antibody Detection

<u>Method</u>	Specimen HP-5		Specimen HP-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	82	-	-	82
Alere Clearview - moderate	7	-	-	7
Alfa Scientific Instant-View	1	-	-	1
Beckman Coulter ICON HP	2	-	-	2
Cardinal Health SP Brand	6	-	-	6
Consult Diagnostics	15	-	-	15
Fisher HealthCare Sure-Vue	2	-	-	2
Henry Schein OneStep+ - waived	8	-	-	8
McKesson Medi-Lab Performance - waived	6	-	-	6
Polymedco Poly stat	1	-	-	1
PSS Select Diagnostics	2	-	-	2
Quidel QuickVue	26	-	-	26
SDI Biomed, Inc.	1	-	-	1
Sekisui OSOM	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	-	2	2	-
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	-	3	3	-
Meridian ImmunoCard	-	3	3	-

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	2	-	2	-	-	-	2	-
Siemens ADVIA	-	2	-	2	-	-	-	2	-
Centaur	-	2	-	2	-	-	-	2	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	2	-	-	2	-
Siemens ADVIA	-	2	-	-	2	-
Centaur	-	2	-	-	2	-

Viral Markers – Anti-HBc (Total/IgG)

<u>Method</u>	<u>Specimen VM-11</u>			<u>Specimen VM-12</u>			<u>Specimen VM-13</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	2	1	3	-	-	3	-	-
Abbott Architect	-	1	-	1	-	-	1	-	-
Roche cobas e 411	-	-	1	1	-	-	1	-	-
Siemens ADVIA									
Centaur	-	1	-	1	-	-	1	-	-

<u>Method</u>	<u>Specimen VM-14</u>			<u>Specimen VM-15</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	3	-	-	-	3	-
Abbott Architect	1	-	-	-	1	-
Roche cobas e 411	1	-	-	-	1	-
Siemens ADVIA						
Centaur	1	-	-	-	1	-

Viral Markers – Anti-HIV

<u>Method</u>	<u>Specimen VM-11</u>			<u>Specimen VM-12</u>			<u>Specimen VM-13</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	7	-	-	7	-	7	-	-
Abbott Architect	-	2	-	-	2	-	2	-	-
Alere Clearview									
HIV1/2 STAT-PAK	-	3	-	-	3	-	3	-	-
Siemens ADVIA									
Centaur	-	2	-	-	2	-	2	-	-

<u>Method</u>	<u>Specimen VM-14</u>			<u>Specimen VM-15</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	7	-	-	7	-
Abbott Architect	-	2	-	-	2	-
Alere Clearview						
HIV1/2 STAT-PAK	-	3	-	-	3	-
Siemens ADVIA						
Centaur	-	2	-	-	2	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	-	-	-	2	-	-	2	-
Siemens ADVIA									
Centaur	2	-	-	-	2	-	-	2	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	2	-	-	2	-
Siemens ADVIA						
Centaur	-	2	-	-	2	-

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	-	-	-	2	-	2	-	-
Siemens ADVIA									
Centaur	2	-	-	-	2	-	2	-	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	-	-	-	2	-
Siemens ADVIA						
Centaur	2	-	-	-	2	-

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-11 through VM-15 are: Negative, Negative, Negative, Positive, and Negative, respectively.

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	4	-	-	4	-	4	-	-
Siemens ADVIA									
Centaur	-	4	-	-	4	-	4	-	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	4	-	-	4	-
Siemens ADVIA						
Centaur	-	4	-	-	4	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	5	-	5	-	-	-	5	-
Abbott Architect	-	1	-	1	-	-	-	1	-
Roche cobas e 411	-	1	-	1	-	-	-	1	-
Siemens ADVIA									
Centaur	-	3	-	3	-	-	-	3	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	-	-	-	5	-
Abbott Architect	1	-	-	-	1	-
Roche cobas e 411	1	-	-	-	1	-
Siemens ADVIA						
Centaur	3	-	-	-	3	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-11			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	9	-	-	9	-	-	9	-
Abbott Architect	-	2	-	-	2	-	-	2	-
OraSure OraQuick									
HCV	-	1	-	-	1	-	-	1	-
Roche cobas e 411	-	2	-	-	2	-	-	2	-
Siemens ADVIA									
Centaur	-	4	-	-	4	-	-	4	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	7	-	9	-	-
Abbott Architect	-	2	-	2	-	-
OraSure OraQuick						
HCV	-	1	-	1	-	-
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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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