

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

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Medical Laboratory
Evaluation 

Immunology
2022 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/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
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 \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	$\pm 30\%$ or 2 SD*
High Sensitivity C-Reactive Protein	$\pm 30\%$ 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	$\pm 25\%$
Total IgM	± 3 SD

*Whichever is greater

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	94	1	1	94
Alere Clearview - moderate	1	-	-	1
Alere Clearview - waived	4	-	-	4
Alere Clearview Mono Plus II - waived	3	-	-	3
Beckman Coulter ICON Mono - waived	1	-	-	1
BioStar Aceava Mono-whole bld	2	-	-	2
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	13	-	-	13
Fisher HealthCare Sure-Vue	2	-	-	2
Henry Schein OneStep+ - moderate	2	-	-	2
Henry Schein OneStep+ - waived	9	1	1	9
Immunostics Inc.	1	-	-	1
LifeSign Status - waived	6	-	-	6
McKesson Medi-Lab Performance - waived	1	-	-	1
Other Waived method	5	-	-	5
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	2	-	-	2
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	28	-	-	28

Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-3</u>		<u>Specimen IM-4</u>		<u>Specimen IM-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	20	-	-	20	-	20
Alere Clearview - moderate	1	-	-	1	-	1
Alere Clearview Mono Plus II - waived	1	-	-	1	-	1
Consult Diagnostics - moderate	1	-	-	1	-	1
Consult Diagnostics - waived	1	-	-	1	-	1
Fisher HealthCare Sure-View	1	-	-	1	-	1
Henry Schein OneStep+ - moderate	2	-	-	2	-	2
Henry Schein OneStep+ - waived	3	-	-	3	-	3
LifeSign Status - waived	1	-	-	1	-	1
Other Waived method	1	-	-	1	-	1
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

<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	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	-

<u>Method</u>	Specimen RF-4		Specimen RF-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
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)

<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	-	-	5	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	5	-	-	-	-	-	-	-	-	-
Specimen RF-2												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	5	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-3												
ALL METHODS	-	5	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	5	-	-	-	-	-	-	-	-	-	-
Specimen RF-4												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	5	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-5												
ALL METHODS	-	-	5	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	5	-	-	-	-	-	-	-	-	-

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	12	117.3	3.6	3.1	120	106 - 129
Specimen RF-2						
All Method	12	7.7	3.9	50.9	9	0 - 20
Specimen RF-3						
All Method	12	61.4	1.7	2.7	63	56 - 67
Specimen RF-4						
All Method	12	6.6	4.4	66.5	4	0 - 20
Specimen RF-5						
All Method	12	116.0	3.8	3.3	118	104 - 128

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	4	-	4	-	4	-
ASI	4	-	4	-	4	-
<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	-	4	-	4		
ASI	-	4	-	4		

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	144.9	3.5	2.4	146	134 - 156
Beckman AU	5	144.8	3.9	2.7	145	133 - 157
Specimen IMP-2						
All Method	12	103.4	3.4	3.3	104	93 - 114
Beckman AU	5	105.0	2.8	2.7	105	96 - 114
Specimen IMP-3						
All Method	12	142.0	5.8	4.1	141	124 - 160
Beckman AU	5	141.2	7.0	5.0	138	120 - 163
Specimen IMP-4						
All Method	12	137.3	4.3	3.1	137	124 - 151
Beckman AU	5	136.6	5.3	3.9	135	120 - 153
Specimen IMP-5						
All Method	12	126.1	5.9	4.7	125	108 - 144
Beckman AU	5	127.4	7.0	5.5	124	106 - 149

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	12	25.1	1.6	6.2	26	20 - 30
Beckman AU	5	25.8	1.1	4.2	26	22 - 30
Specimen IMP-2						
All Method	12	18.6	1.2	6.4	19	15 - 23
Beckman AU	5	19.4	0.5	2.8	19	17 - 22
Specimen IMP-3						
All Method	12	24.1	1.5	6.0	25	19 - 29
Beckman AU	5	24.8	0.8	3.4	25	22 - 28
Specimen IMP-4						
All Method	12	24.1	1.8	7.5	25	18 - 30
Beckman AU	5	25.2	0.8	3.3	25	22 - 28
Specimen IMP-5						
All Method	12	21.3	1.7	7.9	22	16 - 27
Beckman AU	5	22.0	1.2	5.6	22	18 - 26

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	10	243.0	1.7	0.7	244	237 - 249
Specimen IMP-2						
All Method	10	150.0	6.1	4.1	153	131 - 169
Specimen IMP-3						
All Method	10	260.0	11.1	4.3	258	226 - 294
Specimen IMP-4						
All Method	10	556.7	32.3	5.8	565	459 - 654
Specimen IMP-5						
All Method	10	223.3	7.5	3.4	219	200 - 246

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	10	1099.3	35.0	3.2	1105	824 - 1375
Specimen IMP-2						
All Method	10	663.0	21.4	3.2	668	497 - 829
Specimen IMP-3						
All Method	10	1781.8	47.6	2.7	1776	1336 - 2228
Specimen IMP-4						
All Method	10	1024.3	37.9	3.7	1024	768 - 1281
Specimen IMP-5						
All Method	10	980.0	46.6	4.8	981	735 - 1225

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	10	91.7	1.2	1.3	91	88 - 96
Specimen IMP-2						
All Method	10	411.7	59.2	14.4	417	234 - 590
Specimen IMP-3						
All Method	10	91.7	2.5	2.7	92	84 - 100
Specimen IMP-4						
All Method	10	86.7	3.8	4.4	85	75 - 99
Specimen IMP-5						
All Method	10	79.7	2.1	2.6	79	73 - 86

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						
Beckman AU	5	2.716	0.292	10.8	2.80	1.90 - 3.54
All Immunology Methods	14	2.594	0.273	10.5	2.70	1.81 - 3.38
mg/L - units						
All Immunology Methods	12	28.283	4.791	16.9	26.29	18.70 - 37.87

Specimen CR-2

Beckman AU	5	0.162	0.193	119.1	0.10	0.00 - 0.55
All Immunology Methods	14	0.197	0.125	63.5	0.20	0.00 - 0.45
mg/L - units						
All Immunology Methods	12	2.341	1.937	82.7	1.42	0.00 - 6.22

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	17	0.904	0.251	27.8	0.90	0.00 - 1.91
Beckman AU	5	1.762	1.810	102.7	0.96	0.76 - 2.77
Specimen HCR-2						
All Method	18	6.593	0.538	8.2	6.45	4.61 - 8.58
Beckman AU	5	6.290	0.422	6.7	6.13	4.40 - 8.18

Antinuclear Antibody (ANA) - Qualitative

<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	10	1	-	11	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	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
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)

<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	-	-	-	-	-	-	3	1	-	-	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-	-
Specimen AE-2												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-3												
ALL METHODS	-	-	-	-	-	-	-	1	1	1	1	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	-	1	-	1	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-4												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-5												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
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	6	1	-	7	-	7
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	1	-	-	1	-	1
Phadia EliA	1	-	-	1	-	1
TheraTest	4	-	-	4	-	4

<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
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	4	-	4

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	-	2	2	-
Immuno Concepts	-	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	-	2	-	2
Immuno Concepts	-	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	4	2	-	6	6	-
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-
Immuno Concepts	-	1	-	1	1	-
TheraTest	4	-	-	4	4	-

<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
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	-	4	-	4

Specimen AE-1 is not graded 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	7	-	-	7	7	-
Immuno Concepts	1	-	-	1	1	-
Phadia EliA	1	-	-	1	1	-
TheraTest	5	-	-	5	5	-

<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
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	5	-	5

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	-	7	-	7	5	2
Immuno Concepts	-	1	-	1	-	1
Phadia EliA	-	1	-	1	1	-
TheraTest	-	5	-	5	4	1

<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
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	5	-	5

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
Immuno Concepts	-	1	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	-	4	-	4	-	4

<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
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	4	-	4

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	-
Siemens ADVIA Centaur	5	-	-	5	5	-

<u>Method</u>	Specimen RU-4		Specimen RU-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
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: 17.6 IU/mL, <10.0 IU/mL, 37.2 IU/mL, 61.1 IU/mL, and <10.0 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	53	-	13	40
Alere Determine - waived	12	-	11	1
bioLytical Labs INSTI HIV - moderate	2	-	-	2
bioLytical Labs INSTI HIV - waived	11	-	-	11
Chembio HIV 1/2 Assay - waived	13	-	-	13
Clearview HIV1/2 STAT-PAK	2	-	1	1
Orasure OraQuick Advance Rapid HIV-1/2 - waived	12	-	-	12
Other Waived method	1	-	1	-

<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
bioLytical Labs INSTI HIV - moderate	-	5	5	-	-	5

Allergen Specific IgE Antibodies

Specimen AL-1

<u>Method</u>	Common (Short) Ragweed (w1) Allergen CLASS RESULT								Sheep Sorrel (w18) 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	2	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	2	2	-	-	-	-	-	-	2	2	-	-	-	-

<u>Method</u>	Timothy Grass (g6) Allergen CLASS RESULT								Perennial Rye (g5) 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	-	-	-	1	2	1	-
Hitachi CLA-1	1	-	-	-	-	1	-	-	1	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	1	1	1	-	-	-	-	-	1	2	1	-

<u>Method</u>	White Oak (t7) Allergen CLASS RESULT								House Dust Mite (D. farinae) (d2) 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	2	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	2	2	-	-	-	-	-	-	-	2	2	-	-	-

<u>Method</u>	Dog Dander (e5) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	1	1	2	-	-	-
Hitachi CLA-1	1	-	-	-	1	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	1	1	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-2

<u>Method</u>	Bermuda Grass (g2) 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	-	-	-	1	2	-	-	-	-	-	-	-	-	1	1	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	2	-	-	-	-	-	-	-	-	1	1	-	-

	Maple (Sycamore) (t11) Allergen								Grey Alder (t2) 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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	1	-	-	-	-	-	-	-	1	1	-	-	-

	House Dust Mite (D. pteronyssinus) (d1) 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	-	-	-	2	1	2	-	-	-	-	2	1	1	1	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	1	-	-	1	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	1	-	-	-	-	-	1	1	1	-	-	-

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

Total IgE—Quantitative (U/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen AL-1						
All Method	5	195.3	7.0	3.6	196	174 - 217
Specimen AL-2						
All Method	5	116.3	2.5	2.2	116	108 - 124
Specimen AL-3						
All Method	5	18.7	2.9	15.5	17	10 - 28
Specimen AL-4						
All Method	5	8.0	3.5	43.3	6	0 - 19
Specimen AL-5						
All Method	5	82.7	0.6	0.7	83	80 - 85

Syphilis Serology—Qualitative: MHA-TP

<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	-	-	-	-	-	-

<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	-	-	-	-

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	8	-	7	1	7	1
Abbott Architect diagnostics direct Syphilis Health Check	1	-	1	-	1	-
Siemens ADVIA	5	-	4	1	4	1
	2	-	2	-	2	-

<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	1	7	1	7
Abbott Architect diagnostics direct Syphilis Health Check	-	1	-	1
Siemens ADVIA	1	4	1	4
	-	2	-	2

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	12	-	12	-	12	-
ASI	6	-	6	-	6	-
Becton Dickinson	3	-	3	-	3	-
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	-	12	-	12
ASI	-	6	-	6
Becton Dickinson	-	3	-	3
Fisher HealthCare Sure-Vue	-	3	-	3

Syphilis Serology—Semi-Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>N/A (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>
Specimen SY-1									
ALL METHODS	-	-	1	3	1	-	-	-	-
ASI	-	-	-	1	1	-	-	-	-
Becton Dickinson	-	-	1	1	-	-	-	-	-
Specimen SY-2									
ALL METHODS	-	-	1	3	-	1	-	-	-
ASI	-	-	-	2	-	-	-	-	-
Becton Dickinson	-	-	1	1	-	-	-	-	-
Specimen SY-3									
ALL METHODS	-	-	1	3	-	-	1	-	-
ASI	-	-	-	2	-	-	-	-	-
Becton Dickinson	-	-	1	1	-	-	-	-	-
Specimen SY-4									
ALL METHODS	5	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
Specimen SY-5									
ALL METHODS	5	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-

H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-1</u>		<u>Specimen HP-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	-	18
Alere Clearview - moderate	2	-	-	2
Alfa Scientific Instant-View	1	-	-	1
Consult Diagnostics - moderate	1	-	-	1
Consult Diagnostics - waived	1	-	-	1
Henry Schein OneStep+ - waived	5	-	-	5
NDC Pro Advantage	1	-	-	1
Other Waived method	1	-	-	1
Polymedco Poly stat	2	-	-	2
Quidel QuickVue	1	-	-	1
Sekisui OSOM	3	-	-	3

Mycoplasma Antibody

<u>Method</u>	<u>Specimen MY-1</u>		<u>Specimen MY-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	5	-
Meridian ImmunoCard	-	5	5	-

SARS-CoV-2 Serology

<u>Method</u>	<u>Specimen SAB-1</u>		<u>Specimen SAB-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	14	12	2
Abbott Alinity	-	1	1	-
Abbott Architect	-	2	2	-
Assure Tech	-	1	1	-
Beckman ACCESS / 2 / Dxl	-	2	-	2
Healgen Scientific	-	1	1	-
Other EUA method	-	1	1	-
Roche cobas 6000 / e 601	-	2	2	-
Roche cobas e 411	-	2	2	-
Siemens ADVIA	-	1	1	-
VITROS Eci	-	1	1	-

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	-	5	-	-	5	-	-	5	-
Abbott Alinity	-	2	-	-	2	-	-	2	-
Abbott Architect	-	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 Alinity	-	2	-	-	2	-
Abbott Architect	-	2	-	-	2	-
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	-	4	-	-	4	-	4	-	-
Abbott Alinity	-	2	-	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	2	-	-	2	-	2	-	-

<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	4	-	-	4	-	-
Abbott Alinity	2	-	-	2	-	-
Roche cobas 6000 / e 601	2	-	-	2	-	-

Viral Markers – Anti-HIV

<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	-	7	-	7	-	-	-	7	-
Abbott Alinity	-	2	-	2	-	-	-	2	-
Abbott Architect	-	2	-	2	-	-	-	2	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	-	2	-	2	-	-	-	2	-
Siemens ADVIA	-	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	-	7	-	-	7	-
Abbott Alinity	-	2	-	-	2	-
Abbott Architect	-	2	-	-	2	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	-	2	-	-	2	-
Siemens ADVIA	-	1	-	-	1	-

Viral Markers – Anti-HAV (IgM)

<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	-	4	-	-	4	-	-	4	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	1	-	-	1	-	-	1	-
VITROS 5600	-	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	-	4	-	-	4	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	1	-	-	1	-
VITROS 5600	-	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>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 Alinity	2	-	-	2	-	-	-	2	-
Siemens ADVIA	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 Alinity	-	2	-	-	2	-
Siemens ADVIA	-	1	-	-	1	-

Viral Markers – HBeAg

<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	-	-

<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	-

Viral Markers – Anti-HBs

<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	-	-	2	3	-
Abbott Alinity	2	-	-	2	-	-	-	2	-
Abbott Architect	1	-	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	1	-	-	1	-	-	1	-	-
Siemens ADVIA	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 Alinity	-	2	-	-	2	-
Abbott Architect	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	1	-	-	1	-
Siemens ADVIA	-	1	-	-	1	-

Specimen VM-3 is not graded due to lack of participant consensus.

Viral Markers – HBsAg

<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	-	6	1	-	7	-	6	-	1
Abbott Alinity	-	2	-	-	2	-	2	-	-
Abbott Architect	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	-	1	-	1	-	-
Siemens ADVIA	-	2	-	-	2	-	2	-	-
VITROS 5600	-	-	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	-	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

<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	-	12	-	-	12	-	-	12	-
Abbott Alinity	-	2	-	-	2	-	-	2	-
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	-

<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	-	12	-	-	12	-
Abbott Alinity	-	2	-	-	2	-
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	-

Medical Laboratory Evaluation

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