

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Immunology
MLE – M1

Table of Contents

2007 Evaluation Criteria	3
Immunology	
Infectious Mononucleosis	4
Rheumatoid Factor	5
Qualitative	5
Quantitative (Titer).....	6
Quantitative (IU)	7
Anti-Streptolysin O (ASO)	8
Qualitative	8
Quantitative	9
Complement C3	9
Complement C4	10
Antinuclear Antibody (ANA [AN-1 – AN-5]).....	11
Qualitative	11
Antinuclear Antibody (ANA [AE-1 – AE-5])	11
Qualitative	11
Quantitative (Titer).....	12
C-Reactive Protein, Regular	12
Qualitative	12
Quantitative	13
C-Reactive Protein, High Sensitivity	14
Quantitative	14
Rubella	15
Qualitative	15
Quantitative	15
Total IgE	16
Quantitative	16
Allergen Specific IgE Antibodies.....	17
IgA.....	19
IgG.....	19
IgM	20
Syphilis Serology	20
Qualitative: RPR	20
Quantitative: RPR (Titer).....	21
H. pylori Antibody Detection	21
Lyme Disease Serology	22
Mycoplasma Antibody.....	22
Viral Markers	22
Anti-HBc.....	22
Anti-HIV	22
HAV.....	23
HBeAg.....	23
HBsAb	23
HBsAg.....	23
HCV.....	24

2007 Evaluation Criteria

The evaluation criteria used in the 2007 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 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.

Infectious Mononucleosis	80% Participant Consensus
Rheumatoid Factor	80% Participant Consensus
Anti-Streptolysin O (ASO)	80% Participant Consensus
Antinuclear Antibody (ANA)	80% Participant Consensus
C-Reactive Protein	80% Participant Consensus
Rubella Antibody	80% Participant Consensus
H. <i>pylori</i> Antibody Detection	80% Participant Consensus
Total IgE	80% Participant Consensus
Diagnostic Allergy	Not Evaluated
Syphilis Serology	80% Participant Consensus
Lyme Disease Serology	80% Participant Consensus
Mycoplasma Antibody	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 5 or more laboratories. Acceptable performance is established based on a target value \pm the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on pages 39-40 under the heading "Acceptable Ranges for Quantitative Results."

Rheumatoid Factor (International Units)	\pm 3 SD
Rheumatoid Factor (Titer)	Not Evaluated
Anti-Streptolysin O (ASO) Titer	Not Evaluated
Complement C3	\pm 3 SD
Complement C4	\pm 3 SD
Antinuclear Antibody (ANA) Titer	Not Evaluated
C-Reactive Protein	\pm 3 SD
Rubella (International Units)	\pm 3 SD
Total IgE	\pm 3 SD
Total IgA	\pm 3 SD
Total IgG	\pm 25%
Total IgM	\pm 3 SD

Infectious Mononucleosis (cont'd)

<u>Method</u>	<u>Specimen IM-4</u>		<u>Specimen IM-5</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
Inverness ClearviewMono-plusII	3	-	-	3
Inverness Signify Mono Test	1	-	-	1
LifeSign UniStep Mono	2	-	-	2
Mainline Confirms	2	-	-	2
McKesson Medi-Lab Performance - waived	7	-	-	7
Polymedco Poly stat	10	-	-	10
Polymedco Poly stat - waived	5	-	-	5
Quidel QuickVue+	58	-	-	58
Quidel QuickVue+ - waived	4	-	-	4
Seradyn	29	-	-	29
Seradyn Color Q (whole blood)	1	-	-	1
Wampole ColorCard	9	-	-	9
Wampole Mono-Latex	2	-	-	2
Wampole Mono-Plus II	15	-	-	15
Wampole Mono-Plus II (whole blood)	8	-	-	8
Wampole Mono-Test	2	-	-	2

Rheumatoid Factor—Qualitative

<u>Method</u>	<u>Specimen RF-1</u>		<u>Specimen RF-2</u>		<u>Specimen RF-3</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	101	-	101	101	-
ASI	-	2	-	2	2	-
Beckman Synchron	-	3	-	3	3	-
Becton Dickinson	-	1	-	1	1	-
Behring RapiTex - Plate method	-	1	-	1	1	-
Biokit Rheumajet	-	5	-	5	5	-
BMH 902, 911, 912, 914, 917	-	1	-	1	1	-
Diamedix	-	2	-	2	2	-
Fisher HealthCare Sure-View	-	9	-	9	9	-
Immunostics Inc.	-	5	-	5	5	-
J&S Medical Assoc. Accutex	-	1	-	1	1	-
Pulse Scientific	-	1	-	1	1	-
Roche Integra	-	1	-	1	1	-
Seradyn	-	40	-	40	40	-
Sterling Diagnostics, Inc.	-	3	-	3	3	-
Wampole ColorCard	-	1	-	1	1	-
Wampole Rheumatex	-	8	-	8	8	-
Wampole Rheumaton	-	12	-	12	12	-

Rheumatoid Factor—Qualitative (cont'd)

<u>Method</u>	Specimen RF-4		Specimen RF-5	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	101	-	-	101
ASI	2	-	-	2
Beckman Synchron	3	-	-	3
Becton Dickinson	1	-	-	1
Behring RapiTex - Plate method	1	-	-	1
Biokit Rheumajet	5	-	-	5
BMH 902, 911, 912, 914, 917	1	-	-	1
Diamedix	2	-	-	2
Fisher HealthCare Sure-View	9	-	-	9
Immunostics Inc.	5	-	-	5
J&S Medical Assoc. Accutex	1	-	-	1
Pulse Scientific	1	-	-	1
Roche Integra	1	-	-	1
Seradyn	40	-	-	40
Sterling Diagnostics, Inc.	3	-	-	3
Wampole ColorCard	1	-	-	1
Wampole Rheumatex	8	-	-	8
Wampole Rheumaton	12	-	-	12

Rheumatoid Factor—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>2/4</u>	<u>8/10</u>	<u>16/20</u>	<u>32/40</u>	<u>64/80</u>	<u>128/160</u>	<u>256/320</u>	<u>512/640</u>	<u>1024/1280</u>	<u>2048/2560</u>	<u>>2560</u>
Specimen RF-1											
ALL METHODS	2	8	10	2	2	3	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	-	1	-	-	-	-	-	-
Biokit Rheumajet	-	1	2	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	2	2	-	-	-	-	-	-	-	-
Seradyn	2	3	5	-	-	2	-	-	-	-	-
Sterling Diagnostics, Inc.	-	2	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	1	-	1	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>2/4</u>	<u>8/10</u>	<u>16/20</u>	<u>32/40</u>	<u>64/80</u>	<u>128/160</u>	<u>256/320</u>	<u>512/640</u>	<u>1024/1280</u>	<u>2048/2560</u>	<u>>2560</u>
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Specimen RF-2

ALL METHODS	7	12	3	2	1	2	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	3	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	3	-	-	-	-	-	-	-	-	-
Seradyn	4	6	-	-	-	2	-	-	-	-	-
Sterling Diagnostics, Inc.	2	-	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	1	1	-	-	-	-	-	-	-

<u>Specimen/Method</u>	<u>2/4</u>	<u>8/10</u>	<u>16/20</u>	<u>32/40</u>	<u>64/80</u>	<u>128/160</u>	<u>256/320</u>	<u>512/640</u>	<u>1024/1280</u>	<u>2048/2560</u>	<u>>2560</u>
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Specimen RF-5

ALL METHODS	4	15	2	3	2	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	3	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	4	-	-	-	-	-	-	-	-	-
Seradyn	3	7	-	-	1	1	-	-	-	-	-
Sterling Diagnostics, Inc.	1	1	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	1	1	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
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Specimen RF-1

All Beckman Instruments	6	250.5	10.3	4.1	255	232	261
All Method	11	139.5	30.9	22.2	135	118	227
Beckman Synchron	5	250.4	11.5	4.6	255	232	261

Specimen RF-2

All Beckman Instruments	6	101.3	2.8	2.8	102	98	105
All Method	11	76.7	10.6	13.8	80	62	103
Beckman Synchron	5	100.6	2.4	2.4	100	98	104

Specimen RF-3

All Beckman Instruments	7	20.0	0	0	20	20	20
All Method	12	6.5	5.5	84.4	10	0	20
Beckman Synchron	6	20.0	0	0	20	20	20

Rheumatoid Factor—Quantitative (IU) (cont'd)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen RF-4							
All Beckman Instruments	7	20.0	0	0	20	20	20
All Method	12	6.5	5.5	84.1	9	0	20
Beckman Synchron	6	20.0	0	0	20	20	20
Specimen RF-5							
All Beckman Instruments	6	101.8	4.2	4.1	104	96	107
All Method	12	75.5	10.8	14.3	80	61	104
Beckman Synchron	5	101.2	4.3	4.3	100	96	107

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<u>Specimen AS-1</u>		<u>Specimen AS-2</u>		<u>Specimen AS-3</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	4	-	-	4	4	-
Behring RapiTex	1	-	-	1	1	-
Fisher HealthCare Sure-View	2	-	-	2	2	-
Immunostics Inc.	1	-	-	1	1	-

<u>Method</u>	<u>Specimen AS-4</u>		<u>Specimen AS-5</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	4	-	4
Behring RapiTex	-	1	-	1
Fisher HealthCare Sure-View	-	2	-	2
Immunostics Inc.	-	1	-	1

Anti-Streptolysin O (ASO)—Quantitative

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

<u>Specimen/Method</u>	<u>Todd Units / International Units</u>									<u>Streptozyme</u>	
	<u>≤50</u>	<u>100</u>	<u>125</u>	<u>166-200</u>	<u>250-300</u>	<u>333-400</u>	<u>500-600</u>	<u>800-833</u>	<u>≥2500</u>	<u>>100</u>	<u>100-200</u>
Specimen AS-2											
ALL METHODS	-	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	1	-	-	-	-	-	-	-
Specimen AS-4											
ALL METHODS	-	-	-	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-	-
Specimen AS-5											
ALL METHODS	-	-	-	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-	-

Complement C3 (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen COM-1							
All Methods	14	25.6	5.6	21.8	24	20	37
Specimen COM-2							
All Methods	14	123.9	5.4	4.4	125	114	133
Specimen COM-3							
All Methods	14	224.1	11.4	5.1	224	208	244
Specimen COM-4							
All Methods	15	322.3	27.4	8.5	324	261	359
Specimen COM-5							
All Methods	13	407.8	43.4	10.7	391	354	484

Complement C4 (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen COM-1							
All Methods	14	6.3	1.8	28.9	7	4	10
Specimen COM-2							
All Methods	14	28.1	2.7	9.6	29	24	32
Specimen COM-3							
All Methods	15	49.1	5.0	10.3	50	39	57
Specimen COM-4							
All Methods	15	69.9	6.6	9.5	70	54	79
Specimen COM-5							
All Methods	13	91.8	7.2	7.9	93	81	104

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	Specimen AN-1		Specimen AN-2		Specimen AN-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	9	-	9	9	-
Diagnostic Technology	-	6	-	6	6	-
Seradyn Seratest SLE	-	1	-	1	1	-
Stanbio	-	1	-	1	1	-
Wampole	-	1	-	1	1	-

<u>Method</u>	Specimen AN-4		Specimen AN-5	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	9	-	-	9
Diagnostic Technology	6	-	-	6
Seradyn Seratest SLE	1	-	-	1
Stanbio	1	-	-	1
Wampole	1	-	-	1

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	6	10	16	-	-	16
Immuno Concepts	2	3	5	-	-	5
INOVA Diagnostics	1	2	3	-	-	3
Kallestad	2	1	3	-	-	3
Zeus	-	1	1	-	-	1

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	16	16	-
Immuno Concepts	-	5	5	-
INOVA Diagnostics	-	3	3	-
Kallestad	-	3	3	-
Zeus	-	1	1	-

Specimen AE-1 is an ungraded challenge due to less than 80% referee consensus.

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>≥640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
Specimen AE-1											
ALL METHODS	-	-	1	3	-	-	1	-	-	-	-
Immuno Concepts	-	-	1	1	-	-	1	-	-	-	-
INOVA Diagnostics	-	-	-	1	-	-	-	-	-	-	-
Kallestad	-	-	-	1	-	-	-	-	-	-	-
Specimen AE-3											
ALL METHODS	-	-	1	1	2	3	1	-	-	-	-
Immuno Concepts	-	-	-	-	1	2	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-
Kallestad	-	-	-	1	1	-	-	-	-	-	-
Specimen AE-4											
ALL METHODS	-	-	1	1	3	1	2	-	-	-	-
Immuno Concepts	-	-	-	-	2	1	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-
Kallestad	-	-	-	1	1	-	-	-	-	-	-

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-1</u>		<u>Specimen CR-2</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	13	13	-
ASI	-	2	2	-
Dade Dimension/AR/ES/RxL/Xpand	-	1	1	-
Fisher HealthCare Sure-Vue	-	3	3	-
Immunostics Inc.	-	2	2	-
Pulse Scientific	-	1	1	-
Wampole	-	1	1	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
Specimen CR-1					
All Method	39	10.328	12.191	118.0	3.10
mg/dL - units	24	2.945	0.287	9.8	3.02
Beckman Synchron	7	2.430	0.475	19.5	2.60
Dade Dimension/AR/ES/RxL/Xpand	6	3.183	0.172	5.4	3.20
All Immunology Methods	24	2.945	0.287	9.8	3.02
mg/L - units					
All Immunology Methods	11	29.400	2.623	8.9	28.71
Specimen CR-2					
All Method	33	0.215	0.174	81.2	0.20
mg/dL - units	24	0.224	0.197	87.9	0.20
Beckman Synchron	7	0.753	0.755	100.3	0.50
Dade Dimension/AR/ES/RxL/Xpand	6	0.167	0.082	49.0	0.20
All Immunology Methods	24	0.224	0.197	87.9	0.20
mg/L - units					
All Immunology Methods	8	0.426	0.639	150.0	0.23

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
Specimen HCR-1					
All Method mg/dL - units	64	9.075	4.908	54.1	11.00
All Immunology Methods mg/L - units	13	1.212	0.193	15.9	1.19
Other High Sensi. CRP method	5	12.000	1.725	14.4	12.16
Roche Integra hsCRP	6	12.520	0.964	7.7	12.64
All Immunology Methods	43	12.039	1.605	13.3	12.18
Specimen HCR-2					
All Method mg/dL - units	63	0.662	0.452	68.2	0.76
All Immunology Methods mg/L - units	13	0.080	0.024	29.8	0.08
Other High Sensi. CRP method	5	0.748	0.225	30.1	0.76
Roche Integra hsCRP	6	0.758	0.102	13.4	0.81
All Immunology Methods	45	0.807	0.372	46.1	0.82

Rubella—Qualitative

<u>Method</u>	Specimen RU-1		Specimen RU-2		Specimen RU-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	6	-	6	6	-
Abbott AxSYM	-	1	-	1	1	-
Bayer ADVIA Centaur	-	1	-	1	1	-
bioMerieux Vitek, Mini Vidas	-	1	-	1	1	-
Seradyn	-	2	-	2	2	-
Wampole Rubella - Plus	-	1	-	1	1	-
	Specimen RU-4		Specimen RU-5			
ALL METHODS	-	6	5	1		
Abbott AxSYM	-	1	1	-		
Bayer ADVIA Centaur	-	1	1	-		
bioMerieux Vitek, Mini Vidas	-	1	1	-		
Seradyn	-	2	2	-		
Wampole Rubella - Plus	-	1	-	1		

Rubella—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
Specimen RU-1					
All Methods	5	146.84	24.02	16.4	139.9
Specimen RU-2					
All Methods	5	22.34	4.01	17.9	21.1
Specimen RU-3					
All Methods	5	1.18	2.15	182.5	0.1
Specimen RU-4					
All Methods	5	45.34	2.02	4.5	44.4
Specimen RU-5					
All Methods	5	1.16	2.17	187.4	0.8

Total IgE—Quantitative (U/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen AL-1							
All Method	6	242.7	27.7	11.4	243	207	291
Specimen AL-2							
All Method	6	157.5	16.6	10.6	159	137	180
Specimen AL-3							
All Method	7	51.3	3.9	7.5	53	46	55
Specimen AL-4							
All Method	7	52.9	3.1	5.9	51	50	57
Specimen AL-5							
All Method	7	19.9	2.0	9.8	20	17	22

Allergen Specific IgE Antibodies

Specimen AL-1

	Timothy Grass Allergen							Common Ragweed Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	-	-	1	10	-	-	-	-	1	3	8	-	-
Hitachi CLA-1	-	-	-	-	5	-	-	-	-	1	1	2	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	1	1	-	-
Phadia Unicap 100	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	4	-	-	-	-	-	1	4	-	-
	Peanut (Arachis hyogaea) Allergen							White Oak Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	-	1	5	2	-	-	-	-	4	9	-	-	-
Hitachi CLA-1	-	-	-	-	2	-	-	-	-	3	2	-	-	-
Hycor EIA	-	-	-	2	-	-	-	-	-	-	2	-	-	-
Phadia Unicap 100	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	2	-	-	-	-	-	1	4	-	-	-
	Bermuda Grass Allergen							House Dust Mite Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	1	4	8	-	-	-	-	-	-	3	8	-	-
Hitachi CLA-1	-	1	2	2	-	-	-	-	-	-	2	2	-	-
Hycor EIA	-	-	-	2	-	-	-	-	-	-	-	2	-	-
Phadia Unicap 100	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (% ref)	-	-	2	3	-	-	-	-	-	-	1	3	-	-
	Dog Dander Allergen													
	CLASS RESULT													
	0	1	2	3	4	5	6							
ALL METHODS	-	-	1	2	5	-	-							
Hitachi CLA-1	-	-	-	-	4	-	-							
Hycor EIA	-	-	-	1	-	-	-							
Phadia Unicap 100	-	-	-	-	1	-	-							
Phadia UniCap 100 (% ref)	-	-	1	1	-	-	-							

Allergen Specific IgE Antibodies (cont'd)

Specimen AL-2

	Meadow, Kentucky Blue, June Grass Allergens CLASS RESULT							House Dust Mite Allergen CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
	ALL METHODS	-	-	-	1	5	-	-	-	-	3	6	2	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	1	1	1	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	2	-	-	-
Phadia Unicap 100	-	-	-	-	1	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	3	-	-	-	-	1	2	1	-	-
	Perennial Rye Allergen CLASS RESULT							Cat Epithelium Allergen CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
	ALL METHODS	-	-	-	1	4	-	-	-	-	4	4	3	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	3	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	2	-	-	-
Phadia Unicap 100	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	1	3	-	-	-	-	3	2	-	-	-
	Cow's Milk Allergen CLASS RESULT							Honeybee Venom Allergen CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
	ALL METHODS	-	-	7	1	1	-	-	-	-	-	-	-	-
Hitachi CLA-1	-	-	-	1	1	-	-	-	-	-	-	-	-	-
Hycor EIA	-	-	2	-	-	-	-	-	-	-	-	-	-	-
Phadia Unicap 100	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	4	-	-	-	-	-	-	-	-	-	-	-
	Peanut (Arachis hyogaea) Allergen CLASS RESULT													
	0	1	2	3	4	5	6							
	ALL METHODS	-	-	1	6	1	-	-						
Hitachi CLA-1	-	-	-	1	1	-	-							
Hycor EIA	-	-	-	2	-	-	-							
Phadia Unicap 100	-	-	-	1	-	-	-							
Phadia UniCap 100 (% ref)	-	-	1	2	-	-	-							

IgA (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen IP-1							
All Methods	10	32.6	9.8	30.1	31	21	55
Specimen IP-2							
All Methods	9	183.3	9.3	5.1	184	173	197
Specimen IP-3							
All Methods	9	331.1	19.8	6.0	327	310	363
Specimen IP-4							
All Methods	10	479.9	37.1	7.7	479	431	540
Specimen IP-5							
All Methods	8	657.5	55.6	8.5	666	577	724

IgG (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen IP-1							
All Methods	8	165.6	33.0	19.9	159	134	200
Specimen IP-2							
All Methods	10	766.0	20.4	2.7	766	743	798
Specimen IP-3							
All Methods	10	1429.6	57.3	4.0	1433	1316	1510
Specimen IP-4							
All Methods	10	2119.3	88.1	4.2	2127	1943	2266
Specimen IP-5							
All Methods	10	2707.6	188.2	7.0	2733	2416	2991

IgM (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen IP-1							
All Methods	11	24.4	2.1	8.7	25	21	29
Specimen IP-2							
All Methods	11	140.8	9.0	6.4	142	126	152
Specimen IP-3							
All Methods	10	262.3	19.3	7.3	267	236	302
Specimen IP-4							
All Methods	9	355.0	32.7	9.2	347	287	392
Specimen IP-5							
All Methods	9	495.9	62.9	12.7	509	420	574

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	49	-	49	-	-	49
ASI	17	-	17	-	-	17
Becton Dickinson	21	-	21	-	-	21
Biokit	4	-	4	-	-	4
Fisher HealthCare Sure-View	2	-	2	-	-	2
J&S Medical Assoc. Accutex	1	-	1	-	-	1
New Horizons	2	-	2	-	-	2
Stanbio	1	-	1	-	-	1
Wampole Impact RPR	1	-	1	-	-	1
	Specimen SY-4		Specimen SY-5			
ALL METHODS	49	-	-	49		
ASI	17	-	-	17		
Becton Dickinson	21	-	-	21		
Biokit	4	-	-	4		
Fisher HealthCare Sure-View	2	-	-	2		
J&S Medical Assoc. Accutex	1	-	-	1		
New Horizons	2	-	-	2		
Stanbio	1	-	-	1		
Wampole Impact RPR	1	-	-	1		

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>
Specimen SY-1							
ALL METHODS	-	1	8	9	-	-	-
ASI	-	1	5	5	-	-	-
Becton Dickinson	-	-	3	4	-	-	-
Specimen SY-2							
ALL METHODS	1	13	4	-	-	-	-
ASI	1	6	4	-	-	-	-
Becton Dickinson	-	7	-	-	-	-	-
Specimen SY-4							
ALL METHODS	1	9	7	1	-	-	-
ASI	1	7	2	1	-	-	-
Becton Dickinson	-	2	5	-	-	-	-

H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-1</u>		<u>Specimen HP-2</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	2	164	162	3
Abbott FlexPack	-	1	1	-
Applied Biotech SureStep	-	1	1	-
BD LINK 2	-	3	3	-
Beckman Coulter FlexSure	1	12	13	-
bioMerieux Vitek, Mini Vidas	-	1	1	-
Cardinal Health SP Brand	-	3	3	-
DPC Immulite/1000	-	1	1	-
Fisher HealthCare Sure-Vue	-	6	6	-
Henry Schein OneStep+ - waived	-	2	2	-
Instant Technologies i Screen	-	12	12	-
LifeSign Status	-	4	4	-
Meridian ImmunoCard	-	2	2	-
Polymedco Poly stat	-	23	22	-
Quidel QuickVue	-	74	71	3
Wampole Clearview	-	11	11	-

Lyme Disease Serology

<u>Method</u>	Specimen LY-1		Specimen LY-2	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	9	9	-
bioMerieux Vitek, Mini Vidas	-	2	2	-
Remel Rapidot	-	1	1	-
Wampole Impact	-	1	1	-
Wampole PreVue	-	3	3	-
Zeus	-	1	1	-

Mycoplasma Antibody

<u>Method</u>	Specimen MY-1		Specimen MY-2	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	-	-	1

Viral Markers – Anti-HBc

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	3	-	2	1	2	1

<u>Method</u>	Specimen VM-4		Specimen VM-5	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	3	-	2	1

The vendor assay for specimens VM-1 through VM-5 is: Negative, Positive, Positive, Negative, and Positive, respectively.

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	6	-	6	-	6	-
Abbott Quantum	1	-	1	-	1	-
Bio-Rad Evolis	1	-	1	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2	2	-	2	-	2	-
Other IgG Method	1	-	1	-	1	-
Other Total Method	1	-	1	-	1	-

<u>Method</u>	Specimen VM-4		Specimen VM-5	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	6	-	6	-
Abbott Quantum	1	-	1	-
Bio-Rad Evolis	1	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2	2	-	2	-
Other IgG Method	1	-	1	-
Other Total Method	1	-	1	-

Viral Markers – HAV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	3	-	3	-	1	2
	Specimen VM-4		Specimen VM-5			
All Methods	-	3	1	2		

Specimen VM-1: Total is non-reactive.

Specimen VM-2: Total is non-reactive.

Specimen VM-3: Total is reactive and IgM is non-reactive.

Specimen VM-4: Total and IgM are reactive.

Specimen VM-5: Total is reactive and IgM is non-reactive.

Viral Markers – HBeAg

The vendor assay for specimens VM-1 through VM-5 is: Negative, Negative, Negative, Negative and Negative, respectively.

Viral Markers – HBsAb

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	3	-	3	-	2	1
	Specimen VM-4		Specimen VM-5			
All Methods	3	-	3	-		

The vendor assay for specimens VM-1 through VM-5 is: Negative, Negative, Negative, Negative, and Negative, respectively.

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	6	-	-	6	-	6
Abbott Quantum	1	-	-	1	-	1
Bayer ADVIA Centaur	1	-	-	1	-	1
Bio-Rad Evolis	1	-	-	1	-	1
Roche Elecsys 1010/2010	1	-	-	1	-	1
VITROS Eci	1	-	-	1	-	1
	Specimen VM-4		Specimen VM-5			
ALL METHODS	6	-	-	6		
Abbott Quantum	1	-	-	1		
Bayer ADVIA Centaur	1	-	-	1		
Bio-Rad Evolis	1	-	-	1		
Roche Elecsys 1010/2010	1	-	-	1		
VITROS Eci	1	-	-	1		

Viral Markers – HCV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	4	-	4	-	-	4
	Specimen VM-4		Specimen VM-5			
All Methods	4	-	-	4		

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