MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Immunology
MLE-M2

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 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
Lyme Disease Serology	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 ± 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	± 25%
Total IgM	± 3 SD

Infectious Mononucleosis

Method	**Specimen IM-6** ***Positive***	***Negative***	**Specimen IM-7** ***Positive***	***Negative***
ALL METHODS	193	1	1	193
Alere Clearview	4	-	-	4
Alere Clearview Mono Plus II	10	-	-	10
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	9	-	-	9
BioStar Acceava Mono Test	2	-	-	2
BioStar Acceava Mono-whole bld	5	-	-	5
Cardinal Health SP Brand - waived	9	-	-	9
Consult Diagnostics	15	-	-	15
Fisher HealthCare Sure-Vue	9	-	-	9
Henry Schein OneStep+ - waived	15	1	1	15
LifeSign Status - waived	7	-	-	7
McKesson Medi-Lab Performance - waived	9	-	-	9
Other Moderate method	9	-	-	9
Other Waived method	13	-	-	13
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	14	-	-	14
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	54	-	-	54
Seradyn	1	-	-	1
Wampole ColorCard	1	-	-	1
Wampole Mono-Plus II	1	-	-	1

Infectious Mononucleosis

Method	**Specimen IM-8**		**Specimen IM-9**		**Specimen IM-10**	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	76	1	1	76	76	1
Alere Clearview	1	-	-	1	1	-
Alere Clearview Mono Plus II	2	-	-	2	2	-
ASI	1	-	-	1	1	-
Beckman Coulter ICON Mono - waived	9	-	-	9	9	-
BioStar Acceava Mono-whole bld	2	-	-	2	2	-
Cardinal Health SP Brand - waived	1	-	-	1	1	-
Consult Diagnostics	6	-	-	6	6	-
Fisher HealthCare Sure-Vue	5	-	-	5	5	-
Henry Schein OneStep+ - waived	5	-	-	5	5	-
LifeSign Status - waived	3	-	-	3	3	-
McKesson Medi-Lab Performance - waived	3	-	-	3	3	-
Other Moderate method	8	-	-	8	8	-
Other Waived method	1	-	-	1	1	-
Quidel QuickVue+	1	-	-	1	1	-
Quidel QuickVue+ - waived	3	-	-	3	3	-
Sekisui OSOM	4	-	-	4	4	-
Sekisui OSOM (waived)	18	1	1	18	19	-
Seradyn	1	-	-	1	1	-
Wampole ColorCard	1	-	-	1	-	1
Wampole Mono-Plus II	1	-	-	1	1	-

Rheumatoid Factor—Qualitative

Method	Specimen RF-6		Specimen RF-7		Specimen RF-8	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	45	45	-	1	44
Abbott Architect	-	1	1	-	-	1
ASI	-	10	10	-	-	10
Beckman AU	-	1	1	-	-	1
Biokit Rheumajet	-	5	5	-	-	5
Diamedix	-	1	1	-	1	-
Fisher HealthCare Sure-Vue	-	4	4	-	-	4
Immunostics Inc.	-	2	2	-	-	2
Remel SeraTest	-	1	1	-	-	1
Siemens RapiTex	-	1	1	-	-	1
Sterling Diagnostics, Inc.	-	1	1	-	-	1
Teco Diagnostics	-	2	2	-	-	2
TheraTest	-	3	3	-	-	3
Wampole ColorCard	-	9	9	-	-	9
Wampole Rheumatex	-	4	4	-	-	4

Method	Specimen RF-9		Specimen RF-10	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	44	1	1	44
Abbott Architect	1	-	-	1
ASI	10	-	-	10
Beckman AU	1	-	-	1
Biokit Rheumajet	5	-	-	5
Diamedix	-	1	-	1
Fisher HealthCare Sure-Vue	4	-	-	4
Immunostics Inc.	2	-	-	2
Remel SeraTest	1	-	-	1
Siemens RapiTex	1	-	-	1
Sterling Diagnostics, Inc.	1	-	-	1
Teco Diagnostics	2	-	-	2
TheraTest	3	-	-	3
Wampole ColorCard	9	-	1	8
Wampole Rheumatex	4	-	-	4

Rheumatoid Factor—Quantitative (Titer)

This portion is not evaluated. Results reported are as follows:

Specimen/Method	***2/ 4***	***8/ 10***	***16/ 20***	***32/ 40***	***64/ 80***	***128/ 160***	***256/ 320***	***512/ 640***	***1024/ 1280***	***2048/ 2560***	***>2560***
Specimen RF-7											
ALL METHODS	1	4	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	2	-	-	-	-	-	-	-	-	-
Siemens RapiTex	-	1	-	-	-	-	-	-	-	-	-
Wampole ColorCard	-	1	-	-	-	-	-	-	-	-	-
Specimen RF-9											
ALL METHODS	-	-	4	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	3	-	-	-	-	-	-	-	-
Siemens RapiTex	-	-	1	-	-	-	-	-	-	-	-
Wampole ColorCard	-	-	-	1	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU/mL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen RF-6						
All Method	17	5.1	4.2	82.6	4	0 - 14
Specimen RF-7						
All Method	14	57.4	4.1	7.1	57	49 - 66
Specimen RF-8						
All Method	16	5.0	4.5	90.6	4	0 - 15
Specimen RF-9						
All Method	15	132.9	10.6	8.0	132	111 - 155
Specimen RF-10						
All Method	17	4.8	4.5	94.3	4	0 - 14

Anti-Streptolysin O (ASO)—Qualitative

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

Method	Specimen AS-9		Specimen AS-10	
	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	13	100.9	19.0	18.8	91	44 - 158
Specimen IMP-7						
All Method	13	95.9	16.6	17.3	88	46 - 146
Specimen IMP-8						
All Method	13	123.0	15.0	12.2	116	78 - 168
Specimen IMP-9						
All Method	13	70.5	12.8	18.1	62	32 - 109
Specimen IMP-10						
All Method	13	96.5	20.4	21.1	83	35 - 158

Complement C4 (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-6						
All Method	13	21.0	4.0	18.9	19	9 - 33
Specimen IMP-7						
All Method	13	18.3	2.6	14.3	18	10 - 27
Specimen IMP-8						
All Method	13	26.5	2.3	8.8	26	19 - 34
Specimen IMP-9						
All Method	13	14.9	2.6	17.2	14	7 - 23
Specimen IMP-10						
All Method	13	21.8	3.0	13.8	21	12 - 31

IgA (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-6						
All Method	11	180.7	15.2	8.4	179	135 - 227
Specimen IMP-7						
All Method	11	168.0	13.2	7.9	169	128 - 208
Specimen IMP-8						
All Method	11	233.0	15.0	6.4	231	187 - 279
Specimen IMP-9						
All Method	11	142.5	12.3	8.7	141	105 - 180
Specimen IMP-10						
All Method	11	475.5	47.3	9.9	473	333 - 618

IgG (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-6						
All Method	11	2022.5	78.5	3.9	2065	1516 - 2529
Specimen IMP-7						
All Method	11	2008.2	84.6	4.2	2033	1506 - 2511
Specimen IMP-8						
All Method	11	944.3	46.1	4.9	945	708 - 1181
Specimen IMP-9						
All Method	11	662.6	25.0	3.8	660	496 - 829
Specimen IMP-10						
All Method	11	869.1	51.5	5.9	862	651 - 1087

IgM (mg/dL)

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen IMP-6						
All Method	11	420.7	59.3	14.1	425	242 - 599
Specimen IMP-7						
All Method	11	80.4	12.9	16.1	77	41 - 120
Specimen IMP-8						
All Method	11	82.7	12.5	15.1	81	45 - 121
Specimen IMP-9						
All Method	11	65.0	11.5	17.7	65	30 - 100
Specimen IMP-10						
All Method	11	86.3	15.3	17.7	84	40 - 133

Antinuclear Antibody (ANA)—Qualitative Latex Methods

	Specimen AN-6		Specimen AN-7		Specimen AN-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	5	-	-	5	5	-
ASI	2	-	-	2	2	-
Diagnostic Technology	2	-	-	2	2	-
Wampole	1	-	-	1	1	-

	Specimen AN-9		Specimen AN-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	5	5	-
ASI	-	2	2	-
Diagnostic Technology	-	2	2	-
Wampole	-	1	1	-

C-Reactive Protein—Qualitative, Regular

	Specimen CR-3		Specimen CR-4	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	15	-	-	15
ASI	1	-	-	1
Biokit Rheumajet	1	-	-	1
Fisher HealthCare Sure-Vue	8	-	-	8
Siemens Dimension/AR/ES/RxL/Xpand	2	-	-	2
Teco Diagnostics	2	-	-	2
Wampole	1	-	-	1

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

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen CR-3						
mg/dL - units						
All Immunology Methods	20	1.205	0.161	13.4	1.20	0.72 - 1.69
mg/L - units						
All Immunology Methods	11	14.568	5.493	37.7	13.59	0.00 - 31.05
Specimen CR-4						
mg/dL - units						
All Immunology Methods	22	0.144	0.168	116.9	0.10	0.00 - 0.65
mg/L - units						
All Immunology Methods	12	1.990	2.123	106.7	1.55	0.00 - 8.37

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

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen HCR-3						
All Method	45	12.289	1.288	10.5	12.27	8.42 - 16.16
Specimen HCR-4						
All Method	44	3.208	0.544	17.0	3.12	1.57 - 4.85

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	*Positive*	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	8	4	-	12	11	1
Diamedix	-	2	-	2	2	-
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-
Immuno Concepts	4	-	-	4	3	1
INOVA Diagnostics	2	-	-	2	2	-
Phadia EliA	-	1	-	1	1	-
TheraTest	1	-	-	1	1	-

	Specimen AE-9		Specimen AE-10	
Method	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	11	1	1	11
Diamedix	2	-	-	2
GenBio ImmunoDOT Panel 1	1	-	-	1
Immuno Concepts	3	1	1	3
INOVA Diagnostics	2	-	-	2
Phadia EliA	1	-	-	1
TheraTest	1	-	-	1

Specimen AE-6 is graded by 80% referee consensus.

Antinuclear Antibody (ANA)—Quantitative (Titer)

This portion is not evaluated. Titers reported are as follows:

Specimen/Method	*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	-	-	-	-	-	4	-	-	-	-	-
Immuno Concepts	-	-	-	-	-	3	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-
Specimen AE-8											
ALL METHODS	-	-	-	-	-	-	1	2	1	-	-
Immuno Concepts	-	-	-	-	-	-	1	2	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-9											
ALL METHODS	-	-	-	-	-	-	1	2	1	-	-
Immuno Concepts	-	-	-	-	-	-	1	2	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	1	-	-

Anti-dsDNA

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	*Positive*	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	7	-	7	6	1
Diamedix	-	2	-	2	2	-
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
Phadia EliA	-	1	-	1	1	-
TheraTest	-	3	-	3	3	-

	Specimen AE-9		Specimen AE-10	
Method	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	6	2	-	7
Diamedix	2	-	-	2
GenBio ImmunoDOT Panel 1	-	1	-	1
Phadia EliA	1	-	-	1
TheraTest	3	-	-	3

Specimen AE-9 is an ungraded challenge due to less than 80% participant consensus.

Anti-RNP

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	2	-	2	2	-
Phadia EliA	-	1	-	1	1	-

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	1	-	2
Phadia EliA	-	1	-	1

Specimen AE-9 is an ungraded challenge due to less than 80% participant consensus.

Anti-RNP/Sm

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	5	-	5	4	1
Diamedix	-	1	-	1	1	-
GenBio ImmunoDOT Panel 1	-	1	-	1	-	1
TheraTest	-	3	-	3	3	-

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	4	1	-	5
Diamedix	1	-	-	1
GenBio ImmunoDOT Panel 1	-	1	-	1
TheraTest	3	-	-	3

Anti-SSA

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	2	4	1	5	6	-
Diamedix	-	2	-	2	2	-
Phadia EliA	-	1	1	-	1	-
TheraTest	2	1	-	3	3	-

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	6	-	-	6
Diamedix	2	-	-	2
Phadia EliA	1	-	-	1
TheraTest	3	-	-	3

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

Anti-SSB

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	5	-	6	-	6
Diamedix	-	2	-	2	-	2
Phadia EliA	-	1	-	1	-	1
TheraTest	1	2	-	3	-	3

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	6	-	6
Diamedix	-	2	-	2
Phadia EliA	-	1	-	1
TheraTest	-	3	-	3

Anti-SSA/SSB

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	1	-	2	2	-
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	2	-	-	2
GenBio ImmunoDOT Panel 1	1	-	-	1

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

Anti-Sm

	Specimen AE-6		Specimen AE-7		Specimen AE-8	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	5	-	5	1	4
Diamedix	-	1	-	1	-	1
Phadia EliA	-	1	-	1	1	-
TheraTest	-	3	-	3	-	3

	Specimen AE-9		Specimen AE-10	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	4	-	5
Diamedix	-	1	-	1
Phadia EliA	1	-	-	1
TheraTest	-	3	-	3

Rubella—Qualitative

Method	Specimen RU-6		Specimen RU-7		Specimen RU-8	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	6	-	-	6	6	-
bioMerieux Vidas, Mini Vidas	2	-	-	2	2	-
DiaSorin	2	-	-	2	2	-
Siemens ADVIA Centaur	2	-	-	2	2	-

Method	Specimen RU-9		Specimen RU-10	
	Positive	Negative	Positive	Negative
ALL METHODS	6	-	-	6
bioMerieux Vidas, Mini Vidas	2	-	-	2
DiaSorin	2	-	-	2
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: 40 IU/ml, <10 IU/mL, 88.3 IU/mL, 22 IU/mL and <10 IU/mL, respectively.

Anti-HIV

Method	Specimen HIV-6		Specimen HIV-7	
	Positive	Negative	Positive	Negative
ALL METHODS	2	53	53	2
Alere Clearview Complete HIV 1/2	-	4	4	-
Alere Clearview HIV1/2 STAT-PAK	-	11	11	-
Orasure OraQuick Advance Rapid HIV-1/2 - moderate	1	2	2	1
Orasure OraQuick Advance Rapid HIV-1/2 - waived	-	17	17	-
Other Waived method	-	19	19	-

Method	Specimen HIV-8		Specimen HIV-9		Specimen HIV-10	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	-	5	5	-	5	-
Alere Clearview Complete HIV 1/2	-	5	5	-	5	-

Allergen Specific IgE Antibodies

Specimen AL-6

	Bermuda Grass Allergen *CLASS RESULT*								Perennial Rye Allergen *CLASS RESULT*							
Method	**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	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	1	1	2	-	-	-	-	-	-	-	1	-	-
Phadia Unicap 100	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Cockroach - German Allergen *CLASS RESULT*								Aspergillus fumigatus Allergen *CLASS RESULT*							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**	**0**	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	2	-	-	2	-	-	-	-	-	-	1	4	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	1	-	-	1	-	-	-	-	-	-	1	2	-	-	-	-
Phadia UniCap 100 (% ref)	1	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Maple (Box Elder) Allergen *CLASS RESULT*								English Plantain Allergen *CLASS RESULT*							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**	**0**	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	-	1	3	2	-	-	-	-	-	-	3	3	-	-	-	-
DPC-Standard Microplate	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-
Hitachi CLA-1	-	1	2	1	-	-	-	-	-	-	2	2	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Common (Short) Ragweed Allergen *CLASS RESULT*							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	-	-	1	3	1	-	-	-
DPC-Standard Microplate	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	1	1	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-7

	House Dust Mite (D. farinae) Allergen *CLASS RESULT*								Cat Epithelium Allergen *CLASS RESULT*							
Method	**0**	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**	**0**	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	-	-	-	1	2	3	-	-	-	-	-	1	1	3	-	-
DPC-Standard Microplate	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Hitachi CLA-1	-	-	-	-	1	3	-	-	-	-	-	-	-	3	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Dog Dander Allergen *CLASS RESULT*								Cow's Milk 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	3	-	-	-	-	-	3	1	1	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Hitachi CLA-1	-	-	-	-	1	3	-	-	-	-	-	1	1	1	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Timothy Grass Allergen *CLASS RESULT*								Meadow Fescue 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	-	-	-	-	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-

	Mugwort Allergen *CLASS RESULT*							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	-	1	-	-	-	-	-	-
DPC-Standard Microplate	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	1	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	-	-	-

Total IgE—Quantitative (U/mL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen AL-6						
All Method	6	978.5	153.4	15.7	979	518 - 1439
Specimen AL-7						
All Method	6	176.0	19.8	11.2	176	116 - 236
Specimen AL-8						
All Method	6	20.5	4.9	24.1	21	5 - 36
Specimen AL-9						
All Method	6	52.0	14.1	27.2	52	9 - 95
Specimen AL-10						
All Method	6	21.0	5.7	26.9	21	4 - 38

Syphilis Serology—Qualitative: VDRL Slide

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

	Specimen SY-9			Specimen SY-10		
Method	*Reactive*	*Weakly Reactive*	*Non-Reactive*	*Reactive*	*Weakly Reactive*	*Non-Reactive*
ALL METHODS	-	-	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	1	-	-	1	1	-
Siemens ADVIA Centaur	1	-	-	1	1	-

	Specimen SY-9		Specimen SY-10	
Method	*Reactive*	*Non-Reactive*	*Reactive*	*Non-Reactive*
ALL METHODS	-	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	16	-	-	16	16	-
ASI	6	-	-	6	6	-
Becton Dickinson	5	-	-	5	5	-
Fisher HealthCare Sure-Vue	3	-	-	3	3	-
Wampole Impact RPR	1	-	-	1	1	-

	Specimen SY-9		Specimen SY-10	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	-	16	16	-
ASI	-	6	6	-
Becton Dickinson	-	5	5	-
Fisher HealthCare Sure-Vue	-	3	3	-
Wampole Impact RPR	-	1	1	-

Syphilis Serology—Quantitative: RPR (Titer)

Specimen/Method	***1:1***	***1:2***	***1:4***	***1:8***	***1:16***	***1:32***	***1:64***	***1:>64***
Specimen SY-6								
ALL METHODS	-	1	3	1	1	-	-	-
ASI	-	1	1	1	1	-	-	-
Becton Dickinson	-	-	2	-	-	-	-	-
Specimen SY-8								
ALL METHODS	1	4	1	-	-	-	-	-
ASI	1	2	1	-	-	-	-	-
Becton Dickinson	-	2	-	-	-	-	-	-
Specimen SY-10								
ALL METHODS	1	2	3	-	-	-	-	-
ASI	1	1	2	-	-	-	-	-
Becton Dickinson	-	1	1	-	-	-	-	-

Syphilis Serology—Qualitative: diagnostics direct Syphilis Health Check Treponema pallidum antibodies

	Specimen SHC-6		Specimen SHC-7		Specimen SHC-8	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
diagnostics direct Syphilis Health Check	-	7	7	-	-	7

	Specimen SHC-9		Specimen SHC-10	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
diagnostics direct Syphilis Health Check	7	-	7	-

H. *pylori* Antibody Detection

	Specimen HP-3		Specimen HP-4	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	85	85	-
Alere Clearview	-	8	8	-
Alfa Scientific Instant-View	-	1	1	-
Beckman Coulter ICON HP	-	1	1	-
Cardinal Health SP Brand	-	6	6	-
Consult Diagnostics	-	16	16	-
Fisher HealthCare Sure-Vue	-	2	2	-
Henry Schein OneStep+ - waived	-	8	8	-
McKesson Medi-Lab Performance - waived	-	7	7	-
Other Waived method	-	1	1	-
Polymedco Poly stat	-	1	1	-
PSS Select Diagnostics	-	2	2	-
Quidel QuickVue	-	28	28	-
SDI Biomed, Inc.	-	1	1	-

Lyme Disease Serology

	Specimen LY-3		Specimen LY-4	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	3	-	-	3
bioMerieux Vidas, Mini Vidas	1	-	-	1
DiaSorin	2	-	-	2

Mycoplasma Antibody

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

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	-	1	1	-	2	-	-	2	-
Siemens ADVIA Centaur	-	1	1	-	2	-	-	2	-

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

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	3	-	-	-	3	-	3	-	-
Abbott Architect	1	-	-	-	1	-	1	-	-
Roche cobas e 411	1	-	-	-	1	-	1	-	-
Siemens ADVIA Centaur	1	-	-	-	1	-	1	-	-

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

Specimen VM-10 is an ungraded challenge due to less than 80% participant consensus.

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	-	5	-	-	5	-	-	5	-
Abbott Architect	-	2	-	-	2	-	-	2	-
Alere Clearview HIV1/2 STAT-PAK	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-	-	2	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	4	1	-	4	1	-
Abbott Architect	2	-	-	2	-	-
Alere Clearview HIV1/2 STAT-PAK	-	1	-	-	1	-
Siemens ADVIA Centaur	2	-	-	2	-	-

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

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

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	-	2	-	-	2	-	2	-	-
Siemens ADVIA Centaur	-	2	-	-	2	-	2	-	-

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

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-6 through VM-10 are: Positive, 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	-	5	-	-	5	-	-	5	-
Abbott Architect	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	4	-	-	4	-	-	4	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	5	-	-	5	-	-
Abbott Architect	1	-	-	1	-	-
Siemens ADVIA Centaur	4	-	-	4	-	-

Viral Markers – HBsAg

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	5	-	-	-	5	-	-	5	-
Abbott Architect	1	-	-	-	1	-	-	1	-
Roche cobas e 411	1	-	-	-	1	-	-	1	-
Siemens ADVIA Centaur	3	-	-	-	3	-	-	3	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	5	-	-	5	-
Abbott Architect	-	1	-	-	1	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA Centaur	-	3	-	-	3	-

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	-	-	2	8	-
Abbott Architect	-	2	-	2	-	-	-	2	-
OraSure OraQuick HCV	-	1	-	1	-	-	-	1	-
Roche cobas e 411	-	2	-	2	-	-	2	-	-
Siemens ADVIA Centaur	-	4	-	4	-	-	-	4	-

	Specimen VM-9			Specimen VM-10		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	2	8	-	2	8	-
Abbott Architect	-	2	-	-	2	-
OraSure OraQuick HCV	-	1	-	-	1	-
Roche cobas e 411	2	-	-	2	-	-
Siemens ADVIA Centaur	-	4	-	-	4	-

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