

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Immunology
2018 MLE-M3

ACP | Medical Laboratory
Evaluation



Total Commitment to Education and Service
Provided by ACP, Inc.

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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
<i>H. 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
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 3 SD
High Sensitivity C-Reactive Protein	\pm 3 SD
Rheumatoid Factor (International Units)	\pm 2 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

Infectious Mononucleosis

<u>Method</u>	Specimen IM-11		Specimen IM-12	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	164	2	3	163
Alere Clearview - moderate	2	-	-	2
Alere Clearview - waived	7	1	1	7
Alere Clearview Mono Plus II - moderate	1	-	-	1
Alere Clearview Mono Plus II - waived	3	-	-	3
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	9	-	-	9
BioStar Acceava Mono Test	1	-	-	1
BioStar Acceava Mono-whole bld	4	-	-	4
BTNX Rapid Response – moderate	1	-	-	1
Cardinal Health SP Brand - waived	6	-	-	6
Clarity Diagnostics	1	-	-	1
Consult Diagnostics	23	-	1	22
Fisher HealthCare Sure-Vue	5	-	-	5
Henry Schein OneStep+ - waived	17	-	-	17
LifeSign Status - waived	6	-	-	6
McKesson Medi-Lab Performance - waived	1	-	-	1
Other Moderate method	3	-	-	3
Other Waived method	11	1	1	11
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	4	-	-	4
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	52	-	-	52
Serodyn	1	-	-	1

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	48	-	-	48	48	-
Alere Clearview - moderate	2	-	-	2	2	-
Alere Clearview Mono Plus II - moderate	1	-	-	1	1	-
ASI	1	-	-	1	1	-
Beckman Coulter ICON Mono - waived	9	-	-	9	9	-
BioStar Acceava Mono-whole bld	2	-	-	2	2	-
BTNX Rapid Response – moderate	1	-	-	1	1	-
Consult Diagnostics	7	-	-	7	7	-
Fisher HealthCare Sure-Vue	2	-	-	2	2	-
Henry Schein OneStep+ - waived	4	-	-	4	4	-
LifeSign Status - waived	1	-	-	1	1	-
Other Moderate method	3	-	-	3	3	-
Other Waived method	2	-	-	2	2	-
Quidel QuickVue+	1	-	-	1	1	-
Quidel QuickVue+ - waived	2	-	-	2	2	-
Sekisui OSOM	4	-	-	4	4	-
Sekisui OSOM (waived)	5	-	-	5	5	-
Seradyn	1	-	-	1	1	-

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-11		Specimen RF-12		Specimen RF-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	30	-	30	30	-
ASI	-	7	-	7	7	-
Beckman AU	-	1	-	1	1	-
Biokit Rheumajet	-	2	-	2	2	-
Diamedix	-	1	-	1	1	-
Fisher HealthCare Sure-Vue	-	4	-	4	4	-
Immunostics Inc.	-	1	-	1	1	-
INOVA Diagnostics	-	1	-	1	1	-
TheraTest	-	5	-	5	5	-
Wampole ColorCard	-	4	-	4	4	-
Wampole Rheumatex	-	4	-	4	4	-

<u>Method</u>	Specimen RF-14		Specimen RF-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	30	30	-
ASI	-	7	7	-
Beckman AU	-	1	1	-
Biokit Rheumajet	-	2	2	-
Diamedix	-	1	1	-
Fisher HealthCare Sure-Vue	-	4	4	-
Immunostics Inc.	-	1	1	-
INOVA Diagnostics	-	1	1	-
TheraTest	-	5	5	-
Wampole ColorCard	-	4	4	-
Wampole Rheumatex	-	4	4	-

Rheumatoid Factor—Semi-Quantitative (Titer)

<u>Specimen/Method</u>	N/A (Neg)	2/ <u>4</u>	8/ <u>10</u>	16/ <u>20</u>	32/ <u>40</u>	64/ <u>80</u>	128/ <u>160</u>	256/ <u>320</u>	512/ <u>640</u>	1024/ <u>1280</u>	2048/ <u>2560</u>	>2560
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Specimen RF-11

ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-

Specimen RF-12

ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-

Specimen RF-13

ALL METHODS	-	1	1	2	-	-	-	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-	-
Beckman AU	-	-	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	1	-	-	-	-	-	-	-	-	-

Specimen RF-14

ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-

Specimen RF-15

ALL METHODS	-	-	1	2	-	1	-	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-	-
Beckman AU	-	-	-	-	-	-	1	-	-	-	-	-
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	13	6.8	4.1	59.9	6	0 - 16
Specimen RF-12						
All Method	13	6.9	4.1	59.7	5	0 - 16
Specimen RF-13						
All Method	12	61.3	4.7	7.7	62	51 - 71
Specimen RF-14						
All Method	13	6.9	4.1	59.4	6	0 - 16
Specimen RF-15						
All Method	12	107.3	5.8	5.4	109	95 - 119

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	Specimen AS-11		Specimen AS-12		Specimen AS-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	-	-	1	1	-
Method						
<u>Method</u>	Specimen AS-14		Specimen AS-15			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	1	1	-		

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	13	157.2	11.5	7.3	156	122 - 192
Specimen IMP-12						
All Method	13	179.3	4.6	2.6	178	165 - 194
Specimen IMP-13						
All Method	13	45.0	2.2	4.8	45	38 - 52
Specimen IMP-14						
All Method	13	163.8	4.7	2.9	162	149 - 178
Specimen IMP-15						
All Method	13	149.9	3.6	2.4	149	139 - 161

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	13	28.8	2.9	10.1	30	20 - 38
Specimen IMP-12						
All Method	13	36.2	2.6	7.3	36	28 - 45
Specimen IMP-13						
All Method	13	9.0	0.8	9.1	9	6 - 12
Specimen IMP-14						
All Method	13	33.5	2.5	7.5	33	25 - 41
Specimen IMP-15						
All Method	13	30.5	2.6	8.5	30	22 - 39

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	12	226.7	21.8	9.6	224	161 - 293
Beckman AU	10	226.7	5.5	2.4	224	210 - 244
Specimen IMP-12						
All Method	12	255.0	12.9	5.1	257	216 - 294
Beckman AU	10	264.7	6.1	2.3	266	246 - 283
Specimen IMP-13						
All Method	12	62.3	2.7	4.4	64	54 - 71
Beckman AU	10	62.3	2.1	3.3	63	56 - 69
Specimen IMP-14						
All Method	12	508.5	18.5	3.6	504	452 - 565
Beckman AU	10	510.3	23.2	4.5	499	440 - 580
Specimen IMP-15						
All Method	12	209.3	9.5	4.6	208	180 - 238
Beckman AU	10	213.0	9.5	4.5	212	184 - 242

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	12	1110.8	54.0	4.9	1095	833 - 1389
Beckman AU	10	1088.3	25.0	2.3	1094	816 - 1361
Specimen IMP-12						
All Method	12	1900.5	151.0	7.9	1885	1425 - 2376
Beckman AU	10	1793.7	58.1	3.2	1797	1345 - 2243
Specimen IMP-13						
All Method	12	303.0	8.2	2.7	301	227 - 379
Beckman AU	10	302.0	11.5	3.8	298	226 - 378
Specimen IMP-14						
All Method	12	1126.3	58.0	5.2	1110	844 - 1408
Beckman AU	10	1103.3	28.4	2.6	1115	827 - 1380
Specimen IMP-15						
All Method	12	1073.5	49.3	4.6	1058	805 - 1342
Beckman AU	10	1046.3	21.1	2.0	1052	784 - 1308

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	12	430.3	45.9	10.7	447	292 - 568
Beckman AU	10	399.7	46.8	11.7	406	259 - 541
Specimen IMP-12						
All Method	12	109.3	3.9	3.6	109	97 - 122
Beckman AU	10	109.3	3.5	3.2	109	98 - 120
Specimen IMP-13						
All Method	12	27.0	2.0	7.4	27	21 - 33
Beckman AU	10	28.0	2.0	7.1	28	22 - 34
Specimen IMP-14						
All Method	12	96.0	3.7	3.8	96	84 - 108
Beckman AU	10	96.0	3.6	3.8	97	85 - 107
Specimen IMP-15						
All Method	12	93.3	3.1	3.4	93	83 - 103
Beckman AU	10	93.3	3.5	3.8	93	82 - 104

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	Specimen CR-5		Specimen CR-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	-	11
Fisher HealthCare Sure-Vue	8	-	-	8
Siemens Dimension	2	-	-	2
Wampole	1	-	-	1

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	19	2.743	0.324	11.8	2.70	1.77 - 3.72
mg/L - units						
All Immunology Methods	16	27.459	5.271	19.2	25.83	11.64 - 43.28
Specimen CR-6						
mg/dL - units						
All Immunology Methods	19	0.176	0.163	92.7	0.20	0.00 - 0.67
mg/L - units						
All Immunology Methods	16	1.814	2.154	118.7	0.65	0.00 - 8.28

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	23	2.412	0.881	36.5	2.30	0.00 - 5.06
Specimen HCR-6						
All Method	22	0.728	0.365	50.2	0.73	0.00 - 1.83

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	-	15	13	2	14	1
ASI	-	2	-	2	2	-
Bio-Rad	-	1	1	-	1	-
GenBio ImmunoDOT Panel 1	-	1	1	-	-	1
Immuno Concepts	-	3	3	-	3	-
INOVA Diagnostics	-	3	3	-	3	-
TheraTest	-	5	5	-	5	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	15	-	15
ASI	-	2	-	2
Bio-Rad	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	3	-	3
INOVA Diagnostics	-	3	-	3
TheraTest	-	5	-	5

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

<u>Specimen/Method</u>	<u>N/A (Neg)</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>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>>2560</u>
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Specimen AE-11

ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-12

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

Specimen AE-13

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

Specimen AE-14

ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-15

ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	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	1	9	1	9
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	2	-	2	-	2
TheraTest	-	6	-	6	1	5

<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
INOVA Diagnostics	-	2	-	2
TheraTest	-	6	-	6

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	-	3	3	-	-	3
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	2	2	-	-	2

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	3	-	3
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	2	-	2

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	-	8	8	-	-	8
GenBio ImmunoDOT Panel 1	-	1	1	-	-	1
Immuno Concepts	-	1	1	-	-	1
TheraTest	-	6	6	-	-	6

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	-	6	-	6

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	-	9	-	9	-	9
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
TheraTest	-	6	-	6	-	6

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	6	-	6

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	-	9	-	9	-	9
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
TheraTest	-	6	-	6	-	6

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	6	-	6

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	-	9	9	-	-	9
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	2	2	-	-	2
TheraTest	-	6	6	-	-	6

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	6	-	6

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	-
DiSorin	-	2	2	-	2	-
INOVA Diagnostics	-	2	2	-	2	-
Siemens ADVIA Centaur	-	1	1	-	1	-

<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
DiSorin	-	2	-	2
INOVA Diagnostics	-	2	-	2
Siemens ADVIA Centaur	-	1	-	1

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: <10 IU/mL, 41.6 IU/mL, 24.6 IU/mL, <10 IU/mL, and <10 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	63	2	1	64
Alere Clearview Complete HIV 1/2	1	-	-	1
Alere Clearview HIV1/2 STAT-PAK	3	-	-	3
Alere Determine HIV - moderate	4	-	-	4
Alere Determine HIV - waived	4	-	-	4
BD LINK 2	2	-	-	2
bioLytical Labs INSTI HIV - moderate	1	-	-	1
bioLytical Labs INSTI HIV - waived	11	-	-	11
Chembio HIV 1/2 Assay - waived	7	-	-	7
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	1	-	-	1
Orasure OraQuick Advance Rapid HIV-1/2 - waived	15	-	-	15
Other Waived method	2	1	1	2
Trinity Biotech Uni-Gold - waived	12	-	-	12

<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	-
Alere Determine HIV - moderate	-	5	-	5	5	-

Allergen Specific IgE Antibodies

Specimen AL-11

<u>Method</u>	Maple (Box Elder) (t1) Allergen CLASS RESULT							Grey Alder (t2) 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	1	-	-	-	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Cow Milk (f2) Allergen CLASS RESULT							Peanut (f13) 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	1	-	-	-	-	1	-	2	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Sheep Sorrel (w18) Allergen CLASS RESULT							English Plantain (w9) Allergen CLASS RESULT									
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6	
ALL METHODS	-	-	1	1	1	-	-	-	-	1	2	1	-	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	1	-	-	-	-	-	1	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Cat Epithelium (e1) 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	-	-	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	1	1	-	-	-	-	-	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-12

<u>Method</u>	Common (Short) Ragweed (w1) Allergen CLASS RESULT							Russian Thistle (w11) 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	-	-	-	-	-			
ALL METHODS	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-			
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Hitachi CLA-1	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-			
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-			
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-			
Alternaria alternata (m6) Allergen CLASS RESULT							Shrimp (f24) Allergen CLASS RESULT												
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6			
ALL METHODS	1	-	3	-	-	-	-	-	-	-	-	1	1	-	-	-			
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-			
Hitachi CLA-1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Hycor RAST (Ru/mL)	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-			
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-			
House Dust Mite (D. pteronyssinus) (d1) Allergen CLASS RESULT							Bermuda Grass (g2) Allergen CLASS RESULT												
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6			
ALL METHODS	-	-	-	2	1	-	-	-	-	-	-	1	2	-	-	-			
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-			
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-			
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-			
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-			
Timothy Grass (g6) Allergen CLASS RESULT																			
	0	0/1	1	2	3	4	5	6											
ALL METHODS	-	-	-	-	1	-	-	-											
DPC-Standard Microplate	-	-	-	-	-	-	-	-											
Hitachi CLA-1	-	-	-	-	-	-	-	-											
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-											
Phadia UniCap 100 (KU/L)	-	-	-	-	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	5	425.7	39.1	9.2	411	308 - 544
Specimen AL-12						
All Method	5	329.0	48.5	14.8	315	183 - 475
Specimen AL-13						
All Method	5	19.3	2.5	13.0	19	11 - 27
Specimen AL-14						
All Method	5	18.0	1.7	9.6	19	12 - 24
Specimen AL-15						
All Method	5	60.0	7.5	12.6	59	37 - 83

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	-	12	-	12	12	-
Abbott Architect	-	1	-	1	1	-
diagnostics direct Syphilis Health Check	-	9	-	9	9	-
INOVA Diagnostics	-	1	-	1	1	-
Siemens ADVIA Centaur	-	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	12	-	11	1
Abbott Architect	1	-	1	-
diagnostics direct Syphilis Health Check	9	-	8	1
INOVA Diagnostics	1	-	1	-
Siemens ADVIA Centaur	1	-	1	-

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	-	16	-	16	16	-
ASI	-	5	-	5	5	-
Becton Dickinson	-	6	-	6	6	-
Fisher HealthCare Sure-Vue	-	3	-	3	3	-
Stanbio Laboratory	-	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	16	-	16	-
ASI	5	-	5	-
Becton Dickinson	6	-	6	-
Fisher HealthCare Sure-Vue	3	-	3	-
Stanbio Laboratory	1	-	1	-

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>
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Specimen SY-11

ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-

Specimen SY-12

ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-

Specimen SY-13

ALL METHODS	-	1	-	5	1	-	-	-	-
ASI	-	1	-	2	-	-	-	-	-
Becton Dickinson	-	-	-	3	1	-	-	-	-

Specimen SY-14

ALL METHODS	-	-	1	-	5	1	-	-	-
ASI	-	-	1	-	2	-	-	-	-
Becton Dickinson	-	-	-	-	3	1	-	-	-

Specimen SY-15

ALL METHODS	-	1	1	4	1	-	-	-	-
ASI	-	1	1	1	-	-	-	-	-
Becton Dickinson	-	-	-	3	1	-	-	-	-

H. pylori Antibody Detection

<u>Method</u>	Specimen HP-5		Specimen HP-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	57	58	-
Alere Clearview - moderate	-	4	4	-
Alfa Scientific Instant-View	-	1	1	-
Beckman Coulter ICON HP	-	1	1	-
BTNX Rapid Response - waived	-	1	1	-
Cardinal Health SP Brand	-	1	1	-
Consult Diagnostics	-	17	17	-
Fisher HealthCare Sure-Vue	-	2	2	-
Henry Schein OneStep+ - waived	-	9	9	-
McKesson Medi-Lab Performance - waived	1	1	2	-
NDC Pro Advantage	-	1	1	-
Polymedco Poly stat	-	1	1	-
Quidel QuickVue	-	17	17	-
Sekisui OSOM	-	1	1	-

Mycoplasma Antibody

<u>Method</u>	Specimen MY-5		Specimen MY-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	3	3	-
Meridian ImmunoCard	-	3	3	-

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	-	3	-	-	3	-	2	1	-
Abbott Architect	-	1	-	-	1	-	1	-	-
Siemens ADVIA									
Centaur	-	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	-	3	-	-	3	-			
Abbott Architect	-	1	-	-	1	-			
Siemens ADVIA									
Centaur	-	1	-	-	1	-			
VITROS 5600	-	1	-	-	1	-			

Specimen VM-13 ungraded challenge due to less than 80% participant consensus.

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	-	1	-	1	-	-	1	-	-
Abbott Architect	-	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	-	1	-	-	1	-			
Abbott Architect	-	1	-	-	1	-			

Viral Markers – Anti-HIV

<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	-	6	-	-	6	-	-	6	-
Abbott Architect	-	3	-	-	3	-	-	3	-
bioLytical Labs INSTI									
HIV - moderate	-	1	-	-	1	-	-	1	-
Orasure OraQuick									
Advance Rapid HIV-									
1/2 - waived	-	1	-	-	1	-	-	1	-
Siemens ADVIA									
Centaur	-	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>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	6	-	6	-	-			
Abbott Architect	-	3	-	3	-	-			
bioLytical Labs INSTI									
HIV - moderate	-	1	-	1	-	-			
Orasure OraQuick									
Advance Rapid HIV-									
1/2 - waived	-	1	-	1	-	-			
Siemens ADVIA									
Centaur	-	1	-	1	-	-			

Viral Markers – Anti-HAV (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	-	3	-	-	3	-	-	3	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Siemens ADVIA									
Centaur	-	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>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	3	-	-	3	-			
Abbott Architect	-	1	-	-	1	-			
Siemens ADVIA									
Centaur	-	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	2	-	-	2	-	-	-	2	-
Abbott Architect	1	-	-	1	-	-	-	1	-
Siemens ADVIA									
Centaur	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	2	-	-	2	-	-			
Abbott Architect	1	-	-	1	-	-			
Siemens ADVIA									
Centaur	1	-	-	1	-	-			

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-11 through VM-15 are: Negative, Negative, Negative, and Negative, respectively.

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 Architect	-	3	-	-	3	-	-	3	-
Siemens ADVIA									
Centaur	-	2	-	-	2	-	-	2	-
<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 Architect	3	-	-	3	-	-			
Siemens ADVIA									
Centaur	2	-	-	2	-	-			

Viral Markers – HBsAg

<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	2	3	-	4	1	-	4	1	-
Abbott Architect	2	-	-	2	-	-	2	-	-
Siemens ADVIA									
Centaur	-	2	-	2	-	-	2	-	-
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 Architect	-	2	-	-	2	-			
Siemens ADVIA									
Centaur	-	2	-	-	2	-			
VITROS 5600	-	1	-	-	1	-			

Specimen VM-11 ungraded challenge due to less than 80% participant consensus.

Viral Markers – Anti-HCV

<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	6	1	-	6	1	-	-	7	-
Abbott Architect	2	-	-	2	-	-	-	2	-
OraSure OraQuick									
HCV	1	-	-	1	-	-	-	1	-
Roche cobas e 411	1	-	-	1	-	-	-	1	-
Siemens ADVIA									
Centaur	2	-	-	2	-	-	-	2	-
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	-	7	-	-	7	-			
Abbott Architect	-	2	-	-	2	-			
OraSure OraQuick									
HCV	-	1	-	-	1	-			
Roche cobas e 411	-	1	-	-	1	-			
Siemens ADVIA									
Centaur	-	2	-	-	2	-			
VITROS 5600	-	1	-	-	1	-			

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