

# **MEDICAL LABORATORY**

# **EVALUATION**

## **PARTICIPANT SUMMARY**

**2 • 0 • 2 • 2**

Medical Laboratory  
Evaluation 

Immunology  
2022 MLE-M2

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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	$\pm 3$ SD
Complement C4	$\pm 3$ SD
C-Reactive Protein	$\pm 30\%$ or $2$ SD*
High Sensitivity C-Reactive Protein	$\pm 30\%$ or $1$ mg/L*
Rheumatoid Factor (International Units)	$\pm 3$ SD
Rubella (International Units)	$\pm 3$ SD
Total IgA	$\pm 3$ SD
Total IgE	$\pm 3$ SD
Total IgG	$\pm 25\%$
Total IgM	$\pm 3$ SD

\*Whichever is greater

## Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-6</u>		<u>Specimen IM-7</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	95	95	-
Alere Clearview - moderate	-	1	1	-
Alere Clearview - waived	-	4	4	-
Alere Clearview Mono Plus II - waived	-	1	1	-
Beckman Coulter ICON Mono - waived	-	1	1	-
BioStar Aceava Mono-whole bld	-	1	1	-
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	-	1	1	-
Henry Schein OneStep+ - moderate	-	2	2	-
Henry Schein OneStep+ - waived	-	13	13	-
Immunostics Inc.	-	1	1	-
LifeSign Status - waived	-	5	5	-
McKesson Medi-Lab Performance - waived	-	1	1	-
Other Waived method	-	4	4	-
Quidel QuickVue+	-	1	1	-
Quidel QuickVue+ - waived	-	2	2	-
Sekisui OSOM	-	4	4	-
Sekisui OSOM (waived)	-	30	30	-

## Infectious Mononucleosis

<b><u>Method</u></b>	<b>Specimen IM-8</b>		<b>Specimen IM-9</b>		<b>Specimen IM-10</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	-	19	19	-	19	-
Alere Clearview - moderate	-	1	1	-	1	-
Consult Diagnostics - moderate	-	2	2	-	2	-
Consult Diagnostics - waived	-	2	2	-	2	-
Henry Schein OneStep+ - moderate	-	2	2	-	2	-
Henry Schein OneStep+ - waived	-	3	3	-	3	-
Quidel QuickVue+	-	1	1	-	1	-
Quidel QuickVue+ - waived	-	1	1	-	1	-
Sekisui OSOM	-	4	4	-	4	-
Sekisui OSOM (waived)	-	3	3	-	3	-

## Rheumatoid Factor—Qualitative

<b><u>Method</u></b>	<b>Specimen RF-6</b>		<b>Specimen RF-7</b>		<b>Specimen RF-8</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	-	15	15	-	-	15
ASI	-	4	4	-	-	4
Biokit Rheumajet	-	1	1	-	-	1
Fisher HealthCare Sure-View	-	2	2	-	-	2
Phadia Elia	-	1	1	-	-	1
Stanbio Laboratory	-	2	2	-	-	2
TheraTest	-	4	4	-	-	4
Wampole Rheumatex	-	1	1	-	-	1

<b><u>Method</u></b>	<b>Specimen RF-9</b>		<b>Specimen RF-10</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	15	-	-	15
ASI	4	-	-	4
Biokit Rheumajet	1	-	-	1
Fisher HealthCare Sure-View	2	-	-	2
Phadia Elia	1	-	-	1
Stanbio Laboratory	2	-	-	2
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>&gt;2560</u>
<b>Specimen RF-6</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	5	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen RF-7</b>												
ALL METHODS	-	1	2	2	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	2	2	-	-	-	-	-	-	-	-
<b>Specimen RF-8</b>												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	5	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen RF-9</b>												
ALL METHODS	-	-	2	3	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	3	-	-	-	-	-	-	-	-
<b>Specimen RF-10</b>												
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>
<b>Specimen RF-6</b>						
All Method	12	8.6	4.5	51.8	10	0 - 23
<b>Specimen RF-7</b>						
All Method	12	115.5	6.0	5.2	117	97 - 134
<b>Specimen RF-8</b>						
All Method	12	8.5	4.7	54.8	10	0 - 23
<b>Specimen RF-9</b>						
All Method	12	63.5	2.3	3.6	63	56 - 71
<b>Specimen RF-10</b>						
All Method	12	8.6	4.5	51.8	10	0 - 23

## Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<u>Specimen AS-6</u>		<u>Specimen AS-7</u>		<u>Specimen AS-8</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-9</u>		<u>Specimen AS-10</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>
<b>Specimen IMP-6</b>						
All Method	10	133.4	4.5	3.4	132	119 - 148
<b>Specimen IMP-7</b>						
All Method	10	39.9	2.0	4.9	40	34 - 46
<b>Specimen IMP-8</b>						
All Method	10	122.0	5.0	4.1	123	106 - 138
<b>Specimen IMP-9</b>						
All Method	10	135.1	4.9	3.6	134	120 - 150
<b>Specimen IMP-10</b>						
All Method	10	209.9	12.3	5.8	211	173 - 247

**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>
<b>Specimen IMP-6</b>						
All Method	10	24.3	2.4	10.0	25	16 - 32
<b>Specimen IMP-7</b>						
All Method	10	6.9	1.5	21.3	8	2 - 12
<b>Specimen IMP-8</b>						
All Method	10	21.4	2.1	10.0	22	14 - 28
<b>Specimen IMP-9</b>						
All Method	10	24.0	2.3	9.6	25	17 - 31
<b>Specimen IMP-10</b>						
All Method	10	36.3	3.4	9.2	37	26 - 47

**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>
<b>Specimen IMP-6</b>						
All Method	10	536.5	51.6	9.6	537	381 - 692
<b>Specimen IMP-7</b>						
All Method	10	68.0	0.1	0.0	68	67 - 69
<b>Specimen IMP-8</b>						
All Method	10	222.0	8.5	3.8	222	196 - 248
<b>Specimen IMP-9</b>						
All Method	10	257.5	4.9	1.9	258	242 - 273
<b>Specimen IMP-10</b>						
All Method	10	373.0	8.5	2.3	373	347 - 399
<b>IgG (mg/dL)</b>						
<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen IMP-6</b>						
All Method	11	1008.3	16.3	1.6	1005	756 - 1261
Roche cobas 6000 / c 501	5	999.5	7.8	0.8	1000	749 - 1250
<b>Specimen IMP-7</b>						
All Method	11	300.7	7.1	2.4	302	225 - 376
Roche cobas 6000 / c 501	5	300.0	9.9	3.3	300	225 - 375
<b>Specimen IMP-8</b>						
All Method	11	941.0	7.5	0.8	942	705 - 1177
Roche cobas 6000 / c 501	5	937.5	6.4	0.7	938	703 - 1172
<b>Specimen IMP-9</b>						
All Method	11	1709.0	55.7	3.3	1736	1281 - 2137
Roche cobas 6000 / c 501	5	1741.0	7.1	0.4	1741	1305 - 2177
<b>Specimen IMP-10</b>						
All Method	11	1617.7	68.2	4.2	1645	1213 - 2023
Roche cobas 6000 / c 501	5	1656.5	16.3	1.0	1657	1242 - 2071

**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>
<b>Specimen IMP-6</b>						
All Method	10	83.0	1.4	1.7	83	78 - 88
<b>Specimen IMP-7</b>						
All Method	10	27.0	2.8	10.5	27	18 - 36
<b>Specimen IMP-8</b>						
All Method	10	77.5	2.1	2.7	78	71 - 84
<b>Specimen IMP-9</b>						
All Method	10	90.5	0.7	0.8	91	88 - 93
<b>Specimen IMP-10</b>						
All Method	10	133.0	1.4	1.1	133	128 - 138

**C-Reactive Protein—Qualitative, Regular**

<u>Method</u>	<u>Specimen CR-3</u>		<u>Specimen CR-4</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>
<b>Specimen CR-3</b>						
mg/dL - units						
All Immunology Methods	12	1.243	0.153	12.3	1.18	0.87 - 1.62
mg/L - units						
All Immunology Methods	13	12.375	1.587	12.8	12.03	8.66 - 16.09

**Specimen CR-4**

Beckman AU						
All Immunology Methods	12	6.263	0.371	5.9	6.17	4.38 - 8.15
mg/L - units						
All Immunology Methods	13	61.145	3.680	6.0	61.35	42.80 - 79.49

**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>
<b>Specimen HCR-3</b>						
All Method	16	12.021	1.428	11.9	12.08	8.41 - 15.63
<b>Specimen HCR-4</b>						
All Method	16	0.873	0.305	35.0	0.90	0.00 - 1.88

## Antinuclear Antibody (ANA) - Qualitative

<b><u>Method</u></b>	<b>Specimen AE-6</b>		<b>Specimen AE-7</b>		<b>Specimen AE-8</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	10	-	-	10	2	8
Bio-Rad	1	-	-	1	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1
Immuno Concepts	4	-	-	4	-	4
INOVA Diagnostics	1	-	-	1	-	1
TheraTest	3	-	-	3	2	1

<b><u>Method</u></b>	<b>Specimen AE-9</b>		<b>Specimen AE-10</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	10	-	-	8
Bio-Rad	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1
Immuno Concepts	4	-	-	2
INOVA Diagnostics	1	-	-	1
TheraTest	3	-	-	3

**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>&gt;640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
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**Specimen AE-6**

ALL METHODS	-	-	-	-	-	-	-	-	1	1	2	1
Bio-Rad	-	-	-	-	-	-	-	-	-	1	1	-
Immuno Concepts	-	-	-	-	-	-	-	-	1	-	1	1

**Specimen AE-7**

ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-

**Specimen AE-8**

ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-

**Specimen AE-9**

ALL METHODS	-	-	-	-	-	-	1	-	-	2	1	1
Bio-Rad	-	-	-	-	-	-	-	-	-	1	1	-
Immuno Concepts	-	-	-	-	-	-	1	-	-	1	-	1

**Specimen AE-10**

ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-

## Anti-dsDNA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	-	6	-	6
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	1	-	1	-	1
Phadia Elia	-	1	-	1	-	1
TheraTest	-	3	-	3	-	3

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<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
Phadia Elia	-	1	-	1
TheraTest	-	3	-	3

## Anti-RNP

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<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-9		Specimen AE-10	
	<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-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5	-	5
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1
Immuno Concepts	1	-	-	1	-	1
TheraTest	3	-	-	3	-	3

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	-	3	-	3

**Anti-SSA**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5	-	5
Immuno Concepts	-	1	-	1	-	1
Phadia ELIA	-	1	-	1	-	1
TheraTest	-	3	-	3	-	3

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5
Immuno Concepts	1	-	-	1
Phadia ELIA	1	-	-	1
TheraTest	3	-	-	3



## Anti-SSB

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5	-	5
Immuno Concepts	-	1	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	-	3	-	3	-	3

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	1	-	5
Immuno Concepts	1	-	-	1
Phadia EliA	1	-	-	1
TheraTest	2	1	-	3

## Anti-SSA/SSB

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<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-9		Specimen AE-10	
	<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-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	1	-	5	1	4
Immuno Concepts	1	-	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	3	-	-	3	1	2

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	3	-	3

## Rubella—Qualitative

<u>Method</u>	Specimen RU-6		Specimen RU-7		Specimen RU-8	
	<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-9		Specimen RU-10	
	<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-6 through RU-10 are: <10.0 IU/mL, 43.9 IU/mL, <10.0 IU/mL, 43.9 IU/mL, and 76.3 IU/mL, respectively.

## Anti-HIV

<u>Method</u>	Specimen HIV-6		Specimen HIV-7	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	57	56	1
Alere Determine - moderate	-	2	2	-
Alere Determine - waived	-	10	10	-
bioLytical Labs INSTI HIV - moderate	-	1	1	-
bioLytical Labs INSTI HIV - waived	-	14	14	-
Chembio HIV 1/2 Assay - waived	-	14	14	-
Clearview HIV1/2 STAT-PAK	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	12	11	1
Other Waived method	-	3	3	-

<u>Method</u>	Specimen HIV-8		Specimen HIV-9		Specimen HIV-10	
	<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	-	1	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	4	-	4	4	-

## Allergen Specific IgE Antibodies

### Specimen AL-6

<b><u>Method</u></b>	<b>House Dust Mite (D. pteronyssinus) (d1) Allergen</b>							<b>Natural Latex (k82) Allergen</b>								
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>								
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	2	3	-	-	-	-	2	1	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	3	-	-	-	-	2	1	-	-	-	-	-

	<b>Hazel Tree (t4) Allergen</b>							<b>Silver Birch Tree (t3) Allergen</b>								
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>								
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	-	-	-	-	1	-	-	2	2	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	-	-	-	-	-	-	-	2	2	-	-	-

	<b>Olive Tree (t9) Allergen</b>							<b>Shrimp (f24) Allergen</b>								
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>								
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	2	2	-	-	-	-	-	-	3	2	-	-	-	-
Hitachi CLA-1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	2	2	-	-	-	-	-	-	3	2	-	-	-	-

	<b>Soybean (f14) Allergen</b>							
	<b>CLASS RESULT</b>							
	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	1	2	1	-	-	-
Hitachi CLA-1	1	-	-	-	1	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	2	-	-	-	-

# Allergen Specific IgE Antibodies

## Specimen AL-7

<b><u>Method</u></b>	<b>Sweet Vernal Grass (g1) Allergen</b>								<b>Timothy Grass (g6) Allergen</b>								
	<b>CLASS RESULT</b>								<b>CLASS RESULT</b>								
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6	
ALL METHODS	-	-	-	-	2	3	-	-	-	-	-	-	-	1	3	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	-	-	-	2	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	2	1	-	-	-	-	-	-	-	1	1	-	-

  

	<b>Orchard Grass (Cocksfoot) (g3) Allergen</b>								<b>Dog Dander (e5) Allergen</b>							
	<b>CLASS RESULT</b>								<b>CLASS RESULT</b>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	2	1	2	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	-	-	-	-	-	-	-	2	1	-	-	-

  

	<b>Cat Epithelium (e1) Allergen</b>								<b>Apple (f49) Allergen</b>							
	<b>CLASS RESULT</b>								<b>CLASS RESULT</b>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	2	1	2	-	-	1	-	2	2	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	1	-	-	1	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	1	-	-	-	-	-	2	1	-	-	-	-

  

	<b>Cow Milk (f2) Allergen</b>							
	<b>CLASS RESULT</b>							
	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	-	2	1	1	-	-
Hitachi CLA-1	1	-	-	-	-	1	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	1	-	-	-

**Total IgE—Quantitative (U/mL)**

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen AL-6</b>						
All Method	6	181.3	7.0	3.9	182	160 - 203
<b>Specimen AL-7</b>						
All Method	6	175.7	4.0	2.3	175	163 - 188
<b>Specimen AL-8</b>						
All Method	6	18.0	1.0	5.6	18	15 - 21
<b>Specimen AL-9</b>						
All Method	6	85.0	3.0	3.5	85	76 - 94
<b>Specimen AL-10</b>						
All Method	6	17.7	0.6	3.3	18	15 - 20

**Syphilis Serology—Qualitative: MHA-TP**

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<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-9		Specimen SY-10	
	<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-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	8	-	8	8	-
Abbott Architect diagnostics direct Syphilis Health Check	-	1	-	1	1	-
Siemens ADVIA	-	5	-	5	5	-
	-	2	-	2	2	-

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	8	-	8	-
Abbott Architect diagnostics direct Syphilis Health Check	1	-	1	-
Siemens ADVIA	5	-	5	-
	2	-	2	-

**Syphilis Serology—Qualitative: RPR**

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	10	-	10	10	-
ASI	-	5	-	5	5	-
Becton Dickinson	-	1	-	1	1	-
Fisher HealthCare Sure-View	-	3	-	3	3	-
Gold Standard Diagnostics AIX1000	-	1	-	1	1	-

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	9	1	9	1
ASI	4	1	4	1
Becton Dickinson	1	-	1	-
Fisher HealthCare Sure-View	3	-	3	-
Gold Standard Diagnostics AIX1000	1	-	1	-

**Syphilis Serology—Semi-Quantitative: RPR (Titer)**

**Specimen/Method**      **N/A**    **1:1**    **1:2**    **1:4**    **1:8**    **1:16**    **1:32**    **1:64**    **1:>64**  
**(Neg)**

**Specimen SY-6**

ALL METHODS	5	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson Gold Standard	1	-	-	-	-	-	-	-	-
Diagnostics AIX1000	1	-	-	-	-	-	-	-	-

**Specimen SY-7**

ALL METHODS	5	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson Gold Standard	1	-	-	-	-	-	-	-	-
Diagnostics AIX1000	1	-	-	-	-	-	-	-	-

**Specimen SY-8**

ALL METHODS	-	2	3	-	-	-	-	-	-
ASI	-	1	1	-	-	-	-	-	-
Becton Dickinson Gold Standard	-	-	1	-	-	-	-	-	-
Diagnostics AIX1000	-	1	-	-	-	-	-	-	-

**Specimen SY-9**

ALL METHODS	-	-	2	2	1	-	-	-	-
ASI	-	-	1	-	1	-	-	-	-
Becton Dickinson Gold Standard	-	-	-	1	-	-	-	-	-
Diagnostics AIX1000	-	-	-	1	-	-	-	-	-

**Specimen SY-10**

ALL METHODS	1	1	3	-	-	-	-	-	-
ASI	1	-	1	-	-	-	-	-	-
Becton Dickinson Gold Standard	-	-	1	-	-	-	-	-	-
Diagnostics AIX1000	-	1	-	-	-	-	-	-	-

## H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-3</u>		<u>Specimen HP-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	16	1
Alere Clearview - moderate	-	1	1	-
Consult Diagnostics - moderate	-	1	1	-
Henry Schein OneStep+ - waived	-	5	5	-
LifeSign Status	-	1	1	-
NDC Pro Advantage	-	1	1	-
Polymedco Poly stat	-	2	2	-
Quidel QuickVue	-	1	1	-
Sekisui OSOM	-	5	4	1

## Mycoplasma Antibody

<u>Method</u>	<u>Specimen MY-3</u>		<u>Specimen MY-4</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-3</u>		<u>Specimen SAB-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	1	-	14
Abbott Alinity	1	-	-	1
Abbott Architect	2	-	-	2
Beckman ACCESS / 2 / Dxl	1	1	-	2
Healgen Scientific	1	-	-	1
Premier Biotech RightSign	2	-	-	2
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)**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	5	-	-	5	-	-	5	-
Abbott Alinity	-	2	-	-	2	-	-	2	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	5	-	-	5	-
Abbott Alinity	-	2	-	-	2	-
Abbott Architect	-	1	-	-	1	-
Siemens ADVIA	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-

**Viral Markers – Anti-HBc (Total/IgG)**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	5	-	-	5	-	5	-	-
Abbott Alinity	-	2	-	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	3	-	-	3	-	3	-	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	5	-	-	5	-
Abbott Alinity	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	3	-	-	3	-

## Viral Markers – Anti-HIV

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</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	10	-	-	2	8	-	-	10	-
Abbott Alinity	3	-	-	-	3	-	-	3	-
Abbott Architect	2	-	-	1	1	-	-	2	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	4	-	-	-	4	-	-	4	-
Siemens ADVIA	1	-	-	1	-	-	-	1	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	10	-	-	10	-
Abbott Alinity	-	3	-	-	3	-
Abbott Architect	-	2	-	-	2	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	-	4	-	-	4	-
Siemens ADVIA	-	1	-	-	1	-

## Viral Markers – Anti-HAV (IgM)

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</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 Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	-	-	-	5	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	1	-	-	-	1	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Siemens ADVIA	1	-	-	-	1	-
VITROS 5600	1	-	-	-	1	-

**Viral Markers – Anti-HAV (Total/IgG)**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	5	-	-	-	5	-	-	5	-
Abbott Alinity	3	-	-	-	3	-	-	3	-
Siemens ADVIA	2	-	-	-	2	-	-	2	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	5	-	-	5	-	-
Abbott Alinity	3	-	-	3	-	-
Siemens ADVIA	2	-	-	2	-	-

**Viral Markers – HBeAg**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	1	-	-	1	-	1	-	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	1	-	-	1	-

**Viral Markers – Anti-HBs**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
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	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
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

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</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	-	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-9</u>			<u>Specimen VM-10</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-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</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	-	-	2	10	-
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-9</u>			<u>Specimen VM-10</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	-

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