

# MEDICAL LABORATORY EVALUATION

## PARTICIPANT SUMMARY

**2 • 0 • 0 • 3**



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

Immunology  
MLE – B2

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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 (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

<u>Method</u>	<b>Specimen IM-6</b>		<b>Specimen IM-7</b>		<b>Specimen IM-8</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	375	3	374	275	-
ABI SureStep Mono-whole blood	-	4	-	4	2	-
Applied Biotech SureStep	-	3	-	3	3	-
ASI	-	2	-	2	2	-
Biokit	-	2	-	2	2	-
BioStar Acceava Mono Test	-	7	-	7	7	-
BioStar Acceava Mono-whole blood	-	15	-	15	4	-
Fisher HealthCare Sure-Vue	-	14	-	14	14	-
Genzyme Contrast Mono-whole blood	-	3	-	3	2	-
J&S Medical Assoc. Accutex	-	2	-	2	2	-
LifeSign UniStep Mono	-	1	-	1	-	-
Meridian ImmunoCard STAT!	-	1	-	1	-	-
Meridian ImmunoCardSTAT-waived	-	1	-	1	-	-
Murex Mono	-	1	-	1	1	-
Organon Teknika	-	8	-	8	8	-
Polymedco Poly stat	-	10	-	10	6	-
Polymedco Poly stat – waived	-	33	-	33	6	-
Pulse Scientific	-	1	-	1	1	-
Quidel CARDS O.S.	-	1	-	1	1	-
Quidel Quick Vue+	-	76	2	74	72	-
Quidel Quick Vue+ - waived	-	41	1	40	24	-
Remel RIM A.R.C.	-	1	-	1	1	-
Seradyn	2	33	-	35	34	-
Seradyn Color Q – (whole blood)	-	1	-	1	1	-
Stanbio	-	1	-	1	1	-
Wampole ColorCard	-	16	-	16	16	-
Wampole Mono-Latex	-	7	-	7	7	-
Wampole Mono-Plus	-	44	-	44	36	-
Wampole Mono-Plus (whole blood)	-	26	-	26	8	-
Wampole Mono-Test	-	5	-	5	5	-
Wyntek OSOM	-	4	-	4	-	-

<u>Method</u>	<b>Specimen IM-9</b>		<b>Specimen IM-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	272	2	3	271
ABI SureStep Mono-whole blood	2	-	-	2
Applied Biotech SureStep	3	-	-	3
ASI	2	-	-	2
Biokit	2	-	-	2
BioStar Acceava Mono Test	7	-	-	7
BioStar Acceava Mono-whole blood	4	-	-	4
Fisher HealthCare Sure-Vue	13	-	-	13
Genzyme Contrast Mono-whole blood	2	-	1	1
J&S Medical Assoc. Accutex	2	-	-	2
Murex Mono	1	-	-	1
Organon Teknika	8	-	-	8
Polymedco Poly stat	6	-	-	6
Polymedco Poly stat – waived	6	-	-	6
Pulse Scientific	1	-	-	1
Quidel CARDS O.S.	1	-	-	1
Quidel Quick Vue+	72	-	-	72
Quidel Quick Vue+ - waived	24	-	-	24
Remel RIM A.R.C.	1	-	-	1
Seradyn	32	2	2	32

**Infectious Mononucleosis (cont'd)**

<b><u>Method</u></b>	<b>Specimen IM-9</b>		<b>Specimen IM-10</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
Seradyn Color Q – (whole blood)	1	-	-	1
Stanbio	1	-	-	1
Wampole ColorCard	16	-	-	16
Wampole Mono-Latex	7	-	-	7
Wampole Mono-Plus	36	-	-	36
Wampole Mono-Plus (whole blood)	8	-	-	8
Wampole Mono-Test	5	-	-	5

**Rheumatoid Factor—Qualitative**

<b><u>Method</u></b>	<b>Specimen RF-6</b>		<b>Specimen RF-7</b>		<b>Specimen RF-8</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
All Methods	135	2	-	136	136	-
Ampcor	1	-	-	1	1	-
ASI	5	-	-	5	5	-
Beckman Array	3	-	-	3	3	-
Beckman Synchron	3	-	-	3	3	-
Becton Dickinson	1	-	-	1	1	-
Behring RapiTex-Plate method	4	-	-	4	4	-
Biokit Rheumagen	1	-	-	1	1	-
Biokit Rheumajet	5	-	-	5	5	-
Diagnostic Technology	1	-	-	1	1	-
Fisher HealthCare Sure-Vue	12	-	-	12	12	-
Immunostics Inc.	3	-	-	3	3	-
J&S Medical Assoc. Accutex	3	-	-	3	3	-
Pulse Scientific	2	-	-	2	2	-
Seradyn	52	2	-	54	54	-
Stanbio	2	-	-	2	2	-
Sterling Diagnostics, Inc.	2	-	-	2	2	-
Wampole Rheumatex	9	-	-	9	9	-
Wampole Rheumaton	21	-	-	21	21	-

**Rheumatoid Factor—Qualitative (cont'd)**

<u>Method</u>	<b>Specimen RF-9</b>		<b>Specimen RF-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	3	133	134	2
Ampcor	-	1	1	-
ASI	-	5	5	-
Beckman Array	-	3	3	-
Beckman Synchron	-	3	3	-
Becton Dickinson	-	1	1	-
Behring RapiTex-Plate method	-	4	4	-
Biokit Rheumagen	-	1	1	-
Biokit Rheumajet	-	5	5	-
Diagnostic Technology	-	1	1	-
Fisher HealthCare Sure-Vue	-	12	12	-
Immunostics Inc.	-	3	3	-
J&S Medical Assoc. Accutex	-	3	3	-
Pulse Scientific	-	2	2	-
Seradyn	2	52	52	2
Stanbio	-	2	2	-
Sterling Diagnostics, Inc.	-	2	2	-
Wampole Rheumatex	-	9	9	-
Wampole Rheumaton	1	20	21	-

**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>&gt;2560</u>
<b>Specimen RF-7</b>											
All Methods	18	6	5	1	2	-	-	1	-	-	-
Beckman Synchron	-	-	-	-	-	-	-	1	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	1	-	1	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	7	2	-	-	1	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-	-	-
Seradyn	8	4	1	-	1	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	-	1	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

### 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>&gt;2560</u>
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#### Specimen RF-9

All Methods	17	6	3	4	2	-	-	1	-	-	-
Beckman Synchron	-	-	-	-	-	-	-	1	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	1	-	-	1	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	6	3	-	-	1	-	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-	-	-
Seradyn	9	3	-	1	1	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	-	1	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	1	1	-	-	-	-	-	-	-

### 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-7

All Methods	18	76.2	27.1	35.5	75	40	134
Beckman Array	6	-	-	-	74	70	80
Beckman Synchron	3	-	-	-	124	100	134
Fisher HealthCare Sure-Vue	3	-	-	-	40	40	80

#### Specimen RF-9

All Methods	18	75.9	27.3	36.0	76	40	134
Beckman Array	6	-	-	-	74	69	82
Beckman Synchron	3	-	-	-	130	102	134
Fisher HealthCare Sure-Vue	3	-	-	-	40	40	80

### 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	9	-	-	9	9	-
Beckman Nephelometer	1	-	-	1	1	-
Behring RapiTex	2	-	-	2	2	-
Fisher HealthCare Sure-Vue	2	-	-	2	2	-
J&S Medical Assoc. Accutex	1	-	-	1	1	-
Wampole	2	-	-	2	2	-

## Anti-Streptolysin O (ASO)—Qualitative (cont'd)

<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	8	1	1	8
Beckman Nephelometer	1	-	-	1
Behring RapiTex	2	-	-	2
Fisher HealthCare Sure-Vue	2	-	-	2
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>

### Specimen AS-7

All Methods	-	-	-	-	-	-	2	1	-	3
Beckman Nephelometer	-	-	-	-	-	-	1	-	-	-
Behring RapiTex	-	-	-	-	-	-	1	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	1	-	1
Wampole	-	-	-	-	-	-	-	-	-	1

### Specimen AS-10

All Methods	-	-	-	-	-	-	1	2	-	3
Beckman Nephelometer	-	-	-	-	-	-	1	-	-	-
Behring RapiTex	-	-	-	-	-	-	-	1	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	1	-	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-6

All Methods	14	137.9	15.6	11.3	140	115	163
Beckman Array	4	-	-	-	146	142	160
DiaSorin (INCSTAR)	5	-	-	-	125	119	153

### Specimen COM-7

All Methods	14	80.5	7.3	9.0	79	71	96
Beckman Array	4	-	-	-	78	71	81
DiaSorin (INCSTAR)	5	-	-	-	79	74	88

### Specimen COM-8

All Methods	14	79.1	8.0	10.2	77	65	93
Beckman Array	4	-	-	-	75	65	80
DiaSorin (INCSTAR)	5	-	-	-	77	73	90

**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>
<b>Specimen COM-9</b>							
All Methods	14	67.2	7.2	10.7	66	59	85
Beckman Array	4	-	-	-	66	62	69
DiaSorin (INCSTAR)	5	-	-	-	66	59	67

**Specimen COM-10**

All Methods	14	67.4	6.6	9.8	67	59	82
Beckman Array	4	-	-	-	66	59	71
DiaSorin (INCSTAR)	5	-	-	-	67	59	69

**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>
<b>Specimen COM-6</b>							
All Methods	13	33.8	9.7	28.8	30	22	50
Beckman Array	4	-	-	-	47	43	50
DiaSorin (INCSTAR)	5	-	-	-	29	25	218

**Specimen COM-7**

All Methods	10	8.9	1.1	12.4	9	7	11
Beckman Array	-	-	-	-	-	-	-
DiaSorin (INCSTAR)	5	-	-	-	9	8	9

**Specimen COM-8**

All Methods	10	8.7	1.2	13.3	9	7	10
Beckman Array	-	-	-	-	-	-	-
DiaSorin (INCSTAR)	5	-	-	-	9	8	10

**Specimen COM-9**

All Methods	14	20.9	2.1	10.0	21	16	24
Beckman Array	4	-	-	-	22	20	23
DiaSorin (INCSTAR)	5	-	-	-	20	19	24

**Specimen COM-10**

All Methods	14	20.7	2.3	10.9	21	16	24
Beckman Array	4	-	-	-	22	20	23
DiaSorin (INCSTAR)	5	-	-	-	20	17	23

## Antinuclear Antibody (ANA)—Qualitative

<u>Method</u>	<u>Specimen AN-6</u>		<u>Specimen AN-7</u>		<u>Specimen AN-8</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	12	17	11	18	28	1
ASI	4	-	4	-	4	-
Diagnostic Technology	-	4	-	4	4	-
GenBio ImmunoDOT	-	1	-	1	1	-
Immuno Concepts	1	5	1	5	6	-
INOVA Diagnostics	-	2	-	2	2	-
Kallestad	4	-	4	-	4	-
Pulse Scientific	1	-	1	-	1	-
Sanofi IFA	-	1	-	1	1	-
Seradyn	1	-	-	1	-	1
Wampole Impact	-	2	-	2	2	-
Zeus	1	-	1	-	1	-

<u>Method</u>	<u>Specimen AN-9</u>		<u>Specimen AN-10</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	29	-	11	18
ASI	4	-	4	-
Diagnostic Technology	4	-	-	4
GenBio ImmunoDOT	1	-	-	1
Immuno Concepts	6	-	1	5
INOVA Diagnostics	2	-	-	2
Kallestad	4	-	4	-
Pulse Scientific	1	-	1	-
Sanofi IFA	1	-	-	1
Seradyn	1	-	-	1
Wampole Impact	2	-	-	2
Zeus	1	-	1	-

## Antinuclear Antibody (ANA)<sup>3/4</sup>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-6

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

### Specimen AN-7

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

## Antinuclear Antibody (ANA)<sup>3/4</sup>Quantitative (Titer) (cont'd)

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>1024/ 1280</u>	<u>2048/ 2560</u>	<u>32560</u>
<b>Specimen AN-10</b>										
All Methods	1	-	2	2	1	-	-	-	-	-
Diagnostic Technology	1	-	-	-	-	-	-	-	-	-
Immuno Concepts	-	-	2	2	-	-	-	-	-	-
Sanofi IFA	-	-	-	-	1	-	-	-	-	-

## C-Reactive Protein<sup>3/4</sup>Qualitative

<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	16	-	-	16
ASI	1	-	-	1
Beckman Synchron	1	-	-	1
Behring RapiTex	2	-	-	2
Biokit Rheumajet	1	-	-	1
BMH 717	1	-	-	1
Pulse Scientific	2	-	-	2
Seradyn	2	-	-	2
Wampole	3	-	-	3

## C-Reactive Protein<sup>3/4</sup>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>
<b>Specimen CR-3</b>							
All Methods	48	0.107	0.090	84.2	0.08	0.01	0.30
Beckman Array	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	-	-	-
Dade Dimension/AR/ES/RxL/Xpand	4	-	-	-	0.03	0.02	0.07
DiaSorin (INCSTAR)	-	-	-	-	-	-	-
DPC – Immulite	4	-	-	-	0.03	0.03	0.03
Pointe Scientific	-	-	-	-	-	-	-
Polymedco Ultra CRP	22	0.134	0.094	70.0	0.17	0.02	0.30
Roche Cobas/INCSTAR Rgt	5	-	-	-	0.08	0.01	0.13
<b>Specimen CR-4</b>							
All Methods	61	4.701	6.572	139.8	2.00	0.52	24.00
Beckman Array	3	-	-	-	1.71	1.60	1.79
Beckman Synchron	7	-	-	-	1.60	1.40	2.35
Dade Dimension/AR/ES/RxL/Xpand	7	-	-	-	1.90	1.60	2.05
DiaSorin (INCSTAR)	3	-	-	-	2.20	2.00	20.69
DPC – Immulite	4	-	-	-	2.24	1.98	2.36
Pointe Scientific	3	-	-	-	2.10	0.57	2.18
Polymedco Ultra CRP	18	7.689	9.533	124.0	2.25	0.52	30.00
Roche Cobas/INCSTAR Rgt	4	-	-	-	10.66	1.00	20.32

## Rubella<sup>3/4</sup>Qualitative

<u>Method</u>	<u>Specimen RU-6</u>		<u>Specimen RU-7</u>		<u>Specimen RU-8</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	12	-	-	13	12	-
Abbott AxSYM	2	-	-	2	2	-
Abbott IMx	1	-	-	1	1	-
Becton Dickinson	1	-	-	1	1	-
Biokit	1	-	-	1	1	-
bioMerieux Vitek, Mini Vidas	4	-	-	4	4	-
Seradyn	1	-	-	2	1	-
	<u>Specimen RU-9</u>		<u>Specimen RU-10</u>			
All Methods	-	13	12	1		
Abbott AxSYM	-	2	2	-		
Abbott IMx	-	1	1	-		
Becton Dickinson	-	1	1	-		
Biokit	-	1	1	-		
bioMerieux Vitek, Mini Vidas	-	4	4	-		
Seradyn	-	2	1	1		

## Rubella<sup>3/4</sup>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>
<b>Specimen RU-7</b>							
All Methods	5	-	-	-	36.1	31.0	41.5
Abbott AxSYM	3	-	-	-	38.2	36.1	41.5
<b>Specimen RU-9</b>							
All Methods	5	-	-	-	39.1	30.5	41.0
Abbott AxSYM	3	-	-	-	40.2	39.1	41.0

## Total IgE<sup>3/4</sup>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>
<b>Specimen AL-6</b>							
All Methods	11	554.1	75.9	13.7	535	458	731
bioMerieux Vitek, Mini Vidas	1	-	-	-	565	565	565
DPC – Immulite	1	-	-	-	605	605	605
Hycor EIA	2	-	-	-	625	518	731
Pharmacia & Upjohn CAP System	1	-	-	-	524	524	524
Pharmacia & Upjohn Unicap 100	6	-	-	-	521	458	626

**Total IgE<sup>3/4</sup>Quantitative (U/mL) (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>
<b>Specimen AL-7</b>							
All Methods	11	196.2	26.5	13.5	196	139	237
bioMerieux Vitek, Mini Vidas	1	-	-	-	191	191	191
DPC – Immulite	1	-	-	-	237	237	237
Hycor EIA	2	-	-	-	168	139	196
Pharmacia & Upjohn CAP System	1	-	-	-	217	217	217
Pharmacia & Upjohn Unicap 100	6	-	-	-	197	175	228

**Specimen AL-8**

All Methods	11	18.8	1.8	9.5	18	17	23
bioMerieux Vitek, Mini Vidas	1	-	-	-	20	20	20
DPC – Immulite	1	-	-	-	18	18	18
Hycor EIA	2	-	-	-	21	18	23
Pharmacia & Upjohn CAP System	1	-	-	-	18	18	18
Pharmacia & Upjohn Unicap 100	6	-	-	-	18	17	21

**Specimen AL-9**

All Methods	11	18.8	1.7	8.8	18	16	22
bioMerieux Vitek, Mini Vidas	1	-	-	-	18	18	18
DPC – Immulite	1	-	-	-	22	22	22
Hycor EIA	2	-	-	-	19	18	20
Pharmacia & Upjohn CAP System	1	-	-	-	18	18	18
Pharmacia & Upjohn Unicap 100	6	-	-	-	19	16	21

**Specimen AL-10**

All Methods	11	48.1	5.4	11.3	47	39	57
bioMerieux Vitek, Mini Vidas	1	-	-	-	47	47	47
DPC – Immulite	1	-	-	-	57	57	57
Hycor EIA	2	-	-	-	46	44	47
Pharmacia & Upjohn CAP System	1	-	-	-	50	50	50
Pharmacia & Upjohn Unicap 100	6	-	-	-	47	39	56

**Allergen Specific IgE Antibodies**

**Specimen AL-6**

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

**Allergen Specific IgE Antibodies (cont'd)**

**Specimen AL-6**

	Common Ragweed 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	-	-	2	4	9	-	-	-	1	5	8	-	-	-
Hycor EIA	-	-	-	1	1	-	-	-	-	-	2	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	1	-	2	-	-	-	1	-	1	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	2	-	-	-	-	-	2	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	6	-	-	-	-	1	5	-	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	-	-	1	-	-	-	-	-	2	-	-	-	-

	Bermuda Grass 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	-	-	-	4	7	3	-	-	11	3	1	-	-	-
Hycor EIA	-	-	-	-	-	2	-	-	-	1	1	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	1	1	-	-	-	1	2	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	1	-	-	-	2	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	4	1	-	-	6	-	-	-	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	-	-	1	1	-	-	-	2	-	-	-	-	-

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

**Specimen AL-7**

	Bermuda Grass Allergen <i>CLASS RESULT</i>							Maple (Box Elder) Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	1	-	3	8	2	-	-	-	1	10	-	-	-	-
Hycor EIA	-	-	-	-	2	-	-	-	-	2	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	1	1	-	-	-	-	1	1	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	2	-	-	-	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	5	-	-	-	-	-	6	-	-	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	-	2	-	-	-	-	-	-	-	-	-	-	-

**Allergen Specific IgE Antibodies (cont'd)**

**Specimen AL-7**

	Perennial Rye Allergen							House Dust Mite Allergen						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	3	4	-	-	15	1	-	-	-	-	-
Hycor EIA	-	-	-	-	1	-	-	2	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	-	-	2	1	-	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	2	-	-	-	2	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	2	-	-	6	-	-	-	-	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	-	-	1	-	-	-	2	-	-	-	-	-	-
	White Oak Allergen							Meadow Grass, Kentucky Blue Grass, June Grass Allergen						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	5	8	1	-	-	-	-	1	1	5	1	-
Hycor EIA	-	-	-	1	1	-	-	-	-	-	-	-	1	-
Pharmacia & Upjohn CAP (% ref)	-	-	1	1	-	-	-	-	-	1	-	1	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	2	-	-	-	-	-	-	-	1	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	6	-	-	-	-	-	-	-	3	-	-
Pharmacia & Upjohn CAP 100 (KU/L)	-	-	2	-	-	-	-	-	-	-	-	-	-	-
	English Plantain Allergen													
	<i>CLASS RESULT</i>													
	0	1	2	3	4	5	6							
All Methods	10	1	-	-	-	-	-							
Hycor EIA	2	-	-	-	-	-	-							
Pharmacia & Upjohn CAP (% ref)	2	1	-	-	-	-	-							
Pharmacia & Upjohn CAP (KU/L)	2	-	-	-	-	-	-							
Pharmacia UniCap 100 (% ref)	3	-	-	-	-	-	-							
Pharmacia & Upjohn CAP 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>
<b>Specimen IP-6</b>							
All Methods	9	-	-	-	239	193	260
<b>Specimen IP-7</b>							
All Methods	9	-	-	-	127	100	141
<b>Specimen IP-8</b>							
All Methods	9	-	-	-	287	229	349
<b>Specimen IP-9</b>							
All Methods	9	-	-	-	173	146	195

**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>
<b>Specimen IP-10</b>							
All Methods	9	-	-	-	248	192	273

**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>
<b>Specimen IP-6</b>							
All Methods	8	-	-	-	956	800	1048
<b>Specimen IP-7</b>							
All Methods	8	-	-	-	515	489	554
<b>Specimen IP-8</b>							
All Methods	8	-	-	-	2327	2055	2695
<b>Specimen IP-9</b>							
All Methods	8	-	-	-	2471	2234	2926
<b>Specimen IP-10</b>							
All Methods	8	-	-	-	1007	866	1056

**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>
<b>Specimen IP-6</b>							
All Methods	9	-	-	-	82	74	148
<b>Specimen IP-7</b>							
All Methods	9	-	-	-	45	35	103
<b>Specimen IP-8</b>							
All Methods	9	-	-	-	105	93	176
<b>Specimen IP-9</b>							
All Methods	9	-	-	-	383	239	470
<b>Specimen IP-10</b>							
All Methods	9	-	-	-	395	245	468

**Syphilis Serology<sup>3/4</sup>Qualitative: RPR**

<u>Method</u>	<b>Specimen SY-6</b>		<b>Specimen SY-7</b>		<b>Specimen SY-8</b>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	1	54	1	54	54	1
ASI	-	17	-	17	17	-
Becton Dickinson	1	26	1	26	26	1
Biokit	-	1	-	1	1	-
J&S Medical Assoc. Accutex	-	1	-	1	1	-
New Horizons	-	2	-	2	2	-
Scientific Products	-	1	-	1	1	-
Stanbio	-	3	-	3	3	-
Wampole Impact RPR	-	2	-	2	2	-

  

<u>Method</u>	<b>Specimen SY-9</b>		<b>Specimen SY-10</b>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	53	2	53	2
ASI	16	1	16	1
Becton Dickinson	26	1	26	1
Biokit	1	-	1	-
J&S Medical Assoc. Accutex	1	-	1	-
New Horizons	2	-	2	-
Scientific Products	1	-	1	-
Stanbio	3	-	3	-
Wampole Impact RPR	2	-	2	-

**Syphilis Serology<sup>3/4</sup>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>
<b>Specimen SY-8</b>							
All Methods	3	18	3	-	-	-	-
ASI	2	8	2	-	-	-	-
Becton Dickinson	-	9	-	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	1	-	-	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-
<b>Specimen SY-9</b>							
All Methods	4	17	3	-	-	-	-
ASI	2	9	1	-	-	-	-
Becton Dickinson	1	7	1	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	1	-	-	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-
<b>Specimen SY-10</b>							
All Methods	4	14	6	-	-	-	-
ASI	2	9	1	-	-	-	-
Becton Dickinson	1	5	3	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	1	-	-	-	-	-	-
Wampole Impact RPR	-	-	1	-	-	-	-

## H. pylori Antibody Detection

<u>Method</u>	<b>Specimen HP-3</b>		<b>Specimen HP-4</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	226	1	3	224
Abbott FlexPack	2	-	-	2
Applied Biotech SureStep	20	-	-	20
BD LINK 2	8	-	-	8
Beckman Coulter FlexSure	40	-	1	39
DPC – Immulite	1	-	-	1
Fisher HealthCare Sure-Vue	6	-	-	6
LifeSign Status	4	-	-	4
Meridian ImmunoCard	1	-	-	1
Meridian Premier	1	-	-	1
Polymedco Poly stat	29	-	-	29
Quidel QuickVue	109	1	2	108
Remel RIM A.R.C.	1	-	-	1

## Lyme Disease Serology

<u>Method</u>	<b>Specimen LY-3</b>		<b>Specimen LY-4</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	-	-	2
Remel Rapidot	1	-	-	1
Wampole PreVue	1	-	-	1

## Viral Markers – Anti-HIV

<u>Method</u>	<b>Specimen VM-6</b>		<b>Specimen VM-7</b>		<b>Specimen VM-8</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	3	3	-	2	1
Abbott Quantum	-	1	1	-	1	-
Murex SUDS	-	1	1	-	-	1

  

<u>Method</u>	<b>Specimen VM-9</b>		<b>Specimen VM-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	-	-	3
Abbott Quantum	1	-	-	1
Murex SUDS	1	-	-	1

## Viral Markers – HBsAg

<u>Method</u>	<b>Specimen VM-6</b>		<b>Specimen VM-7</b>		<b>Specimen VM-8</b>	
	<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>	<b>Specimen VM-9</b>		<b>Specimen VM-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	1	1	-

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