

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Immunology
MLE – M2

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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-6</u>		<u>Specimen IM-7</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	307	1	4	304
ASI	1	-	-	1
Beckman Coulter ICON Mono - waived	1	-	-	1
BioStar Acceava Mono Test	9	-	-	9
BioStar Acceava Mono-whole bld	17	-	1	16
Cardinal Health SP Brand	5	-	-	5
Cardinal Health SP Brand - waived	14	-	1	13
Fisher HealthCare Sure-Vue	7	-	-	7
Genzyme OSOM	1	-	-	1
Genzyme OSOM (waived)	12	-	-	12
Henry Schein OneStep+ - waived	2	-	-	2
Immunostics Inc.	1	-	-	1
Instant Technologies i Screen-WB	7	-	1	6
Inverness ClearviewMono-plusII	12	-	-	12
Inverness Signify Mono Test	7	1	-	8
LifeSign Status	1	-	-	1
LifeSign UniStep Mono	7	-	-	7
Mainline Confirms	1	-	-	1
McKesson Medi-Lab Performance - waived	11	-	-	11
Polymedco Poly stat	8	-	-	8
Polymedco Poly stat - waived	15	-	-	15
Quidel QuickVue+	72	-	1	71
Quidel QuickVue+ - waived	28	-	-	28
Remel RIM A.R.C.	1	-	-	1
Seradyn	26	-	-	26
Seradyn Color Q (whole blood)	1	-	-	1
Wampole ColorCard	10	-	-	10
Wampole Mono-Latex	2	-	-	2
Wampole Mono-Plus II	15	-	-	15
Wampole Mono-Plus II (whole blood)	8	-	-	8
Wampole Mono-Test	1	-	-	1

<u>Method</u>	<u>Specimen IM-8</u>		<u>Specimen IM-9</u>		<u>Specimen IM-10</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	197	197	-	197	-
ASI	-	1	1	-	1	-
Beckman Coulter ICON Mono - waived	-	1	1	-	1	-
BioStar Acceava Mono Test	-	4	4	-	4	-
BioStar Acceava Mono-whole bld	-	3	3	-	3	-
Cardinal Health SP Brand	-	5	5	-	5	-
Cardinal Health SP Brand - waived	-	3	3	-	3	-
Fisher HealthCare Sure-Vue	-	7	7	-	7	-
Genzyme OSOM	-	1	1	-	1	-
Genzyme OSOM (waived)	-	7	7	-	7	-
Henry Schein OneStep+ - waived	-	2	2	-	2	-
Immunostics Inc.	-	1	1	-	1	-
Instant Technologies i Screen-WB	-	3	3	-	3	-
Inverness ClearviewMono-plusII	-	8	8	-	8	-

Infectious Mononucleosis (cont'd)

<u>Method</u>	Specimen IM-8		Specimen IM-9		Specimen IM-10	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
Inverness Signify Mono Test	-	4	4	-	4	-
LifeSign UniStep Mono	-	1	1	-	1	-
Mainline Confirms	-	1	1	-	1	-
McKesson Medi-Lab Performance - waived	-	8	8	-	8	-
Polymedco Poly stat	-	8	8	-	8	-
Polymedco Poly stat - waived	-	4	4	-	4	-
Quidel QuickVue+	-	52	52	-	52	-
Quidel QuickVue+ - waived	-	15	15	-	15	-
Seradyn	-	26	26	-	26	-
Seradyn Color Q (whole blood)	-	1	1	-	1	-
Wampole ColorCard	-	9	9	-	9	-
Wampole Mono-Latex	-	2	2	-	2	-
Wampole Mono-Plus II	-	13	13	-	13	-
Wampole Mono-Plus II (whole blood)	-	4	4	-	4	-
Wampole Mono-Test	-	1	1	-	1	-

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-6		Specimen RF-7		Specimen RF-8	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	97	1	1	97	96	2
ASI	2	-	-	2	2	-
Beckman Synchron	2	-	-	2	2	-
Becton Dickinson	1	-	-	1	1	-
Behring RapiTex - Plate method	1	-	-	1	1	-
Biokit Rheumagen	1	-	-	1	1	-
Biokit Rheumajet	5	-	-	5	5	-
BMH 902, 911, 912, 914, 917	1	-	-	1	1	-
Diamedix	2	-	-	2	2	-
Fisher HealthCare Sure-Vue	10	-	-	10	10	-
Immunostics Inc.	6	-	-	6	6	-
J&S Medical Assoc. Accutex	1	-	-	1	1	-
Pulse Scientific	1	-	-	1	1	-
Roche Integra	1	-	-	1	1	-
Seradyn	37	-	-	37	37	-
Stanbio	2	-	-	2	2	-
Sterling Diagnostics, Inc.	1	-	-	1	1	-
Wampole ColorCard	1	-	-	1	1	-
Wampole Rheumatex	7	-	-	7	7	-
Wampole Rheumaton	10	-	-	10	9	1

Rheumatoid Factor—Qualitative (cont'd)

<u>Method</u>	Specimen RF-9		Specimen RF-10	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	2	96	2	96
ASI	-	2	-	2
Beckman Synchron	-	2	-	2
Becton Dickinson	-	1	-	1
Behring RapiTex - Plate method	-	1	-	1
Biokit Rheumagen	-	1	-	1
Biokit Rheumajet	-	5	-	5
BMH 902, 911, 912, 914, 917	-	1	-	1
Diamedix	-	2	-	2
Fisher HealthCare Sure-View	-	10	-	10
Immunostics Inc.	-	6	-	6
J&S Medical Assoc. Accutex	-	1	-	1
Pulse Scientific	-	1	-	1
Roche Integra	-	1	-	1
Seradyn	1	36	1	36
Stanbio	-	2	-	2
Sterling Diagnostics, Inc.	-	1	-	1
Wampole ColorCard	-	1	-	1
Wampole Rheumatex	1	6	-	7
Wampole Rheumaton	-	10	-	10

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-7											
ALL METHODS	-	12	9	4	-	2	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumagen	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	1	1	2	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	5	-	-	-	-	-	-	-	-	-
Seradyn	-	4	5	-	-	1	-	-	-	-	-
Sterling Diagnostics, Inc.	-	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-9

ALL METHODS	4	13	4	3	1	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumagen	-	1	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	2	1	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	3	-	-	-	-	-	-	-	-	-
Seradyn	2	6	1	-	-	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	-	1	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	-	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-10

ALL METHODS	4	14	4	2	2	1	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumagen	-	1	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	2	-	1	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	3	-	-	-	-	-	-	-	-	-
Seradyn	2	6	1	-	-	1	-	-	-	-	-
Sterling Diagnostics, Inc.	-	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-6

All Beckman Instruments	7	20.0	0	0	20	20	20
All Method	11	5.5	5.5	100.2	8	0	20
Beckman Synchron	6	20.0	0	0	20	20	20

Specimen RF-7

All Beckman Instruments	7	240.3	11.4	4.7	241	227	257
All Method	10	149.7	89.0	59.4	186	102	391
Beckman Synchron	6	238.7	11.6	4.8	241	227	257

Specimen RF-8

All Beckman Instruments	7	20.0	0	0	20	20	20
All Method	11	5.9	5.4	91.0	8	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-9							
All Beckman Instruments	7	114.7	5.6	4.9	116	106	121
All Method	12	93.4	39.9	42.7	90	63	186
Beckman Synchron	6	114.2	6.0	5.2	116	106	121
Specimen RF-10							
All Beckman Instruments	7	114.9	6.2	5.4	113	108	126
All Method	12	94.2	41.9	44.5	87	64	187
Beckman Synchron	6	114.0	6.4	5.6	113	108	126

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	Specimen AS-6		Specimen AS-7		Specimen AS-8	
	<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-9		Specimen AS-10	
	<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-6

ALL METHODS	-	-	-	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-	-

Specimen AS-7

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>
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Specimen COM-6

All Method	15	262.9	25.6	9.8	267	215	305
DiaSorin	5	252.2	32.1	12.7	267	215	286

Specimen COM-7

All Method	15	30.3	8.8	29.1	27	18	56
DiaSorin	5	30.8	8.8	28.7	37	18	37

Specimen COM-8

All Method	15	434.7	80.0	18.4	427	260	564
DiaSorin	5	380.2	92.8	24.4	376	260	521

Specimen COM-9

All Method	15	143.1	12.9	9.0	142	123	171
DiaSorin	5	134.6	10.3	7.7	140	123	145

Specimen COM-10

All Method	15	366.1	32.8	9.0	364	303	428
DiaSorin	5	340.2	33.1	9.7	341	303	390

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-6							
All Method	15	53.0	7.9	15.0	54	32	67
DiaSorin	5	50.8	11.9	23.5	55	32	64
Specimen COM-7							
All Method	14	6.6	2.5	37.6	7	2	10
DiaSorin	5	5.8	2.4	41.2	7	2	8
Specimen COM-8							
All Method	15	86.9	24.3	28.0	89	43	130
DiaSorin	5	80.0	28.3	35.3	71	53	112
Specimen COM-9							
All Method	15	29.1	5.8	19.8	31	14	39
DiaSorin	5	27.6	8.0	28.8	32	14	33
Specimen COM-10							
All Method	15	73.7	10.7	14.6	77	49	87
DiaSorin	5	70.6	15.7	22.2	71	49	86

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	Specimen AN-6		Specimen AN-7		Specimen AN-8	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	2	7	9	-	2	7
Diagnostic Technology	2	4	6	-	2	4
Seradyn	-	1	1	-	-	1
Stanbio	-	1	1	-	-	1
Wampole	-	1	1	-	-	1

<u>Method</u>	Specimen AN-9		Specimen AN-10	
	<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

Specimens AN-6 and AN-8 are not graded due to less than 80% participant consensus.

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	16	-	-	15	-	15
Immuno Concepts	6	-	-	5	-	5
INOVA Diagnostics	3	-	-	3	-	3
Kallestad	3	-	-	3	-	3
Zeus	1	-	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	16	-	-	15
Immuno Concepts	6	-	-	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-7											
ALL METHODS	-	-	1	1	2	3	2	-	-	-	-
Immuno Concepts	-	-	1	-	-	3	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	-	-	-	-	-	-
Kallestad	-	-	-	1	1	-	-	-	-	-	-
Specimen AE-8											
ALL METHODS	-	-	1	1	3	3	1	-	-	-	-
Immuno Concepts	-	-	1	-	1	3	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	-	-	-	-	-	-
Kallestad	-	-	-	1	1	-	-	-	-	-	-
Specimen AE-10											
ALL METHODS	-	-	-	1	2	1	1	1	2	1	-
Immuno Concepts	-	-	-	1	-	1	1	1	1	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-
Kallestad	-	-	-	-	2	-	-	-	-	-	-

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-3</u>		<u>Specimen CR-4</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	12	-	-	12
ASI	2	-	-	2
Beckman Synchron	1	-	-	1
Dade Dimension/AR/ES/RxL/Xpand	1	-	-	1
Fisher HealthCare Sure-Vue	3	-	-	3
Immunostics Inc.	1	-	-	1
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-3					
All Method mg/dL - units	37	0.460	0.435	94.7	0.30
Beckman Synchron	7	0.357	0.098	27.3	0.30
Dade Dimension/AR/ES/RxL/Xpand	5	0.240	0.089	37.3	0.20
All Immunology Methods mg/L - units	25	0.252	0.146	57.9	0.20
All Immunology Methods	13	1.990	1.801	90.5	1.40

Specimen CR-4

All Method mg/dL - units	42	5.420	6.080	112.2	1.43
Beckman Synchron	8	1.012	0.155	15.3	1.10
Dade Dimension/AR/ES/RxL/Xpand	5	1.480	0.084	5.7	1.50
All Immunology Methods mg/L - units	26	1.266	0.226	17.8	1.39
All Immunology Methods	13	13.861	1.997	14.4	13.50

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-3					
All Method mg/dL - units	62	2.062	0.995	48.2	2.40
All Immunology Methods mg/L - units	10	0.277	0.023	8.3	0.28
Other High Sensi. CRP method	7	2.556	0.223	8.7	2.51
Roche Integra hsCRP	7	2.461	0.102	4.2	2.48
All Immunology Methods	48	2.540	0.401	15.8	2.48

Specimen HCR-4

All Method mg/dL - units	64	11.845	5.865	49.5	14.51
All Immunology Methods mg/L - units	10	1.652	0.245	14.8	1.62
Other High Sensi. CRP method	8	13.464	5.235	38.9	15.64
Roche Integra hsCRP	7	14.533	0.601	4.1	14.77
All Immunology Methods	49	14.728	2.368	16.1	14.99

Rubella—Qualitative

<u>Method</u>	Specimen RU-6		Specimen RU-7		Specimen RU-8	
	<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	2	-	-	2	2	-
Bayer ADVIA Centaur	1	-	-	1	1	-
bioMerieux Vitek, Mini Vidas	2	-	-	2	2	-
Seradyn	2	-	-	2	2	-
Wampole Rubella - Plus	1	-	-	1	1	-
	Specimen RU-9		Specimen RU-10			
ALL METHODS	-	8	-	8		
Abbott AxSYM	-	2	-	2		
Bayer ADVIA Centaur	-	1	-	1		
bioMerieux Vitek, Mini Vidas	-	2	-	2		
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-6					
All Methods	4	-	-	-	5.0
Specimen RU-7					
All Methods	4	-	-	-	149.5
Specimen RU-8					
All Methods	4	-	-	-	5.0
Specimen RU-9					
All Methods	4	-	-	-	25.3
Specimen RU-10					
All Methods	4	-	-	-	26.5

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-6							
All Method	7	267.6	42.0	15.7	275	200	316
Specimen AL-7							
All Method	7	249.0	32.2	12.9	256	188	281
Specimen AL-8							
All Method	9	19.3	4.7	24.3	19	13	30
Specimen AL-9							
All Method	9	18.3	2.9	15.7	19	12	21
Specimen AL-10							
All Method	9	46.2	5.1	11.1	46	40	52

Allergen Specific IgE Antibodies

Specimen AL-6

	English Plantain Allergen							Common Ragweed Allergen						
	CLASS RESULT							CLASS RESULT						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	7	5	1	-	-	-	-	1	1	6	6	-	-	-
Hitachi CLA-1	6	1	-	-	-	-	-	1	1	3	1	-	-	-
Hycor EIA	-	1	1	-	-	-	-	-	-	-	2	-	-	-
Phadia UniCap 100 (% ref)	1	3	-	-	-	-	-	-	-	2	3	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	1	-	-	-	-

	Timothy Grass Allergen							Meadow, Kentucky Blue, June Grass Allergens						
	CLASS RESULT							CLASS RESULT						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	6	5	1	-	-	-	-	-	5	1
Hitachi CLA-1	-	-	-	-	6	-	-	-	-	-	-	-	-	-
Hycor EIA	-	-	-	-	-	-	1	-	-	-	-	-	-	1
Phadia UniCap 100 (% ref)	-	-	-	-	-	5	-	-	-	-	-	-	4	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	1	-

	Dog Dander 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	-	2	3	6	-	-	-	-	2	1	8	-	-	-
Hitachi CLA-1	-	2	-	4	-	-	-	-	2	-	2	-	-	-
Hycor EIA	-	-	-	1	-	-	-	-	-	-	2	-	-	-
Phadia UniCap 100 (% ref)	-	-	2	-	-	-	-	-	-	1	3	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	1	-	-	-	-	-	-	1	-	-	-

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

Allergen Specific IgE Antibodies (cont'd)

Specimen AL-7

	White Oak Allergen <i>CLASS RESULT</i>							Alternaria alternate Allergen <i>CLASS RESULT</i>						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	2	1	11	1	-	-	-	4	8	3	-	-	-	-
Hitachi CLA-1	2	1	3	-	-	-	-	4	2	-	-	-	-	-
Hycor EIA	-	-	1	1	-	-	-	-	-	2	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	5	-	-	-	-	-	4	1	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	2	-	-	-	-	-	2	-	-	-	-	-
	Cat Epithelium Allergen <i>CLASS RESULT</i>							Maple (Box Elder) Allergen <i>CLASS RESULT</i>						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	-	5	6	4	-	-	4	9	-	-	-	-	-
Hitachi CLA-1	-	-	1	1	4	-	-	4	2	-	-	-	-	-
Hycor EIA	-	-	-	2	-	-	-	-	2	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	2	3	-	-	-	-	5	-	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	2	-	-	-	-	-	-	-	-	-	-	-
	House Dust Mite Allergen <i>CLASS RESULT</i>							Bermuda Grass Allergen <i>CLASS RESULT</i>						
	0/1	1	2	3	4	5	6	0/1	1	2	3	4	5	6
ALL METHODS	-	1	4	8	-	-	-	3	2	9	1	-	-	-
Hitachi CLA-1	-	1	2	1	-	-	-	3	2	1	-	-	-	-
Hycor EIA	-	-	-	2	-	-	-	-	-	1	1	-	-	-
Phadia UniCap 100 (% ref)	-	-	1	4	-	-	-	-	-	5	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	1	-	-	-	-	-	2	-	-	-	-
	Egg White Allergen <i>CLASS RESULT</i>													
	0/1	1	2	3	4	5	6							
ALL METHODS	-	-	5	1	-	-	-							
Hitachi CLA-1	-	-	1	-	-	-	-							
Hycor EIA	-	-	-	1	-	-	-							
Phadia UniCap 100 (% ref)	-	-	3	-	-	-	-							
Phadia UniCap 100 (KU/L)	-	-	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-6							
All Methods	11	385.6	24.5	6.3	378	356	424
Specimen IP-7							
All Methods	11	38.6	7.8	20.3	39	27	55
Specimen IP-8							
All Methods	9	700.6	44.8	6.4	706	612	747
Specimen IP-9							
All Methods	11	208.2	16.0	7.7	206	180	236
Specimen IP-10							
All Methods	10	556.4	35.4	6.4	551	507	628

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-6							
All Methods	10	1759.4	41.6	2.4	1763	1682	1831
Specimen IP-7							
All Methods	9	215.7	56.4	26.2	200	163	346
Specimen IP-8							
All Methods	11	3419.7	392.4	11.5	3419	2810	4099
Specimen IP-9							
All Methods	10	947.4	47.6	5.0	951	841	1007
Specimen IP-10							
All Methods	10	2539.3	66.6	2.6	2529	2427	2672

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-6							
All Methods	10	229.2	14.9	6.5	234	203	254
Specimen IP-7							
All Methods	11	23.0	4.2	18.3	24	14	29
Specimen IP-8							
All Methods	10	418.9	35.4	8.5	434	348	456
Specimen IP-9							
All Methods	11	121.2	9.4	7.7	124	105	137
Specimen IP-10							
All Methods	10	335.3	29.5	8.8	333	302	395

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	50	47	3	46	4
ASI	-	16	15	1	14	2
Becton Dickinson	-	20	18	2	19	1
Fisher HealthCare Sure-View	-	6	6	-	5	1
J&S Medical Assoc. Accutex	-	1	1	-	1	-
New Horizons	-	1	1	-	1	-
Stanbio	-	2	2	-	2	-
Wampole Impact RPR	-	2	2	-	2	-
	Specimen SY-9		Specimen SY-10			
ALL METHODS	48	2	1	49		
ASI	15	1	-	16		
Becton Dickinson	19	1	1	19		
Fisher HealthCare Sure-View	6	-	-	6		
J&S Medical Assoc. Accutex	1	-	-	1		
New Horizons	1	-	-	1		
Stanbio	2	-	-	2		
Wampole Impact RPR	2	-	-	2		

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-7							
ALL METHODS	11	5	2	-	-	-	-
ASI	5	4	1	-	-	-	-
Becton Dickinson	6	1	-	-	-	-	-
Wampole Impact RPR	-	-	1	-	-	-	-

Specimen SY-8

ALL METHODS	9	8	1	-	-	-	-
ASI	6	4	-	-	-	-	-
Becton Dickinson	3	4	-	-	-	-	-
Wampole Impact RPR	-	-	1	-	-	-	-

Specimen SY-9

ALL METHODS	-	14	3	1	-	-	-
ASI	-	7	3	-	-	-	-
Becton Dickinson	-	7	-	-	-	-	-
Wampole Impact RPR	-	-	-	1	-	-	-

H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-3</u>		<u>Specimen HP-4</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	161	4	3	162
Abbott Signify	1	-	-	1
Applied Biotech SureStep	1	-	-	1
BD LINK 2	4	-	-	4
Beckman Coulter FlexSure	3	-	-	3
Beckman Coulter ICON HP	9	1	1	9
bioMerieux Vitek, Mini Vidas	1	-	-	1
BioStar Acceava H. pylori	5	-	-	5
Cardinal Health SP Brand	3	-	-	3
DPC Immulite/1000	1	-	-	1
Fisher HealthCare Sure-Vue	6	-	-	6
Instant Technologies i Screen	11	1	1	11
LifeSign Status	5	-	-	5
Meridian ImmunoCard	1	-	-	1
Polymedco Poly stat	20	-	-	20
Quidel QuickVue	76	2	-	78
Wampole Clearview	11	-	-	11

Lyme Disease Serology

<u>Method</u>	Specimen LY-3		Specimen LY-4	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	9	-	-	9
bioMerieux Vitek, Mini Vidas	1	-	-	1
Immunostics Inc.	1	-	-	1
Remel Rapidot	1	-	-	1
Wampole PreVue	3	-	-	3
Zeus	1	-	-	1

Mycoplasma Antibody

<u>Method</u>	Specimen MY-3		Specimen MY-4	
	<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-6		Specimen VM-7		Specimen VM-8	
	<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-9		Specimen VM-10			
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>		
All Methods	1	1	2	-		

The vendor assay for specimens VM-6 through VM-10 is: Negative, Negative, Negative, Positive, and Negative, respectively. Specimen VM-9 is not graded do to lack of participant consensus.

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<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-9		Specimen VM-10			
	<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-6		Specimen VM-7		Specimen VM-8	
	<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-9		Specimen VM-10			
All Methods	2	-	2	-		

Viral Markers – HBeAg

The vendor assay for specimens VM-6 through VM-10 is: Negative, Negative, Negative, Negative and Negative, respectively.

Viral Markers – HBsAb

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<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-9		Specimen VM-10			
All Methods	-	2	2	-		

The vendor assay for specimens VM-6 through VM-10 is: Negative, Negative, Negative, Negative, and Negative, respectively.

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<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
Other IgM Method	-	1	1	-	-	1
Roche Elecsys 1010/2010	-	1	1	-	-	1
	Specimen VM-9		Specimen VM-10			
ALL METHODS	-	5	5	-		
Abbott Quantum	-	1	1	-		
Bayer ADVIA Centaur	-	1	1	-		
Bio-Rad Evolis	-	1	1	-		
Other IgM Method	-	1	1	-		
Roche Elecsys 1010/2010	-	1	1	-		

Viral Markers – HCV

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<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-9		Specimen VM-10			
All Methods	3	-	3	-		
Bayer ADVIA Centaur	2	-	2	-		
Bio-Rad Evolis	1	-	1	-		

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