

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Immunology
MLE – B1

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2003 Evaluation Criteria

The evaluation criteria used in the 2003 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
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	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>	<u>Specimen IM-4</u>		<u>Specimen IM-5</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
Organon Teknika	-	7	-	7
Orion Diag Unistep	-	1	-	1
Polymedco Poly stat	-	5	-	5
Polymedco Poly stat – waived	-	6	-	6
Pulse Scientific	1	-	1	-
Quidel CARDS O.S.	-	5	-	5
Quidel CARDS O.S. – (whole blood)	-	4	-	4
Quidel Quick Vue+	-	63	2	61
Quidel Quick Vue+ - waived	-	23	-	23
Remel RIM A.R.C.	-	1	-	1
Seradyn	-	37	-	37
Seradyn Color Q – (whole blood)	-	2	-	2
Stanbio	-	1	-	1
Wampole ColorCard	-	16	-	16
Wampole Mono-Latex	-	8	-	8
Wampole Mono-Plus	-	36	-	36
Wampole Mono-Plus (whole blood)	-	11	-	11
Wampole Mono-Test	-	6	-	6
Wyntek OSOM	-	-	-	-

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	-	142	142	-	-	142
Alexon (Hycor)	-	1	1	-	-	1
Ampcor	-	1	1	-	-	1
ASI	-	8	8	-	-	8
Beckman Array	-	4	4	-	-	4
Beckman Synchron	-	3	3	-	-	3
Becton Dickinson	-	1	1	-	-	1
Behring RapiTex-Plate method	-	5	5	-	-	5
Biokit Rheumagen	-	1	1	-	-	1
Biokit Rheumajet	-	5	5	-	-	5
Fisher HealthCare Sure-Vue	-	11	11	-	-	11
Immunostics Inc.	-	3	3	-	-	3
J&S Medical Assoc. Accutex	-	4	4	-	-	4
Pulse Scientific	-	1	1	-	-	1
Seradyn	-	52	52	-	-	52
Sigma	-	1	1	-	-	1
Stanbio	-	2	2	-	-	2
Sterling Diagnostics, Inc.	-	2	2	-	-	2
Wampole Rheumatex	-	11	11	-	-	11
Wampole Rheumaton	-	22	22	-	-	22

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	1	141	141	1
Alexon (Hycor)	-	1	1	-
Ampcor	-	1	1	-
ASI	-	8	8	-
Beckman Array	-	4	4	-
Beckman Synchron	-	3	3	-
Becton Dickinson	-	1	1	-
Behring RapiTex-Plate method	-	5	5	-
Biokit Rheumagen	-	1	1	-
Biokit Rheumajet	-	5	5	-
Fisher HealthCare Sure-View	1	10	10	1
Immunostics Inc.	-	3	3	-
J&S Medical Assoc. Accutex	-	4	4	-
Pulse Scientific	-	1	1	-
Seradyn	-	52	52	-
Sigma	-	1	1	-
Stanbio	-	2	2	-
Sterling Diagnostics, Inc.	-	2	2	-
Wampole Rheumatex	-	11	11	-
Wampole Rheumaton	-	22	22	-

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-1											
All Methods	8	13	6	3	1	-	-	1	-	-	-
Alexon (Hycor)	1	-	-	-	-	-	-	-	-	-	-
ASI	-	1	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	-	-	-	1	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	1	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	3	5	-	-	-	-	-	-	-	-	-
Pulse Scientific	-	1	-	-	-	-	-	-	-	-	-
Seradyn	3	5	1	2	1	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	-	1	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	1	-	-	-	-	-	-	-

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

<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-3											
All Methods	10	11	7	2	1	-	-	1	-	-	-
Alexon (Hycor)	1	-	-	-	-	-	-	-	-	-	-
ASI	-	1	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	-	-	-	1	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	1	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	4	4	-	-	-	-	-	-	-	-	-
Pulse Scientific	-	1	-	-	-	-	-	-	-	-	-
Seradyn	4	4	2	1	1	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	-	-	1	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	3	-	-	-	-	-	-	-	-

Specimen RF-4

All Methods	10	12	5	2	2	-	-	1	-	-	-
Alexon (Hycor)	1	-	-	-	-	-	-	-	-	-	-
ASI	-	1	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	-	-	-	1	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	1	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	4	4	-	-	-	-	-	-	-	-	-
Pulse Scientific	-	1	-	-	-	-	-	-	-	-	-
Seradyn	4	4	1	1	2	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	3	-	-	-	-	-	-	-	-

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	18	73.1	31.1	42.5	78	3	151
Beckman Array	6	-	-	-	78	75	83
Beckman Synchron	3	-	-	-	106	102	151
Biokit Rheumajet	1	-	-	-	40	40	40
BMH 717	1	-	-	-	56	56	56
Fisher HealthCare Sure-Vue	3	-	-	-	80	40	80
Seradyn	2	-	-	-	42	3	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-3							
All Methods	18	75.1	29.8	39.6	80	3	149
Beckman Array	6	-	-	-	80	72	83
Beckman Synchron	3	-	-	-	105	102	149
Biokit Rheumajet	1	-	-	-	80	80	80
BMH 717	1	-	-	-	56	56	56
Fisher HealthCare Sure-View	3	-	-	-	80	40	80
Seradyn	2	-	-	-	42	3	80

Specimen RF-4

All Methods	18	72.3	31.5	43.6	77	3	153
Beckman Array	6	-	-	-	77	70	79
Beckman Synchron	3	-	-	-	106	103	153
Biokit Rheumajet	1	-	-	-	40	40	40
BMH 717	1	-	-	-	57	57	57
Fisher HealthCare Sure-View	3	-	-	-	80	40	80
Seradyn	2	-	-	-	42	3	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	8	-	-	8	-	8
ASI	1	-	-	1	-	1
Beckman Nephelometer	1	-	-	1	-	1
Behring RapiTex	2	-	-	2	-	2
Fisher HealthCare Sure-View	1	-	-	1	-	1
J&S Medical Assoc. Accutex	1	-	-	1	-	1
Wampole	1	-	-	1	-	1
	<u>Specimen AS-4</u>		<u>Specimen AS-5</u>			
All Methods	8	-	8	-		
ASI	1	-	1	-		
Beckman Nephelometer	1	-	1	-		
Behring RapiTex	2	-	2	-		
Fisher HealthCare Sure-View	1	-	1	-		
J&S Medical Assoc. Accutex	1	-	1	-		
Wampole	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>100-200</u>	<u>400-800</u>

Specimen AS-2

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

Specimen AS-3

All Methods	-	-	-	-	-	2	1	1	-	2
ASI	-	-	-	-	-	1	-	-	-	-
Beckman Nephelometer	-	-	-	-	-	-	1	-	-	-
Behring RapiTex	-	-	-	-	-	-	-	-	-	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>
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Specimen COM-1

All Methods	14	30.9	4.8	15.4	30	25	41
Beckman Array	4	-	-	-	28	26	29
Beckman Synchron	2	-	-	-	29	28	30
Behring Nephelometer	1	-	-	-	34	34	34
BMH 717	2	-	-	-	31	25	36
DiaSorin (INCSTAR)	2	-	-	-	40	38	41
Radioimmunodiffusion (RID)	2	-	-	-	30	27	32

Specimen COM-2

All Methods	15	128.5	13.8	10.8	133	104	177
Beckman Array	4	-	-	-	144	135	148
Beckman Synchron	2	-	-	-	135	124	145
Behring Nephelometer	1	-	-	-	177	177	177
BMH 717	2	-	-	-	128	123	133
DiaSorin (INCSTAR)	4	-	-	-	114	110	123
Radioimmunodiffusion (RID)	2	-	-	-	119	104	133

Complement C3 (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-3							
All Methods	16	64.8	6.1	9.5	64	50	74
Beckman Array	4	-	-	-	62	62	64
Beckman Synchron	2	-	-	-	68	67	69
Behring Nephelometer	1	-	-	-	72	72	72
BMH 717	2	-	-	-	69	64	73
DiaSorin (INCSTAR)	4	-	-	-	60	50	69
Radioimmunodiffusion (RID)	2	-	-	-	68	62	74

Specimen COM-4

All Methods	16	87.6	8.3	9.4	86	72	104
Beckman Array	4	-	-	-	84	80	85
Beckman Synchron	2	-	-	-	90	90	90
Behring Nephelometer	1	-	-	-	94	94	94
BMH 717	2	-	-	-	95	92	98
DiaSorin (INCSTAR)	4	-	-	-	80	72	85
Radioimmunodiffusion (RID)	2	-	-	-	95	86	104

Specimen COM-5

All Methods	14	31.6	5.5	17.5	30	25	43
Beckman Array	4	-	-	-	28	25	29
Beckman Synchron	2	-	-	-	29	28	30
Behring Nephelometer	1	-	-	-	32	32	32
BMH 717	2	-	-	-	32	29	35
DiaSorin (INCSTAR)	2	-	-	-	39	38	40
Radioimmunodiffusion (RID)	2	-	-	-	34	25	43

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	6.3	3.5	55.7	7	1	10
Beckman Array	3	-	-	-	10	10	10
Beckman Synchron	2	-	-	-	6	2	10
Behring Nephelometer	1	-	-	-	2	2	2
BMH 717	2	-	-	-	5	3	6
DiaSorin (INCSTAR)	2	-	-	-	8	8	8
Radioimmunodiffusion (RID)	1	-	-	-	6	6	6

Specimen COM-2

All Methods	16	31.3	7.6	24.1	29	24	46
Beckman Array	4	-	-	-	44	38	46
Beckman Synchron	2	-	-	-	27	24	29
Behring Nephelometer	1	-	-	-	34	34	34
BMH 717	2	-	-	-	26	25	27
DiaSorin (INCSTAR)	4	-	-	-	27	24	29
Radioimmunodiffusion (RID)	2	-	-	-	27	27	27

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-3							
All Methods	16	19.7	1.6	8.0	19	18	23
Beckman Array	4	-	-	-	20	18	22
Beckman Synchron	2	-	-	-	18	18	18
Behring Nephelometer	1	-	-	-	19	19	19
BMH 717	2	-	-	-	20	19	20
DiaSorin (INCSTAR)	4	-	-	-	21	18	23
Radioimmunodiffusion (RID)	2	-	-	-	20	19	20

Specimen COM-4

All Methods	14	9.1	1.1	12.6	9	7	11
Beckman Array	3	-	-	-	10	10	10
Beckman Synchron	2	-	-	-	8	8	8
Behring Nephelometer	1	-	-	-	8	8	8
BMH 717	2	-	-	-	9	8	9
DiaSorin (INCSTAR)	4	-	-	-	10	9	80
Radioimmunodiffusion (RID)	2	-	-	-	10	9	11

Specimen COM-5

All Methods	12	6.1	3.7	60.1	7	1	10
Beckman Array	3	-	-	-	10	10	10
Beckman Synchron	2	-	-	-	7	3	10
Behring Nephelometer	1	-	-	-	2	2	2
BMH 717	2	-	-	-	3	2	3
DiaSorin (INCSTAR)	2	-	-	-	8	8	8
Radioimmunodiffusion (RID)	1	-	-	-	6	6	6

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	11	17	28	-	28	-
ASI	4	-	4	-	4	-
Diagnostic Technology	-	6	6	-	6	-
GenBio ImmunoDOT	-	1	1	-	1	-
Immuno Concepts	-	4	4	-	4	-
INOVA Diagnostics	-	1	1	-	1	-
Kallestad	3	1	4	-	4	-
Pulse Scientific	1	-	1	-	1	-
Sanofi IFA	-	1	1	-	1	-
Seradyn	-	1	1	-	1	-
Wampole Impact	-	1	1	-	1	-
Zeus	1	-	1	-	1	-

Antinuclear Antibody (ANA)—Qualitative (cont'd)

<u>Method</u>	Specimen AN-4		Specimen AN-5	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	11	17	28	-
ASI	4	-	4	-
Diagnostic Technology	-	6	6	-
GenBio ImmunoDOT	-	1	1	-
Immuno Concepts	-	4	4	-
INOVA Diagnostics	-	1	1	-
Kallestad	3	1	4	-
Pulse Scientific	1	-	1	-
Sanofi IFA	-	1	1	-
Seradyn	-	1	1	-
Wampole Impact	-	1	1	-
Zeus	1	-	1	-

Antinuclear Antibody (ANA)^{3/4}Quantitative (Titer)

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

<u>Specimen/Method</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>3</u> <u>2560</u>
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Specimen AN-1

All Methods	1	-	3	-	2	1	-	-	-	-
Diagnostic Technology	1	-	-	-	-	-	-	-	-	-
Immuno Concepts	-	-	2	-	2	-	-	-	-	-
Kallestad	-	-	1	-	-	-	-	-	-	-
Sanofi IFA	-	-	-	-	-	1	-	-	-	-

Specimen AN-4

All Methods	1	-	2	1	2	1	-	-	-	-
Diagnostic Technology	1	-	-	-	-	-	-	-	-	-
Immuno Concepts	-	-	1	1	2	-	-	-	-	-
Kallestad	-	-	1	-	-	-	-	-	-	-
Sanofi IFA	-	-	-	-	-	1	-	-	-	-

C-Reactive Protein^{3/4}Qualitative

<u>Method</u>	Specimen CR-1		Specimen CR-2	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	15	4	13
ASI	-	1	-	1
Behring RapiTex	-	2	-	2
Biokit Rheumajet	-	1	1	-
BMH 717	-	1	-	1
Dade Dimension/AR/ES/RxL/Xpand	-	1	-	1
Pulse Scientific	-	1	-	1
Seradyn	-	3	1	2
VITROS 250,400,500,700,750,950	-	2	-	2
Wampole	2	2	2	2

C-Reactive Protein^{3/4}Quantitative (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 CR-1							
All Methods	54	4.185	4.616	110.3	1.40	0.52	15.80
Beckman Array	2	-	-	-	1.07	1.03	1.10
Beckman Synchron	4	-	-	-	0.60	0.60	1.20
Behring RapiTex	-	-	-	-	-	-	-
BMH 717	2	-	-	-	1.40	1.20	1.60
Dade Dimension High Sensi CRP	1	-	-	-	1.23	1.23	1.23
Dade Dimension/AR/ES/RxL/Xpand	4	-	-	-	1.27	0.80	1.40
DiaSorin (INCSTAR)	4	-	-	-	1.39	0.93	12.99
DPC – Imulite	4	-	-	-	1.34	1.13	1.60
Pointe Scientific	1	-	-	-	0.91	0.91	0.91
Polymedco Ultra CRP	20	6.045	4.856	80.3	5.05	0.52	15.80
Roche Cobas/INCSTAR Rgt	2	-	-	-	7.04	1.00	13.08
VITROS 250,400,500,700,750,950	2	-	-	-	2.45	2.40	2.50

Specimen CR-2

All Methods	55	4.368	4.686	107.3	1.50	0.49	15.80
Beckman Array	2	-	-	-	1.01	1.00	1.01
Beckman Synchron	4	-	-	-	0.65	0.60	1.21
Behring RapiTex	1	-	-	-	12.00	12.00	12.00
BMH 717	2	-	-	-	1.35	1.20	1.50
Dade Dimension High Sensi CRP	1	-	-	-	1.22	1.22	1.22
Dade Dimension/AR/ES/RxL/Xpand	4	-	-	-	1.23	0.90	1.29
DiaSorin (INCSTAR)	4	-	-	-	1.69	1.12	12.39
DPC – Imulite	4	-	-	-	1.36	1.14	1.62
Pointe Scientific	1	-	-	-	0.90	0.90	0.90
Polymedco Ultra CRP	20	6.087	4.804	78.9	5.05	0.49	15.80
Roche Cobas/INCSTAR Rgt	2	-	-	-	7.27	1.00	13.54
VITROS 250,400,500,700,750,950	2	-	-	-	2.60	2.60	2.60

Rubella^{3/4}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	-	2	2	-	-	2
Abbott IMx	-	1	1	-	-	1
Becton Dickinson	-	1	1	-	-	1
Biokit	-	1	1	-	-	1
bioMerieux Vitek, Mini Vidas	-	3	3	-	-	3
Seradyn	-	2	2	-	-	2
	<u>Specimen RU-4</u>		<u>Specimen RU-5</u>			
All Methods	12	-	12	-		
Abbott AxSYM	2	-	2	-		
Abbott IMx	1	-	1	-		
Becton Dickinson	1	-	1	-		
Biokit	1	-	1	-		
bioMerieux Vitek, Mini Vidas	3	-	3	-		
Seradyn	2	-	2	-		

Rubella^{3/4}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	6	-	-	-	37.7	32.6	80.0
Abbott AxSYM	4	-	-	-	36.0	32.6	42.1
DPC-Immulinite	1	-	-	-	36.5	36.5	36.5
Seradyn	1	-	-	-	80.0	80.0	80.0

Specimen RU-3

All Methods	6	-	-	-	33.8	30.0	160.0
Abbott AxSYM	4	-	-	-	32.3	30.0	34.8
DPC-Immulinite	1	-	-	-	33.6	33.6	33.6
Seradyn	1	-	-	-	160.0	160.0	160.0

Total IgE^{3/4}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 Methods	10	206.8	17.2	8.3	203	187	251
DPC – Immulinite	1	-	-	-	200	200	200
Hycor EIA	2	-	-	-	233	215	251
Pharmacia & Upjohn CAP System	1	-	-	-	205	205	205
Pharmacia & Upjohn Unicap 100	6	-	-	-	200	187	208

Specimen AL-2

All Methods	10	536.8	39.1	7.3	541	474	593
DPC – Immulinite	1	-	-	-	574	574	574
Hycor EIA	2	-	-	-	563	543	582
Pharmacia & Upjohn CAP System	1	-	-	-	593	593	593
Pharmacia & Upjohn Unicap 100	6	-	-	-	516	474	543

Specimen AL-3

All Methods	10	18.7	1.8	9.4	19	16	22
DPC – Immulinite	1	-	-	-	20	20	20
Hycor EIA	2	-	-	-	21	19	22
Pharmacia & Upjohn CAP System	1	-	-	-	20	20	20
Pharmacia & Upjohn Unicap 100	6	-	-	-	18	16	19

Specimen AL-4

All Methods	10	48.1	8.3	17.2	46	39	67
DPC – Immulinite	1	-	-	-	57	57	57
Hycor EIA	2	-	-	-	53	39	67
Pharmacia & Upjohn CAP System	1	-	-	-	49	49	49
Pharmacia & Upjohn Unicap 100	6	-	-	-	45	41	48

Total IgE^{3/4}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-5							
All Methods	10	213.0	33.4	15.7	208	169	295
DPC – Immulite	1	-	-	-	229	229	229
Hycor EIA	2	-	-	-	232	169	295
Pharmacia & Upjohn CAP System	1	-	-	-	223	223	223
Pharmacia & Upjohn Unicap 100	6	-	-	-	204	191	211

Allergen Specific IgE Antibodies

Specimen AL-1

	Dust Mite 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	-	-	11	4	-	-	-	-	-
Hycor EIA	-	-	-	-	2	-	-	-	2	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	3	-	-	1	2	-	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	2	-	-	-	2	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	6	-	-	6	-	-	-	-	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	-	-	2	-	-	-	2	-	-	-	-	-	-

	Alternaria alternata Allergen							Olive Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	1	6	8	-	-	-	-	2	-	-	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	3	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	2	-	-	-	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	2	4	-	-	-	-	1	-	-	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	-	1	1	-	-	-	-	-	-	-	-	-	-

	White Oak Allergen							Bermuda Grass Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	14	-	-	-	-	-	-	-	-	12	2	-	-	-
Hycor EIA	2	-	-	-	-	-	-	-	-	-	2	-	-	-
Pharmacia & Upjohn CAP (% ref)	2	-	-	-	-	-	-	-	-	2	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	2	-	-	-	-	-	-	-	-	2	-	-	-	-
Pharmacia UniCap 100 (% ref)	6	-	-	-	-	-	-	-	-	5	-	-	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	2	-	-	-	-	-	-	-	-	2	-	-	-	-

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

Allergen Specific IgE Antibodies (cont'd)

Specimen AL-2

	Cat Epithelium Allergen <i>CLASS RESULT</i>							Common Ragweed Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	12	2	1	-	-	-	-	-	1	3	11	-	-
Hycor EIA	-	-	1	1	-	-	-	-	-	-	-	2	-	-
Pharmacia & Upjohn CAP (% ref)	-	2	1	-	-	-	-	-	-	-	-	3	-	-
Pharmacia & Upjohn CAP (KU/L)	-	2	-	-	-	-	-	-	-	-	2	-	-	-
Pharmacia UniCap 100 (% ref)	-	6	-	-	-	-	-	-	-	-	-	6	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	2	-	-	-	-	-	-	-	-	1	-	-	-

	Sage Allergen <i>CLASS RESULT</i>							Bermuda Grass Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	-	-	-	-	-	-	5	7	2	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	-	1	1	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	-	-	-	-	-	-	2	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	-	-	-	-	-	-	-	2	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	-	4	1	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	2	-	-	-

	Perennial Rye Allergen <i>CLASS RESULT</i>							Dog Dander Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	2	4	-	-	-	10	-	-	-	-
Hycor EIA	-	-	-	-	-	1	-	-	-	1	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	1	-	-	-	1	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	-	2	-	-	-	-	2	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	2	-	-	-	5	-	-	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	-	-	-	-	-	-	-	-	1	-	-	-	-

	Meadow, Kentucky, June Grass Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6
All Methods	-	-	-	-	2	7	-
Hycor EIA	-	-	-	-	-	1	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	2	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	-	2	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	4	-
Pharmacia & Upjohn CAP 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	7	-	-	-	215	195	233

IgA (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 IP-2							
All Methods	7	-	-	-	573	440	660
Specimen IP-3							
All Methods	7	-	-	-	98	70	141
Specimen IP-4							
All Methods	7	-	-	-	235	211	262
Specimen IP-5							
All Methods	7	-	-	-	222	206	230

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	7	-	-	-	957	800	1102
Specimen IP-2							
All Methods	7	-	-	-	963	800	1073
Specimen IP-3							
All Methods	7	-	-	-	452	395	693
Specimen IP-4							
All Methods	7	-	-	-	1042	960	1169
Specimen IP-5							
All Methods	7	-	-	-	2340	200	2578

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	7	-	-	-	92	83	102
Specimen IP-2							
All Methods	7	-	-	-	95	85	100

IgM (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 IP-3							
All Methods	7	-	-	-	41	37	55
Specimen IP-4							
All Methods	7	-	-	-	339	266	364
Specimen IP-5							
All Methods	7	-	-	-	100	91	113

Syphilis Serology^{3/4} Qualitative: RPR

<u>Method</u>	<u>Specimen SY-1</u>		<u>Specimen SY-2</u>		<u>Specimen SY-3</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	55	-	3	52	-	55
ASI	13	-	2	11	-	13
Becton Dickinson	27	-	-	27	-	27
Biokit	1	-	-	1	-	1
J&S Medical Assoc. Accutex	1	-	-	1	-	1
New Horizons	3	-	-	3	-	3
Pulse Scientific	1	-	-	1	-	1
Stanbio	4	-	-	4	-	4
Wampole Impact RPR	2	-	-	2	-	2
Specimen SY-4						
All Methods	55	-	-	55		
ASI	13	-	-	13		
Becton Dickinson	27	-	-	27		
Biokit	1	-	-	1		
J&S Medical Assoc. Accutex	1	-	-	1		
New Horizons	3	-	-	3		
Pulse Scientific	1	-	-	1		
Stanbio	4	-	-	4		
Wampole Impact RPR	2	-	-	2		

Syphilis Serology^{3/4} 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-1							
All Methods	3	13	6	-	-	-	-
ASI	1	5	4	-	-	-	-
Becton Dickinson	2	5	1	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	-	1	-	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-

Syphilis Serology^{3/4} Quantitative: RPR (Titer) (cont'd)

<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-4							
All Methods	3	17	2	-	-	-	-
ASI	1	8	1	-	-	-	-
Becton Dickinson	2	6	-	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	-	1	-	-	-	-	-
Wampole Impact RPR	-	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	4	220	223	1
Abbott FlexPack	-	1	1	-
Applied Biotech SureStep	-	16	16	-
BD LINK 2	-	10	9	1
Beckman Coulter FlexSure	1	45	46	-
DPC – Immulite	-	1	1	-
Fisher HealthCare Sure-Vue	-	8	8	-
LifeSign Status	-	4	4	-
Meridian ImmunoCard	-	1	1	-
Meridian Premier	-	1	1	-
Polymedco Poly stat	3	23	26	-
Quidel QuickVue	-	109	109	-
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	1	-
Wampole PreVue	-	1	1	-

Viral Markers – Anti-HIV

<u>Method</u>	<u>Specimen VM-1</u>		<u>Specimen VM-2</u>		<u>Specimen VM-3</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	2	2	2	-	4
Abbott Commander	1	-	1	-	-	1
Murex SUDS	1	2	1	2	-	3

Viral Markers – Anti-HIV (cont'd)

<u>Method</u>	<u>Specimen VM-4</u>		<u>Specimen VM-5</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	4	4	-
Abbott Commander	-	1	1	-
Murex SUDS	-	3	3	-

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