

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 9

Immunology
2019 MLE-M1



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

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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/semi-quantitative 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
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

Semi-Quantitative

Antinuclear Antibody (ANA) Titer	80% Participant Consensus
Anti-Streptolysin O (ASO) Titer	80% Participant Consensus
Rheumatoid Factor (Titer)	80% Participant Consensus
RPR Titer	80% Participant Consensus
VDRL Titer	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."

Complement C3	± 3 SD
Complement C4	± 3 SD
C-Reactive Protein	± 3 SD
High Sensitivity C-Reactive Protein	± 3 SD
Rheumatoid Factor (International Units)	± 3 SD
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>	<u>Specimen IM-1</u>		<u>Specimen IM-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	142	141	5
Alere Clearview - waived	-	5	5	-
Alere Clearview Mono Plus II - moderate	-	2	2	-
Alere Clearview Mono Plus II - waived	-	4	4	-
ASI	-	1	1	-
Beckman Coulter ICON Mono - waived	-	3	3	-
BioStar Aceava Mono Test	-	1	1	-
BioStar Aceava Mono-whole bld	-	4	4	-
BTNX Rapid Response – moderate	-	1	1	-
Cardinal Health SP Brand - waived	-	4	4	-
Clarity Diagnostics	-	1	1	-
Consult Diagnostics	-	23	23	-
Fisher HealthCare Sure-Vue	-	4	4	-
Henry Schein OneStep+ - waived	-	15	15	-
LifeSign Status - waived	1	5	5	1
Other Moderate method	-	4	4	-
Other Waived method	-	13	13	-
Quidel QuickVue+	-	1	1	-
Quidel QuickVue+ - waived	-	4	3	1
Sekisui OSOM	-	4	4	-
Sekisui OSOM (waived)	3	42	42	3
Seradyn	-	1	1	-

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	-	40	40	-	-	40
Alere Clearview Mono Plus II - moderate	-	2	2	-	-	2
Alere Clearview Mono Plus II - waived	-	1	1	-	-	1
ASI	-	1	1	-	-	1
Beckman Coulter ICON Mono - waived	-	3	3	-	-	3
BioStar Acceava Mono-whole bld	-	2	2	-	-	2
BTNX Rapid Response – moderate	-	1	1	-	-	1
Consult Diagnostics	-	7	7	-	-	7
Fisher HealthCare Sure-View	-	1	1	-	-	1
Henry Schein OneStep+ - waived	-	3	3	-	-	3
LifeSign Status - waived	-	1	1	-	-	1
Other Moderate method	-	4	4	-	-	4
Other Waived method	-	2	2	-	-	2
Quidel QuickVue+	-	1	1	-	-	1
Quidel QuickVue+ - waived	-	2	2	-	-	2
Sekisui OSOM	-	4	4	-	-	4
Sekisui OSOM (waived)	-	4	4	-	-	4
Seradyn	-	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	28	-	28	-	-	28
ASI	6	-	6	-	-	6
Beckman AU	1	-	1	-	-	1
Biokit Rheumajet	2	-	2	-	-	2
Diamedix	1	-	1	-	-	1
Fisher HealthCare Sure-View	4	-	4	-	-	4
Immunostics Inc.	1	-	1	-	-	1
INOVA Diagnostics	1	-	1	-	-	1
TheraTest	5	-	5	-	-	5
Wampole ColorCard	4	-	4	-	-	4
Wampole Rheumatex	3	-	3	-	-	3

<u>Method</u>	Specimen RF-4		Specimen RF-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	28	28	-
ASI	-	6	6	-
Beckman AU	-	1	1	-
Biokit Rheumajet	-	2	2	-
Diamedix	-	1	1	-
Fisher HealthCare Sure-View	-	4	4	-
Immunostics Inc.	-	1	1	-
INOVA Diagnostics	-	1	1	-
TheraTest	-	5	5	-
Wampole ColorCard	-	4	4	-
Wampole Rheumatex	-	3	3	-

Rheumatoid Factor—Semi-Quantitative (Titer)

<u>Specimen/Method</u>	<u>N/A (Neg)</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	-	2	-	1	-	-	-	-	-	-	-	-
Beckman AU	-	-	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	-	-	-	-	-	-	-	-	-	-
Specimen RF-2												
ALL METHODS	-	-	-	2	-	1	-	-	-	-	-	-
ASI	-	-	-	-	-	1	-	-	-	-	-	-
Beckman AU	-	-	-	2	-	-	-	-	-	-	-	-
Specimen RF-3												
ALL METHODS	3	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-4												
ALL METHODS	3	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-5												
ALL METHODS	-	-	-	2	-	1	-	-	-	-	-	-
ASI	-	-	-	-	-	1	-	-	-	-	-	-
Beckman AU	-	-	-	2	-	-	-	-	-	-	-	-

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	11	71.0	21.0	29.6	65	8 - 134
Specimen RF-2						
All Method	11	112.1	12.3	11.0	111	75 - 149
Specimen RF-3						
All Method	11	8.5	3.7	44.1	8	0 - 20
Specimen RF-4						
All Method	11	8.7	3.5	40.1	8	0 - 20
Specimen RF-5						
All Method	11	111.0	10.9	9.8	110	78 - 144

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>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	152.5	4.7	3.1	152	138 - 167
Specimen IMP-2						
All Method	11	148.7	4.1	2.7	150	136 - 161
Specimen IMP-3						
All Method	12	49.9	2.0	4.0	50	43 - 56
Specimen IMP-4						
All Method	12	145.7	4.3	2.9	147	132 - 159
Specimen IMP-5						
All Method	12	118.3	3.3	2.8	118	108 - 129

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	11	30.2	2.5	8.2	31	22 - 38
Specimen IMP-2						
All Method	12	30.0	2.4	8.2	30	22 - 38
Specimen IMP-3						
All Method	12	9.7	0.8	8.1	10	7 - 13
Specimen IMP-4						
All Method	12	29.3	2.7	9.1	30	21 - 38
Specimen IMP-5						
All Method	12	23.5	1.9	8.0	24	17 - 30

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	236.8	10.0	4.2	235	206 - 267
Specimen IMP-2						
All Method	11	480.0	9.7	2.0	479	450 - 510
Specimen IMP-3						
All Method	11	76.2	7.1	9.3	81	54 - 98
Specimen IMP-4						
All Method	11	214.4	5.3	2.5	217	198 - 231
Specimen IMP-5						
All Method	11	180.2	6.6	3.7	184	160 - 201

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	1810.0	115.7	6.4	1745	1357 - 2263
Specimen IMP-2						
All Method	11	1024.6	62.1	6.1	1041	768 - 1281
Specimen IMP-3						
All Method	11	355.8	19.0	5.3	358	266 - 445
Specimen IMP-4						
All Method	11	1008.0	46.3	4.6	1012	756 - 1260
Specimen IMP-5						
All Method	11	824.4	38.7	4.7	821	618 - 1031

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	97.8	2.4	2.4	98	90 - 105
Specimen IMP-2						
All Method	11	91.8	2.2	2.4	92	85 - 99
Specimen IMP-3						
All Method	11	34.6	5.4	15.6	33	18 - 51
Specimen IMP-4						
All Method	11	394.0	26.4	6.7	396	314 - 474
Specimen IMP-5						
All Method	11	75.6	1.5	2.0	76	71 - 81

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	5	-	5	-
Siemens Dimension	5	-	5	-

C-Reactive Protein—Quantitative (mg/dL or mg/L), 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	19	7.046	0.894	12.7	7.20	4.36 - 9.73
mg/L - units						
All Immunology Methods	16	68.111	6.768	9.9	67.00	47.80 - 88.42
Specimen CR-2						
mg/dL - units						
All Immunology Methods	19	2.914	0.381	13.1	2.90	1.77 - 4.06
mg/L - units						
All Immunology Methods	16	28.903	4.517	15.6	26.85	15.35 - 42.46

C-Reactive Protein—Quantitative (mg/L), 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	24	2.607	0.909	34.9	2.63	0.00 - 5.34
Specimen HCR-2						
All Method	22	0.811	0.270	33.3	0.88	0.00 - 1.62

Antinuclear Antibody (ANA) - Qualitative

<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	15	-	15	-	-	15
ASI	3	-	3	-	-	3
Bio-Rad	1	-	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	1	-	-	1
Immuno Concepts	3	-	3	-	-	3
INOVA Diagnostics	2	-	2	-	-	2
TheraTest	5	-	5	-	-	5

<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
ASI	-	3	-	3
Bio-Rad	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	3	-	3
INOVA Diagnostics	-	2	-	2
TheraTest	-	5	-	5

Antinuclear Antibody (ANA)—Semi-Quantitative (Titer)

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>8/</u> <u>10</u>	<u>16/</u> <u>20</u>	<u>32/</u> <u>40</u>	<u>64/</u> <u>80</u>	<u>128/</u> <u>160</u>	<u>256/</u> <u>320</u>	<u>512/</u> <u>640</u>	<u>>640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
Specimen AE-1												
ALL METHODS	-	-	-	-	-	-	-	2	1	2	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	1	1	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-2												
ALL METHODS	-	-	-	-	-	-	3	1	-	1	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	2	-	-	1	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
Specimen AE-3												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-4												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-5												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-

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	4	5	9	-	-	9
GenBio ImmunoDOT Panel 1	-	1	1	-	-	1
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	1	1	-	-	1
TheraTest	4	2	6	-	-	6

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	6	-	6

Specimen AE-1 is an ungraded challenge due to lack of 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	2	-	1	1	-	2
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	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
INOVA Diagnostics	-	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	8	-	6	2	-	8
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1
Immuno Concepts	1	-	-	1	-	1
TheraTest	6	-	6	-	-	6

<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
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	-	6	-	6

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

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	8	-	8	-	-	8
Immuno Concepts	1	-	1	-	-	1
INOVA Diagnostics	1	-	1	-	-	1
TheraTest	6	-	6	-	-	6

<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
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	6	-	6

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	2	-	8	-	8
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	1	-	-	1	-	1
TheraTest	5	1	-	6	-	6

<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
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	6	-	6

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

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	-	8	-	8	-	8
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	-	6	-	6	-	6

<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
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	6	-	6

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	5	-	-	5	-	5
INOVA Diagnostics	2	-	-	2	-	2
Siemens ADVIA Centaur	3	-	-	3	-	3

<u>Method</u>	Specimen RU-4		Specimen RU-55	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	5	-
INOVA Diagnostics	-	2	2	-
Siemens ADVIA Centaur	-	3	3	-

Rubella—Quantitative (IU/mL)

One lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values on a Beckman Access 2 for specimens RU-1 through RU-5 are: 39.2 IU/mL, <10 IU/mL, <10 IU/mL, <10 IU/mL, and 39.2 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	1	69	70	-
Alere Clearview HIV1/2 STAT-PAK	-	3	3	-
Alere Determine HIV - moderate	-	2	2	-
Alere Determine HIV - waived	-	5	5	-
bioLytical Labs INSTI HIV - moderate	-	2	2	-
bioLytical Labs INSTI HIV - waived	-	10	10	-
Chembio HIV 1/2 Assay - waived	-	10	10	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	19	19	-
Other Waived method	-	3	3	-
Trinity Biotech Uni-Gold - waived	1	14	15	-

<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 Determine HIV - moderate	-	5	5	-	-	5

Allergen Specific IgE Antibodies

Specimen AL-1

Method

	Timothy Grass (g6) Allergen								Meadow Fescue (g4) 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	-	-	-	-	2	2	-	-	-	-	-	-	-	1	1	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	2	-	-	-	-	-	-	-	-	1	1	-	-

	Silver Birch Tree (t3) Allergen								Olive (t9) 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	1	-	-	-	1	-	1	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-

	Dog Dander (e5) Allergen								Cat Epithelium (e1) 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	-	-	4	1	-	-	-	-	-	-	2	1	2	-	-
Hitachi CLA-1	-	-	-	2	1	-	-	-	-	-	-	-	1	2	-	-
Hycor RAST (Ru/mL)	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	-	-	-	-	-	-	-	1	-	-	-	-

	House Dust Mite (D. pteronyssinus) (d1) Allergen							
	CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	1	1	2	1	-	-	-
Hitachi CLA-1	-	1	1	-	1	-	-	-
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-2

<u>Method</u>	Common (Short) Ragweed (w1) Allergen								Maple (Box Elder) (t1) 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	-	-	-	3	1	-	-	-	2	-	2	-	-	-	-	-
Hitachi CLA-1	-	-	-	2	-	-	-	-	2	-	1	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	1	-	-	-	-	-	1	-	-	-	-	-
	White Oak (t7) Allergen								House Dust Mite (D. pteronyssinus) (d1) 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	-	-	-	3	1	-	-	-	-	1	2	1	-	-	-
Hitachi CLA-1	2	-	-	-	2	-	-	-	-	-	1	-	1	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	2	-	-	-	1	1	-	-	-	-	-	1	-	-	-	-
	Bermuda Grass (g2) Allergen								Egg White (f1) 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	1	-	-	-	-	-	-	2	1	1	1	-	-
Hitachi CLA-1	-	-	1	-	-	-	-	-	-	-	1	-	1	1	-	-
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
	Soybean (f14) Allergen															
	CLASS RESULT															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	-	-	-	2	2	-	-	-								
Hitachi CLA-1	-	-	-	1	2	-	-	-								
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-								
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-								

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	151.5	13.4	8.9	152	111 - 192
Specimen AL-2						
All Method	5	131.0	18.4	14.0	131	75 - 187
Specimen AL-3						
All Method	5	56.0	11.3	20.2	56	22 - 90
Specimen AL-4						
All Method	5	15.0	2.8	18.9	15	6 - 24
Specimen AL-5						
All Method	5	15.0	2.8	18.9	15	6 - 24

Syphilis Serology—Qualitative: Treponema pallidum antibodies

<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	-	11	11	-	-	11
Abbott Architect diagnostics direct Syphilis Health Check	-	1	1	-	-	1
INOVA Diagnostics	-	8	8	-	-	8
Siemens ADVIA Centaur	-	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	11	-	11	-
Abbott Architect diagnostics direct Syphilis Health Check	1	-	1	-
INOVA Diagnostics	8	-	8	-
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	-	14	14	-	-	14
ASI	-	5	5	-	-	5
Becton Dickinson	-	5	5	-	-	5
Fisher HealthCare Sure-Vue	-	3	3	-	-	3

<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	14	-	14	-
ASI	5	-	5	-
Becton Dickinson	5	-	5	-
Fisher HealthCare Sure-Vue	3	-	3	-

Syphilis Serology—Semi-Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</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>
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Specimen SY-1

ALL METHODS	6	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-

Specimen SY-2

ALL METHODS	-	-	-	3	3	-	-	-	-
ASI	-	-	-	2	-	-	-	-	-
Becton Dickinson	-	-	-	1	3	-	-	-	-

Specimen SY-3

ALL METHODS	6	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-

Specimen SY-4

ALL METHODS	-	-	-	3	3	-	-	-	-
ASI	-	-	-	1	1	-	-	-	-
Becton Dickinson	-	-	-	2	2	-	-	-	-

Specimen SY-5

ALL METHODS	-	-	2	4	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	1	3	-	-	-	-	-

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	-	52	52	-
Alere Clearview - moderate	-	3	3	-
Alfa Scientific Instant-View	-	1	1	-
Beckman Coulter ICON HP	-	1	1	-
Cardinal Health SP Brand	-	1	1	-
Consult Diagnostics	-	13	13	-
Fisher HealthCare Sure-View	-	2	2	-
Henry Schein OneStep+ - waived	-	9	9	-
McKesson Medi-Lab Performance - waived	-	2	2	-
NDC Pro Advantage	-	1	1	-
Polymedco Poly stat	-	1	1	-
Quidel QuickVue	-	17	17	-
Sekisui OSOM	-	1	1	-

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	5	-	-	5
Meridian ImmunoCard	5	-	-	5

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	-	3	-	-	3	-	-	3	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Siemens ADVIA									
Centaur	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<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	-
Siemens ADVIA						
Centaur	-	1	-	-	1	-
VITROS 5600	-	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>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	1	-	-	-	1	1	-	-
Abbott Architect	-	1	-	-	-	1	1	-	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	-	-	-	1	-
Abbott Architect	1	-	-	-	1	-

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	8	-	-	-	8	-	4	4	-
Abbott Architect	3	-	-	-	3	-	3	-	-
bioLytical Labs INSTI									
HIV - moderate	1	-	-	-	1	-	-	1	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	3	-	-	-	3	-	-	3	-
Siemens ADVIA									
Centaur	1	-	-	-	1	-	1	-	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	8	-	4	4	-
Abbott Architect	-	3	-	3	-	-
bioLytical Labs INSTI						
HIV - moderate	-	1	-	-	1	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	-	3	-	-	3	-
Siemens ADVIA						
Centaur	-	1	-	1	-	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	-	3	-	-	3	-	-	3	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Siemens ADVIA									
Centaur	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<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	-
Siemens ADVIA						
Centaur	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

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

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	-	-	2	-	-
Abbott Architect	1	-	-	1	-	-
Siemens ADVIA						
Centaur	1	-	-	1	-	-

Viral Markers – HBeAg

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

Viral Markers – Anti-HBs

<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>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	2	-	-	-	2	-	-	2	-
Siemens ADVIA									
Centaur	3	-	-	-	3	-	-	3	-

<u>Method</u>	<u>Specimen VM-4</u>			<u>Specimen VM-5</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	5	-	2	3	-
Abbott Architect	-	2	-	1	1	-
Siemens ADVIA						
Centaur	-	3	-	1	2	-

Specimen VM-5 ungraded challenge due to less than 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>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	-	2	-	-	2	-	2	-	-
Siemens ADVIA									
Centaur	-	2	-	-	2	-	2	-	-
VITROS 5600	-	1	-	-	1	-	1	-	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	-	-	-	5	-
Abbott Architect	2	-	-	-	2	-
Siemens ADVIA						
Centaur	2	-	-	-	2	-
VITROS 5600	1	-	-	-	1	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	-	3	-	3	-	-	-	3	-
Roche cobas e 411	-	1	-	1	-	-	-	1	-
Siemens ADVIA									
Centaur	-	2	-	2	-	-	-	2	-
VITROS 5600	-	1	-	1	-	-	-	1	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	9	-	-	-	9	-
Abbott Architect	2	-	-	-	2	-
OraSure OraQuick						
HCV	3	-	-	-	3	-
Roche cobas e 411	1	-	-	-	1	-
Siemens ADVIA						
Centaur	2	-	-	-	2	-
VITROS 5600	1	-	-	-	1	-

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