

# **MEDICAL LABORATORY EVALUATION**

## **PARTICIPANT SUMMARY**

**2 • 0 • 0 • 4**



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

Immunology  
MLE – M2

# Table of Contents

<b>2004 Evaluation Criteria</b> .....	<b>3</b>
<b>Immunology</b>	
<b>Infectious Mononucleosis</b> .....	<b>4</b>
<b>Rheumatoid Factor</b> .....	<b>5</b>
Qualitative .....	5
Quantitative (Titer).....	6
Quantitative (IU).....	7
<b>Anti-Streptolysin O (ASO)</b> .....	<b>7</b>
Qualitative .....	7
Quantitative .....	8
<b>Complement C3</b> .....	<b>8</b>
<b>Complement C4</b> .....	<b>9</b>
<b>Antinuclear Antibody (ANA [AN-6 – AN-10])</b> .....	<b>9</b>
Qualitative .....	9
Quantitative (Titer).....	10
<b>Antinuclear Antibody (ANA [AE-6 – AE-10])</b> .....	<b>10</b>
Qualitative .....	10
Quantitative (Titer).....	11
<b>C-Reactive Protein, Regular</b> .....	<b>11</b>
Qualitative .....	11
Quantitative .....	11
<b>C-Reactive Protein, High Sensitivity</b> .....	<b>12</b>
Quantitative .....	12
<b>Rubella</b> .....	<b>12</b>
Qualitative .....	12
Quantitative .....	13
<b>Total IgE</b> .....	<b>13</b>
Quantitative .....	13
<b>Allergen Specific IgE Antibodies</b> .....	<b>14</b>
<b>IgA</b> .....	<b>16</b>
<b>IgG</b> .....	<b>16</b>
<b>IgM</b> .....	<b>17</b>
<b>Syphilis Serology</b> .....	<b>17</b>
Qualitative: RPR .....	17
Quantitative: RPR (Titer).....	18
<b>H. pylori Antibody Detection</b> .....	<b>18</b>
<b>Lyme Disease Serology</b> .....	<b>19</b>
<b>Mycoplasma Antibody</b> .....	<b>19</b>
<b>Viral Markers</b> .....	<b>19</b>
Anti-HBc.....	19
Anti-HIV .....	19
HAV .....	19
HBeAg.....	19
HBsAb .....	20
HBsAg .....	20
HCV.....	20

## 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

**NOTE: International laboratories that do not have a corresponding US peer group listed in this participant summary, please use the All Method statistics for comparison.**

**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	335	-	335	-	252	-
ABI SureStep Mono-whole blood	4	-	4	-	2	-
Applied Biotech SureStep	3	-	3	-	3	-
ASI	2	-	2	-	2	-
Biokit	1	-	1	-	1	-
BioStar Acceava Mono Test	7	-	7	-	7	-
BioStar Acceava Mono-whole blood	15	-	15	-	6	-
Fisher HealthCare Sure-Vue	15	-	15	-	15	-
Genzyme Contrast Mono	1	-	1	-	1	-
Genzyme Contrast Mono-whole blood	3	-	3	-	2	-
Genzyme OSOM Mono	1	-	1	-	1	-
LifeSign UniStep Mono	1	-	1	-	-	-
Mainline Confirms	1	-	1	-	1	-
Meridian ImmunoCardSTAT-waived	1	-	1	-	-	-
Meridian Monospot (Latex)	1	-	1	-	1	-
Organon Teknika	3	-	3	-	3	-
Polymedco Poly stat	10	-	10	-	7	-
Polymedco Poly stat – waived	18	-	18	-	7	-
Quidel CARDS O.S. (whole blood)	1	-	1	-	1	-
Quidel Quick Vue+	71	-	71	-	64	-
Quidel Quick Vue+ - waived	34	-	34	-	13	-
Remel RIM A.R.C.	2	-	2	-	2	-
Scientific Products	1	-	1	-	1	-
Seradyn	29	-	29	-	28	-
Seradyn Color Q – (whole blood)	3	-	3	-	3	-
Stanbio	1	-	1	-	1	-
Wampole ColorCard	15	-	15	-	15	-
Wampole Mono-Latex	9	-	9	-	9	-
Wampole Mono-Plus	37	-	37	-	30	-
Wampole Mono-Plus (whole blood)	30	-	30	-	13	-
Wampole Mono-Test	8	-	8	-	8	-
Wyntek OSOM	6	-	6	-	4	-

  

	<b>Specimen IM-9</b>		<b>Specimen IM-10</b>	
All Methods	8	243	6	245
ABI SureStep Mono-whole blood	-	2	-	2
Applied Biotech SureStep	-	3	-	3
ASI	-	2	-	2
Biokit	-	1	-	1
BioStar Acceava Mono Test	-	7	-	7
BioStar Acceava Mono-whole blood	-	6	-	6
Fisher HealthCare Sure-Vue	-	15	-	15
Genzyme Contrast Mono	-	1	-	1
Genzyme Contrast Mono-whole blood	-	2	-	2
Genzyme OSOM Mono	-	1	-	1
Mainline Confirms	-	1	-	1
Meridian Monospot (Latex)	-	1	-	1
Organon Teknika	-	3	-	3
Polymedco Poly stat	-	7	-	7
Polymedco Poly stat – waived	-	7	-	7
Quidel CARDS O.S.	-	1	-	1

**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>
Quidel Quick Vue+	6	58	4	60
Quidel Quick Vue+ - waived	2	11	2	11
Remel RIM A.R.C.	-	2	-	2
Scientific Products	-	1	-	1
Seradyn	-	28	-	28
Seradyn Color Q – (whole blood)	-	3	-	3
Wampole ColorCard	-	15	-	15
Wampole Mono-Latex	-	9	-	9
Wampole Mono-Plus	-	30	-	30
Wampole Mono-Plus (whole blood)	-	13	-	13
Wampole Mono-Test	-	8	-	8
Wyntek OSOM	-	4	-	4

**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	125	-	124	-	-	123
Ampcor	1	-	1	-	-	1
ASI	7	-	7	-	-	7
Beckman Array	3	-	3	-	-	3
Beckman Synchron	3	-	3	-	-	3
Becton Dickinson	1	-	1	-	-	1
Behring RapiTex-Plate method	4	-	4	-	-	4
Biokit Rheumajet	4	-	4	-	-	4
BMH 717	1	-	1	-	-	-
Fisher HealthCare Sure-Vue	7	-	6	-	-	6
Immunostics Inc.	3	-	3	-	-	3
J&S Medical Assoc. Accutex	2	-	2	-	-	2
Murex Latex Test	2	-	2	-	-	2
Pulse Scientific	2	-	2	-	-	2
Seradyn	52	-	52	-	-	52
Stanbio	2	-	2	-	-	2
Sterling Diagnostics, Inc.	2	-	2	-	-	2
Wampole ColorCard	2	-	2	-	-	2
Wampole Rheumatex	6	-	6	-	-	6
Wampole Rheumaton	14	-	14	-	-	14

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

<b><u>Method</u></b>	<b>Specimen RF-9</b>		<b>Specimen RF-10</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
All Methods	1	124	124	1
Ampcor	-	1	1	-
ASI	-	7	7	-
Beckman Array	-	3	3	-
Beckman Synchron	-	3	3	-
Becton Dickinson	-	1	1	-
Behring RapiTex-Plate method	-	4	4	-
Biokit Rheumajet	-	4	4	-
BMH 717	-	1	1	-
Fisher HealthCare Sure-View	1	6	7	-
Immunostics Inc.	-	3	3	-
J&S Medical Assoc. Accutex	-	2	2	-
Murex Latex Test	-	2	2	-
Pulse Scientific	-	2	2	-
Seradyn	-	52	52	-
Stanbio	-	2	2	-
Sterling Diagnostics, Inc.	-	2	2	-
Wampole ColorCard	-	2	2	-
Wampole Rheumatex	-	6	6	-
Wampole Rheumaton	-	14	13	1

**Rheumatoid Factor—Quantitative (Titer)**

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

<b><u>Specimen/Method</u></b>	<b><u>2/4</u></b>	<b><u>8/10</u></b>	<b><u>16/20</u></b>	<b><u>32/40</u></b>	<b><u>64/80</u></b>	<b><u>128/160</u></b>	<b><u>256/320</u></b>	<b><u>512/640</u></b>	<b><u>1024/1280</u></b>	<b><u>2048/2560</u></b>	<b><u>&gt;2560</u></b>
<b>Specimen RF-8</b>											
All Methods	16	8	3	4	1	-	-	-	1	-	-
ASI	-	1	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	1	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	-	2	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	2	1	-	1	-	-	-	-	-	-	-
Murex Latex Test	-	1	-	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-	-	-
Seradyn	9	3	1	2	-	-	-	-	-	-	-
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>&gt;2560</u>
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#### Specimen RF-9

All Methods	14	9	2	3	2	-	-	-	1	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	1	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	1	1	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	-	-	1	-	-	-	-	-	-
Murex Latex Test	-	1	-	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-	-	-
Seradyn	8	4	-	2	-	-	-	-	-	-	-
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>
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#### Specimen RF-8

All Methods	15	84.7	36.9	43.6	82	40	151
Beckman Array	4	-	-	-	83	81	86
Beckman Synchron	5	127.2	21.1	16.6	137	103	151

#### Specimen RF-9

All Methods <sup>15</sup>	15	87.5	34.0	38.8	81	40	148
Beckman Array	4	-	-	-	82	81	84
Beckman Synchron	5	126.6	21.1	16.7	138	101	148

### 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	-	6	-	6	6	-
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	-	1	-	1	1	-

<u>Method</u>	<u>Specimen AS-9</u>		<u>Specimen AS-10</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	6	6	-
Beckman Nephelometer	-	1	1	-
Behring RapiTex	-	2	2	-
Fisher HealthCare Sure-Vue	-	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>≥2500</u>	<u>100- 200</u>	<u>400- 800</u>
<b>Specimen AS-6</b>											
All Methods	-	-	-	-	-	1	1	-	-	1	1
Behring RapiTex	-	-	-	-	-	-	1	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-	-
Wampole	-	-	-	-	-	-	-	-	-	1	-
<b>Specimen AS-7</b>											
All Methods	-	-	-	-	-	1	-	-	1	1	1
Behring RapiTex	-	-	-	-	-	-	-	-	1	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-	-
Wampole	-	-	-	-	-	-	-	-	-	1	-
<b>Specimen AS-9</b>											
All Methods	-	-	-	-	-	1	1	-	-	1	1
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>
<b>Specimen COM-6</b>							
All Methods	11	55.7	7.3	13.1	59	38	61
DiaSorin (INCSTAR)	5	52.6	10.1	19.2	59	38	60
<b>Specimen COM-7</b>							
All Methods	10	31.8	10.3	32.2	29	24	58
DiaSorin (INCSTAR)	4	-	-	-	32	24	58
<b>Specimen COM-8</b>							
All Methods	11	123.3	13.4	10.9	124	95	139
DiaSorin (INCSTAR)	5	115.4	14.1	12.2	118	95	132
<b>Specimen COM-9</b>							
All Methods	10	30.8	5.2	16.8	30	25	38
DiaSorin (INCSTAR)	4	-	-	-	34	25	38
<b>Specimen COM-10</b>							
All Methods	11	79.3	6.5	8.1	82	65	85
DiaSorin (INCSTAR)	5	78.6	7.8	9.9	81	65	84

**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	11	16.5	4.3	26.1	17	7	22
DiaSorin (INCSTAR)	5	16.2	6.0	36.9	16	7	22
<b>Specimen COM-7</b>							
All Methods	5	7.4	7.8	105.8	4	2	21
DiaSorin (INCSTAR)	3	-	-	-	7	3	21
<b>Specimen COM-8</b>							
All Methods	11	29.0	7.2	24.9	27	22	43
DiaSorin (INCSTAR)	5	26.2	2.5	9.5	27	22	28
<b>Specimen COM-9</b>							
All Methods	5	4.0	2.7	68.5	2	2	7
DiaSorin (INCSTAR)	3	-	-	-	7	2	7
<b>Specimen COM-10</b>							
All Methods	9	8.3	1.7	20.8	8	6	12
DiaSorin (INCSTAR)	5	7.6	1.1	15.0	8	6	9

**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	9	-	4	5	9	-
ASI	3	-	3	-	3	-
Diagnostic Technology	3	-	-	3	3	-
Pulse Scientific	1	-	1	-	1	-
Wampole Impact	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	3	6	3	6
ASI	3	-	3	-
Diagnostic Technology	-	3	-	3
Pulse Scientific	-	1	-	1
Wampole Impact	-	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>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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### Specimen AN-7

All Methods	1	-	-	-	-	-	-	-	-	-
Diagnostic Technology	1	-	-	-	-	-	-	-	-	-

### Specimen AN-9

All Methods	1	-	-	-	-	-	-	-	-	-
Diagnostic Technology	1	-	-	-	-	-	-	-	-	-

### Specimen AN-10

All Methods	1	-	-	-	-	-	-	-	-	-
Diagnostic Technology	1	-	-	-	-	-	-	-	-	-

## Antinuclear Antibody (ANA)—Qualitative

<u>Method</u>	<u>Specimen AE-6</u>		<u>Specimen AE-7</u>		<u>Specimen AE-8</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	17	-	-	17	17	-
GenBio ImmunoDOT	1	-	-	1	1	-
Immuno Concepts	7	-	-	7	7	-
INOVA Diagnostics	1	-	-	1	1	-
Kallestad	5	-	-	5	5	-
Wampole Impact	1	-	-	1	1	-
Zeus	1	-	-	1	1	-

<u>Method</u>	<u>Specimen AE-9</u>		<u>Specimen AE-10</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	17	-	17
GenBio ImmunoDOT	-	1	-	1
Immuno Concepts	-	7	-	7
INOVA Diagnostics	-	1	-	1
Kallestad	-	5	-	5
Wampole Impact	-	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>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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### Specimen AE-7

All Methods	-	-	-	1	-	1	6	1	1	-
Immuno Concepts	-	-	-	1	-	-	2	1	1	-
INOVA Diagnostics	-	-	-	-	-	-	1	-	-	-
Kallestad	-	-	-	-	-	-	3	-	-	-
Wampole Impact	-	-	-	-	-	1	-	-	-	-

### Specimen AE-9

All Methods	-	-	-	1	2	4	2	1	-	-
Immuno Concepts	-	-	-	1	-	1	2	1	-	-
INOVA Diagnostics	-	-	-	-	1	-	-	-	-	-
Kallestad	-	-	-	-	-	3	-	-	-	-
Wampole Impact	-	-	-	-	1	-	-	-	-	-

### Specimen AE-10

All Methods	-	-	-	-	3	4	1	1	1	-
Immuno Concepts	-	-	-	-	1	1	1	1	1	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-
Kallestad	-	-	-	-	1	2	-	-	-	-
Wampole Impact	-	-	-	-	1	-	-	-	-	-

## C-Reactive Protein—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	14	1	1	14
ASI	2	-	-	2
Beckman Synchron	-	1	1	-
Behring RapiTex	2	-	-	2
Dade Dimension/AR/ES/RxL/Xpand	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>
<b>Specimen CR-3</b>							
All Methods	7	1.846	2.708	146.7	0.20	0.01	7.00
<b>Specimen CR-4</b>							
All Methods	25	11.388	9.235	81.1	12.00	1.60	27.10
Beckman Array	3	-	-	-	18.30	2.23	21.70
Beckman Synchron	7	6.200	7.725	124.6	1.80	1.60	18.00
Dade Dimension/AR/ES/RxL/Xpand	3	-	-	-	21.00	2.10	23.00
DiaSorin (INCSTAR)	4	-	-	-	9.00	1.89	23.60

**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>
<b>Specimen CR-3</b>							
All Methods	38	0.170	0.106	62.5	0.18	0.01	0.45
Kamiya Biomedical hs-CRP	7	0.166	0.103	62.0	0.20	0.02	0.30
Pointe Scientific CRP (HS)	3	-	-	-	0.10	0.01	0.40
Polymedco Full Range CRP	6	0.172	0.076	44.4	0.17	0.09	0.29
Polymedco Ultra CRP	6	0.137	0.058	42.6	0.12	0.10	0.25

**Specimen CR-4**

All Methods	55	14.261	9.272	65.0	20.10	0.69	26.50
Beckman Synchron	3	-	-	-	9.50	2.05	21.20
Dade Dimension High Sensi CRP	8	9.676	10.443	107.9	2.18	1.98	23.00
Dade Dimension/AR/ES/RxL/Xpand	3	-	-	-	2.22	2.13	21.60
Kamiya Biomedical hs-CRP	6	11.882	8.008	67.4	9.29	1.00	22.61
Pointe Scientific CRP (HS)	5	6.072	8.981	147.9	2.47	0.69	22.00
Polymedco Full Range CRP	8	21.170	1.058	5.0	21.26	19.09	22.70
Polymedco Ultra CRP	4	-	-	-	11.72	1.17	21.89

**Rubella—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	2	8	2	7	11	-
Abbott AxSYM	1	1	1	-	3	-
Abbott IMx	-	1	-	1	1	-
Becton Dickinson	-	1	-	1	1	-
bioMerieux Vitek, Mini Vidas	-	2	-	2	2	-
DPC – Immulite	1	-	1	-	1	-
Seradyn	-	3	-	3	3	-
	<u>Specimen RU-9</u>		<u>Specimen RU-10</u>			
All Methods	11	-	11	-		
Abbott AxSYM	3	-	3	-		
Abbott IMx	1	-	1	-		
Becton Dickinson	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-6**

All Methods	3	-	-	-	9.5	9.1	10.2
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**Specimen RU-7**

All Methods	3	-	-	-	9.2	8.0	9.4
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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-6**

All Methods	9	193.9	23.6	12.2	198	136	219
Hycor EIA	1	-	-	-	136	136	136
Pharmacia & Upjohn CAP System	2	-	-	-	212	204	219
Pharmacia & Upjohn Unicap 100	6	197.7	7.7	3.9	196	190	210

**Specimen AL-7**

All Methods	9	792.8	89.8	11.3	783	647	969
Hycor EIA	1	-	-	-	647	647	647
Pharmacia & Upjohn CAP System	2	-	-	-	850	730	969
Pharmacia & Upjohn Unicap 100	6	798.2	40.1	5.0	803	744	848

**Specimen AL-8**

All Methods	9	109.1	14.1	13.0	114	74	120
Hycor EIA	1	-	-	-	74	74	74
Pharmacia & Upjohn CAP System	2	-	-	-	116	114	118
Pharmacia & Upjohn Unicap 100	6	112.7	6.1	5.4	114	105	120

**Specimen AL-9**

All Methods	9	29.9	5.2	17.5	31	18	35
Hycor EIA	1	-	-	-	18	18	18
Pharmacia & Upjohn CAP System	2	-	-	-	28	27	28
Pharmacia & Upjohn Unicap 100	6	32.7	2.0	6.0	33	30	35

**Specimen AL-10**

All Methods	9	107.3	16.3	15.2	114	78	123
Hycor EIA	1	-	-	-	78	78	78
Pharmacia & Upjohn CAP System	2	-	-	-	102	81	123
Pharmacia & Upjohn Unicap 100	6	114.0	3.3	2.9	115	110	118

# Allergen Specific IgE Antibodies

## Specimen AL-6

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

  

	Common (Short) 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	-	-	4	8	1	-	-	12	-	-	-	-	-	-
Hycor EIA	-	-	-	1	1	-	-	2	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	2	-	-	-	1	-	-	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	1	-	-	-	-	1	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	1	5	-	-	-	6	-	-	-	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	1	-	-	-	-	2	-	-	-	-	-	-

  

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

  

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

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

**Specimen AL-7**

	<b>Bermuda Grass Allergen</b>							<b>Russian Thistle Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
All Methods	-	-	-	4	9	-	-	-	-	-	2	2	-	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	2	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	5	-	-	-	-	-	1	1	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	2	-	-	-	-	-	-	-	-	-	-
	<b>Perennial Rye Allergen</b>							<b>Cat Epithelium Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
All Methods	-	-	-	1	3	2	-	-	-	-	3	6	5	-
Hycor EIA	-	-	-	-	-	1	-	-	-	-	-	1	1	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	1	-	-	-	-	-	-	2	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	-	1	-	-	-	-	-	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	2	-	-	-	-	-	-	4	2	-
Pharmacia Unicap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	1	1	-	-
	<b>White Oak Allergen</b>							<b>Meadow Grass, Kentucky Blue Grass, June Grass Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
All Methods	-	-	-	5	7	-	-	-	-	-	-	3	4	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	-	-	1	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	-	-	-	-	-	-	-	1	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	2	4	-	-	-	-	-	-	2	2	-
Pharmacia Unicap 100 (KU/L)	-	-	-	2	-	-	-	-	-	-	-	-	-	-
	<b>Sage Allergen</b>													
	<b>CLASS RESULT</b>													
	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>							
All Methods	-	-	-	-	-	-	-							
Hycor EIA	-	-	-	-	-	-	-							
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	-	-							
Pharmacia & Upjohn CAP (KU/L)	-	-	-	-	-	-	-							
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	-	-							
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>
<b>Specimen IP-6</b>							
All Methods	9	188.6	14.8	7.8	188	161	208
<b>Specimen IP-7</b>							
All Methods	9	440.3	47.1	10.7	469	360	498
<b>Specimen IP-8</b>							
All Methods	9	119.1	10.0	8.4	117	108	135
<b>Specimen IP-9</b>							
All Methods	9	173.1	10.9	6.3	170	154	190
<b>Specimen IP-10</b>							
All Methods	9	170.0	12.3	7.2	172	151	189

**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	9	876.6	54.7	6.2	913	803	936
<b>Specimen IP-7</b>							
All Methods	8	886.0	72.6	8.2	919	769	960
<b>Specimen IP-8</b>							
All Methods	9	515.9	20.2	3.9	511	496	550
<b>Specimen IP-9</b>							
All Methods	9	840.1	42.3	5.0	828	797	936
<b>Specimen IP-10</b>							
All Methods	8	2296.3	85.1	3.7	2315	2149	2380

**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	93.1	8.4	9.1	92	84	113
<b>Specimen IP-7</b>							
All Methods	9	88.6	5.1	5.7	88	82	100
<b>Specimen IP-8</b>							
All Methods	9	41.4	5.7	13.7	39	35	50
<b>Specimen IP-9</b>							
All Methods	8	397.5	46.1	11.6	411	320	448
<b>Specimen IP-10</b>							
All Methods	9	84.6	6.3	7.4	85	70	92

**Syphilis Serology—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	55	-	55	-	-	55
ASI	15	-	15	-	-	15
Becton Dickinson	30	-	30	-	-	30
Biokit	1	-	1	-	-	1
Fisher	1	-	1	-	-	1
Fisher HealthCare Sure-Vue	2	-	2	-	-	2
New Horizons	1	-	1	-	-	1
Scientific Products	1	-	1	-	-	1
Stanbio	1	-	1	-	-	1
Wampole Impact RPR	1	-	1	-	-	1
<b>Specimen SY-9</b>						
All Methods	54	1				
ASI	14	1				
Becton Dickinson	30	-				
Biokit	1	-				
Fisher	1	-				
Fisher HealthCare Sure-Vue	2	-				
New Horizons	1	-				
Scientific Products	1	-				
Stanbio	1	-				
Wampole Impact RPR	1	-				
<b>Specimen SY-10</b>						
All Methods			-	55		
ASI			-	15		
Becton Dickinson			-	30		
Biokit			-	1		
Fisher			-	1		
Fisher HealthCare Sure-Vue			-	2		
New Horizons			-	1		
Scientific Products			-	1		
Stanbio			-	1		
Wampole Impact RPR			-	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>
<b>Specimen SY-6</b>							
All Methods	3	21	1	-	-	-	-
ASI	2	7	-	-	-	-	-
Becton Dickinson	1	11	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	-	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	-	1	-	-	-	-	-
<b>Specimen SY-7</b>							
All Methods	4	18	3	-	-	-	-
ASI	2	6	1	-	-	-	-
Becton Dickinson	1	10	1	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	-	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	1	-	-	-	-	-	-
<b>Specimen SY-9</b>							
All Methods	6	14	5	-	-	-	-
ASI	4	2	3	-	-	-	-
Becton Dickinson	1	10	1	-	-	-	-
Fisher HealthCare Sure-Vue	-	2	-	-	-	-	-
New Horizons	-	-	1	-	-	-	-
Stanbio	1	-	-	-	-	-	-

## H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-3</u>		<u>Specimen HP-4</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	3	203	204	3
Abbott FlexPack	-	1	1	-
Abbot Signify	-	2	2	-
Applied Biotech SureStep	-	22	22	-
BD LINK 2	-	6	7	-
Beckman Coulter FlexSure	1	29	29	1
DPC – Immulite	-	1	1	-
Fisher HealthCare Sure-Vue	-	6	6	-
LifeSign Status	-	4	4	-
Meridian ImmunoCard	-	2	2	-
Meridian Premier	-	1	1	-
Polymedco Poly stat	-	28	28	-
Quidel QuickVue	2	97	97	2
Remel RIM A.R.C.	-	1	1	-

## Lyme Disease Serology

<u>Method</u>	<u>Specimen LY-3</u>		<u>Specimen LY-4</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	6	-	-	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-3</u>		<u>Specimen MY-4</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	2	-	2

## Viral Markers – Anti-HBc

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

## Viral Markers – Anti-HIV

<u>Method</u>	<u>Specimen VM-6</u>		<u>Specimen VM-7</u>		<u>Specimen VM-8</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	3	-	-	3	3	-

  

<u>Method</u>	<u>Specimen VM-9</u>		<u>Specimen VM-10</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	3	-	3	-

## Viral Markers – HAV

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

Specimens VM-7, VM-8, VM-9 and VM-10 are IgG reactive. Specimen VM-6 is IgM non-reactive.

## Viral Markers – HBeAg

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

### Viral Markers – HBsAb

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

### Viral Markers – Anti-HBsAg

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	-	1	1	-	2
	Specimen VM-9		Specimen VM-10			
All Methods	2	-	2	-		

### Viral Markers – HCV

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

## Medical Laboratory Evaluation

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