

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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2004 Evaluation Criteria

The evaluation criteria used in the 2004 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 10 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 44-45 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	Peer Group Mean \pm 3 SD
Complement C4	Peer Group Mean \pm 3 SD
Antinuclear Antibody (ANA) Titer	Not Evaluated
C-Reactive Protein	Peer Group Mean \pm 3 SD
Rubella (International Units)	Not Evaluated
Total IgE	Peer Group Mean \pm 3 SD
Total IgA	Peer Group Mean \pm 3 SD
Total IgG	Peer Group Mean \pm 25%
Total IgM	Peer Group Mean \pm 3 SD

Infectious Mononucleosis (cont'd)

<u>Method</u>	Specimen IM-4		Specimen IM-5	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
Quidel Quick Vue+	-	58	57	1
Quidel Quick Vue+ - waived	-	21	21	-
Remel RIM A.R.C.	-	1	1	-
Seradyn	-	31	30	-
Seradyn Color Q – (whole blood)	-	1	1	-
Stanbio	-	1	1	-
Wampole ColorCard	-	15	15	-
Wampole Mono-Latex	-	9	9	-
Wampole Mono-Plus	-	33	33	-
Wampole Mono-Plus (whole blood)	-	11	11	-
Wampole Mono-Test	-	5	5	-
Wyntek OSOM	-	2	2	-

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-1		Specimen RF-2		Specimen RF-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	129	-	129	129	1
Ampcor	-	1	-	1	1	-
ASI	-	9	-	9	9	-
Beckman Array	-	3	-	3	3	-
Beckman Nephelometer	-	1	-	1	1	-
Beckman Synchron	-	5	-	5	5	-
Becton Dickinson	-	1	-	1	1	-
Behring RapiTex-Plate method	-	4	-	4	4	-
Biokit Rheumajet	-	3	-	3	3	-
BMH 717	-	1	-	1	1	-
Fisher HealthCare Sure-Vue	-	7	-	7	7	-
Immunostics Inc.	-	3	-	3	3	-
J&S Medical Assoc. Accutex	-	3	-	3	3	-
Murex Latex Test	-	1	-	1	1	-
Pulse Scientific	-	2	-	2	2	-
Seradyn	-	53	-	53	53	1
Stanbio	-	2	-	2	2	-
Sterling Diagnostics, Inc.	-	2	-	2	2	-
Wampole ColorCard	-	1	-	1	1	-
Wampole Rheumatex	-	6	-	6	6	-
Wampole Rheumaton	-	15	-	15	15	-

Rheumatoid Factor—Qualitative (cont'd)

<u>Method</u>	<u>Specimen RF-4</u>		<u>Specimen RF-5</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	130	-	-	129
Ampcor	1	-	-	1
ASI	9	-	-	9
Beckman Array	3	-	-	3
Beckman Nephelometer	1	-	-	1
Beckman Synchron	5	-	-	5
Becton Dickinson	1	-	-	1
Behring RapiTex-Plate method	4	-	-	4
Biokit Rheumajet	3	-	-	3
BMH 717	1	-	-	1
Fisher HealthCare Sure-View	7	-	-	7
Immunostics Inc.	3	-	-	3
J&S Medical Assoc. Accutex	3	-	-	3
Murex Latex Test	1	-	-	1
Pulse Scientific	2	-	-	2
Seradyn	54	-	-	53
Stanbio	2	-	-	2
Sterling Diagnostics, Inc.	2	-	-	2
Wampole ColorCard	1	-	-	1
Wampole Rheumatex	6	-	-	6
Wampole Rheumaton	15	-	-	15

Rheumatoid Factor—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>2/</u> <u>4</u>	<u>8/</u> <u>10</u>	<u>16/</u> <u>20</u>	<u>32/</u> <u>40</u>	<u>64/</u> <u>80</u>	<u>128/</u> <u>160</u>	<u>256/</u> <u>320</u>	<u>512/</u> <u>640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>>2560</u>
Specimen RF-1											
All Methods	21	1	3	4	-	-	-	1	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-
Beckman Nephelometer	1	-	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	1	-	-	-	1	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	1	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	4	-	-	-	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-	-	-
Seradyn	11	1	-	1	-	-	-	-	-	-	-
Sterling Diagnostics, Inc.	1	-	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

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

<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-3											
All Methods	18	4	4	2	1	-	-	1	-	-	-
ASI	-	1	-	-	-	-	-	-	-	-	-
Beckman Nephelometer	1	-	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	1	-	-	-	1	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	1	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	3	1	-	-	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-	-	-
Seradyn	11	1	1	-	-	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

Specimen RF-5

All Methods	16	3	3	4	-	-	-	1	-	-	-
ASI	-	1	-	-	-	-	-	-	-	-	-
Beckman Nephelometer	1	-	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	1	-	-	-	1	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex - Plate method	-	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	1	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	1	-	-	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-	-	-
Seradyn	10	1	-	1	-	-	-	-	-	-	-
Sterling Diagnostics, Inc.	1	-	-	-	-	-	-	-	-	-	-
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-1							
All Methods	19	57.4	22.6	39.4	62	8	89
Beckman Array	4	-	-	-	64	56	67
Beckman Synchron	6	80.3	8.5	10.6	84	68	89
Seradyn	4	-	-	-	60	40	160
Specimen RF-2							
All Methods	20	60.8	23.7	39.0	67	6	87
Beckman Array	4	-	-	-	59	6	66
Beckman Synchron	6	80.5	7.8	9.7	84	68	87
Seradyn	4	-	-	-	80	40	80

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

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-5							
All Methods	20	66.2	19.1	28.9	73	30	90
Beckman Array	4	-	-	-	65	57	68
Beckman Synchron	6	80.8	7.5	9.3	83	69	90
Seradyn	4	-	-	-	80	80	80

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	7	-	7	-	-	7
Beckman Nephelometer	1	-	1	-	-	1
Behring RapiTex	2	-	2	-	-	2
Fisher HealthCare Sure-Vue	1	-	1	-	-	1
J&S Medical Assoc. Accutex	1	-	1	-	-	1
Wampole	2	-	2	-	-	2

<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	-	7	7	-
Beckman Nephelometer	-	1	1	-
Behring RapiTex	-	2	2	-
Fisher HealthCare Sure-Vue	-	1	1	-
J&S Medical Assoc. Accutex	-	1	1	-
Wampole	-	2	2	-

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>100-200</u>	<u>400-800</u>

Specimen AS-3

All Methods	-	-	-	-	-	1	-	1	-	2
Behring RapiTex	-	-	-	-	-	-	-	1	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	1
Wampole	-	-	-	-	-	-	-	-	-	1

Specimen AS-4

All Methods	-	-	-	-	-	1	-	1	-	2
Behring RapiTex	-	-	-	-	-	-	-	1	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-
Wampole	-	-	-	-	-	-	-	-	-	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	12	128.5	10.9	8.5	128	111	152
Beckman Synchron	3	-	-	-	127	127	140
DiaSorin (INCSTAR)	4	-	-	-	118	111	128
Specimen COM-2							
All Methods	11	34.4	3.5	10.3	33	31	42
Beckman Synchron	3	-	-	-	33	31	35
DiaSorin (INCSTAR)	3	-	-	-	38	33	38
Specimen COM-3							
All Methods	12	56.3	4.1	7.3	55	51	64
Beckman Synchron	3	-	-	-	62	54	64
DiaSorin (INCSTAR)	4	-	-	-	54	51	56
Specimen COM-4							
All Methods	12	76.0	5.8	7.6	76	68	85
Beckman Synchron	3	-	-	-	75	73	83
DiaSorin (INCSTAR)	4	-	-	-	72	68	76
Specimen COM-5							
All Methods	12	56.1	4.3	7.7	55	51	64
Beckman Synchron	3	-	-	-	60	51	64
DiaSorin (INCSTAR)	4	-	-	-	53	51	59

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	12	29.1	7.1	24.6	26	23	45
Beckman Synchron	3	-	-	-	26	24	30
DiaSorin (INCSTAR)	4	-	-	-	25	23	26
Specimen COM-2							
All Methods	6	5.2	2.8	53.9	5	2	8
Specimen COM-3							
All Methods	11	17.5	1.6	9.0	17	16	21
Beckman Synchron	3	-	-	-	16	16	17
DiaSorin (INCSTAR)	4	-	-	-	17	16	17

Complement C4 (mg/dL) (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 COM-4							
All Methods	10	8.5	1.6	19.4	8	6	12
Beckman Synchron	3	-	-	-	8	8	8
DiaSorin (INCSTAR)	4	-	-	-	9	7	10

Specimen COM-5

All Methods	12	17.9	2.1	11.5	18	15	22
Beckman Synchron	3	-	-	-	16	15	17
DiaSorin (INCSTAR)	4	-	-	-	19	15	20

Antinuclear Antibody (ANA)—Qualitative

<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	24	1	24	1	19	6
ASI	5	-	5	-	5	-
Diagnostic Technology	2	-	2	-	-	2
GenBio ImmunoDOT	1	-	1	-	1	-
Immuno Concepts	5	-	5	-	5	-
INOVA Diagnostics	2	-	2	-	1	1
Kallestad	4	-	4	-	4	-
Pulse Scientific	1	-	1	-	-	1
Wampole Impact	1	-	1	-	-	1
Zeus	1	1	1	1	2	-

<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	21	4	23	2
ASI	5	-	5	-
Diagnostic Technology	-	2	2	-
GenBio ImmunoDOT	1	-	1	-
Immuno Concepts	5	-	5	-
INOVA Diagnostics	2	-	1	1
Kallestad	4	-	4	-
Pulse Scientific	1	-	1	-
Wampole Impact	-	1	1	-
Zeus	2	-	1	1

C-Reactive Protein—Qualitative

<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	14	-	-	14
ASI	2	-	-	2
Behring RapiTex	1	-	-	1
Dade Dimension/AR/ES/RxL/Xpand	1	-	-	1
Immunostics Inc.	1	-	-	1
Pulse Scientific	2	-	-	2
Seradyn	2	-	-	2
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>	<u>Low Value</u>	<u>High Value</u>
Specimen CR-1							
All Methods	9	0.847	1.683	198.7	0.10	0.01	5.00
ASI	-	-	-	-	-	-	-
Beckman Array	1	-	-	-	0.22	0.22	0.22
Beckman Synchron	1	-	-	-	5.00	5.00	5.00
BMH 717	-	-	-	-	-	-	-
Dade Dimension/AR/ES/RxL/Xpand	2	-	-	-	1.10	0.20	2.00
DiaSorin (INCSTAR)	1	-	-	-	0.10	0.10	0.10
DPC – Immulite	1	-	-	-	0.03	0.03	0.03
Polymedco CRP	1	-	-	-	0.05	0.05	0.05
Roche Integra	1	-	-	-	0.01	0.01	0.01
Seradyn	-	-	-	-	-	-	-
Specimen CR-2							
All Methods	28	7.625	7.504	98.4	2.00	0.20	20.43
ASI	1	-	-	-	12.00	12.00	12.00
Beckman Array	3	-	-	-	1.79	1.64	18.40
Beckman Synchron	8	10.075	7.122	70.7	14.50	1.50	17.00
BMH 717	1	-	-	-	2.00	2.00	2.00
Dade Dimension/AR/ES/RxL/Xpand	4	-	-	-	10.25	1.40	20.00
DiaSorin (INCSTAR)	3	-	-	-	2.00	1.89	20.43
DPC – Immulite	1	-	-	-	2.10	2.10	2.10
Polymedco CRP	1	-	-	-	1.11	1.11	1.11
Roche Integra	2	-	-	-	1.06	0.20	1.91
Seradyn	1	-	-	-	12.00	12.00	12.00

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>	<u>Low Value</u>	<u>High Value</u>
Specimen CR-1							
All Methods	36	0.149	0.115	76.9	0.13	0.01	0.45
Beckman Synchron	3	-	-	-	0.20	0.04	0.23
Dade Dimension High Sensi CRP	4	-	-	-	0.08	0.01	0.70
Dade Dimension/AR/ES/RxL/Xpand	1	-	-	-	0.08	0.08	0.08
DiaSorin (INCSTAR)	1	-	-	-	0.45	0.45	0.45
DPC – Immulite	3	-	-	-	0.20	0.03	0.40
Kamiya Biomedical hs-CRP	6	0.158	0.114	71.9	0.20	0.01	0.30
Pointe Scientific CRP (HS)	2	-	-	-	0.11	0.02	0.20
Polymedco Full Range CRP	3	-	-	-	0.12	0.02	0.30
Polymedco Ultra CRP	10	0.214	0.209	97.5	0.17	0.02	0.74
Roche Integra	1	-	-	-	0.07	0.07	0.07

Specimen CR-2

All Methods	45	12.394	8.483	68.4	17.31	0.75	27.10
Beckman Synchron	3	-	-	-	1.96	1.95	19.70
Dade Dimension High Sensi CRP	7	8.929	8.854	99.2	1.99	1.68	19.24
Dade Dimension/AR/ES/RxL/Xpand	3	-	-	-	1.86	1.65	1.97
DiaSorin (INCSTAR)	2	-	-	-	11.30	2.12	20.48
DPC – Immulite	3	-	-	-	19.30	2.31	27.10
Kamiya Biomedical hs-CRP	5	13.960	8.630	61.8	18.90	1.00	21.36
Pointe Scientific CRP (HS)	3	-	-	-	18.00	2.12	19.15
Polymedco Full Range CRP	4	-	-	-	19.24	17.31	19.97
Polymedco Ultra CRP	11	12.263	7.751	63.2	17.05	0.75	20.42
Roche Integra	1	-	-	-	21.76	21.76	21.76

Rubella—Qualitative

<u>Method</u>	<u>Specimen RU-1</u>		<u>Specimen RU-2</u>		<u>Specimen RU-3</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	12	-	-	12	-	12
Abbott AxSYM	3	-	-	3	-	3
Abbott IMx	1	-	-	1	-	1
Becton Dickinson	1	-	-	1	-	1
Biokit	1	-	-	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	-	2	-	2
DPC – Immulite	1	-	-	1	-	1
Seradyn	3	-	-	3	-	3
	<u>Specimen RU-4</u>		<u>Specimen RU-5</u>			
All Methods	12	-	12	-		
Abbott AxSYM	3	-	3	-		
Abbott IMx	1	-	1	-		
Becton Dickinson	1	-	1	-		
Biokit	1	-	1	-		
bioMerieux Vitek, Mini Vidas	2	-	2	-		
DPC – Immulite	1	-	1	-		
Seradyn	3	-	3	-		

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>
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Specimen RU-2

All Methods	3	-	-	-	35.2	30.0	40.5
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Specimen RU-3

All Methods	3	-	-	-	33.6	28.9	40.0
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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>
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Specimen AL-1

All Methods	10	378.5	72.0	19.0	386	249	502
Hycor EIA	2	-	-	-	376	249	502
Pharmacia & Upjohn CAP System	1	-	-	-	361	361	361
Pharmacia & Upjohn Unicap 100	7	381.9	48.7	12.8	393	308	440

Specimen AL-2

All Methods	10	449.4	67.2	14.9	456	329	578
Hycor EIA	2	-	-	-	454	329	578
Pharmacia & Upjohn CAP System	1	-	-	-	421	421	421
Pharmacia & Upjohn Unicap 100	7	452.3	38.1	8.4	461	383	495

Specimen AL-3

All Methods	10	61.8	4.8	7.7	62	52	68
Hycor EIA	2	-	-	-	62	60	63
Pharmacia & Upjohn CAP System	1	-	-	-	57	57	57
Pharmacia & Upjohn Unicap 100	7	62.6	5.4	8.6	64	52	68

Specimen AL-4

All Methods	10	60.9	6.3	10.3	62	50	70
Hycor EIA	2	-	-	-	57	53	61
Pharmacia & Upjohn CAP System	1	-	-	-	59	59	59
Pharmacia & Upjohn Unicap 100	7	62.3	6.8	10.9	62	50	70

Specimen AL-5

All Methods	10	28.9	4.4	15.3	30	20	34
Hycor EIA	2	-	-	-	25	20	29
Pharmacia & Upjohn CAP System	1	-	-	-	29	29	29
Pharmacia & Upjohn Unicap 100	7	30.1	3.8	12.6	31	23	34

Allergen Specific IgE Antibodies

Specimen AL-1

	English Plantain Allergen <i>CLASS RESULT</i>							Cat Epithelium Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	1	12	-	-	-	-	-	-	-	5	12	-	-
Hycor EIA	-	-	2	-	-	-	-	-	-	-	-	2	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	4	-	-	-	-	-	-	-	-	4	-	-
Pharmacia & Upjohn CAP (KU/L)	-	1	-	-	-	-	-	-	-	-	1	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	3	-	-	-	-	-	-	-	-	5	-	-
Pharmacia Unicap 100 (KU/L)	-	-	2	-	-	-	-	-	-	-	3	-	-	-

	Russian Thistle Allergen <i>CLASS RESULT</i>							White Oak Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	5	-	-	-	-	-	-	12	3	-	-	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	2	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	3	-	-	-	-	-	-	2	1	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	1	-	-	-	-	-	-	1	-	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	1	-	-	-	-	-	-	5	-	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	3	-	-	-	-

	Bermuda Grass Allergen <i>CLASS RESULT</i>							Perennial Rye Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	1	4	9	-	-	-	-	-	-	2	4	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	-	-	1	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	3	-	-	-	-	-	-	-	2	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	4	-	-	-	-	-	-	-	1	-
Pharmacia Unicap 100 (KU/L)	-	-	-	2	-	-	-	-	-	-	-	1	-	-

	Common (Short) Ragweed Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6
All Methods	-	-	-	3	12	1	-
Hycor EIA	-	-	-	-	2	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	3	1	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	5	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	1	1	-	-

Allergen Specific IgE Antibodies (cont'd)

Specimen AL-2

	Cat Epithelium Allergen							Maple (Box Elder) Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	5	12	-	-	-	6	6	-	-	-	-
Hycor EIA	-	-	-	-	2	-	-	-	-	2	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	4	-	-	-	1	2	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	5	-	-	-	3	2	-	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	3	-	-	-	-	2	-	-	-	-	-
	House Dust Mite Allergen							Bermuda Grass Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	1	-	-	-	1	15	-	-	-	4	9	-	-	-
Hycor EIA	-	-	-	-	-	2	-	-	-	-	2	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	4	-	-	-	-	3	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	-	-	1	-	-	-	1	-	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	1	-	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	5	-	-	-	-	4	-	-	-
Pharmacia Unicap 100 (KU/L)	1	-	-	-	1	1	-	-	-	2	-	-	-	-
	Perennial Rye Allergen							Dog Dander Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	2	3	1	-	-	-	-	4	5	1	-
Hycor EIA	-	-	-	-	-	1	-	-	-	-	-	-	1	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	2	-	-	-	-	-	-	2	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	-	-	-	3	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	2	-	-	-
	Meadow Grass, Kentucky Blue Grass, June Grass Allergen													
	CLASS RESULT													
	0	1	2	3	4	5	6							
All Methods	-	-	-	1	5	2	-							
Hycor EIA	-	-	-	-	-	1	-							
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	2	1	-							
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-							
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-							
Pharmacia UniCap 100 (% ref)	-	-	-	-	3	-	-							
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-							

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	9	180.3	11.4	6.3	184	155	194
Specimen IP-2							
All Methods	9	177.0	8.0	4.5	175	166	190
Specimen IP-3							
All Methods	9	121.7	9.6	7.9	121	103	134
Specimen IP-4							
All Methods	9	507.3	36.2	7.1	506	440	557
Specimen IP-5							
All Methods	9	195.1	8.2	4.2	197	180	208

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	9	2211.4	102.6	4.6	2211	2000	2359
Specimen IP-2							
All Methods	9	1007.0	39.5	3.9	1003	960	1091
Specimen IP-3							
All Methods	9	531.6	29.7	5.6	522	487	590
Specimen IP-4							
All Methods	9	899.0	46.5	5.2	916	797	941
Specimen IP-5							
All Methods	9	2209.7	293.9	13.3	2288	1438	2401

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	9	400.1	55.3	13.8	424	290	449
Specimen IP-2							
All Methods	9	446.7	105.1	23.5	428	320	710
Specimen IP-3							
All Methods	9	47.4	11.1	23.4	44	39	74
Specimen IP-4							
All Methods	9	91.6	9.2	10.0	88	84	110
Specimen IP-5							
All Methods	9	99.0	9.7	9.8	95	85	119

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	-	52	52	-	-	52
ASI	-	13	13	-	-	13
Becton Dickinson	-	29	29	-	-	29
Biokit	-	1	1	-	-	1
Fisher	-	1	1	-	-	1
Fisher HealthCare Sure-View	-	2	2	-	-	2
J&S Medical Assoc. Accutex	-	1	1	-	-	1
New Horizons	-	1	1	-	-	1
Stanbio	-	1	1	-	-	1
	Specimen SY-4		Specimen SY-5			
All Methods	52	-	-	52		
ASI	13	-	-	13		
Becton Dickinson	29	-	-	29		
Biokit	1	-	-	1		
Fisher	1	-	-	1		
Fisher HealthCare Sure-View	2	-	-	2		
J&S Medical Assoc. Accutex	1	-	-	1		
New Horizons	1	-	-	1		
Stanbio	1	-	-	1		

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>
Specimen SY-2							
All Methods	5	15	2	-	-	-	-
ASI	2	5	1	-	-	-	-
Becton Dickinson	3	6	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	-	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	-	1	-	-	-	-	-

Specimen SY-4

All Methods	4	15	3	-	-	-	-
ASI	1	5	2	-	-	-	-
Becton Dickinson	3	6	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	-	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	-	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	211	2	3	209
Abbott FlexPack	2	-	-	2
Applied Biotech SureStep	20	-	1	19
BD LINK 2	7	-	-	7
Beckman Coulter FlexSure	30	-	1	28
DPC – Immulite	1	-	-	1
Fisher HealthCare Sure-Vue	6	-	-	6
LifeSign Status	3	-	-	3
Meridian ImmunoCard	2	-	-	2
Meridian Premier	1	-	-	1
Polymedco Poly stat	34	1	-	35
Quidel QuickVue	99	1	1	99
Remel RIM A.R.C.	1	-	-	1

Lyme Disease Serology

<u>Method</u>	<u>Specimen LY-1</u>		<u>Specimen LY-2</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	5	6	-
bioMerieux Vitek, Mini Vidas	-	1	1	-
Remel Rapidot	1	-	1	-
Wampole Impact	-	1	1	-
Wampole PreVue	-	3	3	-

Mycoplasma Antibody

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

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	-		

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	1	-	3	-	3	-
	Specimen VM-4		Specimen VM-5			
All Methods	3	-	-	3		

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	-		

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	2	-	2	-	-	2
	Specimen VM-4		Specimen VM-5			
All Methods	2	-	-	2		

Viral Markers – HCV

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

Medical Laboratory Evaluation

2011 Pennsylvania Avenue, NW, Suite 800

Washington, DC 20006-1813

800-338-2746 • 202-261-4500 • Fax: 202-835-0440

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