

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Immunology
MLE – M3

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	8
Complement C3	9
Complement C4	9
Antinuclear Antibody (ANA [AN-11 – AN-15])	10
Qualitative	10
Antinuclear Antibody (ANA [AE-11 – AE-15])	10
Qualitative	10
Quantitative (Titer).....	11
C-Reactive Protein, Regular	11
Qualitative	11
Quantitative	12
C-Reactive Protein, High Sensitivity	12
Quantitative	12
Rubella	13
Qualitative	13
Quantitative	13
Total IgE	14
Quantitative	14
Allergen Specific IgE Antibodies	15
IgA	17
IgG	17
IgM	18
Syphilis Serology	18
Qualitative: RPR	18
Quantitative: RPR (Titer).....	19
H. pylori Antibody Detection	19
Lyme Disease Serology	20
Mycoplasma Antibody	20
Viral Markers	20
Anti-HBc.....	20
Anti-HIV	20
HAV.....	21
HBeAg.....	21
HBsAb	21
HBsAg.....	21
HCV.....	22

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	80% Participant Consensus
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

<u>Method</u>	<u>Specimen IM-11</u>		<u>Specimen IM-12</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	307	306	1
ASI	-	1	1	-
Beckman Coulter ICON Mono - waived	-	1	1	-
BioStar Acceava Mono Test	-	13	13	-
BioStar Acceava Mono-whole bld	-	16	16	-
Cardinal Health SP Brand	-	4	4	-
Cardinal Health SP Brand - waived	-	13	13	-
Fisher HealthCare Sure-Vue	-	7	7	-
Genzyme OSOM	-	1	1	-
Genzyme OSOM (waived)	-	13	13	-
Henry Schein OneStep+ - waived	-	2	2	-
Immunostics Inc.	-	1	1	-
Instant Technologies i Screen-WB	-	6	6	-
Inverness (Wampole) Clearview	-	2	2	-
Inverness ClearviewMono-plusII	-	24	24	-
Inverness Signify Mono Test	-	8	8	-
LifeSign Status	-	2	2	-
LifeSign UniStep Mono	-	8	8	-
McKesson Medi-Lab Performance - waived	-	10	10	-
Polymedco Poly stat	-	5	5	-
Polymedco Poly stat - waived	-	19	19	-
Quidel QuickVue+	-	77	77	-
Quidel QuickVue+ - waived	-	19	18	1
Remel RIM A.R.C.	-	1	1	-
Seradyn	-	22	22	-
Seradyn Color Q (whole blood)	-	1	1	-
Wampole ColorCard	-	7	7	-
Wampole Mono-Latex	-	1	1	-
Wampole Mono-Plus II	-	9	9	-
Wampole Mono-Plus II (whole blood)	-	5	5	-
Wampole Mono-Test	-	1	1	-
Wyntek Diagnostics Signify	-	2	2	-

<u>Method</u>	<u>Specimen IM-13</u>		<u>Specimen IM-14</u>		<u>Specimen IM-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	1	193	2	192	192	2
ASI	-	1	-	1	1	-
Beckman Coulter ICON Mono - waived	-	1	-	1	1	-
BioStar Acceava Mono Test	-	9	1	8	8	1
BioStar Acceava Mono-whole bld	-	1	-	1	1	-
Cardinal Health SP Brand	-	3	-	3	3	-
Cardinal Health SP Brand - waived	-	4	-	4	4	-
Fisher HealthCare Sure-Vue	-	7	-	7	7	-
Genzyme OSOM	-	1	-	1	1	-
Genzyme OSOM (waived)	-	8	-	8	8	-
Henry Schein OneStep+ - waived	-	2	-	2	2	-
Immunostics Inc.	-	1	-	1	1	-
Instant Technologies i Screen-WB	-	3	-	3	3	-
Inverness (Wampole) Clearview	-	2	-	2	2	-

Infectious Mononucleosis (cont'd)

<u>Method</u>	<u>Specimen IM-13</u>		<u>Specimen IM-14</u>		<u>Specimen IM-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
Inverness ClearviewMono-plusII	-	18	-	18	17	1
Inverness Signify Mono Test	-	2	-	2	2	-
LifeSign Status	-	1	-	1	1	-
LifeSign UniStep Mono	-	2	-	2	2	-
McKesson Medi-Lab Performance - waived	-	7	-	7	7	-
Polymedco Poly stat	-	5	-	5	5	-
Polymedco Poly stat - waived	-	8	-	8	8	-
Quidel QuickVue+	-	54	-	54	54	-
Quidel QuickVue+ - waived	1	7	-	8	8	-
Seradyn	-	22	-	22	22	-
Seradyn Color Q (whole blood)	-	1	-	1	1	-
Wampole ColorCard	-	7	-	7	7	-
Wampole Mono-Latex	-	1	-	1	1	-
Wampole Mono-Plus II	-	8	-	8	8	-
Wampole Mono-Plus II (whole blood)	-	2	1	1	2	-
Wampole Mono-Test	-	1	-	1	1	-
Wyntek Diagnostics Signify	-	2	-	2	2	-

Rheumatoid Factor—Qualitative

<u>Method</u>	<u>Specimen RF-11</u>		<u>Specimen RF-12</u>		<u>Specimen RF-13</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	95	1	96	-	1	95
ASI	3	-	3	-	-	3
Beckman Synchron	2	-	2	-	-	2
Becton Dickinson	1	-	1	-	-	1
Behring RapiTex - Plate method	1	-	1	-	-	1
Biokit Rheumajet	4	-	4	-	-	4
BMH 902, 911, 912, 914, 917	1	-	1	-	-	1
Diamedix	2	-	2	-	-	2
Fisher HealthCare Sure-Vue	11	-	11	-	-	11
Immunostics Inc.	7	-	7	-	-	7
J&S Medical Assoc. Accutex	1	-	1	-	-	1
Pulse Scientific	1	-	1	-	-	1
Roche Integra	1	-	1	-	-	1
Seradyn	38	-	38	-	1	37
Stanbio	2	-	2	-	-	2
Wampole ColorCard	3	-	3	-	-	3
Wampole Rheumatex	6	1	7	-	-	7
Wampole Rheumaton	5	-	5	-	-	5

Rheumatoid Factor—Qualitative (cont'd)

<u>Method</u>	Specimen RF-14		Specimen RF-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	2	94	96	-
ASI	-	3	3	-
Beckman Synchron	-	2	2	-
Becton Dickinson	-	1	1	-
Behring RapiTex - Plate method	-	1	1	-
Biokit Rheumajet	-	4	4	-
BMH 902, 911, 912, 914, 917	-	1	1	-
Diamedix	-	2	2	-
Fisher HealthCare Sure-View	1	10	11	-
Immunostics Inc.	-	7	7	-
J&S Medical Assoc. Accutex	-	1	1	-
Pulse Scientific	-	1	1	-
Roche Integra	-	1	1	-
Seradyn	1	37	38	-
Stanbio	-	2	2	-
Wampole ColorCard	-	3	3	-
Wampole Rheumatex	-	7	7	-
Wampole Rheumaton	-	5	5	-

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-13											
ALL METHODS	2	13	8	2	1	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	3	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	1	3	1	-	-	-	-	-	-	-	-
Immunostics Inc.	-	-	1	-	-	-	-	-	-	-	-
Seradyn	1	6	3	1	-	1	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

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-14

ALL METHODS	2	16	5	1	1	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	3	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	4	-	-	-	-	-	-	-	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-	-	-	-
Seradyn	1	7	2	-	-	1	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

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-11

All Beckman Instruments	7	20.0	0.0	0.0	20	20	20
All Method	12	5.9	7.1	119.4	9	0	25
Beckman Synchron	6	20.0	0.0	0.0	20	20	20

Specimen RF-12

All Beckman Instruments	7	20.0	0.0	0.0	20	20	20
All Method	12	6.1	6.8	112.0	9	0	25
Beckman Synchron	6	20.0	0.0	0.0	20	20	20

Specimen RF-13

All Beckman Instruments	7	122.0	15.4	12.6	115	108	147
All Method	12	80.0	49.3	61.6	77	3	222
Beckman Synchron	6	123.7	16.1	13.1	117	108	147

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-14							
All Beckman Instruments	7	121.1	17.1	14.1	115	105	150
All Method	12	81.3	53.2	65.5	77	3	237
Beckman Synchron	6	122.8	18.0	14.7	118	105	150

Specimen RF-15

All Beckman Instruments	7	20.0	0.0	0.0	20	20	20
All Method	12	6.1	6.5	107.1	9	0	24
Beckman Synchron	6	20.0	0.0	0.0	20	20	20

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	Specimen AS-11		Specimen AS-12		Specimen AS-13	
	<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>	Specimen AS-14		Specimen AS-15	
	<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

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-11							
All Method	14	361.4	48.5	13.4	361	237	450
Specimen COM-12							
All Method	12	267.5	18.9	7.1	263	245	304
Specimen COM-13							
All Method	14	145.8	12.4	8.5	144	129	175
Specimen COM-14							
All Method	13	441.6	58.0	13.1	434	350	530
Specimen COM-15							
All Method	12	29.2	7.3	24.9	26	21	46

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-11							
All Method	14	77.1	9.4	12.1	78	65	100
Specimen COM-12							
All Method	14	53.1	4.7	8.9	54	45	58
Specimen COM-13							
All Method	14	29.1	2.8	9.5	28	25	35
Specimen COM-14							
All Method	14	93.5	14.2	15.2	93	71	128
Specimen COM-15							
All Method	14	6.4	1.9	30.3	7	4	10

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	Specimen AN-11		Specimen AN-12		Specimen AN-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	10	-	10	-	3	7
Diagnostic Technology	7	-	7	-	3	4
Seradyn Seratest SLE	1	-	1	-	-	1
Wampole	1	-	1	-	-	1

<u>Method</u>	Specimen AN-14		Specimen AN-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	3	7	10	-
Diagnostic Technology	3	4	7	-
Seradyn Seratest SLE	-	1	1	-
Wampole	-	1	1	-

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	17	-	17	-	-	17
Diamedix	1	-	1	-	-	1
Immuno Concepts	6	-	6	-	-	6
INOVA Diagnostics	3	-	3	-	-	3
Kallestad	3	-	3	-	-	3
Zeus	1	-	1	-	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	17	1	16
Diamedix	-	1	-	1
Immuno Concepts	-	6	1	5
INOVA Diagnostics	-	3	-	3
Kallestad	-	3	-	3
Zeus	-	1	-	1

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-13											
ALL METHODS	-	-	1	-	2	2	2	-	1	1	-
Immuno Concepts	-	-	1	-	-	2	1	-	-	1	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-
Kallestad	-	-	-	-	2	-	-	-	-	-	-
Specimen AE-14											
ALL METHODS	-	-	-	1	3	1	2	-	2	-	-
Immuno Concepts	-	-	-	1	1	-	2	-	1	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-
Kallestad	-	-	-	-	2	-	-	-	-	-	-
Specimen AE-15											
ALL METHODS	-	-	-	3	4	-	1	-	-	-	-
Immuno Concepts	-	-	-	1	2	-	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	-	-	-	-	-	-
Kallestad	-	-	-	2	-	-	-	-	-	-	-

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-5</u>		<u>Specimen CR-6</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-View	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-5					
All Method mg/dL - units	41	0.208	0.200	96.2	0.20
Beckman Synchron	7	0.371	0.150	40.3	0.40
Dade Dimension/AR/ES/RxL/Xpand	5	0.160	0.089	55.9	0.20
Roche Integra	5	0.062	0.080	128.2	0.04
All Immunology Methods	28	0.231	0.201	87.0	0.20
mg/L - units					
All Immunology Methods	14	1.424	2.057	144.5	0.12

Specimen CR-6

All Method mg/dL - units	45	11.828	13.307	112.5	3.21
Beckman Synchron	7	2.829	0.125	4.4	2.80
Dade Dimension/AR/ES/RxL/Xpand	5	3.280	0.130	4.0	3.20
Roche Integra	5	3.258	0.212	6.5	3.21
All Immunology Methods	28	3.049	0.281	9.2	3.06
mg/L - units					
All Immunology Methods	13	30.978	2.133	6.9	31.16

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-5					
All Method mg/dL - units	60	0.692	0.358	51.7	0.80
All Immunology Methods	7	0.076	0.018	23.9	0.08
mg/L - units					
DPC Immulite/1000	8	0.858	0.091	10.6	0.87
Other High Sensi. CRP method	7	0.734	0.205	27.9	0.80
Roche Integra hsCRP	6	0.833	0.050	6.0	0.84
All Immunology Methods	49	0.799	0.270	33.8	0.83

Specimen HCR-6

All Method mg/dL - units	63	13.475	5.471	40.6	15.17
All Immunology Methods	7	1.374	0.195	14.2	1.33
mg/L - units					
DPC Immulite/1000	8	16.762	2.760	16.5	16.90
Other High Sensi. CRP method	7	15.384	0.812	5.3	15.46
Roche Integra hsCRP	6	16.252	0.915	5.6	16.57
All Immunology Methods	51	15.334	2.297	15.0	15.46

Rubella—Qualitative

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	8	-	8	-	8
Abbott AxSYM	-	1	-	1	-	1
Bayer ADVIA Centaur	-	1	-	1	-	1
bioMerieux Vitek, Mini Vidas	-	2	-	2	-	2
DPC Immulite 2000/2500	-	1	-	1	-	1
Seradyn	-	2	-	2	-	2
Wampole Rubella - Plus	-	1	-	1	-	1
	Specimen RU-14		Specimen RU-15			
ALL METHODS	7	1	8	-		
Abbott AxSYM	1	-	1	-		
Bayer ADVIA Centaur	1	-	1	-		
bioMerieux Vitek, Mini Vidas	2	-	2	-		
DPC Immulite 2000/2500	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-11					
All Methods	5	121.72	27.31	22.4	116.7
Specimen RU-12					
All Methods	5	41.40	7.05	17.0	41.5
Specimen RU-13					
All Methods	5	39.82	6.21	15.6	39.9
Specimen RU-14					
All Methods	5	1.54	1.99	129.4	1.1
Specimen RU-15					
All Methods	5	1.48	2.03	137.3	1.0

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-11							
All Method	8	243.0	31.4	12.9	252	192	285
Specimen AL-12							
All Method	6	351.3	68.0	19.4	407	269	414
Specimen AL-13							
All Method	9	19.4	2.8	14.3	19	15	23
Specimen AL-14							
All Method	9	48.0	5.3	11.1	49	41	57
Specimen AL-15							
All Method	9	48.1	7.4	15.4	49	38	57

Allergen Specific IgE Antibodies

Specimen AL-11

	English Plantain Allergen							Cat Epithlium Allergen						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	5	5	3	-	-	-	-	-	-	-	8	6	-	-
Hitachi CLA-1	5	2	-	-	-	-	-	-	-	-	-	6	-	-
Hycor EIA	-	-	2	-	-	-	-	-	-	-	2	-	-	-
Phadia CAP (% ref)	-	1	-	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	2	1	-	-	-	-	-	-	-	4	-	-	-

	Maple (Box Elder) Allergen							Bermuda Grass Allergen						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	6	2	6	-	-	-	-	-	5	8	1	-	-	-
Hitachi CLA-1	6	1	-	-	-	-	-	-	5	1	-	-	-	-
Hycor EIA	-	1	1	-	-	-	-	-	-	1	1	-	-	-
Phadia CAP (% ref)	-	-	1	-	-	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	4	-	-	-	-	-	-	4	-	-	-	-

	Dog Dander Allergen							House Dust Mite Allergen						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	2	9	-	-	-	-	1	4	10	-	-
Hitachi CLA-1	-	-	-	-	7	-	-	-	-	1	2	4	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	2	-	-	-
Phadia CAP (% ref)	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (% ref)	-	-	-	2	-	-	-	-	-	-	-	4	-	-

	Peanut (Arachis hyogaea) Allergen						
	<i>CLASS RESULT</i>						
	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	4	7	-	-
Hitachi CLA-1	-	-	-	-	4	-	-
Hycor EIA	-	-	-	-	2	-	-
Phadia CAP (% ref)	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	2	1	-	-

Allergen Specific IgE Antibodies (cont'd)

Specimen AL-12

	Silver Birch Tree Allergen							House Dust Mite Allergen						
	CLASS RESULT							CLASS RESULT						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	3	2	-	-	-	-	-	-	1	10	3	-	-
Hitachi CLA-1	-	3	-	-	-	-	-	-	-	1	2	3	-	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	2	-	-	-
Phadia CAP (% ref)	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	-	-	-	-	-	-	-	4	-	-	-
	Cat Epithelium Allergen							Cocksfoot Allergen						
	CLASS RESULT							CLASS RESULT						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	8	6	-	-	1	-	-	-	-	2	-
Hitachi CLA-1	-	-	-	-	6	-	-	1	-	-	-	-	-	-
Hycor EIA	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Phadia CAP (% ref)	-	-	-	1	-	-	-	-	-	-	-	-	1	-
Phadia UniCap 100 (% ref)	-	-	-	4	-	-	-	-	-	-	-	-	1	-
	Meadow Fescue Allergen							Egg White Allergen						
	CLASS RESULT							CLASS RESULT						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	-	2	-	-	-	5	2	1	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	1	1	1	-	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Phadia CAP (% ref)	-	-	-	-	-	1	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	1	-	-	-	2	-	-	-	-
	Natural Latex Allergen													
	CLASS RESULT													
	0/1	1	2	3	4	5	6							
ALL METHODS	-	2	-	-	-	-	-							
Hitachi CLA-1	-	-	-	-	-	-	-							
Hycor EIA	-	-	-	-	-	-	-							
Phadia CAP (% ref)	-	-	-	-	-	-	-							
Phadia UniCap 100 (% ref)	-	1	-	-	-	-	-							

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-11							
All Methods	13	512.2	41.1	8.0	512	415	577
Specimen IP-12							
All Methods	13	363.5	22.7	6.3	358	333	409
Specimen IP-13							
All Methods	12	201.6	10.4	5.2	201	190	223
Specimen IP-14							
All Methods	11	658.2	58.1	8.8	674	538	728
Specimen IP-15							
All Methods	13	40.2	7.7	19.3	38	32	55

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-11							
All Methods	13	2516.6	173.8	6.9	2514	2201	2913
Specimen IP-12							
All Methods	13	1750.5	124.8	7.1	1740	1522	2018
Specimen IP-13							
All Methods	12	957.2	52.7	5.5	957	856	1083
Specimen IP-14							
All Methods	12	3184.6	289.1	9.1	3276	2715	3793
Specimen IP-15							
All Methods	9	184.6	32.9	17.8	169	159	262

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-11							
All Methods	13	345.3	41.5	12.0	361	252	387
Specimen IP-12							
All Methods	13	243.9	25.1	10.3	252	195	273
Specimen IP-13							
All Methods	13	135.5	11.8	8.7	135	110	151
Specimen IP-14							
All Methods	11	456.0	63.7	14.0	480	344	536
Specimen IP-15							
All Methods	13	24.6	3.6	14.8	25	19	33

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	36	10	1	46	1	46
ASI	13	4	-	17	-	17
Becton Dickinson	17	1	-	19	-	19
Fisher HealthCare Sure-Vue	2	3	-	5	-	5
J&S Medical Assoc. Accutex	1	-	-	1	-	1
New Horizons	1	-	-	1	-	1
Stanbio	1	1	-	2	-	2
Wampole Impact RPR	1	-	1	-	1	-
	Specimen SY-14		Specimen SY-15			
ALL METHODS	47	-	38	9		
ASI	17	-	14	3		
Becton Dickinson	19	-	16	3		
Fisher HealthCare Sure-Vue	5	-	3	2		
J&S Medical Assoc. Accutex	1	-	1	-		
New Horizons	1	-	1	-		
Stanbio	2	-	2	-		
Wampole Impact RPR	1	-	1	-		

Specimen SY-11 is graded by referee consensus.

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-11							
ALL METHODS	13	1	-	-	1	-	-
ASI	7	1	-	-	1	-	-
Becton Dickinson	6	-	-	-	-	-	-
Specimen SY-14							
ALL METHODS	-	8	7	1	-	-	-
ASI	-	4	5	1	-	-	-
Becton Dickinson	-	4	2	-	-	-	-
Specimen SY-15							
ALL METHODS	16	-	-	-	-	-	-
ASI	10	-	-	-	-	-	-
Becton Dickinson	6	-	-	-	-	-	-

H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-5</u>		<u>Specimen HP-6</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	3	162	160	5
BD LINK 2	-	2	2	-
Beckman Coulter FlexSure	-	2	2	-
Beckman Coulter ICON HP	-	10	10	-
bioMerieux Vitek, Mini Vidas	-	1	1	-
BioStar Acceava H. pylori	-	5	5	-
Cardinal Health SP Brand	-	4	4	-
DPC Immulite/1000	-	1	1	-
Fisher HealthCare Sure-Vue	-	6	6	-
Instant Technologies i Screen	-	17	17	-
Inverness (Wampole) Clearview	1	10	10	1
LifeSign Status	-	2	2	-
Meridian ImmunoCard	-	2	2	-
Polymedco Poly stat	1	18	18	1
Quidel QuickVue	-	77	75	2

Lyme Disease Serology

<u>Method</u>	Specimen LY-5		Specimen LY-6	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	10	-	-	10
bioMerieux Vitek, Mini Vidas	1	-	-	1
Diamedix	1	-	-	1
Immunostics Inc.	1	-	-	1
Remel Rapidot	1	-	-	1
Wampole	1	-	-	1
Wampole Impact	1	-	-	1
Wampole PreVue	3	-	-	3

Mycoplasma Antibody

<u>Method</u>	Specimen MY-5		Specimen MY-6	
	<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-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	-	2	-	2	-

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	1	1	1

The vendor assay for specimens VM-11 through VM-15 is: Negative, Negative, Negative, Positive, and Postive, respectively.

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	7	7	-	7	-
Abbott Quantum	-	1	1	-	1	-
Bio-Rad Evolis	-	1	1	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2	-	2	2	-	2	-
Other IgG Method	-	2	2	-	2	-

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	7	-	7	-
Abbott Quantum	1	-	1	-
Bio-Rad Evolis	1	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2	2	-	2	-
Other IgG Method	2	-	2	-
Other Total Method	7	-	7	-

Viral Markers – HAV

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	-	2	-	2	-
	Specimen VM-14		Specimen VM-15			
All Methods	2	-	2	-		

Viral Markers – HBeAg

The vendor assay for specimens VM-11 through VM-15 is: Negative, Negative, Negative, Negative and Negative, respectively.

Viral Markers – HBsAb

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	-	2	-	2	-
	Specimen VM-14		Specimen VM-15			
All Methods	1	1	1	1		

The vendor assay for specimens VM-11 through VM-15 is: Negative, Negative, Negative, Negative, and Negative, respectively.

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	5	5	-	5	-
Abbott Quantum	-	1	1	-	1	-
Bayer ADVIA Centaur	-	1	1	-	1	-
Bio-Rad Evolis	-	1	1	-	1	-
DPC Immulite/1000	-	1	1	-	1	-
Roche Elecsys 1010/2010	-	1	1	-	1	-
	Specimen VM-14		Specimen VM-15			
ALL METHODS	-	5	-	5		
Abbott Quantum	-	1	-	1		
Bayer ADVIA Centaur	-	1	-	1		
Bio-Rad Evolis	-	1	-	1		
DPC Immulite/1000	-	1	-	1		
Roche Elecsys 1010/2010	-	1	-	1		

Viral Markers – HCV

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	3	-	3	-	3	-
Bayer ADVIA Centaur	2	-	2	-	2	-
Bio-Rad Evolis	1	-	1	-	1	-
	Specimen VM-14		Specimen VM-15			
All Methods	3	-	3	-		
Bayer ADVIA Centaur	2	-	2	-		
Bio-Rad Evolis	1	-	1	-		

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