MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 2 • 1

Medical Laboratory
Evaluation

Immunology
2021 MLE-M3

Table of Contents

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-11		Specimen IM-12	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	-	108	107	1
Alere Clearview - moderate	-	1	1	-
Alere Clearview - waived	-	4	4	-
Alere Clearview Mono Plus II - moderate	-	1	1	-
Alere Clearview Mono Plus II - waived	-	3	3	-
BioStar Acceava Mono Test	-	1	1	-
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	-	3	3	-
Consult Diagnostics - waived	-	15	15	-
Fisher HealthCare Sure-Vue	-	2	2	-
Henry Schein OneStep+ - moderate	-	1	1	-
Henry Schein OneStep+ - waived	-	10	10	-
Immunostics Inc.	-	1	1	-
LifeSign Status - waived	-	6	6	-
Other Waived method	-	6	6	-
Quidel QuickVue+	-	1	1	-
Quidel QuickVue+ - waived	-	2	1	1
Sekisui OSOM	-	4	4	-
Sekisui OSOM (waived)	-	38	38	-

Infectious Mononucleosis

Method	Specimen IM-13		Specimen IM-14		Specimen IM-15	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	21	-	21	21	-
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	-	1	-	1	1	-
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 Waived method	-	2	-	2	2	-
Quidel QuickVue+	-	1	-	1	1	-
Quidel QuickVue+ - waived	-	1	-	1	1	-
Sekisui OSOM	-	4	-	4	4	-
Sekisui OSOM (waived)	-	2	-	2	2	-

Rheumatoid Factor—Qualitative

Method	Specimen RF-11 Positive	Specimen RF-11 Negative	Specimen RF-12 Positive	Specimen RF-12 Negative	Specimen RF-13 Positive	Specimen RF-13 Negative
ALL METHODS	17	-	17	-	-	17
ASI	4	-	4	-	-	4
Biokit Rheumajet	1	-	1	-	-	1
Fisher HealthCare Sure-Vue	2	-	2	-	-	2
Phadia EliA	1	-	1	-	-	1
Stanbio Laboratory	4	-	4	-	-	4
TheraTest	4	-	4	-	-	4
Wampole Rheumatex	1	-	1	-	-	1

Method	Specimen RF-14 Positive	Specimen RF-14 Negative	Specimen RF-15 Positive	Specimen RF-15 Negative
ALL METHODS	17	-	-	17
ASI	4	-	-	4
Biokit Rheumajet	1	-	-	1
Fisher HealthCare Sure-Vue	2	-	-	2
Phadia EliA	1	-	-	1
Stanbio Laboratory	4	-	-	4
TheraTest	4	-	-	4
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-11												
ALL METHODS	-	-	5	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	5	-	-	-	-	-	-	-	-	-
Specimen RF-12												
ALL METHODS	-	5	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	5	-	-	-	-	-	-	-	-	-	-
Specimen RF-13												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	5	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-14												
ALL METHODS	-	2	3	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	3	-	-	-	-	-	-	-	-	-
Specimen RF-15												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	5	-	-	-	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU/mL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen RF-11						
All Method	16	118.3	5.0	4.2	122	103 - 134
Beckman AU	10	118.8	5.0	4.2	120	103 - 134
Specimen RF-12						
All Method	16	64.3	2.9	4.5	66	55 - 73
Beckman AU	10	64.0	2.0	3.1	65	58 - 70
Specimen RF-13						
All Method	15	7.5	5.2	69.1	3	0 - 24
Beckman AU	9	-	-	-	7	0 - 24
Specimen RF-14						
All Method	16	64.0	3.1	4.9	66	54 - 74
Beckman AU	10	63.8	3.1	4.9	65	54 - 74
Specimen RF-15						
All Method	16	6.4	5.7	88.5	2	0 - 24
Beckman AU	10	4.6	5.1	110.4	3	0 - 20

Anti-Streptolysin O (ASO)—Qualitative

Method	Specimen AS-11		Specimen AS-12		Specimen AS-13	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	-	5	5	-	5	-
ASI	-	5	5	-	5	-

Method	Specimen AS-14		Specimen AS-15	
	Positive	Negative	Positive	Negative
ALL METHODS	-	5	-	5
ASI	-	5	-	5

Complement C3 (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-11						
All Method	14	33.6	4.7	14.1	33	19 - 48
Beckman AU	10	34.3	3.8	11.0	33	23 - 46
Specimen IMP-12						
All Method	14	147.2	6.2	4.2	149	128 - 166
Beckman AU	10	146.0	5.7	3.9	147	129 - 163
Specimen IMP-13						
All Method	14	34.2	4.8	13.9	33	19 - 49
Beckman AU	10	35.2	3.8	10.9	34	23 - 47
Specimen IMP-14						
All Method	14	144.3	6.7	4.6	146	124 - 165
Beckman AU	10	142.7	5.1	3.6	144	127 - 158
Specimen IMP-15						
All Method	14	218.3	6.8	3.1	217	197 - 239
Beckman AU	10	216.8	4.5	2.1	216	203 - 231

Complement C4 (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-11						
All Method	14	6.0	1.6	26.4	5	1 - 11
Beckman AU	10	6.2	1.5	23.9	6	1 - 11
Specimen IMP-12						
All Method	14	25.6	1.9	7.6	26	19 - 32
Beckman AU	10	26.3	1.0	3.9	26	23 - 30
Specimen IMP-13						
All Method	14	6.7	1.2	18.4	7	2 - 11
Beckman AU	10	7.0	0.9	12.8	7	4 - 10
Specimen IMP-14						
All Method	14	23.9	2.3	9.6	25	16 - 31
Beckman AU	10	24.8	1.1	4.4	25	21 - 29
Specimen IMP-15						
All Method	14	36.4	2.7	7.5	38	28 - 45
Beckman AU	10	37.7	1.4	3.6	38	33 - 42

IgA (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-11						
All Method	10	45.6	4.7	10.4	44	31 - 60
Specimen IMP-12						
All Method	10	523.0	18.6	3.6	524	467 - 579
Specimen IMP-13						
All Method	10	37.4	4.4	11.7	39	24 - 51
Specimen IMP-14						
All Method	10	230.8	12.3	5.3	231	193 - 268
Specimen IMP-15						
All Method	10	342.8	16.8	4.9	341	292 - 394

IgG (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-11						
All Method	10	236.6	21.7	9.2	238	177 - 296
Specimen IMP-12						
All Method	10	1084.4	57.7	5.3	1064	813 - 1356
Specimen IMP-13						
All Method	10	218.4	30.0	13.8	211	163 - 273
Specimen IMP-14						
All Method	10	1997.0	132.0	6.6	1985	1497 - 2497
Specimen IMP-15						
All Method	10	1711.8	87.0	5.1	1683	1283 - 2140

IgM (mg/dL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen IMP-11						
All Method	10	23.0	1.6	6.9	23	18 - 28
Specimen IMP-12						
All Method	10	106.2	9.8	9.2	102	76 - 136
Specimen IMP-13						
All Method	10	20.8	2.4	11.5	20	13 - 28
Specimen IMP-14						
All Method	10	107.4	9.3	8.7	103	79 - 136
Specimen IMP-15						
All Method	10	158.6	15.9	10.1	152	110 - 207

C-Reactive Protein—Qualitative, Regular

Method	Specimen CR-5		Specimen CR-6	
	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-5						
All Method	27	15.274	13.491	88.3	3.10	0.00 - 42.26
mg/dL - units						
Beckman AU	5	2.740	0.358	13.1	2.80	1.91 - 3.57
All Immunology Methods	14	2.680	0.335	12.5	2.70	1.87 - 3.49
mg/L - units						
All Immunology Methods	13	28.838	3.146	10.9	27.00	20.18 - 37.49
Specimen CR-6						
All Method	23	0.300	0.456	151.7	0.20	0.00 - 1.22
mg/dL - units						
Beckman AU	5	0.162	0.193	119.1	0.10	0.00 - 0.55
All Immunology Methods	14	0.155	0.135	86.9	0.15	0.00 - 0.43
mg/L - units						
All Immunology Methods	12	1.420	1.838	129.4	0.65	0.00 - 5.10

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

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen HCR-5						
All Method	18	11.522	1.347	11.7	11.53	8.06 - 14.98
Beckman AU	5	12.446	1.561	12.5	11.43	8.71 - 16.18
Specimen HCR-6						
All Method	18	0.898	0.411	45.8	0.89	0.00 - 1.90
Beckman AU	4	-	-	-	0.92	0.15 - 2.16

Antinuclear Antibody (ANA) - Qualitative

	Specimen AE-11		Specimen AE-12		Specimen AE-13	
Method	*Positive*	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	11	10	1	11	-
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	-	4	4	-	4	-

	Specimen AE-14		Specimen AE-15	
Method	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	11	-	11
ASI	-	1	-	1
Bio-Rad	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	2	-	2
INOVA Diagnostics	-	2	-	2
TheraTest	-	4	-	4

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-11												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	2	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-12												
ALL METHODS	-	-	-	-	-	1	2	1	-	1	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	1	1	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	1	-	-
Specimen AE-13												
ALL METHODS	-	-	-	-	-	-	1	3	-	1	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	-	1	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	1	-	-	-	-
Specimen AE-14												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	2	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-15												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	2	-	-	-	-	-	-	-	-	-	-	-

Anti-dsDNA

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	-	7	6	1	1	6
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-
Immuno Concepts	-	1	1	-	-	1
Phadia EliA	-	1	1	-	-	1
TheraTest	-	4	4	-	-	4

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	-	7	-	7
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	4	-	4

Anti-RNP

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	-	2	-	2	2	-
Immuno Concepts	-	1	-	1	1	-
Phadia EliA	-	1	-	1	1	-

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	-	2	-	2
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1

Anti-RNP/Sm

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	-	6	4	2	6	-
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-
Immuno Concepts	-	1	-	1	1	-
TheraTest	-	4	4	-	4	-

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	-	6	-	6
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	-	4	-	4

Anti-SSA

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	-	6	6	-	-	6
Immuno Concepts	-	1	1	-	-	1
Phadia EliA	-	1	1	-	-	1
TheraTest	-	4	4	-	-	4

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	-	6	-	6
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	4	-	4

Anti-SSB

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	-	6	-	6	-	6
Immuno Concepts	-	1	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	-	4	-	4	-	4

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	-	6	-	6
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	4	-	4

Anti-SSA/SSB

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	-	1	1	-	-	1
GenBio ImmunoDOT Panel 1	-	1	1	-	-	1

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1

Anti-Sm

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	-	6	-	6	-	6
Immuno Concepts	-	1	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	-	4	-	4	-	4

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	-	6	-	6
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	4	-	4

Rubella—Qualitative

Method	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	5	-	5	-	-	5
Siemens ADVIA Centaur	5	-	5	-	-	5

Method	Specimen RU-14		Specimen RU-15	
	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-11 through RU-15 are: 38.3 IU/mL, 57.2 IU/mL, <10.0 IU/mL, 38.3 IU/mL, and <10.0 IU/mL, respectively.

Anti-HIV

Method	Specimen HIV-11		Specimen HIV-12	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	-	62	62	-
Alere Clearview HIV1/2 STAT-PAK	-	2	2	-
Alere Determine - moderate	-	2	2	-
Alere Determine - waived	-	15	15	-
bioLytical Labs INSTI HIV - moderate	-	2	2	-
bioLytical Labs INSTI HIV - waived	-	11	11	-
Chembio HIV 1/2 Assay - waived	-	13	13	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	14	14	-
Other Waived method	-	3	3	-

Method	Specimen HIV-13		Specimen HIV-14		Specimen HIV-15	
	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-11

Method	Bahia Grass (g17) Allergen CLASS RESULT								Meadow, Kentucky Blue, June Grass (g8) Allergens 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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	1	-	-	-	-	-	-	2	1	-	-	-

Method	Alternaria alternata (m6) Allergen CLASS RESULT								Walnut (f256) Allergen 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	2	-	-	-	-
Hitachi CLA-1	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	-	-	-	-	-	-	1	2	-	-	-	-

Method	Hazelnut (f17) Allergen CLASS RESULT								Lobster (f80) 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	2	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	2	-	-	-	-	-	1	1	2	-	-	-	-

Method	Cat Epithelium (e1) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	1	1	2	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	1	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-12

Method	Silver Birch Tree (t3) Allergen CLASS RESULT								White Oak (t7) 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	-	-	-	-	-	-	-	2	1	-	-	-
Hitachi CLA-1	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	2	-	-	-	-	-	-	-	2	1	-	-	-

Method	House Dust Mite (D. farinae) (d2) Allergen CLASS RESULT								Dog Dander (e5) 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	-	-	-	1	1	1	2	-	-	-	-
Hitachi CLA-1	-	-	-	-	1	-	-	-	1	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	-	-	-	-	-	1	1	2	-	-	-	-

Method	Penicillium chrysogenum (m1) Allergen CLASS RESULT								Orchard Grass (Cocksfoot) (g3) 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	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Method	Timothy Grass (g6) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	2	2	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	2	-	-	-

Total IgE—Quantitative (U/mL)

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen AL-11						
All Method	5	369.7	5.5	1.5	370	353 - 387
Specimen AL-12						
All Method	5	364.0	19.7	5.4	367	304 - 424
Specimen AL-13						
All Method	5	6.7	0.6	8.7	7	4 - 9
Specimen AL-14						
All Method	5	18.0	1.0	5.6	18	15 - 21
Specimen AL-15						
All Method	5	70.7	5.1	7.3	72	55 - 87

Syphilis Serology—Qualitative: MHA-TP

Method	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	-	-	-	-	-	-

Method	Specimen SY-14		Specimen SY-15	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	-	-	-	-

Syphilis Serology—Qualitative: Treponema pallidum antibodies

Method	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	-	8	8	-	8	-
diagnostics direct Syphilis Health Check	-	6	6	-	6	-
Siemens ADVIA	-	2	2	-	2	-

Method	Specimen SY-14		Specimen SY-15	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	-	8	8	-
diagnostics direct Syphilis Health Check	-	6	6	-
Siemens ADVIA Centaur	-	2	2	-

Syphilis Serology—Qualitative: RPR

Method	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	-	10	10	-	10	-
ASI	-	5	5	-	5	-
Becton Dickinson	-	2	2	-	2	-
Fisher HealthCare Sure-Vue	-	3	3	-	3	-

Method	Specimen SY-14		Specimen SY-15	
	Reactive	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	-	10	10	-
ASI	-	5	5	-
Becton Dickinson	-	2	2	-
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-11									
ALL METHODS	4	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	1	-	-	-	-	-	-	-	-
Specimen SY-12									
ALL METHODS	-	-	-	2	2	-	-	-	-
ASI	-	-	-	1	1	-	-	-	-
Becton Dickinson	-	-	-	-	1	-	-	-	-
Specimen SY-13									
ALL METHODS	-	-	2	2	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-
Specimen SY-14									
ALL METHODS	4	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	1	-	-	-	-	-	-	-	-
Specimen SY-15									
ALL METHODS	-	-	2	1	1	-	-	-	-
ASI	-	-	-	1	1	-	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-	-

H. *pylori* Antibody Detection

Method	Specimen HP-5		Specimen HP-6	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	-	25	24	1
Alere Clearview - moderate	-	2	2	-
Alere Clearview - waived	-	1	1	-
Alfa Scientific Instant-View	-	2	2	-
Consult Diagnostics - moderate	-	1	1	-
Henry Schein OneStep+ - moderate	-	1	1	-
Henry Schein OneStep+ - waived	-	7	6	1
McKesson Medi-Lab Performance - waived	-	4	4	-
NDC Pro Advantage	-	1	1	-
Polymedco Poly stat	-	1	1	-
Quidel QuickVue	-	1	1	-
Sekisui OSOM	-	4	4	-

Mycoplasma Antibody

Method	Specimen MY-5		Specimen MY-6	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	1	4	5	-
Meridian ImmunoCard	1	4	5	-

SARS-CoV-2 Serology

Method	Specimen SAB-5		Specimen SAB-6	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	16	-	-	16
Abbott Alinity	1	-	-	1
Abbott Architect	2	-	-	2
Access Bio CareStart	2	-	-	2
Beckman ACCESS / 2 / DxI	3	-	-	3
Healgen Scientific	2	-	-	2
Roche cobas 6000 / e 601	1	-	-	1
Roche cobas e 411	2	-	-	2
Siemens ADVIA	1	-	-	1
Sienna-Clarity COVIBLOCK	1	-	-	1
VITROS ECi	1	-	-	1

Viral Markers – Anti-HBc (IgM)

Method	Specimen VM-11 Positive	Negative	Equivocal	Specimen VM-12 Positive	Negative	Equivocal	Specimen VM-13 Positive	Negative	Equivocal
ALL METHODS	-	5	-	5	-	-	-	5	-
Abbott Alinity	-	3	-	3	-	-	-	3	-
Abbott Architect	-	1	-	1	-	-	-	1	-
VITROS 5600	-	1	-	1	-	-	-	1	-

Method	Specimen VM-14 Positive	Negative	Equivocal	Specimen VM-15 Positive	Negative	Equivocal
ALL METHODS	-	5	-	-	5	-
Abbott Alinity	-	3	-	-	3	-
Abbott Architect	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total/IgG)

Method	Specimen VM-11 Positive	Negative	Equivocal	Specimen VM-12 Positive	Negative	Equivocal	Specimen VM-13 Positive	Negative	Equivocal
ALL METHODS	-	5	-	5	-	-	-	5	-
Abbott Alinity	-	3	-	3	-	-	-	3	-
Roche cobas 6000 / e 601	-	2	-	2	-	-	-	2	-

Method	Specimen VM-14 Positive	Negative	Equivocal	Specimen VM-15 Positive	Negative	Equivocal
ALL METHODS	-	5	-	5	-	-
Abbott Alinity	-	3	-	3	-	-
Roche cobas 6000 / e 601	-	2	-	2	-	-

Viral Markers – Anti-HIV

Method	Specimen VM-11 Positive	Negative	Equivocal	Specimen VM-12 Positive	Negative	Equivocal	Specimen VM-13 Positive	Negative	Equivocal
ALL METHODS	-	6	-	-	6	-	-	6	-
Abbott Alinity	-	2	-	-	2	-	-	2	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	2	-	-	2	-	-	2	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-

Method	Specimen VM-14 Positive	Negative	Equivocal	Specimen VM-15 Positive	Negative	Equivocal
ALL METHODS	6	-	-	-	6	-
Abbott Alinity	2	-	-	-	2	-
Abbott Architect	1	-	-	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	2	-	-	-	2	-
Siemens ADVIA	1	-	-	-	1	-

Viral Markers – Anti-HAV (IgM)

Method	Specimen VM-11 Positive	Negative	Equivocal	Specimen VM-12 Positive	Negative	Equivocal	Specimen VM-13 Positive	Negative	Equivocal
ALL METHODS	-	5	-	-	5	-	-	5	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	2	-	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-	-	1	-

Method	Specimen VM-14 Positive	Negative	Equivocal	Specimen VM-15 Positive	Negative	Equivocal
ALL METHODS	-	5	-	-	5	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

Method	Specimen VM-11 Positive	Negative	Equivocal	Specimen VM-12 Positive	Negative	Equivocal	Specimen VM-13 Positive	Negative	Equivocal
ALL METHODS	5	-	-	-	5	-	-	5	-
Abbott Architect	3	-	-	-	3	-	-	3	-
Siemens ADVIA	2	-	-	-	2	-	-	2	-

Method	Specimen VM-14 Positive	Negative	Equivocal	Specimen VM-15 Positive	Negative	Equivocal
ALL METHODS	5	-	-	-	5	-
Abbott Architect	3	-	-	-	3	-
Siemens ADVIA	2	-	-	-	2	-

Viral Markers – HBeAg

Method	Specimen VM-11 Positive	Negative	Equivocal	Specimen VM-12 Positive	Negative	Equivocal	Specimen VM-13 Positive	Negative	Equivocal
ALL METHODS	-	5	-	1	4	-	-	5	-
Abbott Architect	-	2	-	-	2	-	-	2	-

Method	Specimen VM-14 Positive	Negative	Equivocal	Specimen VM-15 Positive	Negative	Equivocal
ALL METHODS	-	5	-	1	4	-
Abbott Architect	-	2	-	-	2	-

Viral Markers – Anti-HBs

Method	Specimen VM-11 Positive	Negative	Equivocal	Specimen VM-12 Positive	Negative	Equivocal	Specimen VM-13 Positive	Negative	Equivocal
ALL METHODS	5	-	-	-	5	-	-	5	-
Abbott Alinity	2	-	-	-	2	-	-	2	-
Abbott Architect	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	1	-	-	-	1	-	-	1	-
Siemens ADVIA	1	-	-	-	1	-	-	1	-

Method	Specimen VM-14 Positive	Negative	Equivocal	Specimen VM-15 Positive	Negative	Equivocal
ALL METHODS	5	-	-	-	5	-
Abbott Alinity	2	-	-	-	2	-
Abbott Architect	1	-	-	-	1	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Siemens ADVIA	1	-	-	-	1	-

Viral Markers – HBsAg

Method	VM-11 Positive	VM-11 Negative	VM-11 Equivocal	VM-12 Positive	VM-12 Negative	VM-12 Equivocal	VM-13 Positive	VM-13 Negative	VM-13 Equivocal
ALL METHODS	-	7	-	7	-	-	1	5	1
Abbott Alinity	-	2	-	2	-	-	1	1	-
Abbott Architect	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	1	-	1	-	-	-	-	1
Siemens ADVIA	-	2	-	2	-	-	-	2	-
VITROS 5600	-	1	-	1	-	-	-	1	-

Method	VM-14 Positive	VM-14 Negative	VM-14 Equivocal	VM-15 Positive	VM-15 Negative	VM-15 Equivocal
ALL METHODS	-	7	-	7	-	-
Abbott Alinity	-	2	-	2	-	-
Abbott Architect	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Siemens ADVIA	-	2	-	2	-	-
VITROS 5600	-	1	-	1	-	-

Viral Markers – Anti-HCV

Method	VM-11 Positive	VM-11 Negative	VM-11 Equivocal	VM-12 Positive	VM-12 Negative	VM-12 Equivocal	VM-13 Positive	VM-13 Negative	VM-13 Equivocal
ALL METHODS	2	9	-	-	11	-	-	11	-
Abbott Alinity	-	2	-	-	2	-	-	2	-
Abbott Architect	-	1	-	-	1	-	-	1	-
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-14 Positive	VM-14 Negative	VM-14 Equivocal	VM-15 Positive	VM-15 Negative	VM-15 Equivocal
ALL METHODS	-	11	-	-	11	-
Abbott Alinity	-	2	-	-	2	-
Abbott Architect	-	1	-	-	1	-
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	-