

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Immunology
2019 MLE-M3



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
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
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	± 3 SD
High Sensitivity C-Reactive Protein	± 3 SD
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

Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-11</u>		<u>Specimen IM-12</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	146	1	1	146
Alere Clearview - moderate	1	-	-	1
Alere Clearview - waived	6	-	-	6
Alere Clearview Mono Plus II - moderate	2	-	-	2
Alere Clearview Mono Plus II - waived	3	-	-	3
Beckman Coulter ICON Mono - waived	5	-	-	5
BioStar Aceava Mono Test	2	-	-	2
BioStar Aceava Mono-whole bld	3	-	-	3
Cardinal Health SP Brand - waived	4	-	-	4
Clarity Diagnostics	1	-	-	1
Consult Diagnostics	23	-	1	22
Fisher HealthCare Sure-View	4	-	-	4
Henry Schein OneStep+ - waived	15	-	-	15
LifeSign Status - waived	6	-	-	6
Other Moderate method	5	-	-	5
Other Waived method	12	-	-	12
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	3	-	-	3
Sekisui OSOM	5	-	-	5
Sekisui OSOM (waived)	45	1	-	46

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	39	-	1	38	37	2
Alere Clearview - moderate	1	-	-	1	1	-
Alere Clearview Mono Plus II - moderate	2	-	-	2	2	-
Alere Clearview Mono Plus II - waived	1	-	-	1	1	-
Beckman Coulter ICON Mono - waived	5	-	-	5	5	-
BioStar Acceava Mono Test	1	-	-	1	1	-
BioStar Acceava Mono-whole bld	1	-	-	1	1	-
Consult Diagnostics	7	-	-	7	6	1
Fisher HealthCare Sure-View	1	-	-	1	1	-
Henry Schein OneStep+ - waived	2	-	-	2	2	-
LifeSign Status - waived	1	-	-	1	1	-
Other Moderate method	5	-	-	5	5	-
Other Waived method	2	-	-	2	2	-
Quidel QuickVue+	1	-	-	1	1	-
Quidel QuickVue+ - waived	1	-	-	1	1	-
Sekisui OSOM	5	-	1	4	4	1
Sekisui OSOM (waived)	3	-	-	3	3	-

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	25	-	-	25	-	25
ASI	5	-	-	5	-	5
Beckman AU	1	-	-	1	-	1
Biokit Rheumajet	1	-	-	1	-	1
Fisher HealthCare Sure-Vue	2	-	-	2	-	2
Immunostics Inc.	1	-	-	1	-	1
INOVA Diagnostics	2	-	-	2	-	2
TheraTest	5	-	-	5	-	5
Wampole ColorCard	5	-	-	5	-	5
Wampole Rheumatex	2	-	-	2	-	2

<u>Method</u>	Specimen RF-14		Specimen RF-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	-	25
ASI	5	-	-	5
Beckman AU	1	-	-	1
Biokit Rheumajet	1	-	-	1
Fisher HealthCare Sure-Vue	2	-	-	2
Immunostics Inc.	1	-	-	1
INOVA Diagnostics	2	-	-	2
TheraTest	5	-	-	5
Wampole ColorCard	5	-	-	5
Wampole Rheumatex	2	-	-	2

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	-	-	2	3	-	-	-	-	-	-	-	-
Beckman AU	-	-	-	2	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-
Specimen RF-12												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	2	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-13												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	2	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-14												
ALL METHODS	-	-	1	1	1	2	-	-	-	-	-	-
Beckman AU	-	-	-	-	-	2	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	1	1	-	-	-	-	-	-	-
Specimen RF-15												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	2	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-

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>
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Specimen RF-11

All Method	15	60.4	15.7	25.9	62	13 - 108
Beckman AU	10	62.3	18.1	29.1	62	7 - 117

Specimen RF-12

All Method	15	7.3	3.3	44.7	6	0 - 18
Beckman AU	10	8.0	2.1	26.2	9	1 - 15

Specimen RF-13

All Method	15	7.4	3.3	44.6	7	0 - 18
Beckman AU	10	7.8	1.9	24.8	8	2 - 14

Specimen RF-14

All Method	15	109.4	21.5	19.6	113	45 - 174
Beckman AU	10	110.7	26.7	24.1	113	30 - 191

Specimen RF-15

All Method	15	7.4	3.2	43.6	7	0 - 18
Beckman AU	10	8.2	1.9	23.8	9	2 - 14

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	-	1	1	-	1	-
ASI	-	1	1	-	1	-

<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	1	-	-	1
ASI	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	12	147.8	4.9	3.3	147	133 - 163
Specimen IMP-12						
All Method	12	117.3	3.3	2.8	118	107 - 128
Specimen IMP-13						
All Method	12	148.6	3.6	2.4	148	137 - 160
Specimen IMP-14						
All Method	12	34.3	2.4	7.1	34	26 - 42
Specimen IMP-15						
All Method	12	145.2	3.7	2.6	145	134 - 157

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	12	31.2	3.1	9.8	32	21 - 41
Specimen IMP-12						
All Method	12	25.2	4.7	18.8	25	10 - 40
Specimen IMP-13						
All Method	12	30.7	3.1	10.2	31	21 - 41
Specimen IMP-14						
All Method	12	6.5	1.1	16.7	6	3 - 10
Specimen IMP-15						
All Method	12	30.2	3.4	11.2	31	20 - 41

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>
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Specimen IMP-11

All Method	12	489.2	12.0	2.4	489	453 - 526
Beckman AU	10	487.3	16.3	3.3	484	438 - 537

Specimen IMP-12

All Method	12	179.6	2.9	1.6	181	170 - 189
Beckman AU	10	180.3	2.9	1.6	182	171 - 189

Specimen IMP-13

All Method	12	235.2	6.6	2.8	233	215 - 256
Beckman AU	10	234.0	7.5	3.2	233	211 - 257

Specimen IMP-14

All Method	12	48.4	2.4	5.0	49	41 - 56
Beckman AU	10	49.0	2.0	4.1	49	43 - 55

Specimen IMP-15

All Method	12	213.6	2.3	1.1	214	206 - 221
Beckman AU	10	212.3	2.1	1.0	213	206 - 219

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>
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Specimen IMP-11

All Method	12	1045.6	21.8	2.1	1048	784 - 1307
Beckman AU	10	1046.3	8.6	0.8	1048	784 - 1308

Specimen IMP-12

All Method	12	857.2	21.3	2.5	863	642 - 1072
Beckman AU	10	859.7	8.5	1.0	863	644 - 1075

Specimen IMP-13

All Method	12	1878.2	74.4	4.0	1911	1408 - 2348
Beckman AU	10	1876.7	63.8	3.4	1911	1407 - 2346

Specimen IMP-14

All Method	12	239.4	36.6	15.3	238	179 - 300
Beckman AU	10	219.7	15.9	7.3	212	164 - 275

Specimen IMP-15

All Method	12	1032.6	28.6	2.8	1028	774 - 1291
Beckman AU	10	1031.3	12.3	1.2	1028	773 - 1290

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	87.8	3.5	4.0	90	77 - 99
Beckman AU	10	88.3	3.8	4.3	90	76 - 100
Specimen IMP-12						
All Method	12	72.2	3.6	4.9	72	61 - 83
Beckman AU	10	71.3	4.0	5.7	72	59 - 84
Specimen IMP-13						
All Method	12	93.2	4.1	4.4	94	80 - 106
Beckman AU	10	93.0	5.6	6.0	94	76 - 110
Specimen IMP-14						
All Method	12	21.6	2.4	11.1	21	14 - 29
Beckman AU	10	21.3	1.5	7.2	21	16 - 26
Specimen IMP-15						
All Method	12	398.0	38.1	9.6	387	283 - 513
Beckman AU	10	372.7	19.9	5.3	381	313 - 433

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-5</u>		<u>Specimen CR-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	2	-
Siemens Dimension	-	2	2	-

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	0.178	0.147	82.4	0.20	0.00 - 0.62
mg/L - units						
All Immunology Methods	14	1.144	1.766	154.3	0.30	0.00 - 6.45
Specimen CR-6						
mg/dL - units						
All Immunology Methods	19	1.246	0.166	13.4	1.30	0.74 - 1.75
mg/L - units						
All Immunology Methods	14	11.880	1.668	14.0	11.74	6.87 - 16.89

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	22	0.659	0.181	27.4	0.69	0.11 - 1.21
Specimen HCR-6						
All Method	22	9.915	0.762	7.7	9.79	7.63 - 12.21

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	<u>Specimen AE-11</u>		<u>Specimen AE-12</u>		<u>Specimen AE-13</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	14	-	14	12	2
ASI	-	2	-	2	-	2
Bio-Rad	-	1	-	1	1	-
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-
Immuno Concepts	-	3	-	3	3	-
INOVA Diagnostics	-	2	-	2	2	-
TheraTest	-	5	-	5	5	-

<u>Method</u>	<u>Specimen AE-14</u>		<u>Specimen AE-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	14	13	1
ASI	-	2	2	-
Bio-Rad	-	1	1	-
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	3	3	-
INOVA Diagnostics	-	2	2	-
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>
Specimen AE-11												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-12												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-13												
ALL METHODS	-	-	-	-	-	-	-	1	1	3	-	-
Bio-Rad	-	-	-	-	-	-	-	-	-	1	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	1	1	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-14												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-15												
ALL METHODS	-	-	-	-	-	-	-	4	1	-	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	2	1	-	-	-
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	-	9	-	9	-	9
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	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	-	9	4	5
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	1	-
INOVA Diagnostics	-	1	-	1
TheraTest	-	6	3	3

Specimen AE-15 ungraded challenge due to less than 80% participant consensus.

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	-
INOVA Diagnostics	-	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	-
INOVA Diagnostics	-	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	-	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	1	7	7	1
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	1	-
TheraTest	1	5	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	-	8	-	8	-	8
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	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
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
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	-	8	-	8	-	8
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	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
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
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	-	8	-	8	1	7
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	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
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
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	-	2	2	-	2	-
INOVA Diagnostics	-	1	1	-	1	-
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	-	2	-	2
INOVA Diagnostics	-	1	-	1
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: <10.0 IU/mL, 36.7 IU/mL, 21.8 IU/mL, <10.0 IU/mL, and <10.0 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	-	67	67	-
Alere Clearview HIV1/2 STAT-PAK	-	3	3	-
Alere Determine HIV - moderate	-	2	2	-
Alere Determine HIV - waived	-	5	5	-
BD LINK 2	-	2	2	-
bioLytical Labs INSTI HIV - moderate	-	2	2	-
bioLytical Labs INSTI HIV - waived	-	19	19	-
Chembio HIV 1/2 Assay - waived	-	10	10	-
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	15	15	-
Other Waived method	-	3	3	-
Trinity Biotech Uni-Gold - waived	-	4	4	-

<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	-	2	2	-	-	2
Alere Determine HIV - moderate	-	2	2	-	-	2

Allergen Specific IgE Antibodies

Specimen AL-11

<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
	ALL METHODS	-	1	1	2	-	-	-	-	1	1	-	-	-	-	-
Hitachi CLA-1	-	1	-	1	-	-	-	-	1	1	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-

Russian Thistle (w11) Allergen is an ungraded challenge due to less than 80% participant consensus.

<u>Method</u>	Sweet Vernal Grass (g1) 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	-	-	-	-	1	1	-	-	-	-	-	1	1	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-	-	-	-	1	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

<u>Method</u>	Cat Epithelium (e1) Allergen CLASS RESULT								Egg White (f1) 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	1	2	1	-
Hitachi CLA-1	-	-	-	-	1	1	-	-	-	-	-	1	2	1	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-

<u>Method</u>	White Oak (t7) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
	ALL METHODS	-	-	-	2	1	-	-
Hitachi CLA-1	-	-	-	1	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-12

<u>Method</u>	Dog Dander (e5) Allergen								House Dust Mite (<i>D. farinae</i>) (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	-	-	-	2	1	-	-	-	-	-	-	1	1	2	-	-
Hitachi CLA-1	-	-	-	1	1	-	-	-	-	-	-	-	1	2	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
<u>Method</u>	Timothy Grass (g6) Allergen								Meadow Fescue (g4) 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	1	1	-	-	-	-	-	1	1	-	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
<u>Method</u>	Peanut (f13) Allergen								Wheat (f4) 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	1	2	-	-	3	-	-	1	1	1	-	-
Hitachi CLA-1	-	-	-	-	1	2	-	-	3	-	-	1	1	1	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
<u>Method</u>	Cladosporium herbarum (m2) Allergen															
	<i>CLASS RESULT</i>															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	1	-	-	1	-	-	-	-								
Hitachi CLA-1	1	-	-	1	-	-	-	-								
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-								

Cladosporium herbarum (m2) Allergen is an ungraded challenge due to less than 80% participant consensus.

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	244.5	2.1	0.9	245	238 - 251
Specimen AL-12						
All Method	5	464.5	17.7	3.8	465	411 - 518
Specimen AL-13						
All Method	5	18.0	0.1	0.0	18	17 - 19
Specimen AL-14						
All Method	5	18.0	0.1	0.0	18	17 - 19
Specimen AL-15						
All Method	5	80.0	2.8	3.5	80	71 - 89

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	-	1	1	-	1	-
Serodia	-	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	-	1	1	-
Serodia	-	1	1	-

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	12	-
Abbott Architect	-	1	1	-
diagnostics direct Syphilis Health Check	-	9	9	-
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	-	14	14	-	14	-
ASI	-	6	6	-	6	-
Becton Dickinson	-	5	5	-	5	-
Fisher HealthCare Sure-Vue	-	3	3	-	3	-

<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	-	14	14	-
ASI	-	6	6	-
Becton Dickinson	-	5	5	-
Fisher HealthCare Sure-Vue	-	3	3	-

Syphilis Serology—Semi-Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>N/A</u> <u>(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	-	-	2	4	-	1	-	-	-
ASI	-	-	-	2	-	1	-	-	-
Becton Dickinson	-	-	2	2	-	-	-	-	-

Specimen SY-13

ALL METHODS	-	-	2	4	1	-	-	-	-
ASI	-	-	1	1	1	-	-	-	-
Becton Dickinson	-	-	1	3	-	-	-	-	-

Specimen SY-14

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

Specimen SY-15

ALL METHODS	-	-	-	5	2	-	-	-	-
ASI	-	-	-	2	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	48	-	-	48
Alere Clearview - moderate	2	-	-	2
Beckman Coulter ICON HP	1	-	-	1
Consult Diagnostics	14	-	-	14
Fisher HealthCare Sure-View	1	-	-	1
Henry Schein OneStep+ - waived	8	-	-	8
McKesson Medi-Lab Performance - waived	2	-	-	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	1	8	8	1
Meridian ImmunoCard	1	8	8	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	-	4	-	-	4	-	-	4	-
Abbott Architect	-	2	-	-	2	-	-	2	-
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	-	4	-	-	4	-
Abbott Architect	-	2	-	-	2	-
Siemens ADVIA						
Centaur	-	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	-	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	7	-	-	-	7	-	7	-	-
Abbott Architect	2	-	-	-	2	-	2	-	-
bioLytical Labs INSTI									
HIV - moderate	1	-	-	-	1	-	1	-	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	3	-	-	-	3	-	3	-	-
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	3	4	-	-	7	-
Abbott Architect	2	-	-	-	2	-
bioLytical Labs INSTI						
HIV - moderate	-	1	-	-	1	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	-	3	-	-	3	-
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	-	4	-	-	4	-	-	4	-
Abbott Architect	-	2	-	-	2	-	-	2	-
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	-	4	-	4	-	-
Abbott Architect	-	2	-	2	-	-
Siemens ADVIA						
Centaur	-	1	-	1	-	-
VITROS 5600	-	1	-	1	-	-

Viral Markers – Anti-HAV (Total/IgG)

<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	3	-	-	3	-	-	3	-	-
Abbott Architect	2	-	-	2	-	-	2	-	-
Siemens ADVIA									
Centaur	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	3	-	-	3	-	-
Abbott Architect	2	-	-	2	-	-
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, Negative, and Negative, respectively.

Specimens VM-14 and VM-15 ungraded challenge due to less than 80% participant consensus.

Viral Markers – Anti-HBs

<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	-	3	-	3	-	-	3	-	-
Abbott Architect	-	2	-	2	-	-	2	-	-
Siemens ADVIA									
Centaur	-	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	-	3	-	-	3	-
Abbott Architect	-	2	-	-	2	-
Siemens ADVIA						
Centaur	-	1	-	-	1	-

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	-	5	-	-	5	-	-	5	-
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	-	-	4	-	1
Abbott Architect	2	-	-	2	-	-
Siemens ADVIA						
Centaur	2	-	-	2	-	-
VITROS 5600	1	-	-	-	-	1

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	9	-	-	-	9	-	-	9	-
Abbott Architect	2	-	-	-	2	-	-	2	-
OraSure OraQuick									
HCV	3	-	-	-	3	-	-	3	-
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	9	-	-	1	8	-
Abbott Architect	2	-	-	-	2	-
OraSure OraQuick						
HCV	3	-	-	-	3	-
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Siemens ADVIA						
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VITROS 5600	1	-	-	-	1	-

Medical Laboratory Evaluation

25 Massachusetts Ave NW Ste 700

Washington, DC 20001-7401

800-338-2746 • 202-261-4500 • Fax: 202-835-0440

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