MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Immunology
2018 MLE-M1

ACP Medical Laboratory Evaluation

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

Table of Contents

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)	± 2 SD
Rubella (International Units)	± 3 SD
Total IgA	± 3 SD
Total IgE	± 3 SD
Total IgG	± 25%
Total IgM	± 3 SD

Infectious Mononucleosis

Method	**Specimen IM-1** ***Positive***	***Negative***	**Specimen IM-2** ***Positive***	***Negative***
ALL METHODS	-	174	173	-
Alere Clearview - moderate	-	2	2	-
Alere Clearview - waived	-	5	5	-
Alere Clearview Mono Plus II - moderate	-	1	1	-
Alere Clearview Mono Plus II - waived	-	4	4	-
ASI	-	1	1	-
Beckman Coulter ICON Mono - waived	-	10	9	-
BioStar Acceava Mono Test	-	2	2	-
BioStar Acceava Mono-whole bld	-	3	3	-
BTNX Rapid Response – moderate	-	1	1	-
Cardinal Health SP Brand - waived	-	7	7	-
Consult Diagnostics	-	22	22	-
Fisher HealthCare Sure-Vue	-	5	5	-
Henry Schein OneStep+ - waived	-	16	16	-
LifeSign Status - waived	-	9	9	-
McKesson Medi-Lab Performance - waived	-	2	2	-
Other Moderate method	-	3	3	-
Other Waived method	-	15	15	-
Quidel QuickVue+	-	1	1	-
Quidel QuickVue+ - waived	-	5	5	-
Sekisui OSOM	-	4	4	-
Sekisui OSOM (waived)	-	54	54	-
Seradyn	-	1	1	-

Infectious Mononucleosis

Method	Specimen IM-3		Specimen IM-4		Specimen IM-5	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	52	52	-	-	52
Alere Clearview - moderate	-	2	2	-	-	2
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 - waived	-	1	1	-	-	1
Consult Diagnostics	-	6	6	-	-	6
Fisher HealthCare Sure-Vue	-	2	2	-	-	2
Henry Schein OneStep+ - waived	-	4	4	-	-	4
LifeSign Status - waived	-	1	1	-	-	1
McKesson Medi-Lab Performance - waived	-	1	1	-	-	1
Other Moderate method	-	3	3	-	-	3
Other Waived method	-	2	2	-	-	2
Quidel QuickVue+	-	1	1	-	-	1
Quidel QuickVue+ - waived	-	3	3	-	-	3
Sekisui OSOM	-	4	4	-	-	4
Sekisui OSOM (waived)	-	6	6	-	-	6
Seradyn	-	1	1	-	-	1

Rheumatoid Factor—Qualitative

	Specimen RF-1		Specimen RF-2		Specimen RF-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	32	32	-	32	-
ASI	-	9	9	-	9	-
Biokit Rheumajet	-	3	3	-	3	-
Diamedix	-	1	1	-	1	-
Fisher HealthCare Sure-Vue	-	4	4	-	4	-
Immunostics Inc.	-	1	1	-	1	-
INOVA Diagnostics	-	1	1	-	1	-
TheraTest	-	4	4	-	4	-
Wampole ColorCard	-	5	5	-	5	-
Wampole Rheumatex	-	4	4	-	4	-

	Specimen RF-4		Specimen RF-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	32	-	-	32
ASI	9	-	-	9
Biokit Rheumajet	3	-	-	3
Diamedix	1	-	-	1
Fisher HealthCare Sure-Vue	4	-	-	4
Immunostics Inc.	1	-	-	1
INOVA Diagnostics	1	-	-	1
TheraTest	4	-	-	4
Wampole ColorCard	5	-	-	5
Wampole Rheumatex	4	-	-	4

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-1												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	1	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-2												
ALL METHODS	-	-	1	1	1	1	-	-	-	-	-	-
ASI	-	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	1	1	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	1	-	-	-	-	-	-
Specimen RF-3												
ALL METHODS	-	-	2	1	-	1	-	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	1	-	-	-	-	-	-
Specimen RF-4												
ALL METHODS	-	-	-	2	-	1	1	-	-	-	-	-
ASI	-	-	-	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	2	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	-	-	-	1	-	-	-	-	-
Specimen RF-5												
ALL METHODS	4	-	-	-	-	-	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Wampole ColorCard	1	-	-	-	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU/mL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen RF-1						
All Method	14	6.3	5.1	80.7	3	0 - 17
Specimen RF-2						
All Method	14	118.8	11.0	9.2	117	96 - 141
Specimen RF-3						
All Method	14	70.9	13.3	18.7	66	44 - 98
Specimen RF-4						
All Method	14	120.3	11.4	9.5	118	97 - 144
Specimen RF-5						
All Method	14	6.3	4.7	75.3	5	0 - 16

Anti-Streptolysin O (ASO)—Qualitative

Method	**Specimen AS-1**		**Specimen AS-2**		**Specimen AS-3**	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	1	-	1	-	-	1

Method	**Specimen AS-4**		**Specimen AS-5**	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	1	-	-	1

Complement C3 (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-1						
All Method	13	152.6	4.9	3.2	153	137 - 168
Specimen IMP-2						
All Method	14	67.3	4.5	6.7	69	53 - 81
Specimen IMP-3						
All Method	14	154.4	10.4	6.7	158	123 - 186
Specimen IMP-4						
All Method	13	177.5	7.5	4.2	178	154 - 201
Specimen IMP-5						
All Method	14	158.6	12.1	7.7	163	122 - 196

Complement C4 (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-1						
All Method	14	30.3	1.6	5.4	31	25 - 36
Specimen IMP-2						
All Method	14	12.9	0.9	6.7	13	10 - 16
Specimen IMP-3						
All Method	14	30.0	6.2	20.8	29	11 - 49
Specimen IMP-4						
All Method	14	35.6	2.6	7.2	36	27 - 44
Specimen IMP-5						
All Method	14	32.6	2.3	7.2	33	25 - 40

IgA (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-1						
All Method	11	207.8	8.7	4.2	207	181 - 234
Specimen IMP-2						
All Method	11	95.2	2.5	2.6	95	87 - 103
Specimen IMP-3						
All Method	11	229.2	28.4	12.4	219	143 - 315
Specimen IMP-4						
All Method	11	250.7	13.1	5.2	254	211 - 290
Specimen IMP-5						
All Method	11	512.3	23.6	4.6	505	441 - 584

IgG (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-1						
All Method	11	1071.7	80.9	7.5	1063	803 - 1340
Specimen IMP-2						
All Method	11	460.2	26.7	5.8	454	345 - 576
Specimen IMP-3						
All Method	11	1118.0	114.7	10.3	1060	838 - 1398
Specimen IMP-4						
All Method	11	1917.3	198.0	10.3	1860	1437 - 2397
Specimen IMP-5						
All Method	11	1103.5	101.7	9.2	1063	827 - 1380

IgM (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-1						
All Method	11	98.0	9.3	9.4	94	70 - 126
Specimen IMP-2						
All Method	11	43.7	3.9	9.0	43	31 - 56
Specimen IMP-3						
All Method	11	470.0	72.0	15.3	491	253 - 687
Specimen IMP-4						
All Method	11	116.8	11.5	9.9	112	82 - 152
Specimen IMP-5						
All Method	11	103.3	11.2	10.8	98	69 - 137

C-Reactive Protein—Qualitative, Regular

	Specimen CR-1		Specimen CR-2	
Method	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	11	11	-
Fisher HealthCare Sure-Vue	-	8	8	-
Immunostics Inc.	-	1	1	-
Siemens Dimension	-	2	2	-

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

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen CR-1						
mg/dL - units						
All Immunology Methods	21	0.166	0.159	96.0	0.10	0.00 - 0.65
mg/L - units						
All Immunology Methods	16	2.425	2.299	94.8	1.75	0.00 - 9.33
Specimen CR-2						
mg/dL - units						
All Immunology Methods	21	6.469	0.402	6.2	6.50	5.26 - 7.68
mg/L - units						
All Immunology Methods	16	60.024	7.349	12.2	57.45	37.97 - 82.08

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

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen HCR-1						
All Method	26	0.678	0.329	48.6	0.80	0.00 - 1.67
Specimen HCR-2						
All Method	27	9.468	3.517	37.2	10.20	0.00 - 20.03

Antinuclear Antibody (ANA) - Qualitative

	Specimen AE-1		Specimen AE-2		Specimen AE-3	
Method	*Positive*	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	14	-	-	14	-	14
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	4	-	-	4	-	4

	Specimen AE-4		Specimen AE-5	
Method	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	14	-	1	13
ASI	2	-	1	1
Bio-Rad	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1
Immuno Concepts	3	-	-	3
INOVA Diagnostics	3	-	-	3
TheraTest	4	-	-	4

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-1												
ALL METHODS	-	-	-	-	-	1	3	-	1	-	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	1	1	-	1	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-	-
Specimen AE-2												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-3												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-4												
ALL METHODS	-	-	-	-	-	1	-	2	1	1	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	1	-	1	1	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-5												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-

Anti-dsDNA

	Specimen AE-1		Specimen AE-2		Specimen AE-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	9	1	-	10	-	10
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	2	-	-	2	-	2
TheraTest	6	-	-	6	-	6

	Specimen AE-4		Specimen AE-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	9	-	10
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	1	5	-	6

Anti-RNP

	Specimen AE-1		Specimen AE-2		Specimen AE-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	2	-	2	-	2
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	1	-	1	-	1

	Specimen AE-4		Specimen AE-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	1	-	2
Immuno Concepts	-	1	-	1
INOVA Diagnostics	1	-	-	1

Specimen AE-4 is an ungraded challenge due to less than 80% participant consensus.

Anti-RNP/Sm

Method	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	8	1	-	9	-	9
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	1	-	-	1	-	1
TheraTest	6	-	-	6	-	6

Method	Specimen AE-4		Specimen AE-5	
	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-SSA

Method	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	9	-	-	9	-	9
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	2	-	-	2	-	2
TheraTest	6	-	-	6	-	6

Method	Specimen AE-4		Specimen AE-5	
	Positive	Negative	Positive	Negative
ALL METHODS	-	9	-	9
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	6	-	6

Anti-SSB

Method	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	-	9	-	9	-	9
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
TheraTest	-	6	-	6	-	6

Method	Specimen AE-4		Specimen AE-5	
	Positive	Negative	Positive	Negative
ALL METHODS	-	9	-	9
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	6	-	6

Anti-SSA/SSB

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	1	-	-	1	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	-	1	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1

Anti-Sm

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	-	9	-	9	-	9
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	2	-	2	-	2
TheraTest	-	6	-	6	-	6

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	-	9	-	9
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	2	-	2
TheraTest	-	6	-	6

Rubella—Qualitative

Method	Specimen RU-1 Positive	Specimen RU-1 Negative	Specimen RU-2 Positive	Specimen RU-2 Negative	Specimen RU-3 Positive	Specimen RU-3 Negative
ALL METHODS	5	-	-	5	-	5
bioMerieux Vidas, Mini Vidas	2	-	-	2	-	2
DiaSorin	1	-	-	1	-	1
INOVA Diagnostics	1	-	-	1	-	1
Siemens ADVIA Centaur	1	-	-	1	-	1

Method	Specimen RU-4 Positive	Specimen RU-4 Negative	Specimen RU-5 Positive	Specimen RU-5 Negative
ALL METHODS	-	5	5	-
bioMerieux Vidas, Mini Vidas	-	2	2	-
DiaSorin	-	1	1	-
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-1 through RU-5 are: 37.2 IU/mL, 0.1 IU/mL, 0.1 IU/mL, 0.1 IU/mL, and 37.2 IU/mL, respectively.

Anti-HIV

Method	Specimen HIV-1 Positive	Specimen HIV-1 Negative	Specimen HIV-2 Positive	Specimen HIV-2 Negative
ALL METHODS	1	63	63	1
Alere Clearview Complete HIV 1/2	-	1	1	-
Alere Clearview HIV1/2 STAT-PAK	-	4	4	-
Alere Determine HIV - moderate	-	5	5	-
Alere Determine HIV - waived	-	2	2	-
BD LINK 2	-	1	1	-
bioLytical Labs INSTI HIV - waived	-	2	2	-
Chembio HIV 1/2 Assay - waived	-	7	7	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	24	24	-
Other Waived method	1	5	5	1
Trinity Biotech Uni-Gold - waived	-	13	13	-

Method	Specimen HIV-3 Positive	Specimen HIV-3 Negative	Specimen HIV-4 Positive	Specimen HIV-4 Negative	Specimen HIV-5 Positive	Specimen HIV-5 Negative
ALL METHODS	-	5	5	-	-	5
Alere Determine HIV - moderate	-	5	5	-	-	5

Allergen Specific IgE Antibodies

Specimen AL-1

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

	Dog Dander (e5) 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	-	-	2	2	-	-	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-

	White Oak (t7) Allergen *CLASS RESULT*								**Aspergillus fumigatus (m3) Allergen *CLASS RESULT***							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**	**0**	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	-	-	-	3	-	-	-	-	4	1	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	1	-	-	-	-	-	1	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	2	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-

	Peanut (f13) Allergen *CLASS RESULT*							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	1	-	2	2	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-
Hitachi CLA-1	1	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	2	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-2

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**
ALL METHODS	-	-	-	1	2	1	-	-	-	-	-	-	-	2	-	-
DPC-Standard Microplate	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	-	-	-	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	-	-	-	1	1	1	-	-	-	-	-	2	2	1	-	-
DPC-Standard Microplate	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Hycor RAST (Ru/mL)	-	-	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-

	House Dust Mite (D. pteronyssinus) (d1) Allergen *CLASS RESULT*								Cow Milk (f2) Allergen *CLASS RESULT*							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**	**0**	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	-	-	-	-	4	-	-	-	5	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	1	-	-	-	1	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Hycor RAST (Ru/mL)	-	-	-	-	1	-	-	-	1	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	1	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	1	-	-	-	-	-	-	-

	Peanut (f13) Allergen *CLASS RESULT*							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	-	1	2	1	-	-	-	-
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)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen AL-1						
All Method	5	208.0	18.8	9.1	200	151 - 265
Specimen AL-2						
All Method	5	675.0	64.6	9.6	651	481 - 869
Specimen AL-3						
All Method	5	66.5	3.7	5.6	67	55 - 78
Specimen AL-4						
All Method	5	21.0	0.8	3.9	21	18 - 24
Specimen AL-5						
All Method	5	20.8	1.0	4.6	21	17 - 24

Syphilis Serology—Qualitative: VDRL Slide

	Specimen SY-1			Specimen SY-2		
Method	*Reactive*	*Weakly Reactive*	*Non-Reactive*	*Reactive*	*Weakly Reactive*	*Non-Reactive*
ALL METHODS	1	-	-	-	-	1
ASI	1	-	-	-	-	1

	Specimen SY-3			Specimen SY-4		
	Reactive	*Weakly Reactive*	*Non-Reactive*	*Reactive*	*Weakly Reactive*	*Non-Reactive*
ALL METHODS	1	-	-	1	-	-
ASI	1	-	-	1	-	-

	Specimen SY-5		
	Reactive	*Weakly Reactive*	*Non-Reactive*
ALL METHODS	-	-	1
ASI	-	-	1

Syphilis Serology—Qualitative: MHA-TP

	Specimen SY-1			Specimen SY-2		
Method	***Reactive***	***Weakly Reactive***	***Non-Reactive***	***Reactive***	***Weakly Reactive***	***Non-Reactive***
ALL METHODS	1	-	-	-	-	1
ASI	1	-	-	-	-	1

	Specimen SY-3			Specimen SY-4		
	Reactive	***Weakly Reactive***	***Non-Reactive***	***Reactive***	***Weakly Reactive***	***Non-Reactive***
ALL METHODS	1	-	-	1	-	-
ASI	1	-	-	1	-	-

	Specimen SY-5		
	Reactive	***Weakly Reactive***	***Non-Reactive***
ALL METHODS	-	-	1
ASI	-	-	1

Syphilis Serology—Qualitative: Treponema pallidum antibodies

Method	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	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	-

Method	Specimen SY-4		Specimen SY-5	
	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

Method	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	Reactive	Non-Reactive	Reactive	Non-Reactive	Reactive	Non-Reactive
ALL METHODS	18	-	-	18	18	-
ASI	4	-	-	4	4	-
Becton Dickinson	8	-	-	8	8	-
Fisher HealthCare Sure-Vue	3	-	-	3	3	-
Stanbio Laboratory	1	-	-	1	1	-
Wampole Impact RPR	1	-	-	1	1	-

Method	Specimen SY-4		Specimen SY-5	
	Reactive	Non-Reactive	Reactive	Non-Reactive
ALL METHODS	18	-	-	18
ASI	4	-	-	4
Becton Dickinson	8	-	-	8
Fisher HealthCare Sure-Vue	3	-	-	3
Stanbio Laboratory	1	-	-	1
Wampole Impact RPR	1	-	-	1

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-1									
ALL METHODS	-	-	-	2	6	-	-	-	-
ASI	-	-	-	2	1	-	-	-	-
Becton Dickinson	-	-	-	-	5	-	-	-	-
Specimen SY-2									
ALL METHODS	8	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	5	-	-	-	-	-	-	-	-
Specimen SY-3									
ALL METHODS	-	-	2	6	-	-	-	-	-
ASI	-	-	2	1	-	-	-	-	-
Becton Dickinson	-	-	-	5	-	-	-	-	-
Specimen SY-4									
ALL METHODS	-	-	3	5	-	-	-	-	-
ASI	-	-	3	-	-	-	-	-	-
Becton Dickinson	-	-	-	5	-	-	-	-	-
Specimen SY-5									
ALL METHODS	8	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	5	-	-	-	-	-	-	-	-

H. *pylori* Antibody Detection

	Specimen HP-1		Specimen HP-2	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	61	-	1	60
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	18	-	-	18
Fisher HealthCare Sure-Vue	2	-	-	2
Germaine Laboratories	1	-	-	1
Henry Schein OneStep+ - waived	9	-	-	9
McKesson Medi-Lab Performance - waived	2	-	-	2
Polymedco Poly stat	1	-	-	1
Quidel QuickVue	19	-	1	18
Sekisui OSOM	1	-	-	1

Mycoplasma Antibody

	Specimen MY-1		Specimen MY-2	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	2	-	-	2
Meridian ImmunoCard	2	-	-	2

Viral Markers – Anti-HBc (IgM)

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	4	-	-	4	-	3	-	1
Abbott Architect	-	1	-	-	1	-	1	-	-
Siemens ADVIA Centaur	-	2	-	-	2	-	2	-	-
VITROS 5600	-	1	-	-	1	-	-	-	1

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	4	-	-	4	-
Abbott Architect	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total/IgG)

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

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	2	-	-	-	2	-
Abbott Architect	1	-	-	-	1	-
Siemens ADVIA Centaur	1	-	-	-	1	-

Viral Markers – Anti-HIV

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	7	-	-	-	7	-	-	7	-
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	2	-	-	-	2	-	-	2	-

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	3	3	-	1	6	-
Abbott Architect	2	1	-	1	2	-
bioLytical Labs INSTI HIV - moderate	-	1	-	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	1	-	-	1	-
Siemens ADVIA Centaur	1	-	-	-	2	-

Viral Markers – Anti-HAV (IgM)

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	4	-	-	4	-	-	4	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-	-	1	-

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	4	-	-	4	-
Abbott Architect	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

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

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	3	-	3	-	-
Abbott Architect	-	1	-	1	-	-
Siemens ADVIA Centaur	-	2	-	2	-	-

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-1 through VM-5 are: Negative, Negative, Negative, Positive, and Negative, respectively.

Viral Markers – Anti-HBs

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	5	-	-	3	2	-	-	5	-
Abbott Architect	3	-	-	3	-	-	-	3	-
Siemens ADVIA Centaur	2	-	-	-	2	-	-	2	-

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	2	3	-	5	-	-
Abbott Architect	-	3	-	3	-	-
Siemens ADVIA Centaur	2	-	-	2	-	-

Specimen VM-2 and VM-4 are ungraded challenge due to less than 80% participant consensus.

Viral Markers – HBsAg

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	6	-	6	-	-	4	1	1
Abbott Architect	-	2	-	2	-	-	2	-	-
Siemens ADVIA Centaur	-	3	-	3	-	-	2	-	1
VITROS 5600	-	1	-	1	-	-	-	1	-

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	4	1	-	-	6	-
Abbott Architect	2	-	-	-	2	-
Siemens ADVIA Centaur	2	-	-	-	3	-
VITROS 5600	-	1	-	-	1	-

Viral Markers – Anti-HCV

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

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	7	-	-	7	-
Abbott Architect	-	2	-	-	2	-
OraSure OraQuick HCV	-	1	-	-	1	-
Siemens ADVIA Centaur	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-

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