

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Immunology
MLE – M1

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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	\pm 3 SD
Complement C4	\pm 3 SD
Antinuclear Antibody (ANA) Titer	Not Evaluated
C-Reactive Protein	\pm 3 SD
Rubella (International Units)	Not Evaluated
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>
Mainline Confirms	-	1	1	-
McKesson Medi-Lab Performance – waived	-	9	9	-
Meridian ImmunoCard STAT!	-	1	1	-
Polymedco Poly stat	-	9	9	-
Polymedco Poly stat – waived	-	7	7	-
Quidel Quick Vue+	-	63	63	-
Quidel Quick Vue+ - waived	-	7	7	-
Remel RIM A.R.C.	-	1	1	-
Seradyn	-	28	28	-
Seradyn Color Q – (whole blood)	-	1	1	-
Wampole Clearview	-	1	1	-
Wampole ColorCard	-	9	9	-
Wampole Mono-Latex	-	1	1	-
Wampole Mono-Plus II	-	13	13	-
Wampole Mono-Plus II (whole blood)	-	7	7	-
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	1	113	1	113	113	1
ASI	-	5	-	5	5	-
Beckman Synchron	-	2	-	2	2	-
Becton Dickinson	-	1	-	1	1	-
Behring RapiTex - Plate method	-	4	-	4	4	-
Biokit Rheumajet	-	4	-	4	4	-
BMH 902, 911, 912, 914, 917	-	1	-	1	1	-
Diamedix	-	2	-	2	2	-
Fisher HealthCare Sure-Vue	-	9	-	9	9	-
Immunostics Inc.	-	5	-	5	5	-
J&S Medical Assoc. Accutex	-	2	-	2	2	-
Pulse Scientific	-	1	-	1	1	-
Roche Integra	-	1	-	1	1	-
Seradyn	-	49	-	49	49	-
Stanbio	-	1	-	1	1	-
Sterling Diagnostics, Inc.	-	3	-	3	3	-
Wampole ColorCard	-	2	-	2	2	-
Wampole Rheumatex	-	6	-	6	6	-
Wampole Rheumaton	1	12	1	12	12	1

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	112	2	1	113
ASI	5	-	-	5
Beckman Synchron	2	-	-	2
Becton Dickinson	1	-	-	1
Behring RapiTex - Plate method	4	-	-	4
Biokit Rheumajet	4	-	-	4
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	2	-	-	2
Pulse Scientific	1	-	-	1
Roche Integra	1	-	-	1
Seradyn	48	1	-	49
Stanbio	1	-	-	1
Sterling Diagnostics, Inc.	3	-	-	3
Wampole ColorCard	2	-	-	2
Wampole Rheumatex	6	-	-	6
Wampole Rheumaton	12	1	1	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>
Specimen RF-1											
All Methods	7	13	5	3	3	1	-	-	-	-	-
ASI	-	1	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex – Plate method	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	1	-	1	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-View	1	2	1	1	1	-	-	-	-	-	-
Seradyn	5	7	1	-	-	1	-	-	-	-	-
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>
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Specimen RF-2

All Methods	-	9	13	7	1	2	1	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex – Plate method	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	2	-	-	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	3	-	1	-	1	-	-	-	-
Seradyn	-	8	3	3	-	1	-	-	-	-	-
Sterling Diagnostics, Inc.	-	-	2	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	1	1	-	-	-	-	-	-	-

Specimen RF-5

All Methods	7	14	4	3	2	2	-	-	-	-	-
ASI	-	1	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex – Plate method	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	2	-	-	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	3	1	1	-	1	-	-	-	-	-
Seradyn	7	5	1	-	1	-	-	-	-	-	-
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>
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Specimen RF-1

All Method	17	113.6	56.0	49.3	78	41.00	226.00
Beckman Synchron	6	157.3	39.3	24.9	187	116.00	198.00

Specimen RF-2

All Methods	17	195.4	100.5	51.5	148	50.00	398.00
Beckman Synchron	6	282.8	47.9	16.9	305	230.00	336.00

Specimen RF-3

All Methods	17	11.8	8.3	70.1	9	1.00	20.00
Beckman Synchron	6	20.0	0.0	0.0	20	20.00	20.00

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 Methods	17	13.8	12.5	90.9	20	0.0	49.00
Beckman Synchron	6	20.0	0.0	0.0	20	20.00	20.00

Specimen RF-5

All Methods	17	110.2	58.7	53.3	77	37.00	242.00
Beckman Synchron	6	155.3	39.4	25.4	188	111.00	194.00

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	-	3	-	3	3	-
Behring RapiTex	-	1	-	1	1	-
Immunostics Inc.	-	1	-	1	1	-
Fisher HealthCare Sure-Vue	-	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	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-1											
All Methods	1	-	-	-	-	-	-	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	1
Specimen AS-2											
All Methods	1	-	-	-	-	-	-	-	-	-	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	11	144.6	7.0	4.8	145	133	157
DiaSorin (INCSTAR)	5	143.4	6.5	4.5	144	137	152
Specimen COM-2							
All Methods	11	164.4	8.3	5.0	162	151	179
DiaSorin (INCSTAR)	5	166.2	7.8	4.7	162	160	179
Specimen COM-3							
All Methods	11	122.3	4.6	3.8	123	114	129
DiaSorin (INCSTAR)	5	122.0	4.6	3.8	124	114	125
Specimen COM-4							
All Methods	11	206.0	10.5	5.1	205	188	222
DiaSorin (INCSTAR)	5	204.4	9.7	4.8	203	192	216
Specimen COM-5							
All Methods	10	182.6	7.4	4.1	182	166	193
DiaSorin (INCSTAR)	4	-	-	-	184	-	-

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	11	28.4	2.7	9.5	27	24	32
DiaSorin (INCSTAR)	5	28.0	3.4	12.1	27	24	32
Specimen COM-2							
All Methods	11	32.6	2.3	7.2	32	30	35
DiaSorin (INCSTAR)	5	33.2	2.5	7.5	35	30	35
Specimen COM-3							
All Methods	11	24.5	1.9	7.6	24	22	27
DiaSorin (INCSTAR)	5	24.2	1.8	7.4	24	22	26
Specimen COM-4							
All Methods	11	39.9	3.7	9.3	40	35	46
DiaSorin (INCSTAR)	5	40.4	5.0	12.5	40	35	46
Specimen COM-5							
All Methods	11	35.5	2.4	6.7	35	32	40
DiaSorin (INCSTAR)	5	36.2	2.5	6.9	36	34	40

Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	<u>Specimen AN-1</u>		<u>Specimen AN-2</u>		<u>Specimen AN-3</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	2	6	7	1	2	6
Alpha Scientific Medical, Inc.	1	1	2	-	1	1
Diagnostic Technology	-	4	4	-	-	4
Wampole	-	1	1	-	-	1
Pulse Scientific	1	-	-	1	1	-

<u>Method</u>	<u>Specimen AN-4</u>		<u>Specimen AN-5</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	7	1	2	6
Alpha Scientific Medical, Inc.	2	-	1	1
Diagnostic Technology	4	-	-	4
Wampole	1	-	-	1
Pulse Scientific	-	1	1	-

The vendor assay for specimens AN-1 through AN-5 are:

Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods

<u>Method</u>	<u>Specimen AE-1</u>		<u>Specimen AE-2</u>		<u>Specimen AE-3</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	13	1	14	-	1	13
DiaSorin (INCSTAR)	1	-	1	-	-	1
Immuno Concepts	5	-	5	-	-	5
INOVA Diagnostics	1	1	2	-	1	1
Kallestad	2	-	2	-	-	2
Seradyn	1	-	1	-	-	1
Zeus	1	-	1	-	-	1

<u>Method</u>	<u>Specimen AE-4</u>		<u>Specimen AE-5</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	14	1	13
DiaSorin (INCSTAR)	-	1	-	1
Immuno Concepts	-	5	-	5
INOVA Diagnostics	-	2	-	2
Kallestad	-	2	-	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>
Specimen AE-3											
ALL METHODS	-	-	2	1	3	1	2	-	-	-	-
DiaSorin (INCSTAR)	-	-	1	-	-	-	-	-	-	-	-
Immuno Concepts	-	-	1	-	1	1	2	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	-	-	-	-	-	-
Kallestad	-	-	-	1	1	-	-	-	-	-	-
Specimen AE-4											
ALL METHODS	-	-	1	3	4	1	-	-	-	-	-
DiaSorin (INCSTAR)	-	-	-	1	-	-	-	-	-	-	-
Immuno Concepts	-	-	-	1	3	1	-	-	-	-	-
INOVA Diagnostics	-	-	1	-	-	-	-	-	-	-	-
Kallestad	-	-	-	1	1	-	-	-	-	-	-
Specimen AE-5											
ALL METHODS	-	-	-	-	5	2	1	-	-	-	1
DiaSorin (INCSTAR)	-	-	-	-	1	-	-	-	-	-	-
Immuno Concepts	-	-	-	-	2	2	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	1
Kallestad	-	-	-	-	2	-	-	-	-	-	-

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	1	12	13	-
ASI	-	2	2	-
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	-	3	3	-

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 mg/dL - units	39	4.906	6.306	128.5	1.59
Beckman Synchron	9	1.333	0.224	16.8	1.30
Dade Dimension/AR/ES/RxL/Xpand	5	1.260	0.114	9.0	1.30
Roche Integra	5	1.608	0.114	7.1	1.59
All Immunology Methods Method	23	1.450	0.244	16.8	1.40
All Method mg/L - units					
Polymedco CRP	3	-	-	-	15.00
All Immunology Methods Method	9	15.016	3.622	24.1	16.36
Specimen CR-2					
All Method mg/dL - units	35	0.159	0.147	92.4	0.12
Beckman Synchron	9	0.389	0.267	68.6	0.30
Dade Dimension/AR/ES/RxL/Xpand	5	0.160	0.089	55.9	0.20
Roche Integra	5	0.028	0.035	123.6	0.01
All Immunology Methods Method	23	0.181	0.167	92.5	0.20
All Method mg/L - units					
Polymedco CRP	3	-	-	-	0.13
All Immunology Methods Method	8	1.325	2.268	171.2	0.13

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	71	8.470	5.663	66.9	11.00
Dade Dimension High Sensi CRP	8	1.291	0.087	6.8	1.29
DPC Immulite/1000	3	-	-	-	1.47
All Immunology Methods Method mg/L - units	22	1.228	0.164	13.4	1.26
DPC Immulite/1000	3	-	-	-	7.10
Kamiya Biomedical hs-CRP	3	-	-	-	12.00
Pointe Scientific CRP (HS)	4	-	-	-	12.40
Polymedco Full Range CRP	4	-	-	-	11.00
Roche Cobas HS CRP	4	-	-	-	14.40
Roche Integra hsCRP	3	-	-	-	11.00
SDI Biomed, Inc.	4	-	-	-	14.20
All Immunology Methods Method	43	12.619	1.848	14.6	12.73
Specimen HCR-2					
All Method mg/dL - units	73	0.522	0.363	69.6	0.58
Dade Dimension High Sensi CRP	8	0.099	0.039	39.2	0.12
DPC Immulite/1000	3	-	-	-	0.07
All Immunology Methods Method mg/L - units	21	0.087	0.028	32.6	0.08
DPC Immulite/1000	3	-	-	-	0.90
Kamiya Biomedical hs-CRP	3	-	-	-	0.91
Pointe Scientific CRP (HS)	4	-	-	-	0.60
Polymedco Full Range CRP	4	-	-	-	0.70
Roche Cobas HS CRP	4	-	-	-	0.75
Roche Integra hsCRP	3	-	-	-	0.68
SDI Biomed, Inc.	5	0.500	0.283	56.6	0.50
All Immunology Methods Method	47	0.698	0.243	34.9	0.70

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	-	1	5	6	-
Abbott AxSYM	1	-	-	1	1	-
Becton Dickinson	1	-	-	1	1	-
bioMerieux Vitek, Mini Vidas	2	-	-	2	2	-
Seradyn	2	-	1	1	2	-
	Specimen RU-4		Specimen RU-5			
ALL METHODS	-	6	1	5		
Abbott AxSYM	-	1	-	1		
Becton Dickinson	-	1	-	1		
bioMerieux Vitek, Mini Vidas	-	2	-	2		
Seradyn	-	2	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>	<u>Low Value</u>	<u>High Value</u>
Specimen RU-1							
All Methods	5	2.08	4.43	212.9	0.2	0	10.00
Specimen RU-2							
All Methods	5	15.22	8.19	53.8	17.7	1.00	22.20
Specimen RU-3							
All Methods	5	2.06	4.44	215.5	0.1	0.00	10.00
Specimen RU-4							
All Methods	5	97.20	54.57	56.1	114.9	3.20	137.40
Specimen RU-5							
All Methods	5	15.58	8.45	54.2	18.2	1.30	22.20

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	11	133.6	17.9	13.4	135	100.0	166.0
bioMerieux Vitek, Mini Vidas	1	-	-	-	112	-	-
DPC Immulite/1000	2	-	-	-	137	-	-
Hycor EIA	2	-	-	-	166	-	-
Pharmacia & Upjohn Unicap 100	5	138.8	9.7	7.0	136	128.0	154.0
Specimen AL-2							
All Methods	11	105.9	14.8	13.9	109	80.0	126.0
bioMerieux Vitek, Mini Vidas	1	-	-	-	94	-	-
DPC Immulite/1000	2	-	-	-	121	-	-
Hycor EIA	2	-	-	-	99	-	-
Pharmacia & Upjohn Unicap 100	5	115.0	8.1	7.1	114	106.0	126.0
Specimen AL-3							
All Methods	11	18.5	2.2	11.7	19	15.0	21.0
bioMerieux Vitek, Mini Vidas	1	-	-	-	16	-	-
DPC Immulite/1000	2	-	-	-	21	-	-
Hycor EIA	2	-	-	-	21	-	-
Pharmacia & Upjohn Unicap 100	5	18.0	1.6	8.8	18	16.0	20.0
Specimen AL-4							
All Methods	11	19.6	6.2	31.7	19	14.0	37.0
bioMerieux Vitek, Mini Vidas	1	-	-	-	37	-	-
DPC Immulite/1000	2	-	-	-	21	-	-
Hycor EIA	2	-	-	-	15	-	-
Pharmacia & Upjohn Unicap 100	5	17.8	1.6	9.2	17	16.0	20.0
Specimen AL-5							
All Methods	11	43.9	6.2	14.1	44	33.0	51.0
bioMerieux Vitek, Mini Vidas	1	-	-	-	37	-	-
DPC Immulite/1000	2	-	-	-	45	-	-
Hycor EIA	2	-	-	-	50	-	-
Pharmacia & Upjohn Unicap 100	5	47.6	3.5	7.4	48	44.0	51.0

Allergen Specific IgE Antibodies

Specimen AL-1

	Timothy Grass Allergen							Soybean Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	6	2	-	-	-	4	4	1	-	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	2	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	1	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	2	-	-	-	-	-	2	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	3	-	-	-	-	3	-	-	-	-	-
Pharmacia UniCap 100 (KU/L)	-	-	-	-	-	-	-	-	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	-	-	-	-	9	-	-	-	-	4	7	-	-	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	2	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	1	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	2	-	-	-	-	1	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	3	-	-	-	-	1	3	-	-	-
Pharmacia UniCap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	1	-	-	-

	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	9	1	-	-	-	-	-	6	5	-	-	-	-
Hycor EIA	-	1	1	-	-	-	-	-	2	-	-	-	-	-
MAST Immunosystems (LU)	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	2	-	-	-	-	-	-	-	2	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	4	-	-	-	-	-	-	3	1	-	-	-	-
Pharmacia UniCap 100 (KU/L)	-	1	-	-	-	-	-	-	-	1	-	-	-	-

	Dog Dander Allergen						
	CLASS RESULT						
	0	1	2	3	4	5	6
All Methods	-	-	7	-	-	-	-
Hycor EIA	-	-	1	-	-	-	-
MAST Immunosystems (LU)	-	-	1	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	2	-	-	-	-
Pharmacia UniCap 100 (KU/L)	-	-	1	-	-	-	-

Allergen Specific IgE Antibodies (cont'd)

Specimen AL-2

	Meadow Fescue 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	-	-	-	-	-	4	-	9	1	1	-	-	-	-
Hycor EIA	-	-	-	-	-	-	-	2	-	-	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	1	-	1	1	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	2	-	4	-	-	-	-	-	-
Pharmacia UniCap 100 (KU/L)	-	-	-	-	-	-	-	1	-	-	-	-	-	-
	Perennial Rye Allergen							Cat Epithelium Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	-	5	-	11	2	-	-	-	-	-
Hycor EIA	-	-	-	-	-	1	-	2	-	-	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	2	-	2	1	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	2	-	4	-	-	-	-	-	-
Pharmacia UniCap 100 (KU/L)	-	-	-	-	-	-	-	1	-	-	-	-	-	-
	White Oak Allergen							Honeybee Venom Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	10	1	-	-	-	-	-	-	-	-	-	-	-	-
Hycor EIA	2	-	-	-	-	-	-	-	-	-	-	-	-	-
MAST Immunosystems (LU)	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (KU/L)	1	-	-	-	-	-	-	-	-	-	-	-	-	-
	Dog Dander Allergen													
	CLASS RESULT													
	0	1	2	3	4	5	6							
All Methods	3	4	-	-	-	-	-							
Hycor EIA	1	-	-	-	-	-	-							
MAST Immunosystems (LU)	-	1	-	-	-	-	-							
Pharmacia & Upjohn CAP (% ref)	-	1	-	-	-	-	-							
Pharmacia UniCap 100 (% ref)	-	2	-	-	-	-	-							
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-1							
All Methods	11	208.9	16.8	8.1	206	178.0	247.0
Specimen IP-2							
All Methods	11	238.4	17.1	7.2	235	207.0	273.0
Specimen IP-3							
All Methods	11	176.4	16.9	9.6	173	142.0	211.0
Specimen IP-4							
All Methods	11	294.7	26.8	9.1	291	248.0	342.0
Specimen IP-5							
All Methods	11	260.1	22.3	8.6	254	217.0	299.0

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	11	1020.6	57.7	5.6	1012	938.0	1166.0
Specimen IP-2							
All Methods	10	1151.0	47.4	4.1	1154	1097.0	1253.0
Specimen IP-3							
All Methods	11	854.3	30.7	3.6	862	811.0	902.0
Specimen IP-4							
All Methods	10	1405.2	66.5	4.7	1406	1318.0	1546.0
Specimen IP-5							
All Methods	10	1253.8	42.3	3.4	1264	1184.0	1333.0

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	92.3	9.0	9.8	95	69.0	101.0
Specimen IP-2							
All Methods	11	103.8	10.6	10.2	106	76.0	113.0
Specimen IP-3							
All Methods	11	76.9	7.9	10.3	78	56.0	84.0
Specimen IP-4							
All Methods	11	129.8	8.0	6.1	130	120.0	141.0
Specimen IP-5							
All Methods	11	115.4	6.6	5.7	113	107.0	129.0

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	1	53	54	-	54	-
ASI	-	16	16	-	16	-
Becton Dickinson	1	26	27	-	27	-
Biokit	-	4	4	-	4	-
Fisher HealthCare Sure-View	-	1	1	-	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-4		Specimen SY-5			
All Methods	54	-	-	54		
ASI	16	-	-	16		
Becton Dickinson	27	-	-	27		
Biokit	4	-	-	4		
Fisher HealthCare Sure-View	1	-	-	1		
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-2							
All Methods	-	-	15	2	1	-	-
ASI	-	-	8	-	1	-	-
Becton Dickinson	-	-	7	2	-	-	-
Specimen SY-3							
All Methods	-	12	5	-	1	-	-
ASI	-	5	4	-	-	-	-
Becton Dickinson	-	7	1	-	1	-	-
Specimen SY-4							
All Methods	-	12	5	1	-	-	-
ASI	-	5	4	-	-	-	-
Becton Dickinson	-	7	1	1	-	-	-

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	1	203	1	203
Abbott FlexPack	-	2	-	2
Abbott Signify	-	1	-	1
Applied Biotech SureStep	1	3	-	4
BD LINK 2	-	5	-	5
Beckman Coulter FlexSure	-	21	1	20
Cardinal Health SP Brand	-	6	-	6
DPC Immulite/1000	-	1	-	1
Fisher HealthCare Sure-Vue	-	8	-	8
Immunostics Inc.	-	1	-	1
Instant Technologies i Screen	-	9	-	9
LifeSign Status	-	1	-	1
Meridian ImmunoCard	-	1	-	1
Meridian Premier	-	1	-	1
Polymedco Poly stat	-	30	-	30
Quidel QuickVue	-	92	-	92
Wampole	-	1	-	1
Wampole Clearview	-	10	-	10

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	8	1	1	8
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	2	-
Meridian ImmunoCard	1	-	1	-
Remel ELISA	-	1	1	-

Specimen MY-1 was found to be IgG and IgM negative by our vendor. Specimen MY-2 was found to be IgG Positive and IgM negative by our vendor.

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	1	-	1	-	1	-
	Specimen VM-4		Specimen VM-5			
All Methods	1	-	1	-		

The vendor assay for specimens VM-1 through VM-5 are: Positive, Negative, Negative, Positive 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	3	-	3	-	3	-
	Specimen VM-4		Specimen VM-5			
All Methods	3	-	-	3		

Specimen VM-5 was found to be HIV-1 positive but HIV-2 negative by our vendor.

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	1	-	1	-	-	1
	Specimen VM-4		Specimen VM-5			
All Methods	1	-	1	-		

Specimen VM-1: Total is non-reactive.

Specimen VM-2: Total is non-reactive.

Specimen VM-3: Total and IgM are reactive.

Specimen VM-4: Total is non-reactive.

Specimen VM-5: Total is non-reactive.

Viral Markers – HBeAg

The vendor assay for specimens VM-1 through VM-5 are: 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	1	-	1	-	1	-
	Specimen VM-4		Specimen VM-5			
All Methods	1	-	1	-		

Viral Markers – Anti-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	-	3	3	-	3	-
Abbott Quantum	-	1	1	-	1	-
Bio-Rad Evolis	-	1	1	-	1	-
Roche Elecsys 1010/2010	-	1	1	-	1	-
	Specimen VM-4		Specimen VM-5			
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-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	-	2	2	-	2	-
	Specimen VM-4		Specimen VM-5			
All Methods	2	-	2	-		

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