

# **MEDICAL LABORATORY EVALUATION**

**PARTICIPANT SUMMARY**

**2 • 0 • 0 • 6**



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

**Immunology  
MLE – M3**

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## 2006 Evaluation Criteria

The evaluation criteria used in the 2006 MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

### Qualitative

For qualitative procedures, evaluation is based on participant consensus. A minimum percentage of participants must receive a passing score or the challenge is not evaluated due to lack of consensus. These percentages are listed below.

Infectious Mononucleosis	80% Participant Consensus
Rheumatoid Factor	80% Participant Consensus
Anti-Streptolysin O (ASO)	80% Participant Consensus
Antinuclear Antibody (ANA)	80% Participant Consensus
C-Reactive Protein	80% Participant Consensus
Rubella Antibody	80% Participant Consensus
H. <i>pylori</i> Antibody Detection	80% Participant Consensus
Total IgE	80% Participant Consensus
Diagnostic Allergy	Not Evaluated
Syphilis Serology	80% Participant Consensus
Lyme Disease Serology	80% Participant Consensus
Mycoplasma Antibody	80% Participant Consensus
Viral Markers	80% Participant Consensus

### Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each peer group consisting of 5 or more laboratories. Acceptable performance is established based on a target value  $\pm$  the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on pages 39-40 under the heading "Acceptable Ranges for Quantitative Results."

Rheumatoid Factor (Titer)	Not Evaluated
Rheumatoid Factor (International Units)	Not Evaluated
Anti-Streptolysin O (ASO) Titer	Not Evaluated
Complement C3	$\pm$ 3 SD
Complement C4	$\pm$ 3 SD
Antinuclear Antibody (ANA) Titer	Not Evaluated
C-Reactive Protein	$\pm$ 3 SD
Rubella (International Units)	Not Evaluated
Total IgE	$\pm$ 3 SD
Total IgA	$\pm$ 3 SD
Total IgG	$\pm$ 25%
Total IgM	$\pm$ 3 SD

## Infectious Mononucleosis

<u>Method</u>	<b>Specimen IM-11</b>		<b>Specimen IM-12</b>		<b>Specimen IM-13</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	1	337	338	-	1	217
Applied Biotech SureStep	-	1	1	-	-	1
ASI	-	2	2	-	-	2
Beckman Coulter ICON Mono - waived	-	1	1	-	-	1
BioStar Acceava Mono Test	-	6	6	-	-	4
BioStar Acceava Mono-whole bld	-	16	16	-	-	2
Cardinal Health SP Brand	-	5	5	-	-	5
Cardinal Health SP Brand - waived	-	17	17	-	-	6
Fisher HealthCare Sure-Vue	-	16	16	-	-	16
Genzyme OSOM	-	4	4	-	-	4
Genzyme OSOM (waived)	-	10	10	-	-	6
Henry Schein OneStep+ - waived	-	2	2	-	-	2
Immunostics Inc.	-	1	1	-	-	1
Instant Technologies i Screen-WB	-	3	3	-	-	3
Inverness ClearviewMono-plusII	-	6	6	-	-	5
Inverness Signify Mono Test	-	8	8	-	-	5
LifeSign UniStep Mono	-	9	9	-	-	2
Mainline Confirms	-	2	2	-	-	2
McKesson Medi-Lab Performance - waived	-	13	13	-	-	9
Meridian ImmunoCard STAT!	-	1	1	-	-	1
Meridian ImmunoCard STAT! (whole blood)	-	1	1	-	-	-
Polymedco Poly stat	-	11	11	-	-	11
Polymedco Poly stat - waived	-	16	16	-	-	4
Quidel QuickVue+	-	77	77	-	-	56
Quidel QuickVue+ - waived	1	40	41	-	-	9
Remel RIM A.R.C.	-	1	1	-	-	-
Seradyn	-	29	29	-	-	28
Seradyn Color Q (whole blood)	-	1	1	-	-	1
Wampole ColorCard	-	10	10	-	1	8
Wampole Mono-Latex	-	2	2	-	-	2
Wampole Mono-Plus II	-	16	16	-	-	13
Wampole Mono-Plus II (whole blood)	-	6	6	-	-	4
Wampole Mono-Test	-	2	2	-	-	2
Wyntek Diagnostics Signify	-	1	1	-	-	1

	<b>Specimen IM-14</b>		<b>Specimen IM-15</b>	
ALL METHODS	216	2	3	215
Applied Biotech SureStep	1	-	-	1
ASI	2	-	-	2
Beckman Coulter ICON Mono - waived	1	-	-	1
BioStar Acceava Mono Test	4	-	-	4
BioStar Acceava Mono-whole bld	2	-	-	2
Cardinal Health SP Brand	5	-	-	5
Cardinal Health SP Brand - waived	6	-	-	6
Fisher HealthCare Sure-Vue	16	-	-	16
Genzyme OSOM	4	-	-	4
Genzyme OSOM (waived)	6	-	-	6
Henry Schein OneStep+ - waived	2	-	-	2
Immunostics Inc.	1	-	-	1
Instant Technologies i Screen-WB	3	-	-	3

**Infectious Mononucleosis (cont'd)**

<b><u>Method</u></b>	<b>Specimen IM-14</b>		<b>Specimen IM-15</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
Inverness ClearviewMono-plusII	5	-	-	5
Inverness Signify Mono Test	5	-	-	5
LifeSign UniStep Mono	2	-	-	2
Mainline Confirms	2	-	-	2
McKesson Medi-Lab Performance - waived	9	-	-	9
Meridian ImmunoCard STAT!	1	-	-	1
Polymedco Poly stat	11	-	1	10
Polymedco Poly stat - waived	4	-	-	4
Quidel QuickVue+	56	-	-	56
Quidel QuickVue+ - waived	9	-	-	9
Seradyn	27	1	1	27
Seradyn Color Q (whole blood)	1	-	-	1
Wampole ColorCard	9	-	-	9
Wampole Mono-Latex	2	-	-	2
Wampole Mono-Plus II	12	1	1	12
Wampole Mono-Plus II (whole blood)	4	-	-	4
Wampole Mono-Test	2	-	-	2
Wyntek Diagnostics Signify	1	-	-	1

**Rheumatoid Factor—Qualitative**

<b><u>Method</u></b>	<b>Specimen RF-11</b>		<b>Specimen RF-12</b>		<b>Specimen RF-13</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	109	-	-	109	109	-
ASI	6	-	-	6	6	-
Beckman Synchron	2	-	-	2	2	-
Becton Dickinson	1	-	-	1	1	-
Behring RapiTex - Plate method	3	-	-	3	3	-
Biokit Rheumajet	5	-	-	5	5	-
BMH 902, 911, 912, 914, 917	1	-	-	1	1	-
Diamedix	2	-	-	2	2	-
Fisher HealthCare Sure-View	9	-	-	9	9	-
Immunostics Inc.	2	-	-	2	2	-
J&S Medical Assoc. Accutex	2	-	-	2	2	-
Pulse Scientific	1	-	-	1	1	-
Roche Integra	1	-	-	1	1	-
Seradyn	47	-	-	47	47	-
Stanbio	2	-	-	2	2	-
Sterling Diagnostics, Inc.	3	-	-	3	3	-
Wampole ColorCard	1	-	-	1	1	-
Wampole Rheumatex	5	-	-	5	5	-
Wampole Rheumaton	12	-	-	12	12	-

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

<b><u>Method</u></b>	<b>Specimen RF-14</b>		<b>Specimen RF-15</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
ALL METHODS	-	109	1	108
ASI	-	6	-	6
Beckman Synchron	-	2	-	2
Becton Dickinson	-	1	-	1
Behring RapiTex - Plate method	-	3	-	3
Biokit Rheumajet	-	5	-	5
BMH 902, 911, 912, 914, 917	-	1	-	1
Diamedix	-	2	-	2
Fisher HealthCare Sure-View	-	9	1	8
Immunostics Inc.	-	2	-	2
J&S Medical Assoc. Accutex	-	2	-	2
Pulse Scientific	-	1	-	1
Roche Integra	-	1	-	1
Seradyn	-	47	-	47
Stanbio	-	2	-	2
Sterling Diagnostics, Inc.	-	3	-	3
Wampole ColorCard	-	1	-	1
Wampole Rheumatex	-	5	-	5
Wampole Rheumaton	-	12	-	12

**Rheumatoid Factor—Quantitative (Titer)**

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

<b><u>Specimen/Method</u></b>	<b><u>2/</u></b>	<b><u>8/</u></b>	<b><u>16/</u></b>	<b><u>32/</u></b>	<b><u>64/</u></b>	<b><u>128/</u></b>	<b><u>256/</u></b>	<b><u>512/</u></b>	<b><u>1024/</u></b>	<b><u>2048/</u></b>	<b><u>&gt;2560</u></b>
	<b><u>4</u></b>	<b><u>10</u></b>	<b><u>20</u></b>	<b><u>40</u></b>	<b><u>80</u></b>	<b><u>160</u></b>	<b><u>320</u></b>	<b><u>640</u></b>	<b><u>1280</u></b>	<b><u>2560</u></b>	
<b>Specimen RF-12</b>											
ALL METHODS	6	12	4	2	4	-	-	-	-	-	-
ASI	-	1	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	1	2	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	1	2	-	1	1	-	-	-	-	-	-
Seradyn	4	5	2	-	2	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	2	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

### Rheumatoid Factor—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>2/4</u>	<u>8/10</u>	<u>16/20</u>	<u>32/40</u>	<u>64/80</u>	<u>128/160</u>	<u>256/320</u>	<u>512/640</u>	<u>1024/1280</u>	<u>2048/2560</u>	<u>&gt;2560</u>
<b>Specimen RF-14</b>											
ALL METHODS	1	6	14	2	1	3	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	-	3	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	-	2	-	1	1	-	-	-	-	-
Seradyn	-	5	6	-	-	1	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	1	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	1	1	-	-	-	-	-	-	-

<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-15</b>											
ALL METHODS	8	11	2	3	2	1	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	1	2	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	1	-	1	1	-	-	-	-	-	-
Seradyn	4	7	-	-	-	1	-	-	-	-	-
Sterling Diagnostics, Inc.	1	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>
<b>Specimen RF-11</b>							
All Method	16	9.9	8.6	87.1	9	0	20
Beckman Synchron	5	20.0	0.0	0.0	20	20	20
<b>Specimen RF-12</b>							
All Methods	15	81.9	18.7	22.9	76	55	112
Beckman Synchron	5	102.4	5.9	5.8	100	98	112
<b>Specimen RF-13</b>							
All Methods	16	10.2	8.3	81.8	9	0	20
Beckman Synchron	5	20.0	0.0	0.0	20	20	20

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen RF-14</b>							
All Methods	15	172.1	51.1	29.7	159	115	292
Beckman Synchron	5	212.4	12.3	5.8	211	203	233

**Specimen RF-15**

All Methods	15	81.9	18.1	22.1	75	55	107
Beckman Synchron	5	101.6	3.8	3.8	102	97	107

**Anti-Streptolysin O (ASO)—Qualitative**

<u>Method</u>	<u>Specimen AS-11</u>		<u>Specimen AS-12</u>		<u>Specimen AS-13</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	4	-	2	2	4	-
Behring RapiTex	1	-	-	1	1	-
BMH 902, 911, 912, 914, 917	1	-	1	-	1	-
Fisher HealthCare Sure-View	1	-	1	-	1	-
Immunostics Inc.	1	-	-	1	1	-

<u>Method</u>	<u>Specimen AS-14</u>		<u>Specimen AS-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	1	3	1	3
Behring RapiTex	-	1	-	1
BMH 902, 911, 912, 914, 917	1	-	1	-
Fisher HealthCare Sure-View	-	1	-	1
Immunostics Inc.	-	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>&gt;100</u>	<u>100-200</u>
<b>Specimen AS-12</b>											
ALL METHODS	1	-	-	-	-	-	-	-	-	-	-
BMH 902, 911, 912, 914, 917	1	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	-
<b>Specimen AS-14</b>											
ALL METHODS	1	-	-	-	-	1	-	-	-	-	-
BMH 902, 911, 912, 914, 917	1	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-	-
<b>Specimen AS-15</b>											
ALL METHODS	1	-	-	1	-	-	-	-	-	-	-
BMH 902, 911, 912, 914, 917	1	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	-	1	-	-	-	-	-	-	-

## Complement C3 (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen COM-11</b>							
All Methods	12	264.6	20.1	7.6	265	228	299
DiaSorin (INCSTAR)	5	259.8	7.7	2.9	261	249	270
<b>Specimen COM-12</b>							
All Methods	12	101.3	4.6	4.6	100	95	109
DiaSorin (INCSTAR)	5	101.0	5.0	5.0	100	96	109
<b>Specimen COM-13</b>							
All Methods	12	167.8	8.7	5.2	167	151	181
DiaSorin (INCSTAR)	5	164.2	1.8	1.1	164	162	167
<b>Specimen COM-14</b>							
All Methods	12	128.7	6.8	5.3	128	118	140
DiaSorin (INCSTAR)	5	125.2	4.1	3.3	126	118	128
<b>Specimen COM-15</b>							
All Methods	12	195.3	11.8	6.1	197	178	210
DiaSorin (INCSTAR)	5	195.6	12.4	6.3	196	180	210

**Complement C4 (mg/dL)**

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Low Value</u></b>	<b><u>High Value</u></b>
<b>Specimen COM-11</b>							
All Methods	12	41.8	2.6	6.3	42	38	46
DiaSorin (INCSTAR)	5	42.0	3.4	8.1	43	38	46
<b>Specimen COM-12</b>							
All Methods	12	16.7	1.2	7.4	17	15	19
DiaSorin (INCSTAR)	5	16.8	1.1	6.5	17	15	18
<b>Specimen COM-13</b>							
All Methods	12	28.5	1.7	6.1	29	26	31
DiaSorin (INCSTAR)	5	29.4	1.9	6.6	30	26	31
<b>Specimen COM-14</b>							
All Methods	12	22.2	2.1	9.4	23	20	25
DiaSorin (INCSTAR)	5	23.6	2.1	8.8	24	20	25
<b>Specimen COM-15</b>							
All Methods	12	30.9	3.1	10.1	32	25	35
DiaSorin (INCSTAR)	5	30.0	4.2	13.9	32	25	34

**Antinuclear Antibody (ANA)—Qualitative Latex Methods**

<u>Method</u>	Specimen AN-11		Specimen AN-12		Specimen AN-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	9	-	9	-	-	9
Diagnostic Technology	7	-	7	-	-	7
Stanbio	1	-	1	-	-	1
Wampole	1	-	1	-	-	1

<u>Method</u>	Specimen AN-14		Specimen AN-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	9	9	-
Diagnostic Technology	-	7	7	-
Stanbio	-	1	1	-
Wampole	-	1	1	-

**Antinuclear Antibody (ANA)—Qualitative IFA/ELISA Methods**

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	16	3	13	16	-
GenBio ImmunoDOT	-	1	-	1	1	-
Immuno Concepts	-	6	1	5	6	-
INOVA Diagnostics	-	2	-	2	2	-
Kallestad	-	2	1	1	2	-
Seradyn	-	1	1	-	1	-
Zeus	-	1	-	1	1	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	16	16	-
GenBio ImmunoDOT	-	1	1	-
Immuno Concepts	-	6	6	-
INOVA Diagnostics	-	2	2	-
Kallestad	-	2	2	-
Seradyn	-	1	1	-
Zeus	-	1	1	-

## Antinuclear Antibody (ANA)—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>≥640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
<b>Specimen AE-11</b>											
ALL METHODS	-	-	1	1	2	3	-	-	-	-	-
Immuno Concepts	-	-	1	-	1	3	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	-	-	-	-	-	-
Kallestad	-	-	-	1	-	-	-	-	-	-	-
<b>Specimen AE-12</b>											
ALL METHODS	-	-	1	3	2	-	-	-	-	-	-
Immuno Concepts	-	-	1	1	2	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	1	-	-	-	-	-	-	-
Kallestad	-	-	-	1	-	-	-	-	-	-	-
<b>Specimen AE-14</b>											
ALL METHODS	-	-	-	1	1	4	1	-	-	-	-
Immuno Concepts	-	-	-	1	1	2	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	-	-	-	-
Kallestad	-	-	-	-	-	1	-	-	-	-	-

## C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-5</u>		<u>Specimen CR-6</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	1	9	10	-
ASI	-	1	1	-
Behring RapiTex	-	1	1	-
Dade Dimension/AR/ES/RxL/Xpand	-	1	1	-
Fisher HealthCare Sure-View	-	2	2	-
Immunostics Inc.	-	1	1	-
Pulse Scientific	1	-	1	-
Wampole	-	1	1	-

**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>
<b>Specimen CR-5</b>					
All Method	37	9.972	11.489	115.2	2.85
mg/dL - units					
Beckman Synchron	7	2.529	0.170	6.7	2.60
Dade Dimension/AR/ES/RxL/Xpand	5	2.940	0.230	7.8	2.90
Roche Integra	4	-	-	-	2.66
All Immunology Methods	22	2.667	0.279	10.5	2.60
mg/L - units					
Roche Integra	3	-	-	-	24.79
All Immunology Methods	10	26.824	3.086	11.5	26.75
<b>Specimen CR-6</b>					
All Method	33	0.286	0.246	86.3	0.20
mg/dL - units					
Beckman Synchron	7	0.314	0.090	28.6	0.30
Dade Dimension/AR/ES/RxL/Xpand	5	0.200	0.000	0.0	0.20
Roche Integra	4	-	-	-	0.10
All Immunology Methods	22	0.194	0.144	74.2	0.20
mg/L - units					
Roche Integra	3	-	-	-	0.70
All Immunology Methods	10	1.380	1.406	101.9	0.72

**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>
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**Specimen HCR-5**

All Method	72	0.555	0.360	64.9	0.65
mg/dL - units					
Alfa Wassermann hsCRP	3	-	-	-	0.09
Dade Dimension High Sensi CRP	7	0.084	0.032	37.4	0.09
DPC Immulite/1000	4	-	-	-	0.09
Other High Sensi. CRP method	3	-	-	-	0.06
All Immunology Methods	21	0.082	0.022	26.9	0.09
mg/L - units					
DPC Immulite/1000	3	-	-	-	0.80
Kamiya Biomedical hs-CRP	3	-	-	-	0.69
Other High Sensi. CRP method	7	0.716	0.133	18.6	0.79
Pointe Scientific CRP (HS)	4	-	-	-	0.40
Polymedco Full Range CRP	4	-	-	-	0.70
Polymedco Ultra CRP	4	-	-	-	0.82
Roche Cobas HS CRP	3	-	-	-	0.60
Roche Integra hsCRP	4	-	-	-	0.70
SDI Biomed, Inc.	4	-	-	-	1.00
All Immunology Methods	45	0.749	0.177	23.6	0.76

**Specimen HCR-6**

All Method	72	8.840	5.115	57.9	11.20
mg/dL - units					
Alfa Wassermann hsCRP	-	-	-	-	-
Dade Dimension High Sensi CRP	7	1.399	0.118	8.4	1.38
DPC Immulite/1000	4	-	-	-	1.31
Other High Sensi. CRP method	3	-	-	-	1.18
All Immunology Methods	21	1.301	0.202	15.5	1.31
mg/L - units					
DPC Immulite/1000	3	-	-	-	13.30
Kamiya Biomedical hs-CRP	3	-	-	-	12.46
Other High Sensi. CRP method	7	12.094	1.815	15.0	12.55
Pointe Scientific CRP (HS)	4	-	-	-	13.40
Polymedco Full Range CRP	4	-	-	-	11.70
Polymedco Ultra CRP	4	-	-	-	11.00
Roche Cobas HS CRP	3	-	-	-	13.59
Roche Integra hsCRP	4	-	-	-	12.30
SDI Biomed, Inc.	4	-	-	-	13.10
All Immunology Methods	48	11.912	1.845	15.5	12.30

**Rubella—Qualitative**

<u>Method</u>	<b>Specimen RU-11</b>		<b>Specimen RU-12</b>		<b>Specimen RU-13</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	9	9	-	9	-
Abbott AxSYM	-	1	1	-	1	-
Bayer ADVIA Centaur	-	1	1	-	1	-
Beckman ACCESS	-	2	2	-	2	-
bioMerieux Vitek, Mini Vidas	-	2	2	-	2	-
Seradyn	-	2	2	-	2	-
Wampole Rubella - Plus	-	1	1	-	1	-
	<b>Specimen RU-14</b>		<b>Specimen RU-15</b>			
ALL METHODS	-	9	-	9		
Abbott AxSYM	-	1	-	1		
Bayer ADVIA Centaur	-	1	-	1		
Beckman ACCESS	-	2	-	2		
bioMerieux Vitek, Mini Vidas	-	2	-	2		
Seradyn	-	2	-	2		
Wampole Rubella - Plus	-	1	-	1		

**Rubella—Quantitative (IU/mL)**

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
<b>Specimen RU-11</b>					
All Methods	5	44.98	35.06	78.0	40.7
<b>Specimen RU-12</b>					
All Methods	5	2.06	4.44	215.5	0.1
<b>Specimen RU-13</b>					
All Methods	5	2.06	4.44	215.5	0.1
<b>Specimen RU-14</b>					
All Methods	5	145.40	127.66	87.8	123.0
<b>Specimen RU-15</b>					
All Methods	5	17.70	10.87	61.4	19.3

**Total IgE—Quantitative (U/mL)**

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Low Value</u></b>	<b><u>High Value</u></b>
<b>Specimen AL-11</b>							
All Method	12	154.6	24.8	16.1	153	125	223
Phadia Unicap 100	5	153.0	5.3	3.5	153	146	161
<b>Specimen AL-12</b>							
All Method	12	317.1	38.6	12.2	327	231	362
Phadia Unicap 100	5	334.0	17.1	5.1	335	310	356
<b>Specimen AL-13</b>							
All Method	12	69.5	8.7	12.5	69	58	88
Phadia Unicap 100	5	68.6	3.2	4.7	69	65	73
<b>Specimen AL-14</b>							
All Method	12	70.8	5.3	7.4	69	64	80
Phadia Unicap 100	5	68.8	2.7	3.9	69	66	73
<b>Specimen AL-15</b>							
All Method	12	28.0	3.7	13.1	29	20	32
Phadia Unicap 100	5	30.6	1.1	3.7	31	29	32

**Allergen Specific IgE Antibodies**

**Specimen AL-11**

	House Dust Mite Allergen							Egg White 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	-	-	-	14	1	-	-	-	-	7	1	1	-	-
Hycor EIA	-	-	-	2	-	-	-	-	-	-	1	-	-	-
MAST Immunosystems (LU)	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (% ref)	-	-	-	6	-	-	-	-	-	3	-	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	2	1	-	-	-	-	2	-	-	-	-
	<b>Peanut (Arachis hyogaea) Allergen</b>							<b>Bermuda Grass Allergen</b>						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	-	-	7	3	-	-	-	1	12	1	-	-	-
Hycor EIA	-	-	-	1	1	-	-	-	-	2	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	1	-	-	-	-
Phadia UniCap 100 (% ref)	-	-	-	4	-	-	-	-	-	4	1	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	1	1	-	-	-	-	3	-	-	-	-
	<b>Cow's Milk Allergen</b>							<b>Meadow, Kentucky Blue, June Grass Allergen</b>						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	1	10	-	1	-	-	-	-	-	5	2	-	-
Hycor EIA	-	-	2	-	-	-	-	-	-	-	-	1	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Phadia UniCap 100 (% ref)	-	1	4	-	-	-	-	-	-	-	3	-	-	-
Phadia UniCap 100 (KU/L)	-	-	2	-	-	-	-	-	-	-	1	1	-	-
	<b>Cat Epithelium Allergen</b>													
	<i>CLASS RESULT</i>													
	0	1	2	3	4	5	6							
ALL METHODS	-	-	5	8	2	-	-							
Hycor EIA	-	-	-	2	-	-	-							
MAST Immunosystems (LU)	-	-	-	-	1	-	-							
Phadia UniCap 100 (% ref)	-	-	3	3	-	-	-							
Phadia UniCap 100 (KU/L)	-	-	1	2	-	-	-							

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

**Specimen AL-12**

	Timothy Grass Allergen							White Oak Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	-	-	1	2	5	1	-	-	1	11	1	-	-
Hycor EIA	-	-	-	-	-	-	1	-	-	-	2	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (% ref)	-	-	-	-	-	4	-	-	-	-	6	-	-	-
Phadia UniCap 100 (KU/L)	-	-	-	-	-	1	-	-	-	1	2	-	-	-
	Cow's Milk Allergen							House Dust Mite Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	-	11	-	1	-	-	-	-	2	8	2	-	-
Hycor EIA	-	-	2	-	-	-	-	-	-	-	1	1	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (% ref)	-	-	5	-	-	-	-	-	-	1	4	-	-	-
Phadia UniCap 100 (KU/L)	-	-	2	-	-	-	-	-	-	-	1	-	-	-
	Bermuda Grass Allergen							Peanut (Arachis hyogaea) Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
ALL METHODS	-	-	6	8	-	-	-	-	-	2	7	1	-	-
Hycor EIA	-	-	-	2	-	-	-	-	-	-	2	-	-	-
MAST Immunosystems (LU)	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Phadia UniCap 100 (% ref)	-	-	3	2	-	-	-	-	-	2	2	-	-	-
Phadia UniCap 100 (KU/L)	-	-	1	2	-	-	-	-	-	-	2	-	-	-
	English Plantain Allergen													
	CLASS RESULT													
	0	1	2	3	4	5	6							
ALL METHODS	-	1	7	1	-	-	-							
Hycor EIA	-	-	2	-	-	-	-							
MAST Immunosystems (LU)	-	-	-	1	-	-	-							
Phadia UniCap 100 (% ref)	-	-	3	-	-	-	-							
Phadia UniCap 100 (KU/L)	-	-	1	-	-	-	-							

**IgA (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen IP-11</b>							
All Methods	9	371.8	27.1	7.3	376	332	415
<b>Specimen IP-12</b>							
All Methods	8	150.5	8.1	5.4	151	138	167
<b>Specimen IP-13</b>							
All Methods	10	248.0	17.6	7.1	255	221	271
<b>Specimen IP-14</b>							
All Methods	10	192.8	12.9	6.7	194	175	212
<b>Specimen IP-15</b>							
All Methods	9	289.3	18.4	6.4	286	264	318

**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-11</b>							
All Methods	9	1861.7	85.0	4.6	1875	1731	2002
<b>Specimen IP-12</b>							
All Methods	9	738.8	27.7	3.7	743	691	773
<b>Specimen IP-13</b>							
All Methods	9	1239.4	45.4	3.7	1238	1154	1287
<b>Specimen IP-14</b>							
All Methods	8	959.0	20.5	2.1	956	926	992
<b>Specimen IP-15</b>							
All Methods	8	1433.1	35.1	2.5	1446	1369	1468

**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-11</b>							
All Methods	10	159.8	7.5	4.7	159	152	178
<b>Specimen IP-12</b>							
All Methods	10	62.5	4.1	6.5	61	58	68
<b>Specimen IP-13</b>							
All Methods	10	102.9	6.9	6.7	103	88	115
<b>Specimen IP-14</b>							
All Methods	10	79.1	5.4	6.8	79	72	89
<b>Specimen IP-15</b>							
All Methods	10	118.0	10.2	8.7	119	96	136

**Syphilis Serology—Qualitative: RPR**

<u>Method</u>	<u>Specimen SY-11</u>		<u>Specimen SY-12</u>		<u>Specimen SY-13</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	54	-	51	3	51	3
ASI	16	-	15	1	15	1
Becton Dickinson	24	-	24	-	24	-
Biokit	4	-	3	1	2	2
Fisher HealthCare Sure-Vue	2	-	1	1	2	-
J&S Medical Assoc. Accutex	1	-	1	-	1	-
New Horizons	1	-	1	-	1	-
Stanbio	3	-	3	-	3	-
Wampole Impact RPR	2	-	2	-	2	-
<b>Specimen SY-14</b>						
ALL METHODS	1	53	1	53		
ASI	-	16	-	16		
Becton Dickinson	-	24	-	24		
Biokit	-	4	-	4		
Fisher HealthCare Sure-Vue	-	2	-	2		
J&S Medical Assoc. Accutex	-	1	-	1		
New Horizons	-	1	-	1		
Stanbio	-	3	-	3		
Wampole Impact RPR	-	2	-	2		
<b>Specimen SY-15</b>						
ALL METHODS	1	53	1	53		
ASI	-	16	-	16		
Becton Dickinson	-	24	-	24		
Biokit	-	4	-	4		
Fisher HealthCare Sure-Vue	-	2	-	2		
J&S Medical Assoc. Accutex	-	1	-	1		
New Horizons	-	1	-	1		
Stanbio	-	3	-	3		
Wampole Impact RPR	-	2	-	2		

**Syphilis Serology—Quantitative: RPR (Titer)**

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>
<b>Specimen SY-11</b>							
ALL METHODS	-	-	12	4	1	-	-
ASI	-	-	4	4	1	-	-
Becton Dickinson	-	-	8	-	-	-	-
New Horizons	-	-	-	-	-	-	-
<b>Specimen SY-12</b>							
ALL METHODS	4	11	-	1	-	-	-
ASI	3	4	-	1	-	-	-
Becton Dickinson	1	7	-	-	-	-	-
New Horizons	-	-	-	-	-	-	-
<b>Specimen SY-13</b>							
ALL METHODS	4	12	1	-	-	-	-
ASI	3	5	1	-	-	-	-
Becton Dickinson	1	7	-	-	-	-	-
New Horizons	-	-	-	-	-	-	-

**H. pylori Antibody Detection**

<u>Method</u>	<u>Specimen HP-5</u>		<u>Specimen HP-6</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	187	5	1	191
Abbott FlexPack	2	-	-	2
Abbott Signify	1	-	-	1
Applied Biotech SureStep	1	-	-	1
BD LINK 2	5	-	1	4
Beckman Coulter FlexSure	21	-	-	21
bioMerieux Vitek, Mini Vidas	1	-	-	1
Cardinal Health SP Brand	6	-	-	6
DPC Immulite/1000	1	-	-	1
Fisher HealthCare Sure-Vue	8	-	-	8
Henry Schein OneStep+ - waived	1	-	-	1
Instant Technologies i Screen	11	-	-	11
LifeSign Status	2	2	-	4
Meridian ImmunoCard	1	-	-	1
Polymedco Poly stat	26	-	-	26
Quidel QuickVue	81	2	-	83
Wampole Clearview	13	-	-	13

## Lyme Disease Serology

<u>Method</u>	<b>Specimen LY-5</b>		<b>Specimen LY-6</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	-	9	9	-
bioMerieux Vitek, Mini Vidas	-	2	2	-
Immunostics Inc.	-	1	1	-
Remel Rapidot	-	1	1	-
Wampole Impact	-	1	1	-
Wampole PreVue	-	3	3	-
Zeus	-	1	1	-

## Mycoplasma Antibody

<u>Method</u>	<b>Specimen MY-5</b>		<b>Specimen MY-6</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	1	1	-

## Viral Markers – Anti-HBc

<u>Method</u>	<b>Specimen VM-11</b>		<b>Specimen VM-12</b>		<b>Specimen VM-13</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	-	1	1	2	-

  

<u>Method</u>	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	1	2	-

The vendor assay for specimens VM-11 through VM-15 is: Negative, Positive, Negative, Positive and Negative, respectively.

## Viral Markers – Anti-HIV

<u>Method</u>	<b>Specimen VM-11</b>		<b>Specimen VM-12</b>		<b>Specimen VM-13</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	5	-	5	-	-	5
Abbott Quantum	1	-	1	-	-	1
Bio-Rad Evolis	1	-	1	-	-	1
Orasure OraQuick Advance Rapid HIV-1/2	2	-	2	-	-	2

  

<u>Method</u>	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	5	-	5	-
Abbott Quantum	1	-	1	-
Bio-Rad Evolis	1	-	1	-
Orasure OraQuick Advance Rapid HIV-1/2	2	-	2	-

### Viral Markers – HAV

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<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-14		Specimen VM-15			
All Methods	1	1	2	-		

Specimen VM-11: Total is non-reactive.

Specimen VM-12: Total and IgM are reactive

Specimen VM-13: Total is non-reactive.

Specimen VM-14: Total reactive and IgM is non-reactive.

Specimen VM-15: Total is non-reactive.

### Viral Markers – HBeAg

The vendor assay for specimens VM-11 through VM-15 is: Negative, Negative, Negative, Negative and Negative, respectively.

### Viral Markers – HBsAb

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<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-14		Specimen VM-15			
All Methods	1	1	2	-		

The vendor assay for specimens VM-11 through VM-15 is: Negative, Negative, Negative, Positive and Negative, respectively.

### Viral Markers – Anti-HBsAg

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
ALL METHODS	4	-	-	4	4	-
Bayer ADVIA Centaur	1	-	-	1	1	-
Bio-Rad Evolis	1	-	-	1	1	-
DPC Immulite/1000	1	-	-	1	1	-
Roche Elecsys 1010/2010	1	-	-	1	1	-
	Specimen VM-14		Specimen VM-15			
ALL METHODS	4	-	4	-		
Bayer ADVIA Centaur	1	-	1	-		
Bio-Rad Evolis	1	-	1	-		
DPC Immulite/1000	1	-	1	-		
Roche Elecsys 1010/2010	1	-	1	-		

**Viral Markers – HCV**

<b><u>Method</u></b>	<b>Specimen VM-11</b>		<b>Specimen VM-12</b>		<b>Specimen VM-13</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	3	-	3	-	3	-
	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>			
All Methods	-	3	3	-		

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