MEDICAL LABORATORY
EVALUATION

PARTICIPANT SUMMARY

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Immunology
2021 MLE-M1

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/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. *pylori* 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
SARS-CoV-2 Serology	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 ± 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	± 30% or 2 SD*
High Sensitivity C-Reactive Protein	± 30% or 1 mg/L*
Rheumatoid Factor (International Units)	± 3 SD
Rubella (International Units)	± 3 SD
Total IgA	± 3 SD
Total IgE	± 3 SD
Total IgG	± 25%
Total IgM	± 3 SD

*Whichever is greater

Infectious Mononucleosis

Method	Specimen IM-1		Specimen IM-2	
	Positive	Negative	Positive	Negative
ALL METHODS	119	1	-	120
Alere Clearview - moderate	1	-	-	1
Alere Clearview - waived	5	-	-	5
Alere Clearview Mono Plus II - moderate	1	-	-	1
Alere Clearview Mono Plus II - waived	3	-	-	3
BioStar Acceava Mono Test	2	-	-	2
BioStar Acceava Mono-whole bld	3	-	-	3
Cardinal Health SP Brand	1	-	-	1
Cardinal Health SP Brand - waived	4	-	-	4
Clarity Diagnostics	1	-	-	1
Consult Diagnostics - moderate	4	-	-	4
Consult Diagnostics - waived	13	-	-	13
Fisher HealthCare Sure-Vue	2	-	-	2
Henry Schein OneStep+ - moderate	1	-	-	1
Henry Schein OneStep+ - waived	12	1	-	13
LifeSign Status - waived	6	-	-	6
Other Moderate method	1	-	-	1
Other Waived method	7	-	-	7
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	3	-	-	3
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	44	-	-	44

Infectious Mononucleosis

Method	Specimen IM-3		Specimen IM-4		Specimen IM-5	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	27	-	27	-	27
Alere Clearview - moderate	-	1	-	1	-	1
Alere Clearview Mono Plus II - moderate	-	1	-	1	-	1
Alere Clearview Mono Plus II - waived	-	1	-	1	-	1
BioStar Acceava Mono Test	-	1	-	1	-	1
Consult Diagnostics - moderate	-	1	-	1	-	1
Consult Diagnostics - waived	-	5	-	5	-	5
Fisher HealthCare Sure-Vue	-	1	-	1	-	1
Henry Schein OneStep+ - moderate	-	1	-	1	-	1
Henry Schein OneStep+ - waived	-	2	-	2	-	2
LifeSign Status - waived	-	1	-	1	-	1
Other Moderate method	-	1	-	1	-	1
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)	-	2	-	2	-	2

Rheumatoid Factor—Qualitative

Method	Specimen RF-1 Positive	Specimen RF-1 Negative	Specimen RF-2 Positive	Specimen RF-2 Negative	Specimen RF-3 Positive	Specimen RF-3 Negative
ALL METHODS	-	19	19	-	19	-
ASI	-	4	4	-	4	-
Biokit Rheumajet	-	1	1	-	1	-
Fisher HealthCare Sure-Vue	-	3	3	-	3	-
Stanbio Laboratory	-	4	4	-	4	-
TheraTest	-	5	5	-	5	-
Wampole ColorCard	-	1	1	-	1	-
Wampole Rheumatex	-	1	1	-	1	-

Method	Specimen RF-4 Positive	Specimen RF-4 Negative	Specimen RF-5 Positive	Specimen RF-5 Negative
ALL METHODS	19	-	-	19
ASI	4	-	-	4
Biokit Rheumajet	1	-	-	1
Fisher HealthCare Sure-Vue	3	-	-	3
Stanbio Laboratory	4	-	-	4
TheraTest	5	-	-	5
Wampole ColorCard	1	-	-	1
Wampole Rheumatex	1	-	-	1

Rheumatoid Factor—Semi-Quantitative (Titer)

Specimen/Method	N/A (Neg)	2/ 4	8/ 10	16/ 20	32/ 40	64/ 80	128/ 160	256/ 320	512/ 640	1024/ 1280	2048/ 2560	>2560
Specimen RF-1												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-2												
ALL METHODS	-	-	2	3	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	1	-	-	-	-	-	-	-	-
Specimen RF-3												
ALL METHODS	-	-	2	3	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	1	-	-	-	-	-	-	-	-
Specimen RF-4												
ALL METHODS	-	2	3	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	1	-	-	-	-	-	-	-	-	-
Specimen RF-5												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	3	-	-	-	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU/mL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen RF-1						
All Method	14	7.3	2.6	35.4	6	0 - 16
Beckman AU	8	6.7	2.7	39.9	6	0 - 15
Specimen RF-2						
All Method	14	114.1	4.2	3.7	117	101 - 127
Beckman AU	8	116.2	3.7	3.1	118	105 - 128
Specimen RF-3						
All Method	14	113.7	2.7	2.4	113	105 - 122
Beckman AU	8	114.5	2.9	2.6	115	105 - 124
Specimen RF-4						
All Method	14	61.0	1.4	2.3	61	56 - 66
Beckman AU	8	61.2	1.6	2.6	61	56 - 66
Specimen RF-5						
All Method	14	7.4	2.5	33.0	6	0 - 15
Beckman AU	8	7.0	2.4	33.8	6	0 - 15

Anti-Streptolysin O (ASO)—Qualitative

Method	Specimen AS-1 Positive	Negative	Specimen AS-2 Positive	Negative	Specimen AS-3 Positive	Negative
ALL METHODS	1	-	-	1	-	1
ASI	1	-	-	1	-	1

Method	Specimen AS-4 Positive	Negative	Specimen AS-5 Positive	Negative
ALL METHODS	1	-	1	-
ASI	1	-	1	-

Complement C3 (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-1						
All Method	14	150.7	6.1	4.1	152	132 - 170
Beckman AU	6	149.8	6.0	4.0	149	131 - 168
Specimen IMP-2						
All Method	14	48.9	5.1	10.5	49	33 - 65
Beckman AU	6	51.0	5.3	10.4	50	35 - 67
Specimen IMP-3						
All Method	14	127.1	6.0	4.7	127	109 - 146
Beckman AU	6	127.5	4.7	3.7	127	113 - 142
Specimen IMP-4						
All Method	14	151.6	6.8	4.5	150	131 - 173
Beckman AU	6	149.7	4.8	3.2	148	135 - 165
Specimen IMP-5						
All Method	14	147.1	6.8	4.6	145	126 - 168
Beckman AU	6	145.7	6.0	4.1	145	127 - 164

Complement C4 (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-1						
All Method	14	25.7	2.2	8.4	26	19 - 33
Beckman AU	6	26.7	1.8	6.6	28	21 - 32
Specimen IMP-2						
All Method	14	7.5	0.8	11.3	8	4 - 11
Beckman AU	6	7.8	0.8	9.6	8	5 - 11
Specimen IMP-3						
All Method	14	20.7	1.5	7.2	21	16 - 26
Beckman AU	6	21.3	1.2	5.7	22	17 - 25
Specimen IMP-4						
All Method	14	25.4	2.9	11.3	26	16 - 35
Beckman AU	6	26.2	1.8	7.0	27	20 - 32
Specimen IMP-5						
All Method	14	23.9	2.1	8.7	25	17 - 31
Beckman AU	6	24.3	2.2	8.9	25	17 - 31

IgA (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-1						
All Method	12	518.7	11.7	2.3	517	483 - 554
Beckman AU	5	511.0	6.6	1.3	510	491 - 531
Specimen IMP-2						
All Method	12	74.8	4.8	6.4	74	60 - 90
Beckman AU	5	78.7	3.2	4.1	80	69 - 89
Specimen IMP-3						
All Method	12	197.2	8.4	4.3	196	171 - 223
Beckman AU	5	196.7	1.5	0.8	197	192 - 202
Specimen IMP-4						
All Method	12	241.8	12.5	5.2	242	204 - 280
Beckman AU	5	244.3	7.4	3.0	247	222 - 267
Specimen IMP-5						
All Method	12	233.7	9.3	4.0	232	205 - 262
Beckman AU	5	233.7	3.8	1.6	232	222 - 246

IgG (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-1						
All Method	12	1083.0	31.4	2.9	1083	812 - 1354
Beckman AU	5	1071.7	22.0	2.1	1073	803 - 1340
Specimen IMP-2						
All Method	12	335.0	21.8	6.5	336	251 - 419
Beckman AU	5	336.0	23.5	7.0	325	252 - 420
Specimen IMP-3						
All Method	12	949.0	31.4	3.3	950	711 - 1187
Beckman AU	5	951.7	16.6	1.7	954	713 - 1190
Specimen IMP-4						
All Method	12	1156.2	52.2	4.5	1152	867 - 1446
Beckman AU	5	1145.3	53.4	4.7	1138	858 - 1432
Specimen IMP-5						
All Method	12	1979.0	159.2	8.0	2026	1484 - 2474
Beckman AU	5	1878.7	160.7	8.6	1822	1409 - 2349

IgM (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-1						
All Method	12	104.5	7.5	7.2	105	81 - 128
Beckman AU	5	98.0	2.6	2.7	97	90 - 106
Specimen IMP-2						
All Method	12	31.2	2.2	7.2	31	24 - 38
Beckman AU	5	31.3	0.6	1.8	31	29 - 34
Specimen IMP-3						
All Method	12	85.5	5.4	6.4	84	69 - 102
Beckman AU	5	83.0	1.7	2.1	82	77 - 89
Specimen IMP-4						
All Method	12	350.0	22.5	6.4	347	282 - 418
Beckman AU	5	337.3	12.5	3.7	337	299 - 375
Specimen IMP-5						
All Method	12	100.5	6.4	6.4	99	81 - 120
Beckman AU	5	97.3	2.1	2.1	98	91 - 104

C-Reactive Protein—Qualitative, Regular

	Specimen CR-1		Specimen CR-2	
Method	Positive	Negative	Positive	Negative
ALL METHODS	-	4	4	-
Siemens Dimension	-	4	4	-

C-Reactive Protein—Quantitative (mg/dL or mg/L), Regular

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen CR-1						
mg/dL - units						
Beckman AU	6	0.183	0.172	93.9	0.15	0.00 - 0.53
Siemens Dimension	6	0.173	0.065	37.7	0.20	0.04 - 0.31
All Immunology Methods	17	0.163	0.131	80.5	0.20	0.00 - 0.43
mg/L - units						
All Immunology Methods	13	2.015	1.986	98.5	1.40	0.00 - 5.99
Specimen CR-2						
mg/dL - units						
Beckman AU	6	6.332	0.293	4.6	6.37	4.43 - 8.24
Siemens Dimension	6	6.852	0.497	7.3	6.95	4.79 - 8.91
All Immunology Methods	17	6.382	0.575	9.0	6.40	4.46 - 8.30
mg/L - units						
All Immunology Methods	13	64.107	6.580	10.3	62.35	44.87 - 83.34

C-Reactive Protein—Quantitative (mg/L), High Sensitivity

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen HCR-1						
All Method	22	3.170	0.376	11.9	3.03	2.17 - 4.18
Beckman AU	8	3.381	0.741	21.9	3.01	2.36 - 4.40
Specimen HCR-2						
All Method	23	11.981	1.157	9.7	11.82	8.38 - 15.58
Beckman AU	8	12.460	1.351	10.8	11.82	8.72 - 16.20

Antinuclear Antibody (ANA) - Qualitative

Method	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	12	-	-	12	-	12
ASI	1	-	-	1	-	1
Bio-Rad	1	-	-	1	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1
Immuno Concepts	2	-	-	2	-	2
INOVA Diagnostics	2	-	-	2	-	2
TheraTest	5	-	-	5	-	5

Method	Specimen AE-4		Specimen AE-5	
	Positive	Negative	Positive	Negative
ALL METHODS	11	1	-	12
ASI	-	1	-	1
Bio-Rad	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1
Immuno Concepts	2	-	-	2
INOVA Diagnostics	2	-	-	2
TheraTest	5	-	-	5

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

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

Anti-dsDNA

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	-	7	-	7	-	7
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	-	5	-	5	-	5

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	-	7	-	7
GenBio ImmunoDOT Panel 1	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	5	-	5

Anti-RNP

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	1	-	-	1	-	1
Phadia EliA	1	-	-	1	-	1

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	-	1	-	1
Phadia EliA	-	1	-	1

Anti-RNP/Sm

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	6	-	-	6	-	6
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1
TheraTest	5	-	-	5	-	5

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	1	5	-	6
GenBio ImmunoDOT Panel 1	1	-	-	1
TheraTest	-	5	-	5

Anti-SSA

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	-	6	-	6	-	6
Phadia EliA	-	1	-	1	-	1
TheraTest	-	5	-	5	-	5

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	6	-	-	6
Phadia EliA	1	-	-	1
TheraTest	5	-	-	5

Anti-SSB

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	-	6	-	6	-	6
Phadia EliA	-	1	-	1	-	1
TheraTest	-	5	-	5	-	5

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	5	1	-	6
Phadia EliA	1	-	-	1
TheraTest	4	1	-	5

Anti-SSA/SSB

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	-	1	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1

Anti-Sm

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	1	5	-	6	-	6
Phadia EliA	-	1	-	1	-	1
TheraTest	1	4	-	5	-	5

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	-	6	-	6
Phadia EliA	-	1	-	1
TheraTest	-	5	-	5

Rubella—Qualitative

Method	Specimen RU-1		Specimen RU-2		Specimen RU-3	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	5	-	5	5	-
Siemens ADVIA Centaur	-	5	-	5	5	-

Method	Specimen RU-4		Specimen RU-5	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	5	-	-	5
Siemens ADVIA Centaur	5	-	-	5

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: <10.0 IU/mL, <10.0 IU/mL, 37.7 IU/mL, 19.4 IU/mL, and <10.0 IU/mL, respectively.

Anti-HIV

Method	Specimen HIV-1		Specimen HIV-2	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	68	1	2	67
Alere Clearview HIV1/2 STAT-PAK	2	-	-	2
Alere Determine HIV - moderate	2	-	-	2
Alere Determine HIV - waived	16	-	1	15
bioLytical Labs INSTI HIV - moderate	2	-	-	2
bioLytical Labs INSTI HIV - waived	14	-	-	14
Chembio HIV 1/2 Assay - waived	17	-	-	17
Orasure OraQuick Advance Rapid HIV-1/2 - waived	12	1	1	12
Other Waived method	3	-	-	3

Method	Specimen HIV-3		Specimen HIV-4		Specimen HIV-5	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	5	-	5	5	-
bioLytical Labs INSTI HIV - moderate	-	5	-	5	5	-

Allergen Specific IgE Antibodies

Specimen AL-1

Method	Timothy Grass (g6) Allergen CLASS RESULT								Bermuda Grass (g2) 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	-	-	1	-	-	2	2	-	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-	1	-	-	1	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	2	1	-	-	-	-	-	1	2	-	-	-

Method	Silver Birch Tree (t3) Allergen CLASS RESULT								Maple (Box Elder) (t1) 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	-	-	-	-	1	-	2	2	-	-	-	-
Hitachi CLA-1	1	-	1	-	-	-	-	-	1	-	1	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	2	-	-	-	-	-	-	1	2	-	-	-	-

Method	Dog Dander (e5) Allergen CLASS RESULT								English Plantain (w9) 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	1	1	-	-	1	-	2	2	-	-	-	-
Hitachi CLA-1	1	-	-	-	-	1	-	-	1	-	1	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	1	-	-	-	-	-	1	2	-	-	-	-

Method	Common (Short) Ragweed (w1) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	-	2	2	-	-	-
Hitachi CLA-1	1	-	-	1	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	2	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-2

Method	Sweet Vernal Grass (g1) Allergen CLASS RESULT								Meadow Fescue (g4) 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	1	-	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	2	-	-	-	-	-	-	2	1	-	-	-

Method	Cat Epithelium (e1) Allergen CLASS RESULT								Mouse Urine Protein (e72) 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	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	2	-	-	-	-	-	-	-	-	-	-	-

Method	House Dust Mite (D. pteronyssinus) (d1) Allergen CLASS RESULT								Cow Milk (f2) 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	1	-	-	-	-	-	2	1	2	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-	-	-	-	-	-	2	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	2	-	-	-	-	-	-	2	1	-	-	-

Method	Peanut (f13) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	2	3	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	2	1	-	-

Total IgE—Quantitative (U/mL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen AL-1						
All Method	5	177.7	9.3	5.2	182	149 - 206
Specimen AL-2						
All Method	5	204.0	8.9	4.4	207	177 - 231
Specimen AL-3						
All Method	5	6.7	0.6	8.7	7	4 - 9
Specimen AL-4						
All Method	5	77.0	6.0	7.8	77	59 - 95
Specimen AL-5						
All Method	5	17.0	1.7	10.2	18	11 - 23

Syphilis Serology—Qualitative: MHA-TP

Method	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	1	-	-	1	1	-
Serodia	1	-	-	1	1	-

Method	Specimen SY-4		Specimen SY-5	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	1	-	-	1
Serodia	1	-	-	1

Syphilis Serology—Qualitative: Treponema pallidum antibodies

Method	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	9	-	-	9	9	-
Abbott Architect	1	-	-	1	1	-
diagnostics direct Syphilis Health Check	6	-	-	6	6	-
Siemens ADVIA	2	-	-	2	2	-

Method	Specimen SY-4		Specimen SY-5	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	9	-	-	9
Abbott Architect	1	-	-	1
diagnostics direct Syphilis Health Check	6	-	-	6
Siemens ADVIA Centaur	2	-	-	2

Syphilis Serology—Qualitative: RPR

Method	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	13	-	-	13	13	-
ASI	5	-	-	5	5	-
Becton Dickinson	5	-	-	5	5	-
Fisher HealthCare Sure-Vue	3	-	-	3	3	-

Method	Specimen SY-4		Specimen SY-5	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	13	-	-	13
ASI	5	-	-	5
Becton Dickinson	5	-	-	5
Fisher HealthCare Sure-Vue	3	-	-	3

Syphilis Serology—Semi-Quantitative: RPR (Titer)

Specimen/Method	N/A (Neg)	1:1	1:2	1:4	1:8	1:16	1:32	1:64	1:>64
Specimen SY-1									
ALL METHODS	-	-	-	5	1	-	-	-	-
ASI	-	-	-	1	1	-	-	-	-
Becton Dickinson	-	-	-	4	-	-	-	-	-
Specimen SY-2									
ALL METHODS	6	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
Specimen SY-3									
ALL METHODS	-	-	2	4	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	1	3	-	-	-	-	-
Specimen SY-4									
ALL METHODS	-	-	5	1	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	4	-	-	-	-	-	-
Specimen SY-5									
ALL METHODS	6	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-

H. *pylori* Antibody Detection

Method	Specimen HP-1 Positive	Specimen HP-1 Negative	Specimen HP-2 Positive	Specimen HP-2 Negative
ALL METHODS	1	33	34	-
Alere Clearview - moderate	-	2	2	-
Alfa Scientific Instant-View	-	1	1	-
Consult Diagnostics - moderate	-	5	5	-
Consult Diagnostics - waived	-	6	6	-
Henry Schein OneStep+ - waived	-	8	8	-
McKesson Medi-Lab Performance - waived	-	2	2	-
NDC Pro Advantage	-	1	1	-
Polymedco Poly stat	-	1	1	-
Quidel QuickVue	1	7	8	-

Mycoplasma Antibody

Method	Specimen MY-1 Positive	Specimen MY-1 Negative	Specimen MY-2 Positive	Specimen MY-2 Negative
ALL METHODS	5	-	1	4
Meridian ImmunoCard	5	-	1	4

SARS-CoV-2 Serology

Method	Specimen SAB-1 Positive	Specimen SAB-1 Negative	Specimen SAB-2 Positive	Specimen SAB-2 Negative
ALL METHODS	-	17	17	-
Abbott Architect	-	4	4	-
Beckman ACCESS / 2 / DxI	-	3	3	-
Healgen Scientific	-	2	2	-
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas e 411	-	3	3	-
Roche Elecsys	-	1	1	-
Siemens ADVIA	-	1	1	-
VITROS ECi	-	1	1	-

Viral Markers – Anti-HBc (IgM)

Method	Specimen VM-1 Positive	Negative	Equivocal	Specimen VM-2 Positive	Negative	Equivocal	Specimen VM-3 Positive	Negative	Equivocal
ALL METHODS	-	5	-	1	3	1	1	4	-
Abbott Alinity	-	1	-	1	-	-	1	-	-
Abbott Architect	-	2	-	-	1	1	-	2	-
Siemens ADVIA	-	1		-	1	-	-	1	
VITROS 5600	-	1	-	-	1	-	-	1	-

Method	Specimen VM-4 Positive	Negative	Equivocal	Specimen VM-5 Positive	Negative	Equivocal
ALL METHODS	-	5	-	3	1	1
Abbott Alinity	-	1	-	1	-	-
Abbott Architect	-	2	-	1	-	1
Siemens ADVIA	-	1	-	1	-	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total/IgG)

Method	Specimen VM-1 Positive	Negative	Equivocal	Specimen VM-2 Positive	Negative	Equivocal	Specimen VM-3 Positive	Negative	Equivocal
ALL METHODS	-	3	-	3	-	-	3	-	-
Abbott Alinity	-	1	-	1	-	-	1	-	-
Abbott Architect	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-	1	-	-

Method	Specimen VM-4 Positive	Negative	Equivocal	Specimen VM-5 Positive	Negative	Equivocal
ALL METHODS	-	3	-	3	-	-
Abbott Alinity	-	1	-	1	-	-
Abbott Architect	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-

Viral Markers – Anti-HIV

Method	Specimen VM-1 Positive	Negative	Equivocal	Specimen VM-2 Positive	Negative	Equivocal	Specimen VM-3 Positive	Negative	Equivocal
ALL METHODS	-	7	-	-	7	-	-	7	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	2	-	-	2	-	-	2	-
bioLytical Labs INSTI HIV - moderate	-	1	-	-	1	-	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	2	-	-	2	-	-	2	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-

Method	Specimen VM-4 Positive	Negative	Equivocal	Specimen VM-5 Positive	Negative	Equivocal
ALL METHODS	7	-	-	-	7	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	2	-	-	-	2	-
bioLytical Labs INSTI HIV - moderate	1	-	-	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	2	-	-	-	2	-
Siemens ADVIA	1	-	-	-	1	-

Viral Markers – Anti-HAV (IgM)

Method	Specimen VM-1 Positive	Negative	Equivocal	Specimen VM-2 Positive	Negative	Equivocal	Specimen VM-3 Positive	Negative	Equivocal
ALL METHODS	-	5	-	-	5	-	-	5	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

Method	Specimen VM-4 Positive	Negative	Equivocal	Specimen VM-5 Positive	Negative	Equivocal
ALL METHODS	-	5	-	-	5	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

Method	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	Positive	*Negative*	*Equivocal*	*Positive*	*Negative*	*Equivocal*	*Positive*	*Negative*	*Equivocal*
ALL METHODS	-	3	-	3	-	-	-	3	-
Abbott Architect	-	2	-	2	-	-	-	2	-
Siemens ADVIA	-	1	-	1	-	-	-	1	-

Method	Specimen VM-4			Specimen VM-5		
	Positive	*Negative*	*Equivocal*	*Positive*	*Negative*	*Equivocal*
ALL METHODS	3	-	-	3	-	-
Abbott Architect	2	-	-	2	-	-
Siemens ADVIA	1	-	-	1	-	-

Viral Markers – HBeAg

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

Viral Markers – Anti-HBs

Method	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	Positive	*Negative*	*Equivocal*	*Positive*	*Negative*	*Equivocal*	*Positive*	*Negative*	*Equivocal*
ALL METHODS	5	-	-	-	5	-	1	4	-
Abbott Alinity	1	-	-	-	1	-	-	1	-
Abbott Architect	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	1	-	-	-	1	-	1	-	-
Siemens ADVIA	1	-	-	-	1	-	-	1	-

Method	Specimen VM-4			Specimen VM-5		
	Positive	*Negative*	*Equivocal*	*Positive*	*Negative*	*Equivocal*
ALL METHODS	5	-	-	-	5	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	2	-	-	-	2	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Siemens ADVIA	1	-	-	-	1	-

Viral Markers – HBsAg

Method	VM-1 Positive	VM-1 Negative	VM-1 Equivocal	VM-2 Positive	VM-2 Negative	VM-2 Equivocal	VM-3 Positive	VM-3 Negative	VM-3 Equivocal
ALL METHODS	-	7	-	7	-	-	5	1	1
Abbott Alinity	-	1	-	1	-	-	1	-	-
Abbott Architect	-	2	-	2	-	-	1	1	-
Roche cobas 6000 / e 601	-	1	-	1	-	-	1	-	-
Siemens ADVIA	-	2	-	2	-	-	2	-	-
VITROS 5600	-	1	-	1	-	-	-	-	1

Method	VM-4 Positive	VM-4 Negative	VM-4 Equivocal	VM-5 Positive	VM-5 Negative	VM-5 Equivocal
ALL METHODS	-	7	-	7	-	-
Abbott Alinity	-	1	-	1	-	-
Abbott Architect	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Siemens ADVIA	-	2	-	2	-	-
VITROS 5600	-	1	-	1	-	-

Viral Markers – Anti-HCV

Method	VM-1 Positive	VM-1 Negative	VM-1 Equivocal	VM-2 Positive	VM-2 Negative	VM-2 Equivocal	VM-3 Positive	VM-3 Negative	VM-3 Equivocal
ALL METHODS	11	-	-	2	9	-	-	11	-
Abbott Alinity	1	-	-	-	1	-	-	1	-
Abbott Architect	2	-	-	-	2	-	-	2	-
OraSure OraQuick HCV	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	1	-	-	1	-	-	-	1	-
Roche cobas e 411	1	-	-	1	-	-	-	1	-
Siemens ADVIA	3	-	-	-	3	-	-	3	-
VITROS 5600	1	-	-	-	1	-	-	1	-

Method	VM-4 Positive	VM-4 Negative	VM-4 Equivocal	VM-5 Positive	VM-5 Negative	VM-5 Equivocal
ALL METHODS	-	11	-	2	9	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	-	2	-	-	2	-
OraSure OraQuick HCV	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Roche cobas e 411	-	1	-	1	-	-
Siemens ADVIA	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-

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