

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 7

Immunology
2017 MLE-M2



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

Table of Contents

Evaluation Criteria.....	3
Immunology	
Infectious Mononucleosis	4
Rheumatoid Factor.....	6
Qualitative	6
Quantitative (Titer).....	7
Quantitative (IU)	8
Anti-Streptolysin O (ASO).....	8
Complement C3.....	9
Complement C4.....	9
IgA.....	10
IgG.....	10
IgM.....	11
C-Reactive Protein, Regular	11
Qualitative	11
Quantitative	11
C-Reactive Protein, High Sensitivity.....	12
Antinuclear Antibody	12
Qualitative	12
Quantitative (Titer).....	13
Anti-dsDNA.....	14
Anti-RNP	14
Anti-RNP/Sm.....	15
Anti-SSA	15
Anti-SSB	15
Anti-SSA/SSB	16
Anti-Sm	16
Rubella.....	17
Qualitative	17
Quantitative	17
Anti-HIV.....	17
Allergen Specific IgE Antibodies	18
Total IgE.....	20
VDRL Slide.....	20
Syphilis Serology	21
Qualitative: Treponema pallidum antibodies	21
Qualitative: RPR.....	21
Quantitative: RPR (Titer)	22
H. pylori Antibody Detection	23
Mycoplasma Antibody	23
Viral Markers	24
Anti-HBc (IgM).....	24
Anti-HBc (Total/IgG)	24
Anti-HIV.....	25
Anti-HAV (IgM)	25
Anti-HAV (Total/IgG).....	26
HBeAg.....	26
Anti-HBs.....	26
HBsAg.....	27
Anti-HCV	27

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 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

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."

Antinuclear Antibody (ANA) Titer	Not Evaluated
Anti-Streptolysin O (ASO) Titer	Not Evaluated
Complement C3	± 3 SD
Complement C4	± 3 SD
C-Reactive Protein	± 3 SD
High Sensitivity C-Reactive Protein	± 3 SD
Rheumatoid Factor (International Units)	± 2 SD
Rheumatoid Factor (Titer)	Not Evaluated
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>	Specimen IM-6		Specimen IM-7	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	183	4	183	4
Alere Clearview - waived	7	-	7	-
Alere Clearview Mono Plus II - moderate	1	-	1	-
Alere Clearview Mono Plus II - waived	6	-	6	-
ASI	1	-	1	-
Beckman Coulter ICON Mono - waived	9	-	9	-
BioStar Acceava Mono Test	2	-	2	-
BioStar Acceava Mono-whole bld	4	-	4	-
BTNX Rapid Response – moderate	1	-	1	-
Cardinal Health SP Brand	1	-	1	-
Cardinal Health SP Brand - waived	7	-	7	-
Consult Diagnostics	22	1	23	-
Fisher HealthCare Sure-Vue	6	1	7	-
Henry Schein OneStep+ - waived	13	-	13	-
LifeSign Status - waived	9	-	9	-
McKesson Medi-Lab Performance - waived	1	-	1	-
Other Moderate method	4	-	4	-
Other Waived method	17	-	17	-
Quidel QuickVue+	2	-	2	-
Quidel QuickVue+ - waived	11	-	10	1
Sekisui OSOM	5	-	5	-
Sekisui OSOM (waived)	52	-	50	2
Seradyn	1	-	1	-
Wampole ColorCard	-	1	1	-

Infectious Mononucleosis

<u>Method</u>	Specimen IM-8		Specimen IM-9		Specimen IM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	57	57	-	-	57
Alere Clearview Mono Plus II - moderate	-	1	1	-	-	1
Alere Clearview Mono Plus II - waived	-	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
Cardinal Health SP Brand	-	1	1	-	-	1
Cardinal Health SP Brand - waived	-	1	1	-	-	1
Consult Diagnostics	-	8	8	-	-	8
Fisher HealthCare Sure-Vue	-	3	3	-	-	3
Henry Schein OneStep+ - waived	-	3	3	-	-	3
LifeSign Status - waived	-	1	1	-	-	1
Other Moderate method	-	4	4	-	-	4
Other Waived method	-	2	2	-	-	2
Quidel QuickVue+	-	2	2	-	-	2
Quidel QuickVue+ - waived	-	2	2	-	-	2
Sekisui OSOM	-	5	5	-	-	5
Sekisui OSOM (waived)	-	7	7	-	-	7
Seradyn	-	1	1	-	-	1
Wampole ColorCard	-	1	1	-	-	1

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-6		Specimen RF-7		Specimen RF-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	38	-	38	-	-	38
Abbott Architect	1	-	1	-	-	1
ASI	10	-	10	-	-	10
Biokit Rheumajet	4	-	4	-	-	4
Diamedix	1	-	1	-	-	1
Fisher HealthCare Sure-View	4	-	4	-	-	4
Immunostics Inc.	2	-	2	-	-	2
INOVA Diagnostics	1	-	1	-	-	1
TheraTest	4	-	4	-	-	4
Wampole ColorCard	7	-	7	-	-	7
Wampole Rheumatex	3	-	3	-	-	3

<u>Method</u>	Specimen RF-9		Specimen RF-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	38	37	1
Abbott Architect	-	1	1	-
ASI	-	10	10	-
Biokit Rheumajet	-	4	4	-
Diamedix	-	1	1	-
Fisher HealthCare Sure-View	-	4	4	-
Immunostics Inc.	-	2	1	1
INOVA Diagnostics	-	1	1	-
Teco Diagnostics	-	4	4	-
TheraTest	-	7	7	-
Wampole ColorCard	-	3	3	-
Wampole Rheumatex	-	38	37	1

Rheumatoid Factor—Quantitative (Titer)

<u>Specimen/Method</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>	<u>N/A (Neg)</u>
Specimen RF-6												
ALL METHODS	-	1	2	-	-	1	-	-	-	-	-	-
ASI	-	-	-	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	1	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	1	-	-	-	-	-	-	-	-	-
Specimen RF-7												
ALL METHODS	-	-	-	2	-	1	-	-	1	-	-	-
ASI	-	-	-	-	-	-	-	-	1	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	2	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	1	-	-	-	-	-	-
Specimen RF-8												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
ASI	-	-	-	-	-	-	-	-	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-	2
Wampole ColorCard	-	-	-	-	-	-	-	-	-	-	-	1
Specimen RF-9												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	4
ASI	-	-	-	-	-	-	-	-	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-	2
Wampole ColorCard	-	-	-	-	-	-	-	-	-	-	-	1
Specimen RF-10												
ALL METHODS	-	2	1	-	-	-	1	-	-	-	-	-
ASI	-	-	-	-	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	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-6						
All Method	19	86.3	30.4	35.3	73	25 - 148
Specimen RF-7						
All Method	19	163.2	37.2	22.8	163	88 - 238
Specimen RF-8						
All Method	19	7.5	3.7	49.7	7	0 - 15
Specimen RF-9						
All Method	19	7.2	4.0	55.3	7	0 - 16
Specimen RF-10						
All Method	19	84.6	28.4	33.6	72	27 - 142

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	Specimen AS-6		Specimen AS-7		Specimen AS-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	1	1	-	-	1
<u>Method</u>	Specimen AS-9		Specimen AS-10			
	<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-6						
All Method	15	89.6	4.4	5.0	90	76 - 103
Specimen IMP-7						
All Method	15	144.2	4.5	3.1	145	130 - 158
Specimen IMP-8						
All Method	15	57.6	2.0	3.5	58	51 - 64
Specimen IMP-9						
All Method	15	121.1	4.6	3.8	120	107 - 135
Specimen IMP-10						
All Method	15	94.9	4.1	4.3	94	82 - 108

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-6						
All Method	15	17.7	1.0	5.8	17	14 - 21
Specimen IMP-7						
All Method	15	29.1	2.1	7.2	29	22 - 36
Specimen IMP-8						
All Method	15	11.1	0.6	5.4	11	9 - 13
Specimen IMP-9						
All Method	15	24.1	1.8	7.4	24	18 - 30
Specimen IMP-10						
All Method	15	18.5	1.1	6.1	18	15 - 22

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-6						
All Method	11	133.7	9.1	6.8	131	106 - 161
Specimen IMP-7						
All Method	11	499.6	44.1	8.8	500	367 - 632
Specimen IMP-8						
All Method	11	77.9	4.3	5.6	79	64 - 91
Specimen IMP-9						
All Method	11	163.4	9.2	5.6	164	135 - 191
Specimen IMP-10						
All Method	11	125.7	10.3	8.2	122	94 - 157

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-6						
All Method	11	1911.4	113.0	5.9	1873	1433 - 2390
Specimen IMP-7						
All Method	11	975.0	76.3	7.8	965	731 - 1219
Specimen IMP-8						
All Method	11	401.7	33.3	8.3	398	301 - 503
Specimen IMP-9						
All Method	11	837.9	55.3	6.6	816	628 - 1048
Specimen IMP-10						
All Method	11	644.1	64.7	10.1	617	483 - 806

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-6						
All Method	11	60.7	11.4	18.7	56	26 - 95
Specimen IMP-7						
All Method	11	94.2	10.1	10.7	89	64 - 125
Specimen IMP-8						
All Method	11	36.2	5.4	15.0	35	19 - 53
Specimen IMP-9						
All Method	11	77.5	9.8	12.6	73	48 - 107
Specimen IMP-10						
All Method	11	472.5	77.0	16.3	495	241 - 704

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	-	12	12	-
Beckman Synchron	-	1	1	-
Fisher HealthCare Sure-Vue	-	8	8	-
Siemens Dimension/AR/ES/RxL/Xpand	-	2	2	-

C-Reactive Protein—Quantitative (mg/dL), 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-3						
mg/dL - units						
All Immunology Methods	20	0.159	0.145	91.4	0.15	0.00 - 0.60
mg/L - units						
All Immunology Methods	17	1.997	2.223	111.3	0.70	0.00 - 8.67
Specimen CR-4						
mg/dL - units						
All Immunology Methods	20	7.202	0.680	9.4	7.28	5.16 - 9.25
mg/L - units						
All Immunology Methods	17	69.595	9.525	13.7	65.91	41.01 - 98.18

C-Reactive Protein—Quantitative (mg/dL), High Sensitivity

<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 HCR-3

All Method	32	2.574	0.979	38.0	2.64	0.00 - 5.52
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Specimen HCR-4

All Method	29	10.837	1.209	11.2	10.61	7.21 - 14.47
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Antinuclear Antibody (ANA) - Qualitative

<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	12	-	10	2	-	12
ASI	1	-	1	-	-	1
Bio-Rad	1	-	1	-	-	1
Immuno Concepts	3	-	2	1	-	3
Immunostics Inc.	1	-	1	-	-	1
INOVA Diagnostics	2	-	2	-	-	2
Teco Diagnostics	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	-	12	11	1
ASI	-	1	1	-
Bio-Rad	-	1	1	-
Immuno Concepts	-	3	3	-
Immunostics Inc.	-	1	1	-
INOVA Diagnostics	-	2	2	-
Teco Diagnostics	-	1	-	1
TheraTest	-	3	3	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

<u>Specimen/Method</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>	<u>N/A (Neg)</u>
Specimen AE-6												
ALL METHODS	-	-	-	-	-	-	4	1	-	-	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	2	-	-	-	-	-
Immunostics Inc.	-	-	-	-	-	-	-	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-	-
Specimen AE-7												
ALL METHODS	-	-	-	-	-	3	2	-	-	-	-	-
Bio-Rad	-	-	-	-	-	1	-	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	2	-	-	-	-	-
Immunostics Inc.	-	-	-	-	-	1	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-	-
Specimen AE-8												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	5
Bio-Rad	-	-	-	-	-	-	-	-	-	-	-	1
Immuno Concepts	-	-	-	-	-	-	-	-	-	-	-	2
Immunostics Inc.	-	-	-	-	-	-	-	-	-	-	-	1
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	1
Specimen AE-9												
ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	5
Bio-Rad	-	-	-	-	-	-	-	-	-	-	-	1
Immuno Concepts	-	-	-	-	-	-	-	-	-	-	-	2
Immunostics Inc.	-	-	-	-	-	-	-	-	-	-	-	1
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	1
Specimen AE-10												
ALL METHODS	-	-	-	-	-	-	4	1	-	-	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	1	-	-	-	-
Immunostics Inc.	-	-	-	-	-	-	1	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-	-

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	1	6	7	-	-	7
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	1	1	-	-	1
TheraTest	1	4	5	-	-	5

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	5	-	5

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	1	-	-	1	-	1
Immuno Concepts	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
Immuno Concepts	-	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	7	-	6	1	-	7
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	1	-	1	-	-	1
TheraTest	5	-	5	-	-	5

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	6	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	1	4	-	5

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	7	-	7	-	5	2
Immuno Concepts	1	-	1	-	-	1
INOVA Diagnostics	1	-	1	-	-	1
TheraTest	5	-	5	-	5	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	2	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	5	-	-	5

Specimen AE-8 and AE-9 are ungraded challenge due to less than 80% participant consensus.

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	-	7	-	7	-	7
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	-	5	-	5	-	5

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	5	-	5

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	-	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	-	-	-
Immuno Concepts	-	-	-	-

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	7	-	-	7	-	7
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	1	-	-	1	-	1
TheraTest	5	-	-	5	-	5

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	5	-	5

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	-
bioMerieux Vidas, Mini Vidas	1	-	-	1	1	-
DiaSorin	1	-	-	1	1	-
INOVA Diagnostics	1	-	-	1	1	-
Siemens ADVIA Centaur	2	-	-	2	2	-

<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
bioMerieux Vidas, Mini Vidas	1	-	-	1
DiaSorin	1	-	-	1
Roche cobas e 411	1	-	-	1
Siemens ADVIA Centaur	2	-	-	2

Rubella—Quantitative (IU/mL)

One lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values for specimens RU-6 through RU-10 are: 56.4 IU/mL, <10.0 IU/mL, 56.4 IU/mL, 33.5 IU/mL, and <10.0 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	63	-	61	2
Alere Clearview Complete HIV 1/2	4	-	4	-
Alere Clearview HIV1/2 STAT-PAK	4	-	4	-
Alere Determine HIV 1/2 Ag/Ab Combo	1	-	1	-
Chembio HIV 1/2 Assay - moderate	1	-	1	-
Chembio HIV 1/2 Assay - waived	2	-	2	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	20	-	19	1
Other Waived method	16	-	16	-
Trinity Biotech Uni-Gold - waived	14	-	13	1

<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
Chembio HIV 1/2 Assay - moderate	5	-	-	5	-	5

Allergen Specific IgE Antibodies

Specimen AL-6

Method

Silver Birch Tree (t3) Allergen CLASS RESULT								Timothy Grass (g6) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	1	-	3	-	-	-	-	-	-	-	-	-	3	1	-
-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
-	1	-	-	-	-	-	-	-	-	-	-	-	2	-	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
-	-	-	1	-	-	-	-	-	-	-	-	-	-	1	-
-	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-

Perennial Rye (g5) Allergen CLASS RESULT								Cat Epithelium (e1) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	-	-	-	-	-	2	-	-	-	-	3	2	2	-	-
-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-	-	1	2	-	-
-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
-	-	-	-	-	-	1	-	-	-	-	1	-	-	-	-
-	-	-	-	-	-	1	-	-	-	-	1	-	-	-	-

House Dust Mite (D. pteronyssinus) (d1) Allergen CLASS RESULT								Cow's Milk (f2) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
-	-	-	4	1	1	-	-	-	-	2	3	-	-	-	-
-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
-	-	-	1	-	1	-	-	-	-	-	1	-	-	-	-
-	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-
-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-
-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-

Wheat (f4) Allergen CLASS RESULT							
0	0/1	1	2	3	4	5	6
-	-	1	3	-	-	-	-
-	-	-	1	-	-	-	-
-	-	1	-	-	-	-	-
-	-	-	1	-	-	-	-
-	-	-	1	-	-	-	-
-	-	-	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-7

Method

Cocksfoot (g3) 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	-	2	3	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	1	-	2	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Dog Dander (e5) Allergen CLASS RESULT									House Dust Mite (D. farinae) (d2) Allergen CLASS RESULT								
0	0/1	1	2	3	4	5	6		0	0/1	1	2	3	4	5	6	
ALL METHODS	-	-	-	1	2	3	-	-	-	-	-	1	3	2	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	3	-	-	-	-	-	-	-	2	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

White Oak (t7) Allergen CLASS RESULT									Maple (Box Elder) (t1) Allergen CLASS RESULT								
0	0/1	1	2	3	4	5	6		0	0/1	1	2	3	4	5	6	
ALL METHODS	-	-	-	3	2	-	-	-	2	2	2	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	1	2	-	-	-	1	2	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-	-

Specimen Maple (Box Elder) (t1) Allergen is an ungraded challenge due to less than 80% participant consensus.

Peanut (f13) Allergen CLASS RESULT								
0	0/1	1	2	3	4	5	6	
ALL METHODS	-	-	-	-	2	2	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	1	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	1	-	-	-
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-6						
All Method	5	499.3	70.6	14.1	469	287 - 712
Specimen AL-7						
All Method	5	320.0	19.5	6.1	319	261 - 379
Specimen AL-8						
All Method	5	20.0	2.0	10.0	20	14 - 26
Specimen AL-9						
All Method	5	71.3	4.6	6.5	74	57 - 86
Specimen AL-10						
All Method	5	20.7	2.3	11.2	22	13 - 28

VDRL Slide

<u>Method</u>	Specimen SY-6			Specimen SY-7		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	-	-	-	-	-
ASI	-	-	-	-	-	-
	Specimen SY-8			Specimen SY-9		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	-	-	-	-	-
ASI	-	-	-	-	-	-
	Specimen SY-10					
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>			
ALL METHODS	-	-	-			
ASI	-	-	-			

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	-	11	10	1	-	11
diagnostics direct Syphilis Health Check	-	9	9	-	-	9
INOVA Diagnostics	-	1	-	1	-	1
Siemens ADVIA Centaur	-	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	11	-	11	-
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-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	-	14	14	-	-	14
ASI	-	4	4	-	-	4
Becton Dickinson	-	5	5	-	-	5
Fisher HealthCare Sure-Vue	-	3	3	-	-	3
Wampole Impact RPR	-	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	14	-	14	-
ASI	4	-	4	-
Becton Dickinson	5	-	5	-
Fisher HealthCare Sure-Vue	3	-	3	-
Wampole Impact RPR	1	-	1	-

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</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>	<u>N/A</u> <u>(Neg)</u>
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Specimen SY-6

ALL METHODS	-	-	-	-	-	-	-	-	6
ASI	-	-	-	-	-	-	-	-	2
Becton Dickinson	-	-	-	-	-	-	-	-	4

Specimen SY-7

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

Specimen SY-8

ALL METHODS	-	-	-	-	-	-	-	-	6
ASI	-	-	-	-	-	-	-	-	2
Becton Dickinson	-	-	-	-	-	-	-	-	4

Specimen SY-9

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

Specimen SY-10

ALL METHODS	-	-	1	5	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	-	4	-	-	-	-	-

H. pylori Antibody Detection

<u>Method</u>	Specimen HP-3		Specimen HP-4	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	63	2	2	63
Alere Clearview - moderate	4	-	-	4
Alfa Scientific Instant-View	1	-	-	1
Cardinal Health SP Brand	2	-	-	2
Consult Diagnostics	19	1	1	19
Fisher HealthCare Sure-View	2	-	-	2
Henry Schein OneStep+ - waived	10	-	-	10
Immunostics Inc.	1	-	-	1
McKesson Medi-Lab Performance - waived	1	1	1	1
NDC Pro Advantage	1	-	-	1
Quidel QuickVue	21	-	-	21
Sekisui OSOM	1	-	-	1

Mycoplasma Antibody

<u>Method</u>	Specimen MY-3		Specimen MY-4	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	-	2
Meridian ImmunoCard	2	-	-	2

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	3	-	1	-	4	-
Siemens ADVIA									
Centaur	-	3	-	3	-	-	-	3	-
VITROS 5600	-	1	-	-	-	1	-	1	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	4	-	-	4	-
Siemens ADVIA						
Centaur	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total/IgG)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-
Siemens ADVIA									
Centaur	-	2	-	2	-	-	-	2	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	-	-	2	-	-
Siemens ADVIA						
Centaur	2	-	-	2	-	-

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	3	-	-	3	-	3	-	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	-	1	-	-	1	-	1	-	-
Siemens ADVIA									
Centaur	-	2	-	-	2	-	2	-	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	5	-	1	5	-
Abbott Architect	-	3	-	-	3	-
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-6			Specimen VM-7			Specimen VM-8		
	<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	-
Siemens ADVIA									
Centaur	3	-	-	-	3	-	-	3	-
VITROS 5600	1	-	-	-	1	-	-	1	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	4	-	-	4	-
Siemens ADVIA						
Centaur	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	-
Siemens ADVIA									
Centaur	3	-	-	-	3	-	3	-	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	3	-	3	-	-
Siemens ADVIA						
Centaur	-	3	-	3	-	-

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-6 through VM-10 are: Negative, Negative, Negative, Negative, and Negative, respectively.

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	-
Siemens ADVIA									
Centaur	-	5	-	-	5	-	5	-	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	-	-	5	-	-
Siemens ADVIA						
Centaur	5	-	-	5	-	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	5	-	2	-	7	-
Abbott Architect	-	1	-	1	-	-	-	1	-
Siemens ADVIA									
Centaur	-	4	-	3	-	1	-	4	-
Siemens									
Immulin/1000	-	1	-	1	-	-	-	1	-
VITROS 5600	-	1	-	-	-	1	-	1	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	5	1	-	7	-
Abbott Architect	1	-	-	-	1	-
Siemens ADVIA						
Centaur	-	3	1	-	4	-
Siemens						
Immulin/1000	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	1	-	-	1	-	-	1	-
Siemens ADVIA									
Centaur	-	5	-	-	5	-	-	5	-
VITROS 5600	-	1	-	-	1	-	-	1	-

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

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