

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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2006 Evaluation Criteria

The evaluation criteria used in the 2006 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 (Titer)	Not Evaluated
Rheumatoid Factor (International Units)	Not Evaluated
Anti-Streptolysin O (ASO) Titer	Not Evaluated
Complement C3	± 3 SD
Complement C4	± 3 SD
Antinuclear Antibody (ANA) Titer	Not Evaluated
C-Reactive Protein	± 3 SD
Rubella (International Units)	Not Evaluated
Total IgE	± 3 SD
Total IgA	± 3 SD
Total IgG	$\pm 25\%$
Total IgM	± 3 SD

Infectious Mononucleosis

<u>Method</u>	Specimen IM-6		Specimen IM-7		Specimen IM-8	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	6	335	337	4	223	-
Applied Biotech SureStep	-	2	2	-	2	-
ASI	-	2	2	-	2	-
Beckman Coulter ICON Mono - waived	-	1	1	-	1	-
BioStar Acceava Mono Test	-	5	5	-	4	-
BioStar Acceava Mono-whole bld	-	18	17	1	3	-
Cardinal Health SP Brand	-	8	8	-	8	-
Cardinal Health SP Brand - waived	-	16	16	-	6	-
Fisher HealthCare Sure-Vue	-	17	17	-	17	-
GenBio ImmunoDOT	-	1	1	-	1	-
Genzyme OSOM (waived)	-	13	13	-	7	-
Henry Schein OneStep+ - waived	-	3	3	-	2	-
Instant Technologies i Screen	-	1	1	-	1	-
Instant Technologies i Screen-WB	-	2	2	-	1	-
Inverness ClearviewMono-plusII	-	7	7	-	4	-
Inverness Signify Mono Test	-	3	3	-	2	-
LifeSign UniStep Mono	-	10	10	-	2	-
Mainline Confirms	-	2	2	-	2	-
McKesson Medi-Lab Performance - waived	-	13	13	-	9	-
Meridian ImmunoCard STAT!	-	1	1	-	1	-
Meridian ImmunoCard STAT! (whole blood)	-	1	1	-	-	-
Polymedco Poly stat	-	9	9	-	9	-
Polymedco Poly stat - waived	-	17	17	-	6	-
Quidel QuickVue+	4	80	84	-	65	-
Quidel QuickVue+ - waived	1	34	35	-	4	-
Remel RIM A.R.C.	-	1	1	-	-	-
Seradyn	-	29	28	1	28	-
Seradyn Color Q (whole blood)	-	1	1	-	1	-
Wampole ColorCard	1	9	9	1	9	-
Wampole Mono-Latex	-	1	1	-	1	-
Wampole Mono-Plus II	-	20	19	1	19	-
Wampole Mono-Plus II (whole blood)	-	5	5	-	3	-
Wampole Mono-Test	-	2	2	-	2	-
	Specimen IM-9		Specimen IM-10			
ALL METHODS	10	213	2	220		
Applied Biotech SureStep	-	2	-	2		
ASI	-	2	-	2		
Beckman Coulter ICON Mono - waived	-	1	-	1		
BioStar Acceava Mono Test	-	4	-	4		
BioStar Acceava Mono-whole bld	-	3	-	3		
Cardinal Health SP Brand	-	8	-	8		
Cardinal Health SP Brand - waived	-	6	-	6		
Fisher HealthCare Sure-Vue	-	17	-	17		
GenBio ImmunoDOT	-	1	-	1		
Genzyme OSOM (waived)	-	7	-	7		
Henry Schein OneStep+ - waived	-	2	-	2		
Instant Technologies i Screen	-	1	-	1		
Instant Technologies i Screen-WB	-	1	-	1		

Infectious Mononucleosis (cont'd)

<u>Method</u>	Specimen IM-9		Specimen IM-10	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
Inverness ClearviewMono-plusII	-	4	-	4
Inverness Signify Mono Test	-	2	-	2
LifeSign UniStep Mono	-	2	-	2
Mainline Confirms	-	2	-	2
McKesson Medi-Lab Performance - waived	-	9	-	9
Meridian ImmunoCard STAT!	-	1	-	1
Polymedco Poly stat	-	9	-	9
Polymedco Poly stat - waived	-	6	-	6
Quidel QuickVue+	8	57	2	63
Quidel QuickVue+ - waived	-	4	-	4
Seradyn	1	27	-	27
Seradyn Color Q (whole blood)	-	1	-	1
Wampole ColorCard	-	9	-	9
Wampole Mono-Latex	-	1	-	1
Wampole Mono-Plus II	1	18	-	19
Wampole Mono-Plus II (whole blood)	-	3	-	3
Wampole Mono-Test	-	2	-	2

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	1	109	110	-	110	-
ASI	-	7	7	-	7	-
Beckman Synchron	-	2	2	-	2	-
Becton Dickinson	-	1	1	-	1	-
Behring RapiTex - Plate method	-	3	3	-	3	-
Biokit Rheumajet	-	5	5	-	5	-
Diamedix	-	2	2	-	2	-
Fisher HealthCare Sure-Vue	-	8	8	-	8	-
Immunostics Inc.	-	4	4	-	4	-
J&S Medical Assoc. Accutex	-	2	2	-	2	-
Pulse Scientific	-	1	1	-	1	-
Roche Integra	-	1	1	-	1	-
Seradyn	-	49	49	-	49	-
Stanbio	-	2	2	-	2	-
Sterling Diagnostics, Inc.	-	3	3	-	3	-
Wampole ColorCard	-	1	1	-	1	-
Wampole Rheumatex	-	5	5	-	5	-
Wampole Rheumaton	1	11	12	-	12	-

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	-	110	109	1
ASI	-	7	7	-
Beckman Synchron	-	2	2	-
Becton Dickinson	-	1	1	-
Behring RapiTex - Plate method	-	3	3	-
Biokit Rheumajet	-	5	5	-
Diamedix	-	2	2	-
Fisher HealthCare Sure-Vue	-	8	8	-
Immunostics Inc.	-	4	4	-
J&S Medical Assoc. Accutex	-	2	2	-
Pulse Scientific	-	1	1	-
Roche Integra	-	1	1	-
Seradyn	-	49	48	1
Stanbio	-	2	2	-
Sterling Diagnostics, Inc.	-	3	3	-
Wampole ColorCard	-	1	1	-
Wampole Rheumatex	-	5	5	-
Wampole Rheumaton	-	12	12	-

Rheumatoid Factor—Quantitative (Titer)

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

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

Specimen RF-6

ALL METHODS	4	18	4	2	4	1	-	-	-	-	-
ASI	-	1	-	1	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	2	1	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	4	-	-	-	1	-	-	-	-	-
Seradyn	3	9	1	-	2	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	2	-	-	-	-	-	-	-	-	-
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>
Specimen RF-9											
ALL METHODS	6	14	5	3	5	-	-	-	-	-	-
ASI	-	1	-	-	1	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	2	1	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	-	3	1	-	1	-	-	-	-	-	-
Seradyn	5	6	1	1	2	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	2	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU)

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

<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-6							
All Method	17	113.1	51.4	45.5	85	61	234
Beckman Synchron	6	150.0	38.4	25.6	184	112	187
Specimen RF-7							
All Methods	17	18.8	19.2	101.8	20	0	60
Beckman Synchron	6	20.0	0.0	0.0	20	20	20
Specimen RF-8							
All Methods	17	19.4	20.5	106.1	20	0	67
Beckman Synchron	6	20.0	0.0	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 Methods	17	115.8	54.2	46.8	90	65	255
Beckman Synchron	6	150.7	39.3	26.1	185	108	189

Specimen RF-10

All Methods	17	19.3	20.8	107.7	20	0	69
Beckman Synchron	6	20.0	0.0	0.0	20	20	20

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	<u>Specimen AS-6</u>		<u>Specimen AS-7</u>		<u>Specimen AS-8</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	1	2	1	2	3	-
Behring RapiTex	-	1	-	1	1	-
Fisher HealthCare Sure-Vue	-	1	-	1	1	-
Immunostics Inc.	1	-	1	-	1	-

<u>Method</u>	<u>Specimen AS-9</u>		<u>Specimen AS-10</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	3	-	-	3
Behring RapiTex	1	-	-	1
Immunostics Inc.	1	-	-	1
Fisher HealthCare Sure-Vue	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	-	-	-	-	-	-	-	-	-	-
BMH 902, 911, 912, 914, 917	1	-	-	-	-	-	-	-	-	-	-
Specimen AS-7											
ALL METHODS	1	-	-	-	-	-	-	-	-	-	-
BMH 902, 911, 912, 914, 917	1	-	-	-	-	-	-	-	-	-	-
Specimen AS-10											
ALL METHODS	1	-	-	-	-	-	-	-	-	-	-
BMH 902, 911, 912, 914, 917	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-6							
All Methods	12	166.7	11.3	6.8	169	146	189
DiaSorin (INCSTAR)	5	167.2	13.3	8.0	165	153	189
Specimen COM-7							
All Methods	12	195.7	14.5	7.4	198	173	226
DiaSorin (INCSTAR)	5	195.8	19.5	10.0	198	177	226
Specimen COM-8							
All Methods	12	99.8	6.0	6.0	100	91	112
DiaSorin (INCSTAR)	5	100.2	9.3	9.3	97	91	112
Specimen COM-9							
All Methods	12	254.6	20.9	8.2	262	217	284
DiaSorin (INCSTAR)	5	259.2	16.8	6.5	260	240	284
Specimen COM-10							
All Methods	12	128.5	10.0	7.8	129	117	148
DiaSorin (INCSTAR)	5	128.2	12.6	9.8	123	118	148

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 Methods	12	27.8	1.7	6.3	28	25	30
DiaSorin (INCSTAR)	5	27.4	2.1	7.6	27	25	30
Specimen COM-7							
All Methods	12	32.2	1.6	5.1	32	30	35
DiaSorin (INCSTAR)	5	31.6	0.9	2.8	31	31	33
Specimen COM-8							
All Methods	12	16.8	2.0	12.1	17	14	21
DiaSorin (INCSTAR)	5	16.6	2.1	12.5	16	15	20
Specimen COM-9							
All Methods	12	41.5	2.4	5.7	42	39	46
DiaSorin (INCSTAR)	5	40.4	2.1	5.1	40	39	44
Specimen COM-10							
All Methods	12	21.1	2.1	9.8	21	18	25
DiaSorin (INCSTAR)	5	20.0	1.9	9.4	19	18	22

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	1	8	1	8	9	-
Diagnostic Technology	1	6	1	6	7	-
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	-	1	8
Alpha Scientific Medical, Inc.	7	-	1	6
Diagnostic Technology	1	-	-	1
Wampole	1	-	-	1

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	-	17	-	17	17	-
DiaSorin (INCSTAR)	-	1	-	1	1	-
GenBio ImmunoDOT	-	1	-	1	1	-
Immuno Concepts	-	6	-	6	6	-
INOVA Diagnostics	-	2	-	2	2	-
Kallestad	-	3	-	3	3	-
Seradyn	-	1	-	1	1	-
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	17	-	-	16
DiaSorin (INCSTAR)	1	-	-	1
GenBio ImmunoDOT	1	-	-	1
Immuno Concepts	6	-	-	6
INOVA Diagnostics	2	-	-	2
Kallestad	3	-	-	2
Seradyn	1	-	-	1
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>
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Specimen AE-6

ALL METHODS	-	-	1	1	4	-	3	-	-	-	-
DiaSorin (INCSTAR)	-	-	-	1	-	-	-	-	-	-	-
Immuno Concepts	-	-	1	-	2	-	2	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-	-
Kallestad	-	-	-	-	2	-	-	-	-	-	-

Specimen AE-7

ALL METHODS	-	-	-	1	-	5	2	-	1	-	-
DiaSorin (INCSTAR)	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	1	-	2	2	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	1	-	-
Kallestad	-	-	-	-	-	2	-	-	-	-	-

Specimen AE-10

ALL METHODS	-	-	-	1	1	4	2	-	1	-	-
DiaSorin (INCSTAR)	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	-	-	-	1	1	1	2	-	-	-	-
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	13	-	-	13
ASI	2	-	-	2
Beckman Synchron	1	-	-	1
Behring RapiTex	1	-	-	1
Dade Dimension/AR/ES/RxL/Xpand	1	-	-	1
Fisher HealthCare Sure-Vue	2	-	-	2
Immunostics Inc.	3	-	-	3
Pulse Scientific	1	-	-	1
Wampole	2	-	-	2

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	36	0.236	0.203	86.2	0.20
mg/dL - units					
Beckman Synchron	8	0.328	0.152	46.5	0.30
Dade Dimension/AR/ES/RxL/Xpand	7	0.186	0.037	20.1	0.20
Roche Integra	5	0.060	0.026	44.2	0.05
All Immunology Methods	27	0.208	0.149	71.5	0.20
mg/L - units					
Roche Integra	3	-	-	-	0.48
All Immunology Methods	10	0.640	0.667	104.2	0.36
Specimen CR-4					
All Method	40	4.640	5.861	126.3	1.50
mg/dL - units					
Beckman Synchron	8	1.112	0.146	13.1	1.10
Dade Dimension/AR/ES/RxL/Xpand	8	1.508	0.101	6.7	1.50
Roche Integra	5	1.368	0.044	3.2	1.39
All Immunology Methods Method	28	1.358	0.219	16.1	1.40
mg/L - units					
Polymedco CRP	3	-	-	-	13.41
All Immunology Methods Method	10	14.551	1.742	12.0	14.53

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	74	1.467	0.965	65.8	1.80
mg/dL - units					
Alfa Wassermann hsCRP	3	-	-	-	0.20
Dade Dimension High Sensi CRP	5	0.426	0.045	10.5	0.45
DPC Immulite/1000	4	-	-	-	0.23
All Immunology Methods	22	0.270	0.143	52.9	0.21
mg/L - units					
DiaSorin (INCSTAR)	3	-	-	-	1.70
DPC Immulite/1000	3	-	-	-	1.95
Other High Sensi. CRP method	6	2.070	0.469	22.7	2.20
Pointe Scientific CRP (HS)	3	-	-	-	1.80
Polymedco Ultra CRP	4	-	-	-	2.06
Roche Cobas HS CRP	4	-	-	-	2.30
Roche Integra hsCRP	4	-	-	-	2.00
All Immunology Methods	40	2.028	0.318	15.7	2.01
Specimen HCR-4					
All Method	73	6.851	4.309	62.9	8.97
mg/dL - units					
Alfa Wassermann hsCRP	3	-	-	-	0.89
Dade Dimension High Sensi CRP	5	1.028	0.061	5.9	1.05
DPC Immulite/1000	4	-	-	-	1.09
All Immunology Methods	21	0.980	0.146	14.9	0.98
mg/L - units					
DiaSorin (INCSTAR)	3	-	-	-	7.97
DPC Immulite/1000	3	-	-	-	9.40
Other High Sensi. CRP method	6	10.108	0.645	6.4	10.40
Pointe Scientific CRP (HS)	3	-	-	-	10.90
Polymedco Ultra CRP	4	-	-	-	9.30
Roche Cobas HS CRP	4	-	-	-	11.40
Roche Integra hsCRP	4	-	-	-	9.00
All Immunology Methods	41	9.604	1.219	12.7	9.60

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	-	7	-	7	-	7
Abbott AxSYM	-	1	-	1	-	1
Beckman ACCESS	-	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	7	-	7	-		
Abbott AxSYM	1	-	1	-		
Beckman ACCESS	1	-	1	-		
bioMerieux Vitek, Mini Vidas	2	-	2	-		
Seradyn	2	-	2	-		
Wampole Rubella - Plus	1	-	1	-		

Rubella—Quantitative (IU/mL)

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

<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	-	-	-	112.5
Specimen RU-7					
All Methods	4	-	-	-	45.8
Specimen RU-8					
All Methods	4	-	-	-	40.3
Specimen RU-9					
All Methods	4	-	-	-	0.1
Specimen RU-10					
All Methods	4	-	-	-	0.1

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	9	2404.4	253.5	10.5	2430	2000	2711
Specimen AL-7							
All Methods	9	213.8	12.1	5.7	218	196	229
Specimen AL-8							
All Methods	12	27.9	4.9	17.6	27	20	39
Specimen AL-9							
All Methods	10	56.1	3.1	5.5	57	51	60
Specimen AL-10							
All Methods	12	55.0	6.0	11.0	55	47	70

Allergen Specific IgE Antibodies

Specimen AL-6

	Egg White Allergen							Cow's Milk Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	4	2	1	1	-	-	1	3	6	-	1	-	-
Hitachi Chemical Diagnostics	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hycor EIA	-	-	1	-	-	-	-	1	1	-	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	2	-	-	-	-	-	-	-	2	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	1	-	1	-	-	-	-	1	3	-	-	-	-
Pharmacia UniCap 100 (KU/L)	-	1	-	-	-	-	-	-	1	-	-	-	-	-

	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	-	-	-	-	8	-	-	-	3	6	2	1	-	-
Hitachi Chemical Diagnostics	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Hycor EIA	-	-	-	-	2	-	-	-	-	1	1	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	-	-	-	-	2	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	3	-	-	-	2	3	-	-	-	-
Pharmacia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	1	-	-	-	-	-

	Soybean Allergen							Wheat Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	4	3	1	1	-	-	-	3	6	-	1	-	-
Hitachi Chemical Diagnostics	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hycor EIA	-	-	1	1	-	-	-	-	-	2	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	1	1	-	-	-	-	-	-	2	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	2	1	-	-	-	-	-	2	1	-	-	-	-
Pharmacia UniCap 100 (KU/L)	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Dog Dander Allergen						
	CLASS RESULT						
	0	1	2	3	4	5	6
ALL METHODS	-	-	4	2	2	-	-
Hitachi Chemical Diagnostics	-	-	-	-	1	-	-
Hycor EIA	-	-	-	1	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	2	1	-	-	-
Pharmacia UniCap 100 (KU/L)	-	-	1	-	-	-	-

Allergen Specific IgE Antibodies (cont'd)

Specimen AL-7

	Dust Mite Allergen							Meadow, Kentucky Blue, June Grass Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	-	-	4	8	-	-	-	-	-	2	4	-	-
Hitachi Chemical Diagnostics	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Hycor EIA	-	-	-	1	1	-	-	-	-	-	1	-	-	-
MAST Immunosystems (LU)	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	2	-	-	-	-	-	1	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	4	-	-	-	-	-	-	2	-	-
Pharmacia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
	Cat Epithelium Allergen							Egg White Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	-	-	12	2	-	-	-	-	3	4	1	-	-
Hitachi Chemical Diagnostics	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Hycor EIA	-	-	-	2	-	-	-	-	-	-	1	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	3	-	-	-	-	-	-	2	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	5	-	-	-	-	-	1	1	-	-	-
Pharmacia UniCap 100 (KU/L)	-	-	-	1	-	-	-	-	-	1	-	-	-	-
	Cow's Milk Allergen							Peanut (Arachis hyogaea) Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	-	7	3	1	-	-	-	-	-	-	8	-	-
Hitachi Chemical Diagnostics	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hycor EIA	-	-	2	-	-	-	-	-	-	-	-	2	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	2	-	-	-	-	-	-	-	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	3	1	-	-	-	-	-	-	-	3	-	-
Pharmacia UniCap 100 (KU/L)	-	-	1	-	-	-	-	-	-	-	-	1	-	-
	Bermuda Grass Allergen													
	CLASS RESULT													
	0	1	2	3	4	5	6							
ALL METHODS	-	1	7	4	-	-	-							
Hitachi Chemical Diagnostics	-	1	-	-	-	-	-							
Hycor EIA	-	-	1	1	-	-	-							
MAST Immunosystems (LU)	-	-	-	1	-	-	-							
Pharmacia & Upjohn CAP (% ref)	-	-	1	1	-	-	-							
Pharmacia UniCap 100 (% ref)	-	-	3	1	-	-	-							
Pharmacia 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	247.9	21.6	8.7	247	207	285
Specimen IP-7							
All Methods	11	287.3	25.1	8.7	286	240	323
Specimen IP-8							
All Methods	11	150.2	10.4	6.9	150	127	163
Specimen IP-9							
All Methods	10	381.9	31.9	8.4	378	329	441
Specimen IP-10							
All Methods	11	191.3	13.4	7.0	191	170	217

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	1204.7	74.9	6.2	1220	1081	1320
Specimen IP-7							
All Methods	10	1424.9	81.0	5.7	1460	1263	1515
Specimen IP-8							
All Methods	10	723.5	33.3	4.6	728	676	786
Specimen IP-9							
All Methods	9	1835.9	69.5	3.8	1862	1701	1907
Specimen IP-10							
All Methods	11	929.1	58.8	6.3	940	847	1002

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	11	102.4	5.5	5.4	101	94	112
Specimen IP-7							
All Methods	10	118.8	6.4	5.4	118	110	129
Specimen IP-8							
All Methods	10	58.9	7.2	12.2	58	43	68
Specimen IP-9							
All Methods	11	153.7	12.3	8.0	154	129	173
Specimen IP-10							
All Methods	10	79.1	5.2	6.5	81	72	86

Syphilis Serology—Qualitative: RPR

<u>Method</u>	<u>Specimen SY-6</u>		<u>Specimen SY-7</u>		<u>Specimen SY-8</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	52	1	-	53	1	52
ASI	16	-	-	16	-	16
Becton Dickinson	24	-	-	24	-	24
Biokit	4	-	-	4	-	4
Fisher HealthCare Sure-Vue	2	-	-	2	-	2
J&S Medical Assoc. Accutex	1	-	-	1	-	1
New Horizons	1	-	-	1	-	1
Stanbio	2	-	-	2	-	2
Wampole Impact RPR	1	1	-	2	1	1
Specimen SY-9						
All Methods	52	1	53	-		
ASI	15	1	16	-		
Becton Dickinson	24	-	24	-		
Biokit	4	-	4	-		
Fisher HealthCare Sure-Vue	2	-	2	-		
J&S Medical Assoc. Accutex	1	-	1	-		
New Horizons	1	-	1	-		
Stanbio	2	-	2	-		
Wampole Impact RPR	2	-	2	-		
Specimen SY-10						
All Methods						
ASI						
Becton Dickinson						
Biokit						
Fisher HealthCare Sure-Vue						
J&S Medical Assoc. Accutex						
New Horizons						
Stanbio						
Wampole Impact RPR						

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-6							
ALL METHODS	1	5	9	2	-	-	-
ASI	1	3	4	1	-	-	-
Becton Dickinson	-	2	5	1	-	-	-
Specimen SY-9							
ALL METHODS	-	-	10	6	1	-	-
ASI	-	-	6	2	1	-	-
Becton Dickinson	-	-	4	4	-	-	-
Specimen SY-10							
ALL METHODS	-	8	8	1	-	-	-
ASI	-	5	3	1	-	-	-
Becton Dickinson	-	3	5	-	-	-	-

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	1	204	198	7
Abbott FlexPack	-	4	4	-
Abbott Signify	-	1	1	-
Applied Biotech SureStep	-	2	2	-
BD LINK 2	-	5	5	-
Beckman Coulter FlexSure	-	19	17	2
Cardinal Health SP Brand	-	6	6	-
DPC Immulite/1000	-	1	1	-
Fisher HealthCare Sure-Vue	-	6	5	1
Instant Technologies i Screen	-	12	12	-
LifeSign Status	-	3	3	-
Meridian ImmunoCard	-	1	1	-
Meridian Premier	-	1	1	-
Polymedco Poly stat	-	28	26	2
Quidel QuickVue	1	93	92	2
Wampole Clearview	-	12	12	-

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 Impact	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	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	1	-	1	-

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

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	5	-	5	-	5	-
Abbott Quantum	1	-	1	-	1	-
Bio-Rad Evolis	1	-	1	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2	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	-	5	5	-
Abbott Quantum	-	1	1	-
Bio-Rad Evolis	-	1	1	-
Orasure OraQuick Advance Rapid HIV-1/2	-	2	2	-

Specimen VM-9 was found to be HIV-1 positive but HIV-2 negative by our vendor.

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	-	1	1	-	1	-
	Specimen VM-9		Specimen VM-10			
All Methods	1	-	1	-		

Specimen VM-6: Total and IgM are reactive

Specimen VM-7: Total is non-reactive.

Specimen VM-8: Total is non-reactive.

Specimen VM-9: Total is non-reactive.

Specimen VM-10: Total is reactive and IgM is non-reactive.

Viral Markers – HBeAg

The vendor assay for specimens VM-6 through VM-10 are: 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	1	-	1	-	1	-
	Specimen VM-9		Specimen VM-10			
All Methods	1	-	-	1		

Viral Markers – Anti-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	3	-	-	3	3	-
Abbott Quantum	1	-	-	1	1	-
Bio-Rad Evolis	1	-	-	1	1	-
Roche Elecsys 1010/2010	1	-	-	1	1	-
	Specimen VM-9		Specimen VM-10			
All Methods	-	3	3	-		
Abbott Quantum	-	1	1	-		
Bio-Rad Evolis	-	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	1	-	1	-	1	-
	Specimen VM-9		Specimen VM-10			
All Methods	1	-	-	1		

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