

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 5

Immunology
MLE-M1



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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	± 3 SD
Complement C4	± 3 SD
C-Reactive Protein	± 3 SD
High Sensitivity C-Reactive Protein	± 3 SD
Rheumatoid Factor (International Units)	± 2 SD
Rheumatoid Factor (Titer)	Not Evaluated
Rubella (International Units)	± 3 SD
Total IgA	± 3 SD
Total IgE	± 3 SD
Total IgG	$\pm 25\%$
Total IgM	± 3 SD

Infectious Mononucleosis

<u>Method</u>	Specimen IM-1		Specimen IM-2	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	199	199	1
Alere Clearview	-	10	10	-
Alere Clearview Mono Plus II	-	4	4	-
ASI	-	1	1	-
Beckman Coulter ICON Mono - waived	-	10	10	-
BioStar Acceava Mono Test	-	2	2	-
BioStar Acceava Mono-whole bld	-	6	6	-
Cardinal Health SP Brand - waived	-	7	7	-
Consult Diagnostics	-	13	13	-
Fisher HealthCare Sure-Vue	-	8	8	-
Henry Schein OneStep+ - waived	-	14	14	-
LifeSign Status - waived	-	9	9	-
McKesson Medi-Lab Performance - waived	-	7	7	-
Other Moderate method	-	10	10	-
Other Waived method	1	16	16	1
Quidel QuickVue+	-	1	1	-
Quidel QuickVue+ - waived	-	12	12	-
Sekisui OSOM	-	5	5	-
Sekisui OSOM (waived)	-	57	57	-
Seradyn	-	1	1	-
Wampole ColorCard	-	1	1	-
Wampole Mono-Plus II	-	2	2	-

Infectious Mononucleosis

<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	-	77	76	1	77	-
Alere Clearview	-	1	1	-	1	-
Alere Clearview Mono Plus II	-	1	1	-	1	-
ASI	-	1	1	-	1	-
Beckman Coulter ICON Mono - waived	-	10	10	-	10	-
BioStar Aceava Mono-whole bld	-	3	3	-	3	-
Cardinal Health SP Brand - waived	-	1	1	-	1	-
Consult Diagnostics	-	4	4	-	4	-
Fisher HealthCare Sure-Vue	-	4	4	-	4	-
Henry Schein OneStep+ - waived	-	4	4	-	4	-
LifeSign Status - waived	-	3	3	-	3	-
McKesson Medi-Lab Performance - waived	-	1	1	-	1	-
Other Moderate method	-	9	9	-	9	-
Other Waived method	-	3	3	-	3	-
Quidel QuickVue+	-	1	1	-	1	-
Quidel QuickVue+ - waived	-	2	2	-	2	-
Sekisui OSOM	-	5	5	-	5	-
Sekisui OSOM (waived)	-	19	18	1	19	-
Seradyn	-	1	1	-	1	-
Wampole ColorCard	-	1	1	-	1	-
Wampole Mono-Plus II	-	1	1	-	1	-

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-1		Specimen RF-2		Specimen RF-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	45	-	45	45	-
Abbott Architect	-	1	-	1	1	-
ASI	-	9	-	9	9	-
Beckman AU	-	2	-	2	2	-
Biokit Rheumajet	-	5	-	5	5	-
Diamedix	-	1	-	1	1	-
Fisher HealthCare Sure-Vue	-	3	-	3	3	-
Immunostics Inc.	-	3	-	3	3	-
Remel SeraTest	-	1	-	1	1	-
Siemens RapiTex	-	1	-	1	1	-
Sterling Diagnostics, Inc.	-	1	-	1	1	-
Teco Diagnostics	-	1	-	1	1	-
TheraTest	-	3	-	3	3	-
Wampole ColorCard	-	10	-	10	10	-
Wampole Rheumatex	-	4	-	4	4	-

<u>Method</u>	Specimen RF-4		Specimen RF-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	45	-	45	-
Abbott Architect	1	-	1	-
ASI	9	-	9	-
Beckman AU	2	-	2	-
Biokit Rheumajet	5	-	5	-
Diamedix	1	-	1	-
Fisher HealthCare Sure-Vue	3	-	3	-
Immunostics Inc.	3	-	3	-
Remel SeraTest	1	-	1	-
Siemens RapiTex	1	-	1	-
Sterling Diagnostics, Inc.	1	-	1	-
Teco Diagnostics	1	-	1	-
TheraTest	3	-	3	-
Wampole ColorCard	10	-	10	-
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>
Specimen RF-3											
ALL METHODS	-	2	1	1	1	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	2	-	-	1	-	-	-	-	-	-
Siemens RapiTex	-	-	-	1	-	-	-	-	-	-	-
Wampole ColorCard	-	-	1	-	-	-	-	-	-	-	-
Specimen RF-4											
ALL METHODS	-	-	4	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-View	-	-	2	-	-	1	-	-	-	-	-
Siemens RapiTex	-	-	1	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	1	-	-	-	-	-	-	-	-
Specimen RF-5											
ALL METHODS	-	4	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	2	-	-	1	-	-	-	-	-	-
Siemens RapiTex	-	1	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	1	-	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen RF-1						
All Method	19	5.1	4.3	84.9	4	0 - 14
Specimen RF-2						
All Method	19	5.2	4.4	85.3	4	0 - 14
Specimen RF-3						
All Method	17	71.9	9.9	13.8	69	52 - 92
Specimen RF-4						
All Method	19	145.7	32.4	22.2	141	81 - 211
Specimen RF-5						
All Method	18	78.3	22.3	28.5	71	33 - 123

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
ASI	-	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	-		
ASI	1	-	1	-		

Complement C3 (mg/dL)

<u><i>Specimen/Method</i></u>	<u><i>Labs</i></u>	<u><i>Mean</i></u>	<u><i>SD</i></u>	<u><i>CV</i></u>	<u><i>Median</i></u>	<u><i>Range</i></u>
Specimen IMP-1						
All Method	14	108.7	24.8	22.8	98	34 - 184
Specimen IMP-2						
All Method	14	106.7	28.8	27.0	92	20 - 194
Specimen IMP-3						
All Method	14	132.4	14.7	11.1	127	88 - 177
Specimen IMP-4						
All Method	14	103.6	21.7	20.9	93	38 - 169
Specimen IMP-5						
All Method	14	133.0	15.2	11.4	130	87 - 179

Complement C4 (mg/dL)

<u><i>Specimen/Method</i></u>	<u><i>Labs</i></u>	<u><i>Mean</i></u>	<u><i>SD</i></u>	<u><i>CV</i></u>	<u><i>Median</i></u>	<u><i>Range</i></u>
Specimen IMP-1						
All Method	14	24.1	5.4	22.6	22	7 - 41
Specimen IMP-2						
All Method	14	23.4	6.2	26.5	21	4 - 42
Specimen IMP-3						
All Method	14	30.1	2.2	7.3	31	23 - 37
Specimen IMP-4						
All Method	14	20.6	4.4	21.3	19	7 - 34
Specimen IMP-5						
All Method	14	30.7	2.9	9.5	30	21 - 40

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	11	548.1	45.6	8.3	543	411 - 686
Specimen IMP-2						
All Method	11	220.7	14.1	6.4	215	178 - 263
Specimen IMP-3						
All Method	11	251.1	16.3	6.5	251	202 - 300
Specimen IMP-4						
All Method	11	180.6	13.5	7.5	178	140 - 222
Specimen IMP-5						
All Method	11	255.2	17.7	6.9	252	201 - 309

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	11	922.8	50.5	5.5	917	692 - 1154
Specimen IMP-2						
All Method	11	961.9	40.9	4.3	975	721 - 1203
Specimen IMP-3						
All Method	11	987.1	67.3	6.8	977	740 - 1234
Specimen IMP-4						
All Method	11	2007.5	108.6	5.4	2062	1505 - 2510
Specimen IMP-5						
All Method	11	975.0	63.8	6.5	965	731 - 1219

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	11	427.5	75.1	17.6	455	202 - 653
Specimen IMP-2						
All Method	11	380.0	56.0	14.7	396	212 - 548
Specimen IMP-3						
All Method	11	85.1	9.3	10.9	84	57 - 113
Specimen IMP-4						
All Method	11	410.1	62.9	15.3	429	221 - 599
Specimen IMP-5						
All Method	11	83.6	9.8	11.8	83	54 - 114

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	5	-	5	-	5	-
Diagnostic Technology	3	-	3	-	3	-
Wampole	2	-	2	-	2	-

<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	-	5	-	5
Diagnostic Technology	-	3	-	3
Wampole	-	2	-	2

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	14	-	-	14
ASI	1	-	-	1
Biokit Rheumajet	1	-	-	1
Fisher HealthCare Sure-Vue	8	-	-	8
Siemens Dimension/AR/ES/RxL/Xpand	2	-	-	2
Teco Diagnostics	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 Immunology Methods	22	2.854	0.325	11.4	2.90	1.87 - 3.83
mg/L - units						
All Immunology Methods	13	29.895	5.933	19.8	30.00	12.09 - 47.70
Specimen CR-2						
mg/dL - units						
All Immunology Methods	22	0.160	0.175	109.8	0.10	0.00 - 0.69
mg/L - units						
All Immunology Methods	13	1.928	2.018	104.7	1.10	0.00 - 7.99

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	42	0.808	0.265	32.8	0.82	0.01 - 1.61
Specimen HCR-2						
All Method	41	12.894	1.066	8.3	12.70	9.69 - 16.10

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	-	13	13	-	9	4
Diamedix	-	2	2	-	2	-
GenBio ImmunoDOT Panel 1	-	1	1	-	1	-
Immuno Concepts	-	4	4	-	1	3
INOVA Diagnostics	-	2	2	-	1	1
Phadia ELIA	-	1	1	-	1	-
TheraTest	-	2	2	-	2	-

<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	-	13	13	-
Diamedix	-	2	2	-
GenBio ImmunoDOT Panel 1	-	1	1	-
Immuno Concepts	-	4	4	-
INOVA Diagnostics	-	2	2	-
Kallestad	-	1	1	-
TheraTest	-	2	2	-

Specimen AE-3 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-2

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

Specimen AE-3

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

Specimen AE-14

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

Anti-dsDNA

<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	-	7	2	5	-	7
Diamedix	-	2	2	-	-	2
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	-	3	-	3	-	3

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	7	-
Diamedix	-	2	2	-
GenBio ImmunoDOT Panel 1	-	1	1	-
Phadia EliA	-	1	1	-
TheraTest	-	3	3	-

Specimen AE-2 is an ungraded challenge due to less than 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	1	-	-	1
Phadia EliA	-	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	-	1
Phadia EliA	-	1	-	1

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	-	6	6	-	-	6
Diamedix	-	2	2	-	-	2
GenBio ImmunoDOT Panel 1	-	1	1	-	-	1
TheraTest	-	3	3	-	-	3

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	5	1
Diamedix	-	2	2	-
GenBio ImmunoDOT Panel 1	-	1	-	1
TheraTest	-	3	3	-

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	-	6	6	-	6	-
Diamedix	-	2	2	-	2	-
Phadia EliA	-	1	1	-	1	-
TheraTest	-	3	3	-	3	-

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

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	-	6	-	6	-	6
Diamedix	-	2	-	2	-	2
Phadia EliA	-	1	-	1	-	1
TheraTest	-	3	-	3	-	3

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

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	-	1	-
GenBio ImmunoDOT Panel 1	-	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	1	-
GenBio ImmunoDOT Panel 1	-	1	1	-

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	-	6	-	6	-	6
Diamedix	-	2	-	2	-	2
Phadia EliA	-	1	-	1	-	1
TheraTest	-	3	-	3	-	3

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

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	-	6	-	-	6
bioMerieux Vidas, Mini Vidas	2	-	2	-	-	2
DiaSorin	2	-	2	-	-	2
Siemens ADVIA Centaur	2	-	2	-	-	2

<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
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-1 through RU-5 are: 29 IU/ml, 104 IU/mL, <10 IU/mL, 38 IU/mL and <10 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	51	-	-	51
Alere Clearview Complete HIV 1/2	14	-	-	14
Alere Clearview HIV1/2 STAT-PAK	1	-	-	1
BD LINK 2	1	-	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - waived	16	-	-	16
Other Waived method	18	-	-	18

<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>Negative</u>
ALL METHODS	5	-	5	-	-	5
Alere Clearview Complete HIV 1/2	5	-	5	-	-	5

Allergen Specific IgE Antibodies

Specimen AL-1

Method

	Peanut Allergen CLASS RESULT								Bermuda Grass Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	1	2	-	-	-	-	4	2	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	4	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-

	Walnut Tree Pollen 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	2	-	-	1	-	-	-	-	-	-	2	2	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	2	-	-	-	-	-	-	-	-	-	2	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

Walnut Tree Pollen Allergen is an ungraded challenge due to less than 80% participant consensus.

	Soybean Allergen CLASS RESULT								House Dust Mite (D. farinae) 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	2	-	-	-	-	-	-	1	1	3	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	-	-	-	2	-	-	-	-	-	-	-	-	3	-	-
Phadia UniCap 100 (% ref)	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-

	Sweet Vernal Grass Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-2

<u>Method</u>	Maple (Box Elder) Allergen CLASS RESULT								Cockroach - German Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	2	3	1	-	-	-	-	-	-	1	1	-	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	2	2	-	-	-	-	-	-	-	1	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	White Oak Allergen CLASS RESULT								House Dust Mite (D. pteronyssinus) 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	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	-	-	3	-	-	-	-	-	-	-	-	1	1	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-

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

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

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	5	176.5	16.3	9.2	177	127 - 226
Specimen AL-2						
All Method	5	297.0	39.6	13.3	297	178 - 416
Specimen AL-3						
All Method	5	28.0	5.7	20.2	28	11 - 45
Specimen AL-4						
All Method	5	25.5	2.1	8.3	26	19 - 32
Specimen AL-5						
All Method	5	56.0	4.2	7.6	56	43 - 69

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>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	-	2	2	-	-	-	1	1

<u>Method</u>	<u>Specimen SY-4</u>			<u>Specimen SY-5</u>		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	2	-	-	2	-	-

Specimen SY-3 is an ungraded challenge due to less than 80% participant consensus. The vendor assay for this specimen was non-reactive.

Syphilis Serology—Qualitative: Treponema pallidum antibodies

<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
Siemens ADVIA Centaur	-	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	-
Siemens ADVIA Centaur	1	-	1	-

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<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	-	6	6	-	-	6
Becton Dickinson	-	7	7	-	-	7
Fisher HealthCare Sure-Vue	-	3	3	-	-	3
Wampole Impact RPR	-	1	1	-	-	1

<u>Method</u>	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	17	-	17	-
ASI	6	-	6	-
Becton Dickinson	7	-	7	-
Fisher HealthCare Sure-Vue	3	-	3	-
Wampole Impact RPR	1	-	1	-

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-2								
ALL METHODS	-	1	5	2	-	-	-	-
ASI	-	1	2	1	-	-	-	-
Becton Dickinson	-	-	3	1	-	-	-	-
Specimen SY-4								
ALL METHODS	1	-	7	-	-	-	-	-
ASI	1	-	3	-	-	-	-	-
Becton Dickinson	-	-	4	-	-	-	-	-
Specimen SY-5								
ALL METHODS	-	1	7	-	-	-	-	-
ASI	-	1	3	-	-	-	-	-
Becton Dickinson	-	-	4	-	-	-	-	-

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

<u>Method</u>	Specimen SHC-1		Specimen SHC-2		Specimen SHC-3	
	<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	6	1	7	-	7	-

<u>Method</u>	Specimen SHC-4		Specimen SHC-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
diagnostics direct Syphilis Health Check	6	1	7	-

H. pylori Antibody Detection

<u>Method</u>	Specimen HP-1		Specimen HP-2	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	86	-	1	85
Alere Clearview	8	-	-	8
Alfa Scientific Instant-View	1	-	-	1
Beckman Coulter ICON HP	2	-	-	2
Cardinal Health SP Brand	6	-	-	6
Consult Diagnostics	12	-	-	12
Fisher HealthCare Sure-Vue	2	-	-	2
Henry Schein OneStep+ - waived	8	-	-	8
Jant Pharmacal Accutest	1	-	-	1
McKesson Medi-Lab Performance - waived	7	-	1	6
Other Waived method	1	-	-	1
Polymedco Poly stat	1	-	-	1
PSS Select Diagnostics	2	-	-	2
Quidel QuickVue	28	-	-	28
SDI Biomed, Inc.	1	-	-	1

Lyme Disease Serology

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

Viral Markers – Anti-HBc (IgM)

<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	-	1	-	1
Siemens ADVIA Centaur	-	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	-	1	-	1
Siemens ADVIA Centaur	-	1	-	1

Viral Markers – Anti-HBc (Total/IgG)

<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	4	5	-	3	2
Abbott Architect	-	3	3	-	1	2
Siemens ADVIA Centaur	1	1	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	4	1	4	1
Abbott Architect	3	-	3	-
Siemens ADVIA Centaur	1	1	1	1

Specimen VM-3 is an ungraded challenge due to less than 80% referee 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	-	6	-	6	-	6
Abbott Architect	-	2	-	2	-	2
Siemens ADVIA Centaur	-	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	-	6	6	-
Abbott Architect	-	2	2	-
Siemens ADVIA Centaur	-	2	2	-

Viral Markers – Anti-HAV (IgM)

<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	-	2	-	2	2	-
Abbott Architect	-	1	-	1	1	-
Siemens ADVIA Centaur	-	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	-	2	-	2
Abbott Architect	-	1	-	1
Siemens ADVIA Centaur	-	1	-	1

Viral Markers – Anti-HAV (Total/IgG)

<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	2	-	2	-	2	-
Siemens ADVIA Centaur	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	2	-	2	-
Siemens ADVIA Centaur	2	-	2	-

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-1 through VM-5 are: Negative, Negative, Negative, Negative, and Negative, respectively.

Viral Markers – Anti-HBs

<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 Architect	-	2	-	2	-	2
Siemens ADVIA Centaur	-	3	-	3	-	3

<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 Architect	-	2	2	-
Siemens ADVIA Centaur	-	3	3	-

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 Architect	-	2	-	2	-	2
Siemens ADVIA Centaur	-	3	-	3	-	3

<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 Architect	2	-	-	2
Siemens ADVIA Centaur	3	-	-	3

Viral Markers – Anti-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	8	-	8	-	8	-
Abbott Architect	3	-	3	-	3	-
OraSure OraQuick HCV	1	-	1	-	1	-
Roche cobas e 411	1	-	1	-	1	-
Siemens ADVIA Centaur	3	-	3	-	3	-

<u>Method</u>	Specimen VM-4		Specimen VM-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	7	1	7
Abbott Architect	-	3	-	3
OraSure OraQuick HCV	-	1	-	1
Roche cobas e 411	1	-	1	-
Siemens ADVIA Centaur	-	3	-	3

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