

**MEDICAL LABORATORY**

**EVALUATION**

**PARTICIPANT SUMMARY**

**2 • 0 • 0 • 5**



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

Immunology  
MLE – M3

# Table of Contents

<b>2005 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>8</b>
Qualitative .....	8
Quantitative .....	8
<b>Complement C3</b> .....	<b>9</b>
<b>Complement C4</b> .....	<b>9</b>
<b>Antinuclear Antibody (ANA [AN-11 – AN-15])</b> .....	<b>10</b>
Qualitative .....	10
<b>Antinuclear Antibody (ANA [AE-11 – AE-15])</b> .....	<b>10</b>
Qualitative .....	10
Quantitative (Titer).....	11
<b>C-Reactive Protein, Regular</b> .....	<b>11</b>
Qualitative .....	11
Quantitative .....	12
<b>C-Reactive Protein, High Sensitivity</b> .....	<b>13</b>
Quantitative .....	13
<b>Rubella</b> .....	<b>14</b>
Qualitative .....	14
Quantitative .....	14
<b>Total IgE</b> .....	<b>15</b>
Quantitative .....	15
<b>Allergen Specific IgE Antibodies</b> .....	<b>16</b>
<b>IgA</b> .....	<b>18</b>
<b>IgG</b> .....	<b>18</b>
<b>IgM</b> .....	<b>19</b>
<b>Syphilis Serology</b> .....	<b>19</b>
Qualitative: RPR .....	19
Quantitative: RPR (Titer).....	20
<b>H. pylori Antibody Detection</b> .....	<b>20</b>
<b>Lyme Disease Serology</b> .....	<b>21</b>
<b>Mycoplasma Antibody</b> .....	<b>21</b>
<b>Viral Markers</b> .....	<b>21</b>
Anti-HBc.....	21
Anti-HIV .....	21
HAV.....	22
HBeAg.....	22
HBsAb .....	22
HBsAg.....	22
HCV.....	23
<b>International Labs</b> .....	<b>24</b>

## 2005 Evaluation Criteria

The evaluation criteria used in the 2005 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 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	Peer Group Mean $\pm$ 3 SD
Complement C4	Peer Group Mean $\pm$ 3 SD
Antinuclear Antibody (ANA) Titer	Not Evaluated
C-Reactive Protein	Peer Group Mean $\pm$ 3 SD
Rubella (International Units)	Not Evaluated
Total IgE	Peer Group Mean $\pm$ 3 SD
Total IgA	Peer Group Mean $\pm$ 3 SD
Total IgG	Peer Group Mean $\pm$ 25%
Total IgM	Peer Group Mean $\pm$ 3 SD



**Infectious Mononucleosis (cont'd)**

<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>
Mainline Confirms	1	-	-	1
McKesson Medi-Lab Performance	6	-	-	6
Meridian Monospot (Latex)	1	-	-	1
Polymedco Poly stat	12	-	-	12
Polymedco Poly stat – waived	6	-	-	6
Quidel Quick Vue+	60	-	-	60
Quidel Quick Vue+ - waived	6	-	-	6
Remel RIM A.R.C.	1	-	-	1
Seradyn	29	-	-	29
Seradyn Color Q – (whole blood)	1	-	-	1
Wampole ColorCard	11	-	-	11
Wampole Mono-Latex	2	-	-	2
Wampole Mono-Plus	13	-	-	13
Wampole Mono-Plus (whole blood)	10	-	-	10
Wampole Mono-Test	5	-	1	4

**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	-	119	-	119	119	-
ASI	-	8	-	8	8	-
Beckman Synchron	-	1	-	1	1	-
Beckman Synchron LX/Pro / DxC	-	1	-	1	1	-
Becton Dickinson	-	1	-	1	1	-
Behring RapiTex-Plate method	-	4	-	4	4	-
Biokit Rheumagen	-	1	-	1	1	-
Biokit Rheumajet	-	4	-	4	4	-
BMH 717	-	1	-	1	1	-
Fisher HealthCare Sure-Vue	-	9	-	9	9	-
Immunostics Inc.	-	3	-	3	3	-
J&S Medical Assoc. Accutex	-	2	-	2	2	-
Murex Latex Test	-	1	-	1	1	-
Pulse Scientific	-	1	-	1	1	-
Rocha Integra	-	1	-	1	1	-
Seradyn	-	53	-	53	53	-
Sterling Diagnostics, Inc.	-	3	-	3	3	-
Wampole ColorCard	-	2	-	2	2	-
Wampole Rheumatex	-	6	-	6	6	-
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	1	118	118	1
ASI	-	8	8	-
Beckman Synchron	-	1	1	-
Beckman Synchron LX/Pro / DxC	-	1	1	-
Becton Dickinson	-	1	1	-
Behring RapiTex-Plate method	-	4	4	-
Biokit Rheumagen	-	1	1	-
Biokit Rheumajet	-	4	4	-
BMH 717	-	1	1	-
Fisher HealthCare Sure-View	-	9	9	-
Immunostics Inc.	-	3	3	-
J&S Medical Assoc. Accutex	-	2	2	-
Murex Latex Test	-	1	1	-
Pulse Scientific	-	1	1	-
Roche Integra	-	1	1	-
Seradyn	1	52	52	1
Sterling Diagnostics, Inc.	-	3	3	-
Wampole ColorCard	-	2	2	-
Wampole Rheumatex	-	6	6	-
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>2/4</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-11</b>											
All Methods	5	15	8	2	1	1	-	-	-	-	-
ASI	-	2	-	-	-	-	-	-	-	-	-
Beckman Synchron LX/Pro / DxC	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumagen	-	-	-	-	-	1	-	-	-	-	-
Biokit Rheumajet	-	2	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	1	3	1	-	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Seradyn	3	6	4	1	-	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	1	-	-	-	-	-	-	-	-
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>
------------------------	------------	-------------	--------------	--------------	--------------	----------------	----------------	----------------	------------------	------------------	-----------------

#### Specimen RF-12

All Methods	5	16	6	3	2	-	-	-	-	-	-
ASI	-	1	1	-	-	-	-	-	-	-	-
Beckman Synchron LX/Pro / DxC	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumagen	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	2	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	4	-	-	-	-	-	-	-	-	-
Murex Latex Test	-	1	-	-	-	-	-	-	-	-	-
Seradyn	4	6	2	1	1	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	1	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

#### Specimen RF-14

All Methods	6	13	8	3	2	-	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-	-	-
Beckman Synchron LX/Pro / DxC	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumagen	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	-	2	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	3	-	-	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Seradyn	3	5	5	-	1	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	2	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

### Rheumatoid Factor—Quantitative (IU)

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
------------------------	-------------	-------------	-----------	-----------	---------------	------------------	-------------------

#### Specimen RF-11

All Methods	16	134.1	75.0	55.9	108	35	240
Beckman Synchron	6	202.5	41.5	20.5	225	136	236

#### Specimen RF-12

All Methods	16	134.8	75.3	55.9	106	36	244
Beckman Synchron	6	201.5	44.1	21.9	227	131	232

#### Specimen RF-13

All Methods	4	-	-	-	3	2	4
-------------	---	---	---	---	---	---	---

**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	16	134.9	75.6	56.0	104	36	254
Beckman Synchron	6	199.8	44.2	22.1	223	127	234

**Specimen RF-15**

All Methods	4	-	-	-	4	2	4
-------------	---	---	---	---	---	---	---

**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	3	-	-	3	-	3
Behring RapiTex	2	-	-	2	-	2
Fisher HealthCare Sure-Vue	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	3	-	-	3
Behring RapiTex	2	-	-	2
Fisher HealthCare Sure-Vue	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	-	-	-	-	-	-	-	-	-	-	2
Behring RapiTex	-	-	-	-	-	-	-	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	1
<b>Specimen AS-13</b>											
All Methods	-	-	-	-	-	-	-	-	-	-	2
Behring RapiTex	-	-	-	-	-	-	-	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	-	1
<b>Specimen AS-15</b>											
All Methods	-	-	-	-	-	-	-	-	-	-	2
Behring RapiTex	-	-	-	-	-	-	-	-	-	-	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	11	142.1	11.4	8.0	142	117	157
DiaSorin (INCSTAR)	4	-	-	-	143	117	151
<b>Specimen COM-12</b>							
All Methods	11	114.0	8.2	7.2	113	99	125
DiaSorin (INCSTAR)	4	-	-	-	110	99	122
<b>Specimen COM-13</b>							
All Methods	11	89.4	6.0	6.7	90	75	97
DiaSorin (INCSTAR)	4	-	-	-	86	75	93
<b>Specimen COM-14</b>							
All Methods	11	130.3	10.2	7.8	129	109	141
DiaSorin (INCSTAR)	4	-	-	-	127	109	141
<b>Specimen COM-15</b>							
All Methods	11	101.6	8.6	8.5	103	88	116
DiaSorin (INCSTAR)	4	-	-	-	95	88	108

**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-11</b>							
All Methods	11	24.2	3.9	16.2	24	14	28
DiaSorin (INCSTAR)	4	-	-	-	24	14	27
<b>Specimen COM-12</b>							
All Methods	11	20.3	2.0	9.9	20	17	23
DiaSorin (INCSTAR)	4	-	-	-	20	17	22
<b>Specimen COM-13</b>							
All Methods	11	14.5	2.2	14.9	15	10	18
DiaSorin (INCSTAR)	4	-	-	-	14	10	16
<b>Specimen COM-14</b>							
All Methods	11	22.3	2.7	12.2	23	17	26
DiaSorin (INCSTAR)	4	-	-	-	22	17	25
<b>Specimen COM-15</b>							
All Methods	11	17.8	2.8	15.6	18	12	22
DiaSorin (INCSTAR)	4	-	-	-	17	12	19

## Antinuclear Antibody (ANA)—Qualitative Latex Methods

<u>Method</u>	<u>Specimen AN-11</u>		<u>Specimen AN-12</u>		<u>Specimen AN-13</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	2	7	1	5	3
Alpha Scientific Medical, Inc.	-	-	1	-	1	-
ASI	-	-	2	-	2	-
Diagnostic Technology	-	2	2	-	-	2
Pulse Scientific	1	-	1	-	1	-
Vernistics	-	-	1	-	-	1

<u>Method</u>	<u>Specimen AN-14</u>		<u>Specimen AN-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	8	-	4	3
Alpha Scientific Medical, Inc.	1	-	1	-
ASI	2	-	2	-
Diagnostic Technology	2	-	-	2
Pulse Scientific	1	-	1	-
Vernistics	1	-	-	1

The vendor assay for specimens AN-11 through AN-15 are: Positive, Negative, Positive, Negative, and Positive, respectively. Positive samples reacted with Total DNA and ssA/ssB. They were negative for ds. DNA and Rnp/sm.

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

<u>Method</u>	<u>Specimen AE-11</u>		<u>Specimen AE-12</u>		<u>Specimen AE-13</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	12	-	12	12	-
Immuno Concepts	-	6	-	6	6	-
INOVA Diagnostics	-	1	-	1	1	-
Kallestad	-	3	-	3	3	-
Seradyn	-	1	-	1	1	-

<u>Method</u>	<u>Specimen AE-14</u>		<u>Specimen AE-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	11	12	-
Immuno Concepts	1	5	6	-
INOVA Diagnostics	-	1	1	-
Kallestad	-	3	3	-
Seradyn	-	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>
------------------------	------------------	-------------------	-------------------	-------------------	---------------------	---------------------	---------------------	-------------	-----------------------	-----------------------	--------------

### Specimen AE-11

All Methods	-	-	-	1	-	3	1	-	2	-	-
Immuno Concepts	-	-	-	1	-	2	1	-	1	-	-
Kallestad	-	-	-	-	-	1	-	-	1	-	-

### Specimen AE-12

All Methods	-	-	1	1	5	-	-	-	-	-	-
Immuno Concepts	-	-	1	1	3	-	-	-	-	-	-
Kallestad	-	-	-	-	2	-	-	-	-	-	-

### Specimen AE-14

All Methods	-	-	1	1	4	-	-	-	-	-	-
Immuno Concepts	-	-	1	1	2	-	-	-	-	-	-
Kallestad	-	-	-	-	2	-	-	-	-	-	-

## 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	-	14	14	-
ASI	-	2	2	-
Behring RapiTex	-	1	1	-
Dade Dimension/AR/ES/RxL/Xpand	-	1	1	-
Fisher HealthCare Sure-View	-	2	2	-
Immunosits Inc.	-	3	3	-
Pulse Scientific	-	1	1	-
Wampole	-	3	3	-

**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 Methods mg/dL – units	37	3.055	4.494	147.1	1.40
Beckman Synchron	10	1.130	0.142	12.6	1.15
Dade Dimension/AR/ES/RxL/Xpa	6	1.433	0.103	7.2	1.40
Roche Integra	5	1.444	0.052	3.6	1.42
All Immunology Methods	29	1.333	0.201	15.1	1.40
All Methods mg/L - units					
Polymedco CRP	3	-	-	-	14.20
All Immunology Methods	6	15.845	4.133	26.1	14.21
<b>Specimen CR-6</b>					
All Methods mg/dL – units	7	0.183	0.187	102.2	0.10
Beckman Synchron	3	-	-	-	0.30
All Immunology Methods	6	0.203	0.196	96.4	0.20

**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>
<b>Specimen HCR-5</b>					
All Methods	72	8.755	5.265	60.1	11.00
mg/dL - units					
Dade Dimension High Sensi CR	8	1.395	0.090	6.5	1.38
All Immunology Methods	19	1.274	0.181	14.2	1.30
mg/L - units					
Dade Dimension High Sensi CR	3	-	-	-	13.97
Kamiya Biomedical hs-CRP	4	-	-	-	12.42
Pointe Scientific CRP (HS)	5	12.902	1.116	8.7	13.10
Polymedco Full Range CRP	5	11.234	0.778	6.9	11.00
Polymedco Ultra CRP	4	-	-	-	9.60
Roche Cobas HS CRP	6	11.852	3.378	28.5	12.99
Roche Integra hsCRP	4	-	-	-	10.88
SDI Biomed, Inc.	3	-	-	-	12.49
All Immunology Methods	45	12.296	1.461	11.9	12.70
<b>Specimen HCR-6</b>					
All Methods	68	0.558	0.294	52.8	0.66
mg/dL - units					
Dade Dimension High Sensi CR	8	0.375	0.037	9.9	0.39
All Immunology Methods	21	0.235	0.162	68.7	0.28
mg/L - units					
Dade Dimension High Sensi CR	3	-	-	-	3.74
Kamiya Biomedical hs-CRP	4	-	-	-	0.87
Pointe Scientific CRP (HS)	4	-	-	-	0.50
Polymedco Full Range CRP	5	0.680	0.045	6.6	0.70
Polymedco Ultra CRP	4	-	-	-	0.71
Roche Cobas HS CRP	6	0.735	0.101	13.8	0.69
Roche Integra hsCRP	4	-	-	-	0.92
SDI Biomed, Inc.	3	-	-	-	0.40
All Immunology Methods	44	0.731	0.177	24.2	0.71

**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	-
Abbott IMx	1	-	-	1	1	-
Beckman (Sanofi) ACCESS	1	-	-	1	1	-
Becton Dickinson	1	-	-	1	1	-
bioMerieux Vitek, Mini Vidas	2	-	-	2	2	-
Seradyn	1	-	-	1	1	-
Wampole Rubella – Plus	1	-	-	1	1	-
	<b>Specimen RU-14</b>		<b>Specimen RU-15</b>			
All Methods	9	-	-	9		
Abbott AxSYM	1	-	-	1		
Abbott IMx	1	-	-	1		
Beckman (Sanofi) ACCESS	1	-	-	1		
Becton Dickinson	1	-	-	1		
bioMerieux Vitek, Mini Vidas	2	-	-	2		
Seradyn	1	-	-	1		
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>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen RU-12</b>							
All Methods	3	-	-	-	123.8	4.1	156.5
<b>Specimen RU-14</b>							
All Methods	3	-	-	-	0.1	0.1	0.7
<b>Specimen RU-15</b>							
All Methods	3	-	-	-	106.5	4.2	128.3

**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>
<b>Specimen AL-11</b>							
All Methods	7	3975.0	1956.9	49.2	5000	2000	6825
bioMerieux Vitek, Mini Vidas	1	-	-	-	6825	6825	6825
DPC Immulite/1000	1	-	-	-	2000	2000	2000
Hycor EIA	1	-	-	-	2000	2000	2000
Pharmacia & Upjohn Unicap 100	3	-	-	-	5000	5000	5000
<b>Specimen AL-12</b>							
All Methods	10	453.6	39.3	8.7	460	401	516
bioMerieux Vitek, Mini Vidas	1	-	-	-	503	503	503
DPC Immulite/1000	1	-	-	-	426	426	426
Hycor EIA	1	-	-	-	405	405	405
Pharmacia & Upjohn Unicap 100	6	466.8	30.1	6.5	467	423	516
<b>Specimen AL-13</b>							
All Methods	10	19.6	1.2	6.0	19	18	22
bioMerieux Vitek, Mini Vidas	1	-	-	-	19	19	19
DPC Immulite/1000	1	-	-	-	19	19	19
Hycor EIA	1	-	-	-	19	19	19
Pharmacia & Upjohn Unicap 100	6	19.8	1.5	7.4	20	18	22
<b>Specimen AL-14</b>							
All Methods	9	48.0	3.4	7.1	49	42	52
bioMerieux Vitek, Mini Vidas	1	-	-	-	50	50	50
DPC Immulite/1000	1	-	-	-	51	51	51
Hycor EIA	1	-	-	-	52	52	52
Pharmacia & Upjohn Unicap 100	6	46.5	3.1	6.8	46	42	51
<b>Specimen AL-15</b>							
All Methods	9	48.7	2.7	5.5	49	45	53
bioMerieux Vitek, Mini Vidas	1	-	-	-	49	49	49
DPC Immulite/1000	1	-	-	-	53	53	53
Hycor EIA	1	-	-	-	49	49	49
Pharmacia & Upjohn Unicap 100	6	47.8	2.6	5.5	47	45	52

# Allergen Specific IgE Antibodies

## Specimen AL-11

	Cat Epithelium Allergen <i>CLASS RESULT</i>							Dust Mite Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	4	9	1	-	-	1	1	10	2	-
Hycor EIA	-	-	-	-	-	2	-	-	-	-	-	2	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	2	-	-	-	-	-	1	2	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	5	-	-	-	-	-	5	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	1	-	-	-

	Bermuda Grass Allergen <i>CLASS RESULT</i>							Perennial Rye Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	1	8	2	-	-	-	-	-	4	2
Hycor EIA	-	-	-	-	-	2	-	-	-	-	-	-	-	1
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	2	-	-	-	-	-	-	2	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	1	-	-	-	-	-	-	1
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	4	-	-	-	-	-	-	2	-

	Olive 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	-	-	-	-	1	-	-	-	-	-	-	4	8	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	-	-	2	-
MAST Immunosystems	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	-	-	-	-	-	-	1	1	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	-	-	5	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	1	-	-

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

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

**Specimen AL-12**

	<b>Meadow, Kentucky, June Grass Allergen CLASS RESULT</b>							<b>Bermuda Grass Allergen 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	5	-	-	-	-	-	4	7	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	1	1	-	-
MAST Immunosystems (LU)	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	2	-	-	-	-	-	1	1	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	2	-	-	-	-	-	-	4	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-
	<b>Dog Dander Allergen CLASS RESULT</b>							<b>Common Ragweed Allergen 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	6	2	-	-	-	-	-	-	-	3	9	-	-
Hycor EIA	-	-	1	-	-	-	-	-	-	-	-	2	-	-
MAST Immunosystems (LU)	-	-	1	-	-	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	1	-	-	-	-	-	-	-	-	1	1	-	-
Pharmacia & Upjohn UniCap 100	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	1	3	-	-	-	-	-	-	-	-	-	5	-	-
Pharmacia Unicap 100 (KU/L)	-	1	-	-	-	-	-	-	-	-	1	-	-	-
	<b>Cat Epithelium Allergen CLASS RESULT</b>							<b>Russian Thistle Allergen 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	-	-	3	8	3	-	-	-	-	-	-	3	-	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	1	2	-	-	-	-	-	-	-	2	-	-
Pharmacia & Upjohn UniCap 100	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	5	-	-	-	-	-	-	-	1	-	-
Pharmacia Unicap 100 (KU/L)	-	-	1	-	-	-	-	-	-	-	-	-	-	-
	<b>English Plantain Allergen 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	-	-	-	5	4	-	-							
Hycor EIA	-	-	-	2	-	-	-							
MAST Immunosystems (LU)	-	-	-	-	1	-	-							
Pharmacia & Upjohn CAP (% ref)	-	-	-	1	2	-	-							
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-							
Pharmacia UniCap 100 (% ref)	-	-	-	1	1	-	-							
Pharmacia 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	11	237.0	8.0	3.4	236	226	246
<b>Specimen IP-12</b>							
All Methods	10	189.2	5.4	2.8	191	177	195
<b>Specimen IP-13</b>							
All Methods	10	141.3	5.2	3.7	141	130	148
<b>Specimen IP-14</b>							
All Methods	10	213.9	7.0	3.3	216	196	220
<b>Specimen IP-15</b>							
All Methods	9	166.7	2.9	1.7	167	163	171

**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	10	1144.2	68.0	5.9	1133	1047	1240
<b>Specimen IP-12</b>							
All Methods	10	916.5	40.9	4.5	904	867	990
<b>Specimen IP-13</b>							
All Methods	10	692.1	25.6	3.7	685	673	759
<b>Specimen IP-14</b>							
All Methods	10	1046.5	50.5	4.8	1025	992	1127
<b>Specimen IP-15</b>							
All Methods	10	823.6	28.6	3.5	820	790	875

**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	98.2	5.8	5.9	99	87	107
<b>Specimen IP-12</b>							
All Methods	11	79.4	3.6	4.6	79	73	85
<b>Specimen IP-13</b>							
All Methods	11	59.7	3.8	6.4	59	54	65
<b>Specimen IP-14</b>							
All Methods	11	88.8	5.0	5.6	87	82	98
<b>Specimen IP-15</b>							
All Methods	11	70.2	4.2	5.9	71	63	77

**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	55	-	-	55	55	-
ASI	16	-	-	16	16	-
Becton Dickinson	25	-	-	25	25	-
Biokit	3	-	-	3	3	-
Fisher HealthCare Sure-Vue	5	-	-	5	5	-
J&S Medical Assoc. Accutex	1	-	-	1	1	-
New Horizons	1	-	-	1	1	-
Stanbio	1	-	-	1	1	-
Wampole Impact RPR	2	-	-	2	2	-
	<u>Specimen SY-14</u>		<u>Specimen SY-15</u>			
All Methods	-	55	54	1		
ASI	-	16	15	1		
Becton Dickinson	-	25	25	-		
Biokit	-	3	3	-		
Fisher HealthCare Sure-Vue	-	5	5	-		
J&S Medical Assoc. Accutex	-	1	1	-		
New Horizons	-	1	1	-		
Stanbio	-	1	1	-		
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	6	13	1	-	-	-	-
ASI	5	5	-	-	-	-	-
Becton Dickinson	-	7	1	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	-	-	-	-	-
Stanbio	1	-	-	-	-	-	-
<b>Specimen SY-13</b>							
All Methods	5	15	-	-	-	-	-
ASI	4	6	-	-	-	-	-
Becton Dickinson	-	8	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	-	-	-	-	-
Stanbio	1	-	-	-	-	-	-
<b>Specimen SY-15</b>							
All Methods	4	15	-	-	-	-	-
ASI	4	5	-	-	-	-	-
Becton Dickinson	-	8	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	-	-	-	-	-
Stanbio	-	1	-	-	-	-	-

## 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	205	1	4	202
Abbott FlexPack	2	-	-	2
Abbot Signify	3	-	-	3
Acon Laboratories	1	-	-	1
Applied Biotech SureStep	8	-	-	8
BD LINK 2	3	-	-	3
Beckman Coulter FlexSure	22	-	1	21
Cardinal Health SP Brand	3	-	-	3
DPC Immulite/1000	1	-	-	1
Fisher HealthCare Sure-Vue	9	-	1	8
Instant Technologies i Screen	6	-	-	6
LifeSign Status	2	-	-	2
Meridian ImmunoCard	2	-	-	2
Polymedco Poly stat	28	-	-	28
Quidel QuickVue	98	1	2	97
Wampole Clearview	10	-	-	10

## Lyme Disease Serology

<u>Method</u>	Specimen LY-5		Specimen LY-6	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	7	7	-
bioMerieux Vitek, Mini Vidas	-	1	1	-
Remel Rapidot	-	1	1	-
Wampole Impact	-	1	1	-
Wampole PreVue	-	3	3	-

## Mycoplasma Antibody

<u>Method</u>	Specimen MY-5		Specimen MY-6	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	4	-	2	2
Meridian ImmunoCard	3	-	1	2
Remel ELISA	1	-	1	-

Specimen MY-6 is an ungraded challenge due to less than 80% participant consensus.

## Viral Markers – Anti-HBc

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

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

## Viral Markers – Anti-HIV

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

**Viral Markers – HAV**

<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	1	-	1	-	1	-
	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>			
All Methods	1	-	-	1		

Specimen VM-11: Total is Positive; IgM is Negative.  
 Specimen VM-12: Total is Positive; IgM is Negative.  
 Specimen VM-13: Total is Positive; IgM is Negative.  
 Specimen VM-14: Total and IgM are Negative.  
 Specimen VM-15: Total and IgM are Positive.

**Viral Markers – HBeAg**

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

**Viral Markers – HBsAb**

<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	1	-	1	-	1	-
	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>			
All Methods	1	-	1	-		

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

**Viral Markers – Anti-HBsAg**

<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	4	-	4	-	4	-
Abbott Quantum	1	-	1	-	1	-
Roche Elecsys 1010/2010	1	-	1	-	1	-
VITROS ECI	1	-	1	-	1	-
	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>			
All Methods	-	4	4	-		
Abbott Quantum	-	1	1	-		
Roche Elecsys 1010/2010	-	1	1	-		
VITROS ECI	-	1	1	-		

## Viral Markers – HCV

<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	-	1	1	-	1	-
	Specimen VM-14		Specimen VM-15			
All Methods	1	-	1	-		

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

# INTERNATIONAL LABS

## Syphilis Serology—Qualitative: VDRL Slide (International Labs)

<b><u>Method</u></b>	<b>Specimen SY-11</b>			<b>Specimen SY-12</b>			<b>Specimen SY-13</b>		
	<b><u>Reactive</u></b>	<b><u>Weakly Reactive</u></b>	<b><u>Non- Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Weakly Reactive</u></b>	<b><u>Non- Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Weakly Reactive</u></b>	<b><u>Non- Reactive</u></b>
All Methods	6	1	2	-	-	10	6	1	2
BioBacter	3	1	2	-	-	7	4	-	2
Wiener Lab	3	-	-	-	-	3	2	1	-
	<b>Specimen SY-14</b>			<b>Specimen SY-15</b>					
All Methods	-	-	10	8	-	1			
BioBacter	-	-	7	5	-	1			
Wiener Lab	-	-	3	3	-	-			

Specimens SY-11 and SY-13 are ungraded challenges due to less than 80% participant consensus.

## Syphilis Serology—Quantitative: VDRL Slide Titer (International Labs)

<b><u>Specimen/Method</u></b>	<b><u>0 dils</u></b>	<b><u>1 dil</u></b>	<b><u>2 dils</u></b>	<b><u>4 dils</u></b>	<b><u>8 dils</u></b>	<b><u>16 dils</u></b>	<b><u>32 dils</u></b>	<b><u>&gt;32 dils</u></b>
<b>Specimen SY-11</b>								
All Methods	3	4	1	-	-	-	-	-
BioBacter	2	3	-	-	-	-	-	-
Wiener Lab	1	1	1	-	-	-	-	-
<b>Specimen SY-13</b>								
All Methods	3	2	2	-	-	-	-	-
BioBacter	2	2	1	-	-	-	-	-
Wiener Lab	1	-	1	-	-	-	-	-
<b>Specimen SY-15</b>								
All Methods	4	3	2	-	-	-	-	-
BioBacter	2	3	1	-	-	-	-	-
Wiener Lab	2	-	1	-	-	-	-	-

**Syphilis Serology—Qualitative: FTA-ABS (*Treponema pallidum* Antibodies) (International Labs)**

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	3	-	-	3	3	-
	Specimen SY-14		Specimen SY-15			
All Methods	-	3	3	-		

**Syphilis Serology—Qualitative: RPR (International Labs)**

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	5	1	-	6	5	1
Abbott Syfacard-R	1	-	-	1	1	-
BioSystems	-	1	-	1	1	1
Serodia	1	-	-	1	1	-
SPINREACT	1	-	-	1	1	-
Wiener Lab	1	-	-	1	1	-
	Specimen SY-14		Specimen SY-15			
All Methods	-	6	5	1		
Abbott Syfacard-R	-	1	1	-		
BioSystems	-	1	1	1		
Serodia	-	1	1	-		
SPINREACT	-	1	1	-		
Wiener Lab	-	1	1	-		

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

<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>	<u>&gt;64</u>
<b>Specimen SY-11</b>								
All Methods	3	2	-	-	-	-	-	1
Abbott Syfacard-R	1	-	-	-	-	-	-	-
Serodia	-	-	-	-	-	-	-	1
SPINREACT	-	1	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-
<b>Specimen SY-13</b>								
All Methods	3	1	1	-	-	-	-	1
Abbott Syfacard-R	1	-	-	-	-	-	-	-
Serodia	-	-	-	-	-	-	-	1
SPINREACT	-	1	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-

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

**Specimen SY-15**

<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>	<u>&gt;64</u>
All Methods	1	4	-	-	-	-	-	1
Abbott Syfacard-R	-	1	-	-	-	-	-	-
Serodia	-	-	-	-	-	-	-	1
SPINREACT	-	1	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-

**Viral Markers – Anti-HBc (International)**

<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	18	-	7	11	18	-
Abbott AxSYM	2	-	-	2	2	-
Abbott AxSYM – IgM	3	-	3	-	3	-
Abbott AxSYM – Total	2	-	-	2	2	-
Beckman (Sanofi) ACCESS	1	-	-	1	1	-
bioMerieux Vitek, Mini Vidas	1	-	-	1	1	-
Dade Behring BEP 2000	1	-	1	-	1	-
Roche Cobas CORE	1	-	1	-	1	-
Roche Elecsys 1010/2010	2	-	-	2	2	-
VITROS Eci	3	-	-	3	3	-

  

<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	17	1	18	-
Abbott AxSYM	2	-	2	-
Abbott AxSYM – IgM	3	-	3	-
Abbott AxSYM – Total	1	1	2	-
Beckman (Sanofi) ACCESS	1	-	1	-
bioMerieux Vitek, Mini Vidas	1	-	1	-
Dade Behring BEP 2000	1	-	1	-
Roche Cobas CORE	1	-	1	-
Roche Elecsys 1010/2010	2	-	2	-
VITROS Eci	3	-	3	-

### Viral Markers – Anti-HIV (International)

<u>Method</u>	<u>Specimen VM-11</u>		<u>Specimen VM-12</u>		<u>Specimen VM-13</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	22	-	-	22	22	-
Abbott AxSYM	2	-	-	2	2	-
Abbott AxSYM – IgM	1	-	-	1	1	-
Abbott AxSYM – Total	3	-	-	3	3	-
Bayer Advia Centaur	1	-	-	1	1	-
Beckman (Sanofi) ACCESS	1	-	-	1	1	-
bioMerieux Vitek, Mini Vidas	2	-	-	2	2	-
Roche Cobas CORE	1	-	-	1	1	-
Roche Elecsys 1010/2010	2	-	-	2	2	-
VITROS ECi	4	-	-	4	4	-

<u>Method</u>	<u>Specimen VM-14</u>		<u>Specimen VM-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	22	21	1
Abbott AxSYM	-	2	2	-
Abbott AxSYM – IgM	-	1	-	1
Abbott AxSYM – Total	-	3	3	-
Bayer Advia Centaur	-	1	1	-
Beckman (Sanofi) ACCESS	-	1	1	-
bioMerieux Vitek, Mini Vidas	-	2	2	-
Roche Cobas CORE	-	1	1	-
Roche Elecsys 1010/2010	-	2	2	-
VITROS ECi	-	4	4	-

### Viral Markers – HAV (International)

<u>Method</u>	<u>Specimen VM-11</u>		<u>Specimen VM-12</u>		<u>Specimen VM-13</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	7	12	7	12	7	12
Abbott AxSYM	-	2	-	2	-	2
Abbott AxSYM – IgM	2	-	2	-	2	-
Abbott AxSYM – Total	1	2	1	2	1	2
bioMerieux Vidas – IgM	1	-	1	-	1	-
bioMerieux Vitek, Mini Vidas	-	3	-	3	-	3
Dade Behring BEP 2000	1	-	1	-	1	-
Roche Elecsys 1010/2010	-	2	-	2	-	2
Roche Modular Analytics	-	1	-	1	-	1
VITROS ECi	2	-	2	-	2	-

### Viral Markers – HAV (International)

<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	16	3	1	18
Abbott AxSYM	2	-	-	2
Abbott AxSYM – IgM	2	-	-	2
Abbott AxSYM – Total	3	-	1	2
bioMerieux Vidas – IgM	1	-	-	1
bioMerieux Vitek, Mini Vidas	1	2	-	3
Dade Behring BEP 2000	-	1	-	1
Roche Elecsys 1010/2010	2	-	-	2
Roche Modular Analytics	1	-	-	1
VITROS ECI	2	-	-	2

Specimen VM-11: Total is Positive; IgM is Negative.

Specimen VM-12: Total is Positive; IgM is Negative.

Specimen VM-13: Total is Positive; IgM is Negative.

Specimen VM-14: Total and IgM are Negative.

Specimen VM-15: Total and IgM are Positive.

### Viral Markers – HBeAg (International)

<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	9	-	9	-	9	-
Abbott AxSYM	1	-	1	-	1	-
Abbott AxSYM – IgM	1	-	1	-	1	-
Abbott AxSYM – Total	1	-	1	-	1	-
Dade Behring BEP 2000	1	-	1	-	1	-
Roche Elecsys 1010/2010	1	-	1	-	1	-
VITROS ECI	1	-	1	-	1	-

  

<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	9	-	9	-
Abbott AxSYM	1	-	1	-
Abbott AxSYM – IgM	1	-	1	-
Abbott AxSYM – Total	1	-	1	-
Dade Behring BEP 2000	1	-	1	-
Roche Elecsys 1010/2010	1	-	1	-
VITROS ECI	1	-	1	-

**Viral Markers – HBsAb (International)**

<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	19	1	20	-	20	-
Abbott AxSYM	3	-	3	-	3	-
Abbott AxSYM – IgM	1	-	1	-	1	-
Abbott AxSYM – Total	3	-	3	-	3	-
Beckman (Sanofi) ACCESS	-	1	1	-	1	-
Dade Behring BEP 2000	1	-	1	-	1	-
Roche Elecsys 1010/2010	3	-	3	-	3	-
Roche Modular Analytics	2	-	2	-	2	-
VITROS ECi	4	-	4	-	4	-
	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>			
All Methods	20	-	20	-		
Abbott AxSYM	3	-	3	-		
Abbott AxSYM – IgM	1	-	1	-		
Abbott AxSYM – Total	3	-	3	-		
Beckman (Sanofi) ACCESS	1	-	1	-		
Dade Behring BEP 2000	1	-	1	-		
Roche Elecsys 1010/2010	3	-	3	-		
Roche Modular Analytics	2	-	2	-		
VITROS ECi	4	-	4	-		

**Viral Markers – Anti-HBsAg (International)**

<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	19	4	23	-	23	-
Abbott AxSYM	1	1	2	-	2	-
Abbott AxSYM – IgM	-	2	2	-	2	-
Abbott AxSYM – Total	2	1	3	-	3	-
Beckman (Sanofi) ACCESS	1	-	1	-	1	-
bioMerieux Vitek, Mini Vidas	1	-	1	-	1	-
Dade Behring BEP 2000	1	-	1	-	1	-
Roche Cobas CORE	1	-	1	-	1	-
Roche Elecsys 1010/2010	2	-	2	-	2	-
Roche Modular Analytics	2	-	2	-	2	-
VITROS ECi	4	-	4	-	4	-

**Viral Markers – Anti-HBsAg (International)**

<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	22	22	-
Abbott AxSYM	-	2	2	-
Abbott AxSYM – IgM	-	1	1	-
Abbott AxSYM – Total	-	3	3	-
Beckman (Sanofi) ACCESS	-	1	1	-
bioMerieux Vitek, Mini Vidas	-	1	1	-
Dade Behring BEP 2000	-	1	1	-
Roche Cobas CORE	-	1	1	-
Roche Elecsys 1010/2010	-	2	2	-
Roche Modular Analytics	-	2	2	-
VITROS Eci	-	4	4	-

**Viral Markers – HCV (International)**

<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	1	20	21	-	21	-
Abbott AxSYM	-	2	2	-	2	-
Abbott AxSYM – IgM	-	1	1	-	1	-
Abbott AxSYM – Total	-	5	5	-	5	-
Bayer Advia Centaur	-	1	1	-	1	-
Beckman (Sanofi) ACCESS	-	1	1	-	1	-
bioMerieux Vitek, Mini Vidas	-	1	1	-	1	-
VITROS Eci	-	5	5	-	5	-

  

	<b>Specimen VM-14</b>		<b>Specimen VM-15</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	21	-	20	1
Abbott AxSYM	2	-	2	-
Abbott AxSYM – IgM	1	-	1	-
Abbott AxSYM – Total	5	-	5	-
Bayer Advia Centaur	1	-	1	-
Beckman (Sanofi) ACCESS	1	-	1	-
bioMerieux Vitek, Mini Vidas	1	-	1	-
VITROS Eci	5	-	5	-

**Medical Laboratory Evaluation**

2011 Pennsylvania Avenue, NW, Suite 800

Washington, DC 20006-1813

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

[www.acponline.org/mle](http://www.acponline.org/mle)