MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Immunology
2020 MLE-M1

ACP | Medical Laboratory Evaluation

Total Commitment to Education and Service
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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

Method	**Specimen IM-1** ***Positive***	***Negative***	**Specimen IM-2** ***Positive***	***Negative***
ALL METHODS	129	1	1	129
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
BioStar Acceava Mono Test	2	-	-	2
BioStar Acceava Mono-whole bld	3	-	-	3
Cardinal Health SP Brand - waived	4	-	-	4
Clarity Diagnostics	1	-	-	1
Consult Diagnostics - moderate	13	1	1	13
Consult Diagnostics - waived	6	-	-	6
Fisher HealthCare Sure-Vue	2	-	-	2
Henry Schein OneStep+ - moderate	1	-	-	1
Henry Schein OneStep+ - waived	14	-	-	14
LifeSign Status - waived	6	-	-	6
Other Moderate method	3	-	-	3
Other Waived method	12	-	-	12
Quidel QuickVue+	1	-	-	1
Quidel QuickVue+ - waived	3	-	-	3
Sekisui OSOM	4	-	-	4
Sekisui OSOM (waived)	42	-	-	42

Infectious Mononucleosis

	Specimen IM-3		Specimen IM-4		Specimen IM-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	32	-	32	32	-
Alere Clearview - moderate	-	1	-	1	1	-
Alere Clearview Mono Plus II - moderate	-	2	-	2	2	-
Alere Clearview Mono Plus II - waived	-	1	-	1	1	-
BioStar Acceava Mono Test	-	1	-	1	1	-
BioStar Acceava Mono-whole bld	-	1	-	1	1	-
Consult Diagnostics - moderate	-	7	-	7	7	-
Fisher HealthCare Sure-Vue	-	1	-	1	1	-
Henry Schein OneStep+ - moderate	-	1	-	1	1	-
Henry Schein OneStep+ - waived	-	2	-	2	2	-
LifeSign Status - waived	-	1	-	1	1	-
Other Moderate method	-	3	-	3	3	-
Other Waived method	-	2	-	2	2	-
Quidel QuickVue+	-	1	-	1	1	-
Quidel QuickVue+ - waived	-	2	-	2	2	-
Sekisui OSOM	-	4	-	4	4	-
Sekisui OSOM (waived)	-	2	-	2	2	-

Rheumatoid Factor—Qualitative

	Specimen RF-1		Specimen RF-2		Specimen RF-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	23	-	23	22	1
ASI	-	5	-	5	5	-
Beckman AU	-	1	-	1	1	-
Biokit Rheumajet	-	2	-	2	2	-
Fisher HealthCare Sure-Vue	-	3	-	3	3	-
INOVA Diagnostics	-	1	-	1	1	-
Stanbio Laboratory	-	1	-	1	1	-
TheraTest	-	5	-	5	5	-
Wampole ColorCard	-	4	-	4	3	1
Wampole Rheumatex	-	1	-	1	1	-

	Specimen RF-4		Specimen RF-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	23	-	23	-
ASI	5	-	5	-
Beckman AU	1	-	1	-
Biokit Rheumajet	2	-	2	-
Fisher HealthCare Sure-Vue	3	-	3	-
INOVA Diagnostics	1	-	1	-
Stanbio Laboratory	1	-	1	-
TheraTest	5	-	5	-
Wampole ColorCard	4	-	4	-
Wampole Rheumatex	1	-	1	-

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	3	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-2												
ALL METHODS	3	-	-	-	-	-	-	-	-	-	-	-
Beckman AU	1	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-3												
ALL METHODS	-	-	2	-	1	-	-	-	-	-	-	-
Beckman AU	-	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-
Specimen RF-4												
ALL METHODS	-	-	2	-	1	-	-	-	-	-	-	-
Beckman AU	-	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-
Specimen RF-5												
ALL METHODS	-	1	1	1	-	-	-	-	-	-	-	-
Beckman AU	-	-	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	1	-	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU/mL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen RF-1						
All Method	14	9.1	1.9	20.7	8	3 - 15
Beckman AU	10	8.7	2.0	22.7	9	2 - 15
Specimen RF-2						
All Method	14	9.1	1.9	20.7	8	3 - 15
Beckman AU	10	8.7	2.0	22.7	9	2 - 15
Specimen RF-3						
All Method	14	77.6	5.8	7.5	78	60 - 96
Beckman AU	10	79.3	5.6	7.0	78	62 - 97
Specimen RF-4						
All Method	14	78.5	5.4	6.9	79	62 - 95
Beckman AU	10	80.2	5.0	6.2	78	65 - 96
Specimen RF-5						
All Method	14	50.0	4.0	8.1	51	37 - 63
Beckman AU	10	50.7	4.4	8.6	51	37 - 64

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	-
ASI	-	1	1	-	1	-

Method	Specimen AS-4		Specimen AS-5	
	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-1						
All Method	16	117.0	5.1	4.3	116	101 - 133
Beckman AU	10	115.5	5.2	4.5	115	99 - 132
Specimen IMP-2						
All Method	16	116.7	4.7	4.0	116	102 - 131
Beckman AU	10	115.2	4.8	4.1	114	100 - 130
Specimen IMP-3						
All Method	16	118.9	4.3	3.7	118	105 - 132
Beckman AU	10	118.2	3.7	3.1	118	107 - 130
Specimen IMP-4						
All Method	16	117.2	5.5	4.7	115	100 - 134
Beckman AU	10	115.3	4.8	4.2	114	100 - 130
Specimen IMP-5						
All Method	16	46.9	2.0	4.2	46	40 - 53
Beckman AU	10	46.8	2.4	5.1	46	39 - 55

Complement C4 (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-1						
All Method	16	19.9	2.0	9.9	20	13 - 26
Beckman AU	10	20.8	1.7	8.3	21	15 - 27
Specimen IMP-2						
All Method	16	19.8	1.6	8.3	19	14 - 25
Beckman AU	10	20.5	1.5	7.4	21	15 - 26
Specimen IMP-3						
All Method	16	20.0	2.0	10.0	20	14 - 26
Beckman AU	10	21.0	1.5	7.4	21	16 - 26
Specimen IMP-4						
All Method	16	20.4	1.6	7.8	20	15 - 26
Beckman AU	10	21.2	1.5	7.0	21	16 - 26
Specimen IMP-5						
All Method	16	7.9	0.9	11.8	8	5 - 11
Beckman AU	10	8.0	1.1	13.7	8	4 - 12

IgA (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-1						
All Method	16	192.2	4.0	2.1	192	180 - 205
Beckman AU	10	190.7	3.2	1.7	192	181 - 201
Specimen IMP-2						
All Method	16	196.2	3.7	1.9	197	185 - 208
Beckman AU	10	194.0	2.6	1.4	193	186 - 202
Specimen IMP-3						
All Method	16	194.2	3.6	1.8	193	183 - 205
Beckman AU	10	193.3	1.5	0.8	193	188 - 198
Specimen IMP-4						
All Method	16	458.8	14.5	3.2	460	415 - 503
Beckman AU	10	449.7	9.3	2.1	447	421 - 478
Specimen IMP-5						
All Method	16	74.6	4.3	5.8	74	61 - 88
Beckman AU	10	77.0	2.6	3.4	78	69 - 85

IgG (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-1						
All Method	16	910.4	23.3	2.6	905	682 - 1138
Beckman AU	10	901.0	19.3	2.1	893	675 - 1127
Specimen IMP-2						
All Method	16	1867.4	114.6	6.1	1805	1400 - 2335
Beckman AU	10	1870.3	150.1	8.0	1805	1402 - 2338
Specimen IMP-3						
All Method	16	908.8	25.9	2.9	905	681 - 1136
Beckman AU	10	903.3	33.0	3.7	894	677 - 1130
Specimen IMP-4						
All Method	16	870.0	30.0	3.4	856	652 - 1088
Beckman AU	10	866.3	37.0	4.3	847	649 - 1083
Specimen IMP-5						
All Method	16	349.0	19.2	5.5	352	261 - 437
Beckman AU	10	343.7	24.6	7.2	331	257 - 430

IgM (mg/dL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen IMP-1						
All Method	16	79.4	2.7	3.4	81	71 - 88
Beckman AU	10	79.7	3.2	4.0	81	70 - 90
Specimen IMP-2						
All Method	16	79.8	2.9	3.6	80	71 - 89
Beckman AU	10	79.7	3.5	4.4	80	69 - 91
Specimen IMP-3						
All Method	16	371.6	26.1	7.0	357	293 - 450
Beckman AU	10	352.7	3.8	1.1	351	341 - 365
Specimen IMP-4						
All Method	16	77.2	3.1	4.0	78	67 - 87
Beckman AU	10	78.0	3.6	4.6	79	67 - 89
Specimen IMP-5						
All Method	16	32.6	1.9	6.0	32	26 - 39
Beckman AU	10	33.0	1.7	5.2	32	27 - 39

C-Reactive Protein—Qualitative, Regular

	Specimen CR-1		Specimen CR-2	
Method	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	4	4	-
Siemens Dimension	-	4	4	-

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	15	0.167	0.131	78.1	0.20	0.00 - 0.56
mg/L - units						
All Immunology Methods	15	1.381	1.988	144.0	0.30	0.00 - 7.35
Specimen CR-2						
mg/dL - units						
All Immunology Methods	15	2.715	0.383	14.1	2.82	1.56 - 3.87
mg/L - units						
All Immunology Methods	14	28.666	5.736	20.0	27.10	11.45 - 45.88

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

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen HCR-1						
All Method	20	10.475	0.977	9.3	10.46	7.54 - 13.41
Specimen HCR-2						
All Method	19	0.859	0.320	37.2	0.99	0.00 - 1.82

Antinuclear Antibody (ANA) - Qualitative

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

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

Anti-dsDNA

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

	Specimen AE-4		Specimen AE-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	8	-	8
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	5	-	5

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	-	2	-	2
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1

Anti-RNP/Sm

Method	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	5	2	-	7	7	-
GenBio ImmunoDOT Panel 1	-	1	-	1	1	-
Immuno Concepts	-	1	-	1	1	-
TheraTest	5	-	-	5	5	-

Method	Specimen AE-4		Specimen AE-5	
	Positive	Negative	Positive	Negative
ALL METHODS	1	6	-	7
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	1	4	-	5

Anti-SSA

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

Method	Specimen AE-4		Specimen AE-5	
	Positive	Negative	Positive	Negative
ALL METHODS	-	7	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	5	-	5

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

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	-	7	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	5	-	5

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

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	-	7	-	7
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1
TheraTest	-	5	-	5

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
INOVA Diagnostics	-	2	2	-	-	2
Siemens ADVIA Centaur	-	3	3	-	-	3

Method	Specimen RU-4 Positive	Specimen RU-4 Negative	Specimen RU-5 Positive	Specimen RU-5 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-1 through RU-5 are: <10.0 IU/mL, 36.1 IU/mL, <10.0 IU/mL, 36.1 IU/mL, and <10.0 IU/mL, respectively.

Anti-HIV

Method	Specimen HIV-1 Positive	Specimen HIV-1 Negative	Specimen HIV-2 Positive	Specimen HIV-2 Negative
ALL METHODS	66	-	-	66
Alere Clearview HIV1/2 STAT-PAK	2	-	-	2
Alere Determine HIV - moderate	2	-	-	2
Alere Determine HIV - waived	13	-	-	13
BD LINK 2	2	-	-	2
bioLytical Labs INSTI HIV - moderate	2	-	-	2
bioLytical Labs INSTI HIV - waived	15	-	-	15
Chembio HIV 1/2 Assay - waived	14	-	-	14
Orasure OraQuick Advance Rapid HIV-1/2 - waived	12	-	-	12
Other Waived method	3	-	-	3
Trinity Biotech Uni-Gold - waived	1	-	-	1

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

	Timothy Grass (g6) Allergen CLASS RESULT								Meadow Fescue (g4) 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	1	1	-	-	-	-	-	1	-	1	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	1	-	-	-	-	-	-	1	-	1	-	-

	Wheat (f4) Allergen CLASS RESULT								Walnut (f256) 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	-	-	-	-	-
Hitachi CLA-1	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-

	Dog Dander (e5) Allergen CLASS RESULT								White Oak (t7) 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	-	-	-	-	1	2	-	-	-	-
Hitachi CLA-1	-	-	-	1	-	1	-	-	-	-	1	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	-	-	-	-	-	-	-	2	-	-	-	-

	Maple (Box Elder) (t1) Allergen CLASS RESULT							
	0	**0/1**	**1**	**2**	**3**	**4**	**5**	**6**
ALL METHODS	2	-	2	-	-	-	-	-
Hitachi CLA-1	2	-	-	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	2	-	-	-	-	-

Allergen Specific IgE Antibodies

Specimen AL-2

Method	Sweet Vernal Grass (g1) Allergen CLASS RESULT								Perennial Rye (g5) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	1	1	-	-	-	-	-	1	1	1	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	-	1	1	-	-	-

	Silver Birch Tree (t3) 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	2	-	-	-	-	-	-	-	1	1	1	-	-
Hitachi CLA-1	-	-	1	-	-	-	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	-	-	-	-	-	-	-	1	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	-	-	-	2	-	1	-	-	-	-	-	1	1	2	-	-
Hitachi CLA-1	-	-	-	-	-	1	-	-	-	-	-	-	-	2	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	-	-	-	-	-	-	-	1	1	-	-	-

	Sheep Sorrel (w18) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	2	-	1	-	-	-	-	-
Hitachi CLA-1	2	-	-	-	-	-	-	-
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	149.0	7.0	4.7	152	128 - 170
Specimen AL-2						
All Method	5	222.7	7.5	3.4	223	200 - 246
Specimen AL-3						
All Method	5	9.0	1.0	11.1	9	6 - 12
Specimen AL-4						
All Method	5	9.0	0.1	0.0	9	8 - 10
Specimen AL-5						
All Method	5	76.3	7.4	9.7	79	54 - 99

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		Specimen SY-3	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	-	1	1	-	1	-
Serodia	-	1	1	-	1	-

	Specimen SY-4		Specimen SY-5	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	-	1	-	1
Serodia	-	1	-	1

Syphilis Serology—Qualitative: Treponema pallidum antibodies

	Specimen SY-1		Specimen SY-2		Specimen SY-3	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	-	9	9	-	9	-
Abbott Architect	-	1	1	-	1	-
diagnostics direct Syphilis Health Check	-	6	6	-	6	-
INOVA Diagnostics	-	1	1	-	1	-
Siemens ADVIA Centaur	-	1	1	-	1	-

	Specimen SY-4		Specimen SY-5	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	-	9	-	9
Abbott Architect	-	1	-	1
diagnostics direct Syphilis Health Check	-	6	-	6
INOVA Diagnostics	-	1	-	1
Siemens ADVIA Centaur	-	1	-	1

Syphilis Serology—Qualitative: RPR

	Specimen SY-1		Specimen SY-2		Specimen SY-3	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	-	15	14	1	15	-
Abbott Architect	-	1	-	1	1	-
ASI	-	6	6	-	6	-
Becton Dickinson	-	5	5	-	5	-
Fisher HealthCare Sure-Vue	-	3	3	-	3	-

	Specimen SY-4		Specimen SY-5	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	1	14	-	15
Abbott Architect	1	-	-	1
ASI	-	6	-	6
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-1									
ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
Specimen SY-2									
ALL METHODS	-	-	-	4	3	-	-	-	-
ASI	-	-	-	1	2	-	-	-	-
Becton Dickinson	-	-	-	3	1	-	-	-	-
Specimen SY-3									
ALL METHODS	-	-	5	2	-	-	-	-	-
ASI	-	-	2	1	-	-	-	-	-
Becton Dickinson	-	-	3	1	-	-	-	-	-
Specimen SY-4									
ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
Specimen SY-5									
ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	3	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-

H. *pylori* Antibody Detection

Method	Specimen HP-1 *Positive*	Specimen HP-1 *Negative*	Specimen HP-2 *Positive*	Specimen HP-2 *Negative*
ALL METHODS	37	-	1	36
Alere Clearview - moderate	3	-	-	3
Alfa Scientific Instant-View	1	-	-	1
Consult Diagnostics - moderate	12	-	-	12
Henry Schein OneStep+ - waived	8	-	1	7
McKesson Medi-Lab Performance - waived	1	-	-	1
NDC Pro Advantage	2	-	-	2
Polymedco Poly stat	1	-	-	1
Quidel QuickVue	9	-	-	9

Mycoplasma Antibody

Method	Specimen MY-1 *Positive*	Specimen MY-1 *Negative*	Specimen MY-2 *Positive*	Specimen MY-2 *Negative*
ALL METHODS	-	5	5	-
Meridian ImmunoCard	-	5	5	-

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	-	2	-	-	2	-	-	2	-
Abbott Architect	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

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

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	2	-	2	-	-
Abbott Architect	-	2	-	2	-	-

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	9	-	-	5	4	-	-	9	-
Abbott Architect	4	-	-	4	-	-	-	4	-
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-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	9	-	-	9	-
Abbott Architect	-	4	-	-	4	-
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-1			Specimen VM-2			Specimen VM-3		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	3	-	-	3	-	-	3	-
Abbott Architect	-	2	-	-	2	-	-	2	-
VITROS 5600	-	1	-	-	1	-	-	1	-

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

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

Viral Markers – HBeAg

One participant reported results for HBeAg. The vendor assay values for specimens VM-1 through VM-5 are: Negative, Positive, Negative, Negative, 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	3	-	-	-	3	-	3	-	-
Abbott Architect	2	-	-	-	2	-	2	-	-
Siemens ADVIA Centaur	1	-	-	-	1	-	1	-	-

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

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	5	-	5	-	-
Abbott Architect	-	3	-	3	-	-
Siemens ADVIA Centaur	-	1	-	1	-	-
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	-	8	-	-	8	-	-	8	-
Abbott Architect	-	3	-	-	3	-	-	3	-
OraSure OraQuick HCV	-	3	-	-	3	-	-	3	-
Siemens ADVIA Centaur	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

	Specimen VM-4			Specimen VM-5		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	8	-	-	8	-	-
Abbott Architect	3	-	-	3	-	-
OraSure OraQuick HCV	3	-	-	3	-	-
Siemens ADVIA Centaur	1	-	-	1	-	-
VITROS 5600	1	-	-	1	-	-

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