

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

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Medical Laboratory
Evaluation 

Immunology
2022 MLE-M3

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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-11</u>		<u>Specimen IM-7</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	91	1	-	92
Alere Clearview - moderate	-	1	-	1
Alere Clearview - waived	3	-	-	3
Alere Clearview Mono Plus II - waived	1	-	-	1
Beckman Coulter ICON Mono - waived	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	14	-	-	14
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+ - waived	1	-	-	1
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	30	-	-	30

Infectious Mononucleosis

<u>Method</u>	Specimen IM-13		Specimen IM-14		Specimen IM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	-	18	17	1
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	-
Sekisui OSOM	4	-	-	4	4	-
Sekisui OSOM (waived)	4	-	-	4	4	-

Rheumatoid Factor—Qualitative

<u>Method</u>	<u>Specimen RF-11</u>		<u>Specimen RF-12</u>		<u>Specimen RF-13</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	-	16	-	16
ASI	4	-	-	4	-	4
Biokit Rheumajet	1	-	-	1	-	1
Fisher HealthCare Sure-View	2	-	-	2	-	2
Phadia ELIA	1	-	-	1	-	1
Stanbio Laboratory	3	-	-	3	-	3
TheraTest	4	-	-	4	-	4
Wampole Rheumatex	1	-	-	1	-	1

<u>Method</u>	<u>Specimen RF-14</u>		<u>Specimen RF-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16	-
ASI	4	-	4	-
Biokit Rheumajet	1	-	1	-
Fisher HealthCare Sure-View	2	-	2	-
Phadia ELIA	1	-	1	-
Stanbio Laboratory	3	-	3	-
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-11												
ALL METHODS	-	-	-	-	5	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	-	2	-	-	-	-	-	-	-
Specimen RF-12												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-13												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-14												
ALL METHODS	-	-	-	-	-	3	2	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	1	-	-	-	-	-
Specimen RF-15												
ALL METHODS	-	-	-	-	1	2	2	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	-	1	-	1	-	-	-	-	-

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-11						
All Method	11	64.3	1.6	2.5	65	59 - 69
Specimen RF-12						
All Method	11	9.3	3.7	39.5	10	0 - 21
Specimen RF-13						
All Method	11	9.1	3.6	39.9	10	0 - 21
Specimen RF-14						
All Method	11	110.8	4.1	3.7	111	98 - 123
Specimen RF-15						
All Method	11	64.4	1.5	2.3	65	59 - 69

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<u>Specimen AS-11</u>		<u>Specimen AS-12</u>		<u>Specimen AS-13</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-14</u>		<u>Specimen AS-15</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-11						
All Method	10	99.8	8.0	8.1	101	75 - 124
Specimen IMP-12						
All Method	10	141.0	6.2	4.4	141	122 - 160
Specimen IMP-13						
All Method	10	23.4	3.5	15.0	23	12 - 34
Specimen IMP-14						
All Method	10	38.5	3.1	8.2	40	29 - 48
Specimen IMP-15						
All Method	10	235.7	15.8	6.7	229	188 - 283

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-11						
All Method	10	19.2	1.6	8.6	20	14 - 25
Specimen IMP-12						
All Method	10	24.0	2.2	9.1	25	17 - 31
Specimen IMP-13						
All Method	10	6.7	2.2	32.4	8	0 - 14
Specimen IMP-14						
All Method	10	7.0	1.5	22.1	8	2 - 12
Specimen IMP-15						
All Method	10	40.3	1.9	4.6	41	34 - 46

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-11						
All Method	10	134.0	5.7	4.2	134	117 - 151
Specimen IMP-12						
All Method	10	247.0	4.2	1.7	247	234 - 260
Specimen IMP-13						
All Method	10	46.0	5.7	12.3	46	29 - 63
Specimen IMP-14						
All Method	10	65.5	7.8	11.9	66	42 - 89
Specimen IMP-15						
All Method	10	399.5	2.1	0.5	400	393 - 406
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-11						
All Method	11	680.7	20.8	3.1	685	510 - 851
Roche cobas 6000 / c 501	5	671.5	19.1	2.8	672	503 - 840
Specimen IMP-12						
All Method	11	1749.0	35.6	2.0	1752	1311 - 2187
Roche cobas 6000 / c 501	5	1767.5	21.9	1.2	1768	1325 - 2210
Specimen IMP-13						
All Method	11	173.0	10.4	6.0	178	129 - 217
Roche cobas 6000 / c 501	5	169.5	12.0	7.1	170	127 - 212
Specimen IMP-14						
All Method	11	295.7	6.4	2.1	292	221 - 370
Roche cobas 6000 / c 501	5	297.5	7.8	2.6	298	223 - 372
Specimen IMP-15						
All Method	11	1819.3	56.6	3.1	1804	1364 - 2275
Roche cobas 6000 / c 501	5	1827.0	77.8	4.3	1827	1370 - 2284

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-11						
All Method	10	455.5	13.4	2.9	456	415 - 496
Specimen IMP-12						
All Method	10	89.5	3.5	4.0	90	78 - 101
Specimen IMP-13						
All Method	10	22.5	3.5	15.7	23	11 - 34
Specimen IMP-14						
All Method	10	26.0	1.4	5.4	26	21 - 31
Specimen IMP-15						
All Method	10	143.5	9.2	6.4	144	115 - 172

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	Specimen CR-3		Specimen CR-6	
	<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-5						
mg/dL - units						
All Immunology Methods	12	0.206	0.139	67.5	0.20	0.00 - 0.49
mg/L - units						
All Immunology Methods	12	1.978	1.997	101.0	0.80	0.00 - 5.98

Specimen CR-6

Beckman AU						
All Immunology Methods	12	2.632	0.255	9.7	2.61	1.84 - 3.43
mg/L - units						
All Immunology Methods	11	26.965	4.455	16.5	25.40	18.05 - 35.88

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-5						
All Method	16	3.101	0.970	31.3	3.00	2.10 - 4.11
Specimen HCR-6						
All Method	14	11.643	0.562	4.8	11.52	8.14 - 15.14

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	10	10	-	9	1
Bio-Rad	-	1	1	-	1	-
GenBio ImmunoDOT Panel 1	-	1	1	-	1	-
Immuno Concepts	-	2	2	-	2	-
INOVA Diagnostics	-	1	1	-	-	1
TheraTest	-	3	3	-	3	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	10	10	-
Bio-Rad	-	1	1	-
GenBio ImmunoDOT Panel 1	-	1	1	-
Immuno Concepts	-	2	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>>640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
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Specimen AE-11

ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-12

ALL METHODS	-	-	-	-	-	-	-	2	-	3	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	-	1	-	-

Specimen AE-13

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

Specimen AE-14

ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-15

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

Anti-dsDNA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	10	10	-	8	2
GenBio ImmunoDOT Panel 1	-	1	1	-	-	1
Immuno Concepts	-	1	1	-	1	-
Phadia Elia	-	1	1	-	1	-
TheraTest	-	3	3	-	2	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	10	-	10
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
Phadia Elia	-	1	-	1
TheraTest	-	3	-	3

Anti-RNP

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<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-14		Specimen AE-15	
	<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-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	4	1	5	-
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-
Immuno Concepts	-	1	1	-	1	-
TheraTest	-	3	3	-	3	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<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-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	5	-	3	2
Immuno Concepts	-	1	1	-	-	1
Phadia ELIA	-	1	1	-	-	1
TheraTest	-	3	3	-	3	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<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-11		Specimen AE-12		Specimen AE-13	
	<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-14		Specimen AE-15	
	<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-SSA/SSB

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<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-14		Specimen AE-15	
	<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-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	2	4	5	1
Immuno Concepts	-	1	1	-	1	-
Phadia EliA	-	1	1	-	-	1
TheraTest	-	3	-	3	3	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	4	2
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	3	3	-

Specimen AE-12 is an ungraded challenge due to lack of participant consensus.

Rubella—Qualitative

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<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	5	-	-	5	5	-

<u>Method</u>	Specimen RU-14		Specimen RU-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	5	-
Siemens ADVIA	-	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: 58.6 IU/mL, <10.0 IU/mL, 43.7 IU/mL, <10.0 IU/mL, and 43.7 IU/mL, respectively.

Anti-HIV

<u>Method</u>	Specimen HIV-11		Specimen HIV-12	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	60	1	1	60
Alere Determine - moderate	2	-	-	2
Alere Determine - waived	10	-	-	10
BD LINK 2	1	-	-	1
bioLytical Labs INSTI HIV - moderate	2	-	-	2
bioLytical Labs INSTI HIV - waived	17	-	-	17
Chembio HIV 1/2 Assay - waived	13	-	-	13
Orasure OraQuick Advance Rapid HIV-1/2 - waived	12	-	-	12
Other Waived method	3	1	1	3

<u>Method</u>	Specimen HIV-13		Specimen HIV-14		Specimen HIV-15	
	<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	3	-	-	3	-	3
Orasure OraQuick Advance Rapid HIV-1/2 - waived	2	-	-	2	-	2

Allergen Specific IgE Antibodies

Specimen AL-11

Method

ALL METHODS
Hitachi CLA-1
Phadia ImmunoCAP System (KU/L)

Cat Epithelium (e1) 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
-	-	-	3	1	1	-	-	-	-	-	3	2	-	-	-
-	-	-	-	1	1	-	-	-	-	-	-	2	-	-	-
-	-	-	3	-	-	-	-	-	-	-	3	-	-	-	-

ALL METHODS
Hitachi CLA-1
Phadia ImmunoCAP System (KU/L)

Cladosporium herbarum (m2) Allergen CLASS RESULT								Aspergillus fumigatus (m3) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
2	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-
1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-

ALL METHODS
Hitachi CLA-1
Phadia ImmunoCAP System (KU/L)

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
-	-	1	2	-	-	-	-	-	-	1	1	1	-	-	-
-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-
-	-	1	1	-	-	-	-	-	-	1	1	-	-	-	-

ALL METHODS
Hitachi CLA-1
Phadia ImmunoCAP System (KU/L)

Soybean (f14) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6
1	2	-	-	-	-	-	-
1	-	-	-	-	-	-	-
-	2	-	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-12

<u>Method</u>	Sweet Vernal Grass (g1) Allergen								Meadow, Kentucky Blue, June Grass (g8) Allergens							
	<i>CLASS RESULT</i>								<i>CLASS RESULT</i>							
	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	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	1	1	-	-	-	-	-	-	1	1	-	-
<u>Method</u>	Common (Short) Ragweed (w1) Allergen								House Dust Mite (D. farinae) (d2) Allergen							
	<i>CLASS RESULT</i>								<i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	2	2	-	-	-	-	-	-	-	1	1	1	-	-
Hitachi CLA-1	1	-	1	-	-	-	-	-	-	-	-	-	-	1	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	2	-	-	-	-	-	-	-	1	1	-	-	-
<u>Method</u>	Peanut (f13) Allergen								Crab (f23) Allergen							
	<i>CLASS RESULT</i>								<i>CLASS RESULT</i>							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	2	1	-	-	-	-	1	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	2	-	-	-	-	-	1	1	-	-	-	-
<u>Method</u>	Lobster (f80) Allergen															
	<i>CLASS RESULT</i>															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	-	-	1	1	-	-	-	-								
Hitachi CLA-1	-	-	-	-	-	-	-	-								
Phadia ImmunoCAP System (KU/L)	-	-	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-11						
All Method	6	383.3	24.7	6.4	395	309 - 458
Specimen AL-12						
All Method	6	359.7	32.1	8.9	373	263 - 457
Specimen AL-13						
All Method	6	7.3	0.6	7.9	7	5 - 10
Specimen AL-14						
All Method	6	16.0	1.0	6.3	16	13 - 19
Specimen AL-15						
All Method	6	16.3	1.2	7.1	17	12 - 20

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<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-14		Specimen SY-15	
	<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-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	9	-	v	8	9	-
Abbott Architect diagnostics direct Syphilis Health Check	1	-	-	1	1	-
Siemens ADVIA	6	-	-	5	6	-
	2	-	-	2	2	-

<u>Method</u>	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	9	-	-	9
Abbott Architect diagnostics direct Syphilis Health Check	1	-	-	1
Siemens ADVIA	6	-	-	6
	2	-	-	2

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	9	-	-	9	9	-
ASI	5	-	-	5	5	-
Fisher HealthCare Sure-Vue Gold Standard Diagnostics AIX1000	3	-	-	3	3	-
	1	-	-	1	1	-

<u>Method</u>	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	9	-	-	9
ASI	5	-	-	5
Fisher HealthCare Sure-Vue Gold Standard Diagnostics AIX1000	3	-	-	3
	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-11

SY-11	-	2	2	1	-	-	-	-	-
ALL METHODS	-	1	-	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-
Gold Standard									
Diagnostics AIX1000	-	2	2	1	-	-	-	-	-

Specimen SY-12

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

Specimen SY-13

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

Specimen SY-14

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

Specimen SY-15

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

H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-5</u>		<u>Specimen HP-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	3	1	19
Alere Clearview - moderate	1	-	-	1
Consult Diagnostics - moderate	1	-	-	1
Henry Schein OneStep+ - waived	5	1	-	6
NDC Pro Advantage	-	1	1	-
Other Waived method	1	-	-	1
Polymedco Poly stat	2	-	-	2
Quidel QuickVue	3	-	-	3
Sekisui OSOM	4	1	-	5

Mycoplasma Antibody

<u>Method</u>	<u>Specimen MY-5</u>		<u>Specimen MY-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	1	1	4
Meridian ImmunoCard	4	1	1	4

SARS-CoV-2 Serology

<u>Method</u>	<u>Specimen SAB-5</u>		<u>Specimen SAB-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	11	11	-
Abbott Alinity	-	1	1	-
Abbott Architect	-	1	1	-
Beckman ACCESS / 2 / Dxl	-	2	2	-
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-11			Specimen VM-12			Specimen VM-13		
	<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	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<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	-	-
Siemens ADVIA	-	1	-	1	-	-
VITROS 5600	-	1	-	1	-	-

Viral Markers – Anti-HBc (Total/IgG)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	-
Roche cobas 6000 / e 601	1	-	-	-	1	-	-	1	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<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	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-

Viral Markers – Anti-HIV

<u>Method</u>	<u>Specimen VM-11</u>			<u>Specimen VM-12</u>			<u>Specimen VM-13</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-14</u>			<u>Specimen VM-15</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-11</u>			<u>Specimen VM-12</u>			<u>Specimen VM-13</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-14</u>			<u>Specimen VM-15</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)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	-	-
Siemens ADVIA	-	1	-	-	1	-	1	-	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<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	-
Siemens ADVIA	-	1	-	-	1	-

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-	1	-	-
Siemens ADVIA	-	1	-	1	-	-	1	-	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<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	-

Viral Markers – HBsAg

<u>Method</u>	<u>Specimen VM-11</u>			<u>Specimen VM-12</u>			<u>Specimen VM-13</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	-	-	4	3	-	-	7	-
Abbott Alinity	2	-	-	2	-	-	-	2	-
Abbott Architect	1	-	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	1	-	-	-	1	-	-	1	-
Siemens ADVIA	2	-	-	1	1	-	-	2	-
VITROS 5600	1	-	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-14</u>			<u>Specimen VM-15</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	-	-

Specimen VM-12 is an ungraded challenge due to lack of participant consensus.

Viral Markers – Anti-HCV

<u>Method</u>	<u>Specimen VM-11</u>			<u>Specimen VM-12</u>			<u>Specimen VM-13</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	-	13	-	12	1	-	-	13	-
Abbott Alinity	-	2	-	1	1	-	-	2	-
Abbott Architect	-	3	-	3	-	-	-	3	-
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-14</u>			<u>Specimen VM-15</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	13	-	1	11	1
Abbott Alinity	-	2	-	-	2	-
Abbott Architect	-	3	-	-	3	-
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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