MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Immunology
2019 MLE-M2

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
H. *pylori* 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 ± 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	± 25%
Total IgM	± 3 SD

Infectious Mononucleosis

	Specimen IM-6		Specimen IM-7	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	148	-	-	148
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	3	-	-	3
BioStar Acceava Mono Test	2	-	-	2
BioStar Acceava Mono-whole bld	4	-	-	4
Cardinal Health SP Brand - waived	5	-	-	5
Clarity Diagnostics	1	-	-	1
Consult Diagnostics	21	-	-	21
Fisher HealthCare Sure-Vue	4	-	-	4
Henry Schein OneStep+ - waived	15	-	-	15
LifeSign Status - waived	6	-	-	6
Other Moderate method	4	-	-	4
Other Waived method	11	-	-	11
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	4	-	-	4
Sekisui OSOM	5	-	-	5
Sekisui OSOM (waived)	47	-	-	47

Infectious Mononucleosis

	Specimen IM-8		Specimen IM-9		Specimen IM-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	39	-	1	38	-	39
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	3	-	-	3	-	3
BioStar Acceava Mono Test	1	-	-	1	-	1
BioStar Acceava Mono-whole bld	1	-	-	1	-	1
Consult Diagnostics	7	-	1	6	-	7
Fisher HealthCare Sure-Vue	1	-	-	1	-	1
Henry Schein OneStep+ - waived	2	-	-	2	-	2
LifeSign Status - waived	1	-	-	1	-	1
Other Moderate method	4	-	-	4	-	4
Other Waived method	2	-	-	2	-	2
Quidel QuickVue+	1	-	-	1	-	1
Quidel QuickVue+ - waived	2	-	-	2	-	2
Sekisui OSOM	5	-	-	5	-	5
Sekisui OSOM (waived)	3	-	-	3	-	3

Rheumatoid Factor—Qualitative

Method	Specimen RF-6		Specimen RF-7		Specimen RF-8	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	1	26	27	-	27	-
ASI	1	5	6	-	6	-
Biokit Rheumajet	-	1	1	-	1	-
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	-	3	3	-	3	-

Method	Specimen RF-9		Specimen RF-10	
	Positive	Negative	Positive	Negative
ALL METHODS	27	-	1	26
ASI	6	-	1	5
Biokit Rheumajet	1	-	-	1
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	3	-	-	3

Rheumatoid Factor—Semi-Quantitative (Titer)

Specimen/Method	*N/A (Neg)*	*2/ 4*	*8/ 10*	*16/ 20*	*32/ 40*	*64/ 80*	*128/ 160*	*256/ 320*	*512/ 640*	*1024/ 1280*	*2048/ 2560*	*>2560*
Specimen RF-6												
ALL METHODS	3	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-7												
ALL METHODS	-	1	2	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-
Specimen RF-8												
ALL METHODS	-	-	2	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	1	1	-	-	-	-	-	-	-	-
Specimen RF-9												
ALL METHODS	-	1	2	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-
Specimen RF-10												
ALL METHODS	3	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU/mL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen RF-6						
All Method	17	8.4	4.0	48.2	7	0 - 21
Beckman AU	10	9.0	2.0	22.2	10	3 - 15
Specimen RF-7						
All Method	17	62.9	7.8	12.5	66	39 - 87
Beckman AU	10	62.3	8.5	13.6	62	36 - 88
Specimen RF-8						
All Method	17	127.1	10.8	8.5	139	94 - 160
Beckman AU	10	126.2	11.8	9.4	123	90 - 162
Specimen RF-9						
All Method	17	63.1	8.4	13.3	67	38 - 89
Beckman AU	10	63.0	9.8	15.5	63	33 - 93
Specimen RF-10						
All Method	17	8.2	3.4	41.6	8	0 - 19
Beckman AU	10	8.8	1.6	18.1	10	4 - 14

Anti-Streptolysin O (ASO)—Qualitative

	Specimen AS-6		Specimen AS-7		Specimen AS-8	
Method	*Positive*	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	1	-	-	1	-	1
ASI	1	-	-	1	-	1

	Specimen AS-9		Specimen AS-10	
Method	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	1	1	-
ASI	-	1	1	-

Complement C3 (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-6						
All Method	12	52.5	2.3	4.4	52	45 - 60
Specimen IMP-7						
All Method	12	151.0	5.3	3.5	152	135 - 167
Specimen IMP-8						
All Method	11	147.7	3.6	2.4	148	137 - 159
Specimen IMP-9						
All Method	11	147.0	3.4	2.3	146	136 - 158
Specimen IMP-10						
All Method	11	119.4	3.2	2.7	119	109 - 129

Complement C4 (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-6						
All Method	12	9.8	0.8	7.7	10	7 - 13
Specimen IMP-7						
All Method	12	30.6	1.7	5.7	31	25 - 36
Specimen IMP-8						
All Method	11	29.3	1.6	5.5	29	24 - 35
Specimen IMP-9						
All Method	11	30.5	1.8	5.8	30	25 - 36
Specimen IMP-10						
All Method	11	23.5	1.1	4.8	23	20 - 27

IgA (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-6						
All Method	12	74.2	5.5	7.5	75	57 - 91
Beckman AU	10	78.0	2.6	3.4	79	70 - 86
Specimen IMP-7						
All Method	12	228.8	5.8	2.5	227	211 - 247
Beckman AU	10	231.0	6.9	3.0	227	210 - 252
Specimen IMP-8						
All Method	12	215.0	6.0	2.8	214	197 - 233
Beckman AU	10	217.0	7.2	3.3	219	195 - 239
Specimen IMP-9						
All Method	12	472.8	15.1	3.2	478	427 - 518
Beckman AU	10	473.3	20.4	4.3	478	412 - 535
Specimen IMP-10						
All Method	12	176.0	6.0	3.4	174	158 - 194
Beckman AU	10	179.3	5.0	2.8	180	164 - 195

IgG (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-6						
All Method	12	357.0	18.0	5.0	354	267 - 447
Beckman AU	10	360.3	12.7	3.5	354	270 - 451
Specimen IMP-7						
All Method	12	1902.2	126.9	6.7	1857	1426 - 2378
Beckman AU	10	1926.7	123.3	6.4	1857	1445 - 2409
Specimen IMP-8						
All Method	12	1040.6	47.8	4.6	1053	780 - 1301
Beckman AU	10	1060.3	13.6	1.3	1053	795 - 1326
Specimen IMP-9						
All Method	12	1059.6	75.8	7.2	1061	794 - 1325
Beckman AU	10	1091.3	62.3	5.7	1061	818 - 1365
Specimen IMP-10						
All Method	12	839.6	35.3	4.2	848	629 - 1050
Beckman AU	10	847.0	5.6	0.7	848	635 - 1059

IgM (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-6						
All Method	12	32.2	2.6	8.0	33	24 - 40
Beckman AU	10	34.0	1.0	2.9	34	31 - 37
Specimen IMP-7						
All Method	12	94.4	2.3	2.4	95	87 - 102
Beckman AU	10	95.0	2.6	2.8	96	87 - 103
Specimen IMP-8						
All Method	12	395.4	28.8	7.3	403	308 - 482
Beckman AU	10	379.7	27.1	7.1	386	298 - 461
Specimen IMP-9						
All Method	12	90.2	2.4	2.6	90	83 - 98
Beckman AU	10	91.3	2.1	2.3	92	85 - 98
Specimen IMP-10						
All Method	12	73.2	2.0	2.8	74	67 - 80
Beckman AU	10	73.3	2.1	2.8	74	67 - 80

C-Reactive Protein—Qualitative, Regular

	Specimen CR-3		Specimen CR-4	
Method	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	5	-	-	5
Siemens Dimension	5	-	-	5

C-Reactive Protein—Quantitative (mg/dL or mg/L), Regular

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen CR-3						
mg/dL - units						
All Immunology Methods	20	2.817	0.284	10.1	2.89	1.96 - 3.67
mg/L - units						
All Immunology Methods	15	28.341	3.981	14.0	27.90	16.39 - 40.29
Specimen CR-4						
mg/dL - units						
All Immunology Methods	20	0.145	0.152	105.3	0.10	0.00 - 0.61
mg/L - units						
All Immunology Methods	15	1.800	1.961	108.9	1.00	0.00 - 7.69

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

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen HCR-3						
All Method	22	2.480	0.418	16.9	2.41	1.22 - 3.74
Specimen HCR-4						
All Method	22	10.527	1.654	15.7	10.68	5.56 - 15.50

Antinuclear Antibody (ANA) - Qualitative

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	*Positive*	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	15	-	-	15	11	4
ASI	3	-	-	3	-	3
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	-

	Specimen AE-9		Specimen AE-10	
Method	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	12	3	-	15
ASI	-	3	-	3
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)

Specimen/Method	*N/A (Neg)*	*8/ 10*	*16/ 20*	*32/ 40*	*64/ 80*	*128/ 160*	*256/ 320*	*512/ 640*	*>640*	*1024/ 1280*	*2048/ 2560*	*≥2560*
Specimen AE-6												
ALL METHODS	-	-	-	-	-	-	-	2	1	2	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	1	1	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-7												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-8												
ALL METHODS	-	-	-	-	-	-	-	2	1	1	1	-
Bio-Rad	-	-	-	-	-	-	-	-	-	1	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	1	-	1	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
Specimen AE-9												
ALL METHODS	-	-	-	-	-	-	1	3	1	-	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	1	1	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
Specimen AE-10												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-

Anti-dsDNA

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	8	-	9	8	1
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	-	1	-	1	1	-
INOVA Diagnostics	-	1	-	1	1	-
TheraTest	1	5	-	6	6	-

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	9	-	9
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	6	-	6

Anti-RNP

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	2	-	-	2	-	2
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	1	-	-	1	-	1

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	2	-	2
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1

Anti-RNP/Sm

Method	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	8	-	2	6	-	8
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1
Immuno Concepts	1	-	-	1	-	1
TheraTest	6	-	2	4	-	6

Method	Specimen AE-9		Specimen AE-10	
	Positive	Negative	Positive	Negative
ALL METHODS	-	8	-	8
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	-	6	-	6

Anti-SSA

Method	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	-	8	-	8	-	8
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	-	6	-	6	-	6

Method	Specimen AE-9		Specimen AE-10	
	Positive	Negative	Positive	Negative
ALL METHODS	8	-	-	8
Immuno Concepts	1	-	-	1
INOVA Diagnostics	1	-	-	1
TheraTest	6	-	-	6

Anti-SSB

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	8	-	8	-	8
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	-	1	-	1
TheraTest	-	6	-	6	-	6

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	7	1	-	8
Immuno Concepts	1	-	-	1
INOVA Diagnostics	1	-	-	1
TheraTest	5	1	-	6

Anti-SSA/SSB

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	1	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1

Anti-Sm

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	3	5	-	8	-	8
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	1	-	-	1	-	1
TheraTest	2	4	-	6	-	6

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	8	-	8
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	6	-	6

Specimen AE-6 ungraded challenge due to less than 80% participant consensus.

Rubella—Qualitative

Method	Specimen RU-6 Positive	Specimen RU-6 Negative	Specimen RU-7 Positive	Specimen RU-7 Negative	Specimen RU-8 Positive	Specimen RU-8 Negative
ALL METHODS	5	-	-	5	5	-
INOVA Diagnostics	2	-	-	2	2	-
Siemens ADVIA Centaur	3	-	-	3	3	-

Method	Specimen RU-9 Positive	Specimen RU-9 Negative	Specimen RU-10 Positive	Specimen RU-10 Negative
ALL METHODS	-	5	5	-
INOVA Diagnostics	-	2	2	-
Siemens ADVIA Centaur	-	3	3	-

Rubella—Quantitative (IU/mL)

One lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values on a Beckman Access 2 for specimens RU-6 through RU-10 are: 50.0 IU/mL, <10 IU/mL, 68.8 IU/mL, <10 IU/mL, and 68.8 IU/mL, respectively.

Anti-HIV

Method	Specimen HIV-6 Positive	Specimen HIV-6 Negative	Specimen HIV-7 Positive	Specimen HIV-7 Negative
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	12	-	-	12
Chembio HIV 1/2 Assay - waived	10	-	-	10
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	2	-	-	2
Orasure OraQuick Advance Rapid HIV-1/2 - waived	14	-	-	14
Other Waived method	3	-	-	3
Trinity Biotech Uni-Gold - waived	12	-	-	12

Method	Specimen HIV-8 Positive	Specimen HIV-8 Negative	Specimen HIV-9 Positive	Specimen HIV-9 Negative	Specimen HIV-10 Positive	Specimen HIV-10 Negative
ALL METHODS	5	-	-	5	5	-
Alere Determine HIV - moderate	5	-	-	5	5	-

Allergen Specific IgE Antibodies

Specimen AL-6

Method	White Oak (t7) 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	-	-	-	4	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hycor EIA	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-

	House Dust Mite (D. farinae) (d2) 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	4	-	-	-	-	-	-	1	4	1	-	-
Hitachi CLA-1	-	-	-	-	1	-	-	-	-	-	-	-	1	1	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Cow Milk (f2) Allergen CLASS RESULT								Cladosporium herbarum (m2) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	2	4	-	-	-	-	2	1	1	1	-	-	-	-
Hitachi CLA-1	-	-	1	1	-	-	-	-	-	-	1	1	-	-	-	-
Hycor EIA	-	-	-	1	-	-	-	-	1	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-	1	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-

	English Plantain (w9) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	2	-	2	-	-	-
Hitachi CLA-1	-	-	2	-	-	-	-	-
Hycor EIA	-	-	-	-	1	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-
Phadia UniCap 100 (KU/L)	1	-	-	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-7

Method	House Dust Mite (D. pteronyssinus) (d1) Allergen *CLASS RESULT*								Sweet Vernal Grass (g1) Allergen *CLASS RESULT*							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**	**0**	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	-	-	-	4	1	-	-	-	-	-	-	-	-	2	-	-
Hitachi CLA-1	-	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-
Hycor EIA	-	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-
Hycor RAST (Ru/mL)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-

	Bahia Grass (g17) 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**
ALL METHODS	-	-	-	-	3	-	-	-	-	-	1	2	1	1	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	1	1	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	1	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-

	Dog Dander (e5) Allergen *CLASS RESULT*								Penicillium chrysogenum (m1) 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	-	-	-	-	2	-	-	1	1	-	-	-
Hitachi CLA-1	-	-	-	2	-	-	-	-	1	-	-	-	-	-	-	-
Hycor EIA	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-

	Alternaria alternata (m6) Allergen *CLASS RESULT*							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	-	-	6	-	-	-	-	-
Hitachi CLA-1	-	-	2	-	-	-	-	-
Hycor EIA	-	-	1	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-

Total IgE—Quantitative (U/mL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen AL-6						
All Method	5	464.5	42.4	9.1	471	337 - 592
Specimen AL-7						
All Method	5	170.0	32.8	19.3	174	71 - 269
Specimen AL-8						
All Method	5	17.3	2.6	15.2	17	9 - 26
Specimen AL-9						
All Method	5	70.3	18.8	26.7	70	13 - 127
Specimen AL-10						
All Method	5	17.8	1.9	10.7	19	12 - 24

Syphilis Serology—Qualitative: MHA-TP

	Specimen SY-6		Specimen SY-7		Specimen SY-8	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	1	-	1	-	-	1
Serodia	1	-	1	-	-	1

	Specimen SY-9		Specimen SY-10	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	1	-	-	1
Serodia	1	-	-	1

Syphilis Serology—Qualitative: Treponema pallidum antibodies

	Specimen SY-6		Specimen SY-7		Specimen SY-8	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
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

	Specimen SY-9		Specimen SY-10	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
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

	Specimen SY-6		Specimen SY-7		Specimen SY-8	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	15	-	15	-	-	15
ASI	7	-	7	-	-	7
Becton Dickinson	5	-	5	-	-	5
Fisher HealthCare Sure-Vue	3	-	3	-	-	3

	Specimen SY-9		Specimen SY-10	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	14	1	-	15
ASI	6	1	-	7
Becton Dickinson	5	-	-	5
Fisher HealthCare Sure-Vue	3	-	-	3

Syphilis Serology—Semi-Quantitative: RPR (Titer)

Specimen/Method	***N/A (Neg)***	***1:1***	***1:2***	***1:4***	***1:8***	***1:16***	***1:32***	***1:64***	***1:>64***
Specimen SY-6									
ALL METHODS	-	-	6	1	-	-	-	-	-
ASI	-	-	2	1	-	-	-	-	-
Becton Dickinson	-	-	4	-	-	-	-	-	-
Specimen SY-7									
ALL METHODS	-	1	-	5	1	-	-	-	-
ASI	-	1	-	1	1	-	-	-	-
Becton Dickinson	-	-	-	4	-	-	-	-	-
Specimen SY-8									
ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
Specimen SY-9									
ALL METHODS	1	-	4	2	-	-	-	-	-
ASI	1	-	-	2	-	-	-	-	-
Becton Dickinson	-	-	4	-	-	-	-	-	-
Specimen SY-10									
ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-

H. *pylori* Antibody Detection

	Specimen HP-3		Specimen HP-4	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	50	1	-	51
Alere Clearview - moderate	3	-	-	3
Cardinal Health SP Brand	1	-	-	1
Consult Diagnostics	13	1	-	14
Fisher HealthCare Sure-Vue	2	-	-	2
Henry Schein OneStep+ - waived	8	-	-	8
McKesson Medi-Lab Performance - waived	1	-	-	1
NDC Pro Advantage	2	-	-	2
Polymedco Poly stat	1	-	-	1
Quidel QuickVue	17	-	-	17
Sekisui OSOM	1	-	-	1

Mycoplasma Antibody

	Specimen MY-3		Specimen MY-4	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	7	7	-
Meridian ImmunoCard	-	7	7	-

Viral Markers – Anti-HBc (IgM)

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	4	-	-	-	4	-	-	4	-
Abbott Architect	2	-	-	-	2	-	-	2	-
Siemens ADVIA Centaur	1	-	-	-	1	-	-	1	-
VITROS 5600	1	-	-	-	1	-	-	1	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	4	-	-	4	-
Abbott Architect	-	2	-	-	2	-
Siemens ADVIA Centaur	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total/IgG)

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	1	-	-	-	1	-	1	-	-
Abbott Architect	1	-	-	-	1	-	1	-	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	1	-	-	1	-
Abbott Architect	-	1	-	-	1	-

Viral Markers – Anti-HIV

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	8	-	-	8	-	-	8	-
Abbott Architect	-	3	-	-	3	-	-	3	-
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	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	8	-	8	-	-
Abbott Architect	-	3	-	3	-	-
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)

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	4	-	-	4	-	-	4	-
Abbott Architect	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	4	-	-	4	-
Abbott Architect	-	2	-	-	2	-
Siemens ADVIA Centaur	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	3	-	3	-	-	-	3	-
Abbott Architect	-	2	-	2	-	-	-	2	-
Siemens ADVIA Centaur	-	1	-	1	-	-	-	1	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
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-6 through VM-10 are: Negative, Negative, Negative, Negative, and Negative, respectively.

Viral Markers – Anti-HBs

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	3	-	3	-	-	3	-	-
Abbott Architect	-	2	-	2	-	-	2	-	-
Siemens ADVIA Centaur	-	1	-	1	-	-	1	-	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	3	-	3	-	-
Abbott Architect	-	2	-	2	-	-
Siemens ADVIA Centaur	-	1	-	1	-	-

Viral Markers – HBsAg

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	6	-	-	-	6	-	-	6	-
Abbott Architect	3	-	-	-	3	-	-	3	-
Siemens ADVIA Centaur	2	-	-	-	2	-	-	2	-
VITROS 5600	1	-	-	-	1	-	-	1	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	6	-	-	6	-
Abbott Architect	-	3	-	-	3	-
Siemens ADVIA Centaur	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HCV

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	10	-	-	10	-	-	10	-
Abbott Architect	-	3	-	-	3	-	-	3	-
OraSure OraQuick HCV	-	3	-	-	3	-	-	3	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-	-	1	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	10	-	-	-	10	-
Abbott Architect	3	-	-	-	3	-
OraSure OraQuick HCV	3	-	-	-	3	-
Roche cobas e 411	1	-	-	-	1	-
Siemens ADVIA Centaur	2	-	-	-	2	-
VITROS 5600	1	-	-	-	1	-

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