

# **MEDICAL LABORATORY EVALUATION**

## **PARTICIPANT SUMMARY**

# **2 • 0 • 0 • 5**



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

Immunology  
MLE – M2

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## 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**

<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	339	1	337	3	225	2
ABI SureStep Mono-whole blood	1	-	1	-	1	-
Applied Biotech SureStep	4	-	4	-	2	-
ASI	3	-	3	-	3	-
BioStar Acceava Mono Test	10	-	10	-	9	-
BioStar Acceava Mono-whole blood	14	-	14	-	4	-
Cardinal Health SP Brand-Mono	9	-	8	1	9	-
Fisher HealthCare Sure-Vue	17	-	17	-	17	-
Genzyme Contrast Mono	1	-	1	-	1	-
Genzyme OSOM	8	-	8	-	5	-
Immunostics – IMMUNO/IM	1	-	1	-	1	-
Inverness ClearviewMONO-plusII	5	-	5	-	3	-
Inverness Signify Mono Test	1	-	1	-	1	-
J&S Medical Assoc. Accutex	1	-	1	-	1	-
LifeSign UniStep Mono	7	-	6	1	1	-
Mainline Confirms	1	-	1	-	1	-
McKesson Medi-Lab Performance	10	-	10	-	6	-
Meridian ImmunoCardSTAT-waived	1	-	1	-	-	-
Meridian Monospot (Latex)	1	-	1	-	1	-
Polymedco Poly stat	11	-	11	-	11	-
Polymedco Poly stat – waived	21	-	21	-	7	-
Quidel Quick Vue+	71	-	71	-	52	-
Quidel Quick Vue+ - waived	47	1	47	1	11	2
Remel RIM A.R.C.	1	-	1	-	1	-
Seradyn	31	-	31	-	29	-
Seradyn Color Q – (whole blood)	1	-	1	-	1	-
Wampole ColorCard	12	-	12	-	12	-
Wampole Mono-Latex	4	-	4	-	4	-
Wampole Mono-Plus	13	-	13	-	11	-
Wampole Mono-Plus (whole blood)	23	-	23	-	11	-
Wampole Mono-Test	6	-	6	-	6	-

<u>Method</u>	<b>Specimen IM-9</b>		<b>Specimen IM-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	14	214	14	214
ABI SureStep Mono-whole blood	-	1	-	1
Applied Biotech SureStep	-	2	-	2
ASI	2	1	2	1
BioStar Acceava Mono Test	-	9	-	9
BioStar Acceava Mono-whole blood	-	4	-	4
Cardinal Health SP Brand-Mono	-	9	-	9
Fisher HealthCare Sure-Vue	1	16	1	16
Genzyme Contrast Mono	-	1	-	1
Genzyme OSOM	-	5	-	5
Immunostics – IMMUNO/IM	1	-	1	-
Inverness ClearviewMono-plusII	-	3	-	3
Inverness Signify Mono Test	-	1	-	1
J&S Medical Assoc. Accutex	1	-	1	-
LifeSign UniStep Mono	-	1	-	1

## Infectious Mononucleosis (cont'd)

<u>Method</u>	<u>Specimen IM-9</u>		<u>Specimen IM-10</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
Mainline Confirms	-	1	-	1
McKesson Medi-Lab Performance	-	6	-	6
Meridian Monospot (Latex)	-	1	-	1
Polymedco Poly stat	-	11	-	11
Polymedco Poly stat – waived	-	7	-	7
Quidel Quick Vue+	-	53	-	53
Quidel Quick Vue+ - waived	2	11	2	11
Remel RIM A.R.C.	-	1	-	1
Seradyn	2	27	1	28
Seradyn Color Q – (whole blood)	-	1	-	1
Wampole ColorCard	1	11	1	11
Wampole Mono-Latex	2	2	3	1
Wampole Mono-Plus	-	11	-	11
Wampole Mono-Plus (whole blood)	-	11	-	11
Wampole Mono-Test	2	4	2	4

## Rheumatoid Factor—Qualitative

<u>Method</u>	<u>Specimen RF-6</u>		<u>Specimen RF-7</u>		<u>Specimen RF-8</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	117	1	118	-	-	118
ASI	8	-	8	-	-	8
Beckman Synchron	3	-	3	-	-	3
Becton Dickinson	1	-	1	-	-	1
Behring RapiTex-Plate method	3	-	3	-	-	3
Biokit Rheumagen	1	-	1	-	-	1
Biokit Rheumajet	3	-	3	-	-	3
BMH 717	1	-	1	-	-	1
Dade Dimension/AR/ES/RxL/Xpand	1	-	1	-	-	1
Fisher HealthCare Sure-Vue	11	-	11	-	-	11
Immunostics Inc.	1	-	1	-	-	1
J&S Medical Assoc. Accutex	3	-	3	-	-	3
Murex Latex Test	1	-	1	-	-	1
Pulse Scientific	1	-	1	-	-	1
Rocha Integra	1	-	1	-	-	1
Seradyn	51	-	51	-	-	51
Stanbio	1	-	1	-	-	1
Sterling Diagnostics, Inc.	3	-	3	-	-	3
Teco Diagnostics	1	-	1	-	-	1
Wampole ColorCard	1	-	1	-	-	1
Wampole Rheumatex	8	-	8	-	-	8
Wampole Rheumaton	9	1	10	-	-	10

**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	117	117	1
ASI	-	8	8	-
Beckman Synchron	-	3	3	-
Becton Dickinson	-	1	1	-
Behring RapiTex-Plate method	-	3	3	-
Biokit Rheumagen	-	1	1	-
Biokit Rheumajet	-	3	3	-
BMH 717	-	1	1	-
Dade Dimension/AR/ES/RxL/Xpand	-	1	1	-
Fisher HealthCare Sure-View	-	11	11	-
Immunostics Inc.	-	1	1	-
J&S Medical Assoc. Accutex	-	3	3	-
Murex Latex Test	-	1	1	-
Pulse Scientific	-	1	1	-
Roche Integra	-	1	1	-
Seradyn	-	51	51	-
Stanbio	-	1	1	-
Sterling Diagnostics, Inc.	-	3	3	-
Teco Diagnostics	-	1	1	-
Wampole ColorCard	-	1	1	-
Wampole Rheumatex	-	8	8	-
Wampole Rheumaton	1	9	9	1

### 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>
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#### Specimen RF-8

All Methods	5	15	6	3	2	1	-	-	-	-	-
ASI	-	-	-	2	1	-	-	-	-	-	-
Beckman Synchron	-	-	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumagen	-	-	-	-	1	-	-	-	-	-	-
Biokit Rheumajet	-	3	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	3	1	1	-	-	1	-	-	-	-	-
Murex Latex Test	-	1	-	-	-	-	-	-	-	-	-
Seradyn	2	8	2	1	-	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	2	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

#### Specimen RF-9

All Methods	7	14	5	3	2	1	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumagen	-	-	-	-	1	-	-	-	-	-	-
Biokit Rheumajet	-	3	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	3	2	-	-	-	1	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Seradyn	3	7	2	-	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>
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#### Specimen RF-7

All Methods	3	-	-	-	5	5	9
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#### Specimen RF-8

All Methods	17	102.8	58.7	57.1	74	40	212
Beckman Synchron	5	168.6	40.6	24.1	184	124	212

#### Specimen RF-9

All Methods	17	105.2	56.1	53.3	80	40	210
Beckman Synchron	5	168.2	40.0	23.8	186	123	210

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

<u>Method</u>	Specimen AS-6		Specimen AS-7		Specimen AS-8	
	<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>	Specimen AS-9		Specimen AS-10	
	<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>100-200</u>	<u>400-800</u>

**Specimen AS-7**

All Methods	-	-	-	-	-	-	-	-	-	2	-
Behring RapiTex	-	-	-	-	-	-	-	-	-	1	-
Fisher HealthCare Sure-Vue	-	-	-	-	-	-	-	-	-	1	-

**Specimen AS-9**

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-6</b>							
All Methods	11	170.7	13.8	8.1	167	153	193
DiaSorin (INCSTAR)	4	-	-	-	170	158	193
<b>Specimen COM-7</b>							
All Methods	11	124.4	8.0	6.5	124	112	136
DiaSorin (INCSTAR)	4	-	-	-	128	119	132
<b>Specimen COM-8</b>							
All Methods	11	120.8	9.1	7.5	120	107	132
DiaSorin (INCSTAR)	4	-	-	-	122	115	132
<b>Specimen COM-9</b>							
All Methods	11	153.4	11.7	7.6	149	137	174
DiaSorin (INCSTAR)	4	-	-	-	150	148	158
<b>Specimen COM-10</b>							
All Methods	11	189.6	14.3	7.5	186	174	216
DiaSorin (INCSTAR)	4	-	-	-	187	179	216

**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	29.5	2.3	7.9	29	26	33
DiaSorin (INCSTAR)	3	-	-	-	30	29	33
<b>Specimen COM-7</b>							
All Methods	11	21.3	2.2	10.5	21	17	24
DiaSorin (INCSTAR)	3	-	-	-	22	20	24
<b>Specimen COM-8</b>							
All Methods	11	21.2	2.2	10.5	21	18	24
DiaSorin (INCSTAR)	3	-	-	-	24	19	24
<b>Specimen COM-9</b>							
All Methods	11	26.6	2.7	10.3	27	21	30
DiaSorin (INCSTAR)	3	-	-	-	29	25	29
<b>Specimen COM-10</b>							
All Methods	11	33.0	2.3	7.0	33	29	36
DiaSorin (INCSTAR)	3	-	-	-	33	32	36

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

<b><u>Method</u></b>	<b>Specimen AN-6</b>		<b>Specimen AN-7</b>		<b>Specimen AN-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	9	-	4	5	9	-
Diagnostic Technology	7	-	3	4	7	-
Pulse Scientific	1	-	1	-	1	-
Wampole	1	-	-	1	1	-

<b><u>Method</u></b>	<b>Specimen AN-9</b>		<b>Specimen AN-10</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
All Methods	4	5	4	5
Diagnostic Technology	3	4	3	4
Pulse Scientific	1	-	1	-
Wampole	-	1	-	1

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

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

<b><u>Method</u></b>	<b>Specimen AE-6</b>		<b>Specimen AE-7</b>		<b>Specimen AE-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	12	-	1	11	12	-
Immuno Concepts	6	-	-	6	6	-
INOVA Diagnostics	1	-	1	-	1	-
Kallestad	3	-	-	3	3	-
Seradyn	1	-	-	1	1	-

<b><u>Method</u></b>	<b>Specimen AE-9</b>		<b>Specimen AE-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	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>
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### Specimen AE-7

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

### Specimen AE-9

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

### Specimen AE-10

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

## 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	-	13	13	-
ASI	-	2	2	-
Behring RapiTex	-	2	2	-
Dade Dimension/AR/ES/RxL/Xpand	-	1	1	-
Fisher HealthCare Sure-View	-	1	1	-
Immunosits Inc.	-	1	1	-
Pulse Scientific	-	1	1	-
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>
<b>Specimen CR-3</b>					
All Methods mg/dL – units	35	6.776	8.926	131.7	2.80
Beckman Synchron	9	2.589	0.183	7.1	2.60
Dade Dimension/AR/ES/RxL/Xpa	5	2.914	0.077	2.7	2.90
Roche Integra	4	-	-	-	2.7
All Immunology Methods mg/L - units	23	2.722	0.215	7.9	2.70
All Immunology Methods	6	26.040	1.789	6.9	26.12

**Specimen CR-4**

All Methods mg/dL - units	11	0.165	0.175	106.5	0.10
All Immunology Methods mg/L - units	4	-	-	-	0.02
All Immunology Methods	5	0.132	0.082	61.9	0.10

**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-3</b>					
All Methods mg/dL - units	59	0.495	0.337	68.2	0.59
Dade Dimension High Sensi CR	7	0.080	0.020	25.0	0.08
All Immunology Methods mg/L - units	17	0.078	0.015	19.1	0.08
Kamiya Biomedical hs-CRP	4	-	-	-	0.78
Pointe Scientific CRP (HS)	3	-	-	-	0.40
Polymedco Full Range CRP	4	-	-	-	0.72
Polymedco Ultra CRP	3	-	-	-	0.78
Roche Cobas HS CRP	6	0.635	0.064	10.1	0.65
SDI Biomed, Inc.	3	-	-	-	0.20
All Immunology Methods	38	0.675	0.230	34.1	0.72

**Specimen HCR-4**

All Methods mg/dL - units	62	9.064	5.200	57.4	11.95
Dade Dimension High Sensi CR	7	1.294	0.054	4.2	1.29
All Immunology Methods mg/L - units	17	1.197	0.175	14.6	1.23
Kamiya Biomedical hs-CRP	4	-	-	-	11.03
Pointe Scientific CRP (HS)	4	-	-	-	13.10
Polymedco Full Range CRP	5	11.842	0.404	3.4	11.90
Polymedco Ultra CRP	3	-	-	-	9.62
Roche Cobas HS CRP	6	12.878	0.627	4.9	12.72
SDI Biomed, Inc.	4	-	-	-	12.12
All Immunology Methods	41	12.305	1.408	11.4	12.37

**Rubella—Qualitative**

<u>Method</u>	<b>Specimen RU-6</b>		<b>Specimen RU-7</b>		<b>Specimen RU-8</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
Becton Dickinson	-	1	1	-	-	1
bioMerieux Vitek, Mini Vidas	-	3	3	-	-	3
Seradyn	-	2	2	-	-	2
Wampole Rubella – Plus	-	1	1	-	-	1
	<b>Specimen RU-9</b>		<b>Specimen RU-10</b>			
All Methods	9	-	-	9		
Abbott AxSYM	1	-	-	1		
Abbott IMx	1	-	-	1		
Becton Dickinson	1	-	-	1		
bioMerieux Vitek, Mini Vidas	3	-	-	3		
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>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen RU-6</b>							
All Methods	3	-	-	-	108.7	3.0	115.9
<b>Specimen RU-8</b>							
All Methods	3	-	-	-	114.4	2.8	119.4
<b>Specimen RU-10</b>							
All Methods	3	-	-	-	114.8	2.3	147.2

**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-6</b>							
All Methods	8	1249.5	92.4	7.4	1268	1060	1336
bioMerieux Vitek, Mini Vidas	1	-	-	-	1325	1325	1325
Hycor EIA	1	-	-	-	1060	1060	1060
Pharmacia & Upjohn Unicap 100	6	1268.5	56.6	4.5	1268	1196	1336
<b>Specimen AL-7</b>							
All Methods	9	435.9	34.2	7.8	434	375	485
bioMerieux Vitek, Mini Vidas	1	-	-	-	400	400	400
Hycor EIA	2	-	-	-	403	375	431
Pharmacia & Upjohn Unicap 100	6	452.8	22.8	5.0	454	424	485
<b>Specimen AL-8</b>							
All Methods	9	19.4	4.5	23.2	19	16	31
bioMerieux Vitek, Mini Vidas	1	-	-	-	16	16	16
Hycor EIA	2	-	-	-	24	16	31
Pharmacia & Upjohn Unicap 100	6	18.7	0.5	2.8	19	18	19
<b>Specimen AL-9</b>							
All Methods	9	18.8	1.9	9.9	19	16	23
bioMerieux Vitek, Mini Vidas	1	-	-	-	18	18	18
Hycor EIA	2	-	-	-	20	16	23
Pharmacia & Upjohn Unicap 100	6	18.7	0.5	2.8	19	18	19
<b>Specimen AL-10</b>							
All Methods	9	83.8	7.4	8.9	85	72	96
bioMerieux Vitek, Mini Vidas	1	-	-	-	73	73	73
Hycor EIA	2	-	-	-	84	72	96
Pharmacia & Upjohn Unicap 100	6	85.5	2.1	2.4	86	82	88

## Allergen Specific IgE Antibodies

### Specimen AL-6

	House Dust Mite Allergen (d2)							Alternaria alternata Allergen (m6)						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	1	4	8	-	-	-	-	-	2	8	3	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	-	-	2	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	2	1	-	-	-	-	-	-	2	1	-
Pharmacia & Upjohn UniCap 100	-	-	-	1	-	-	-	-	-	-	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	5	-	-	-	-	-	-	5	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	1	-	-	-
	Perennial Rye Allergen (g5)							Olive Allergen (t9)						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	-	4	2	-	-	-	-	1	-	-
Hycor EIA	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	2	-	-	-	-	-	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	1	-	-	-	-	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	2	-	-	-	-	-	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Common (Short) Ragweed Allergen (w1)							Meadow Grass, Kentucky Blue Grass, June Grass Allergen (g8)						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	1	10	1	-	-	-	-	1	4	1
Hycor EIA	-	-	-	-	-	2	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	3	-	-	-	-	-	-	2	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	5	-	-	-	-	-	-	2	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	-	-	-	1
	Dog Dander Allergen (e5)													
	CLASS RESULT													
	0	1	2	3	4	5	6							
All Methods	-	-	1	2	5	-	-							
Hycor EIA	-	-	-	-	1	-	-							
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	-	-							
Pharmacia & Upjohn UniCap 100	-	-	-	1	-	-	-							
Pharmacia UniCap 100 (% ref)	-	-	1	-	3	-	-							
Pharmacia Unicap 100 (KU/L)	-	-	-	1	-	-	-							

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

**Specimen AL-7**

	<b>Bermuda Grass Allergen (g2)</b>							<b>Cat Epithelium Allergen (e1)</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	8	-	1	-	-	2	9	1	1	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	1	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	2	-	-	-	-	-	3	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	1	-	-	-	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	4	-	-	-	-	-	5	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	1	-	-	-	-
	<b>Sage Allergen (RF344)</b>							<b>White Oak Allergen (t7)</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	-	-	-	-	-	-	-	-	-	2	7	2	-	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	-	2	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	-	-	-	-	-	2	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	-	-	-	-	-	5	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	1	-	-	-	-
	<b>Russian Thistle Allergen (w11)</b>							<b>English Plantain Allergen (w9)</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	-	-	-	-	3	-	-	-	-	-	5	3	-	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	2	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	2	-	-	-	-	-	-	3	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	-	-	2	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	1	-	-	-
	<b>Maple (Box Elder) Allergen (t1)</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	-	-	1	8	1	-	-							
Hycor EIA	-	-	-	2	-	-	-							
Pharmacia & Upjohn CAP (% ref)	-	-	-	1	1	-	-							
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-							
Pharmacia UniCap 100 (% ref)	-	-	-	5	-	-	-							
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-6</b>							
All Methods	11	266.1	26.3	9.9	265	205	298
<b>Specimen IP-7</b>							
All Methods	10	195.8	10.6	5.4	197	180	210
<b>Specimen IP-8</b>							
All Methods	10	190.5	9.8	5.2	191	173	208
<b>Specimen IP-9</b>							
All Methods	10	243.7	13.0	5.3	240	224	264
<b>Specimen IP-10</b>							
All Methods	11	298.8	27.7	9.3	300	235	333

**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	10	1340.1	80.1	6.0	1319	1274	1536
<b>Specimen IP-7</b>							
All Methods	9	944.4	36.5	3.9	948	879	987
<b>Specimen IP-8</b>							
All Methods	9	940.9	33.5	3.6	929	891	992
<b>Specimen IP-9</b>							
All Methods	10	1208.9	26.0	2.2	1208	1166	1249
<b>Specimen IP-10</b>							
All Methods	10	1461.9	43.0	2.9	1463	1381	1528

**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	11	113.4	8.2	7.3	111	103	128
<b>Specimen IP-7</b>							
All Methods	10	79.8	12.4	15.5	83	46	89
<b>Specimen IP-8</b>							
All Methods	11	82.2	4.4	5.4	82	76	91
<b>Specimen IP-9</b>							
All Methods	11	106.4	7.0	6.6	103	99	118
<b>Specimen IP-10</b>							
All Methods	11	127.3	10.4	8.2	124	115	144

**Syphilis Serology—Qualitative: RPR**

<u>Method</u>	<u>Specimen SY-6</u>		<u>Specimen SY-7</u>		<u>Specimen SY-8</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	53	2	53	2	-	55
ASI	14	-	14	-	-	14
Becton Dickinson	27	-	27	-	-	27
Biokit	3	-	3	-	-	3
Fisher HealthCare Sure-Vue	3	-	3	-	-	3
J&S Medical Assoc. Accutex	1	-	1	-	-	1
New Horizons	1	-	1	-	-	1
Stanbio	1	1	1	1	-	2
Wampole Impact RPR	1	1	1	1	-	2
<b>Specimen SY-9</b>						
All Methods	51	4				
ASI	13	1				
Becton Dickinson	26	1				
Biokit	3	-				
Fisher HealthCare Sure-Vue	3	-				
J&S Medical Assoc. Accutex	1	-				
New Horizons	1	-				
Stanbio	1	1				
Wampole Impact RPR	1	1				
<b>Specimen SY-10</b>						
All Methods			1	54		
ASI			-	14		
Becton Dickinson			-	27		
Biokit			-	3		
Fisher HealthCare Sure-Vue			-	3		
J&S Medical Assoc. Accutex			-	1		
New Horizons			-	1		
Stanbio			1	1		
Wampole Impact RPR			-	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-6</b>							
All Methods	13	7	-	-	-	-	-
ASI	6	3	-	-	-	-	-
Becton Dickinson	6	2	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	1	-	-	-	-	-

<b>Specimen SY-7</b>							
All Methods	13	7	-	-	-	-	-
ASI	7	2	-	-	-	-	-
Becton Dickinson	4	4	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-

<b>Specimen SY-9</b>							
All Methods	13	7	-	-	-	-	-
ASI	5	4	-	-	-	-	-
Becton Dickinson	7	1	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	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	14	202	212	4
Abbott FlexPack	-	1	1	-
Abbot Signify	-	2	2	-
Acon Laboratories	-	1	1	-
Applied Biotech SureStep	1	13	14	-
BD LINK 2	-	3	3	-
Beckman Coulter FlexSure	1	26	27	-
DPC Immulite/1000	-	1	1	-
Fisher HealthCare Sure-Vue	3	4	7	-
LifeSign Status	-	2	2	-
Meridian ImmunoCard	-	2	2	-
Meridian Premier	-	1	1	-
Polymedco Poly stat	4	28	32	-
Quidel QuickVue	5	98	99	4
Remel RIM A.R.C.	-	1	1	-
Wampole Clearview	-	9	9	-

**Lyme Disease Serology**

<u>Method</u>	<b>Specimen LY-3</b>		<b>Specimen LY-4</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	8	-	-	8
bioMerieux Vitek, Mini Vidas	2	-	-	2
Remel Rapidot	1	-	-	1
Wampole Impact	1	-	-	1
Wampole PreVue	4	-	-	4

**Mycoplasma Antibody**

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

**Viral Markers – Anti-HBc**

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

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

**Viral Markers – Anti-HIV**

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

**Viral Markers – HAV**

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

Specimen VM-6: Total is Negative; IgM is Negative.  
 Specimen VM-7: Total is Negative; IgM is Negative.  
 Specimen VM-8: Total is Negative; IgM is Negative.  
 Specimen VM-9: Total and IgM are Positive.  
 Specimen VM-10: Total is Negative; IgM is Negative.

**Viral Markers – HBeAg**

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

**Viral Markers – HBsAb**

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

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

**Viral Markers – Anti-HBsAg**

<u>Method</u>	<b>Specimen VM-6</b>		<b>Specimen VM-7</b>		<b>Specimen VM-8</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	4	4	-	4	-
Abbott Quantum	-	2	2	-	2	-
Roche Elecsys 1010/2010	-	1	1	-	1	-
VITROS Eci	-	1	1	-	1	-
	<b>Specimen VM-9</b>		<b>Specimen VM-10</b>			
All Methods	-	4	4	-		
Abbott Quantum	-	2	2	-		
Roche Elecsys 1010/2010	-	1	1	-		
VITROS Eci	-	1	1	-		

**Viral Markers – HCV**

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

# INTERNATIONAL LABS

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

<u>Method</u>	<u>Specimen SY-6</u>			<u>Specimen SY-7</u>			<u>Specimen SY-8</u>		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
All Methods	5	1	2	5	1	2	-	-	8
BioBacter	3	-	1	3	-	1	-	-	4
Wiener Lab	1	-	-	1	-	-	-	-	1

  

<u>Method</u>	<u>Specimen SY-9</u>			<u>Specimen SY-10</u>		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
All Methods	5	1	1	-	-	8
BioBacter	3	-	1	-	-	4
Wiener Lab	1	-	-	-	-	1

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

<u>Specimen/Method</u>	<u>0 dils</u>	<u>1 dil</u>	<u>2 dils</u>	<u>4 dils</u>	<u>8 dils</u>	<u>16 dils</u>	<u>32 dils</u>	<u>&gt;32 dils</u>
<b>Specimen SY-6</b>								
All Methods	4	1	1	-	-	-	-	-
BioBacter	3	-	-	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-
<b>Specimen SY-7</b>								
All Methods	4	1	1	-	-	-	-	-
BioBacter	3	-	-	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-
<b>Specimen SY-9</b>								
All Methods	4	2	1	-	-	-	-	-
BioBacter	3	-	-	-	-	-	-	-
Wiener Lab	-	-	2	-	-	-	-	-

## Syphilis Serology—Qualitative: MHA-TP (International Labs)

<u>Method</u>	<u>Specimen SY-6</u>		<u>Specimen SY-7</u>		<u>Specimen SY-8</u>	
	<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
Serodia	2	-	2	-	-	2

  

<u>Method</u>	<u>Specimen SY-9</u>		<u>Specimen SY-10</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	3	-	-	3
Serodia	2	-	-	2

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

<b><u>Method</u></b>	<b>Specimen SY-6</b>		<b>Specimen SY-7</b>		<b>Specimen SY-8</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
All Methods	2	-	2	-	-	2
	<b>Specimen SY-9</b>		<b>Specimen SY-10</b>			
All Methods	2	-	-	2		

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

<b><u>Method</u></b>	<b>Specimen SY-6</b>		<b>Specimen SY-7</b>		<b>Specimen SY-8</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
All Methods	12	-	12	-	-	12
Becton Dickinson	2	-	2	-	-	2
bioMerieux Vitek, Mini Vidas	1	-	1	-	-	1
BioSystems	2	-	2	-	-	2
Immunostics Inc.	1	-	1	-	-	1
Omega Diagnostics	2	-	2	-	-	2
Serodia	1	-	1	-	-	1
SPINREACT	1	-	1	-	-	1
	<b>Specimen SY-9</b>		<b>Specimen SY-10</b>			
All Methods	12	-	-	12		
Becton Dickinson	2	-	-	2		
bioMerieux Vitek, Mini Vidas	1	-	-	1		
BioSystems	2	-	-	2		
Immunostics Inc.	1	-	-	1		
Omega Diagnostics	2	-	-	2		
Serodia	1	-	-	1		
SPINREACT	1	-	-	1		

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

<b><u>Specimen/Method</u></b>	<b><u>1</u></b>	<b><u>2</u></b>	<b><u>4</u></b>	<b><u>8</u></b>	<b><u>16</u></b>	<b><u>32</u></b>	<b><u>64</u></b>	<b><u>&gt;64</u></b>
<b>Specimen SY-6</b>								
All Methods	3	4	-	-	-	-	-	1
bioMerieux Vitek, Mini Vidas	1	-	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-
Omega Diagnostics	-	1	-	-	-	-	-	-
Serodia	-	-	-	-	-	-	-	1
SPINREACT	-	1	-	-	-	-	-	-
<b>Specimen SY-7</b>								
All Methods	2	4	1	-	-	-	-	1
bioMerieux Vitek, Mini Vidas	-	1	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-
Omega Diagnostics	-	1	-	-	-	-	-	-
Serodia	-	-	-	-	-	-	-	1
SPINREACT	-	-	1	-	-	-	-	-

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

**Specimen SY-9**

<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	3	4	-	-	-	-	-	1
bioMerieux Vitek, Mini Vidas	1	-	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-
Omega Diagnostics	-	1	-	-	-	-	-	-
Serodia	-	-	-	-	-	-	-	1
SPINREACT	-	1	-	-	-	-	-	-

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

<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	18	21	-	21	-
Abbott AxSYM	-	4	4	-	4	-
Abbott AxSYM – IgM	2	-	2	-	2	-
Abbott AxSYM – Total	-	2	2	-	2	-
Beckman (Sanofi) ACCESS	1	-	1	-	1	-
bioMerieux Vidas – IgM	-	2	2	-	2	-
bioMerieux Vitek, Mini Vidas	-	2	2	-	2	-
Dade Behring PEP 2000	-	1	1	-	1	-
Roche Cobas CORE	-	2	2	-	2	-
Roche Elecsys 1010/2010	-	1	1	-	1	-
Roche Modular Analytics	-	1	1	-	1	-
VITROS Eci	-	2	2	-	2	-

  

<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	18	21	-
Abbott AxSYM	-	4	4	-
Abbott AxSYM – IgM	2	-	2	-
Abbott AxSYM – Total	-	2	2	-
Beckman (Sanofi) ACCESS	1	-	1	-
bioMerieux Vidas – IgM	-	2	2	-
bioMerieux Vitek, Mini Vidas	-	2	2	-
Dade Behring PEP 2000	-	1	1	-
Roche Cobas CORE	-	2	2	-
Roche Elecsys 1010/2010	-	1	1	-
Roche Modular Analytics	-	1	1	-
VITROS Eci	-	2	2	-

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

<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	27	-	26	-	-	27
Abbott AxSYM	6	-	5	-	-	6
Abbott AxSYM – IgM	2	-	2	-	-	2
Abbott AxSYM – Total	2	-	2	-	-	2
Beckman (Sanofi) ACCESS	1	-	1	-	-	1
Bio-Rad Evolis	1	-	1	-	-	1
bioMerieux Vidas - IgM	3	-	3	-	-	3
bioMerieux Vitek, Mini Vidas	3	-	3	-	-	3
Roche Cobas CORE	2	-	2	-	-	2
Roche Elecsys 1010/2010	3	-	3	-	-	3
VITROS Eci	3	-	3	-	-	3

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

<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	27	-	26	1
Abbott AxSYM	6	-	6	-
Abbott AxSYM – IgM	2	-	2	-
Abbott AxSYM – Total	2	-	2	-
Beckman (Sanofi) ACCESS	1	-	1	-
Bio-Rad Evolis	1	-	1	-
bioMerieux Vidas - IgM	3	-	3	-
bioMerieux Vitek, Mini Vidas	3	-	3	-
Roche Cobas CORE	2	-	1	1
Roche Elecsys 1010/2010	3	-	3	-
VITROS Eci	3	-	3	-

### Viral Markers – HAV (International)

<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	23	-	23	-	10	13
Abbott AxSYM	3	-	3	-	-	3
Abbott AxSYM – IgM	3	-	3	-	3	-
Abbott AxSYM – Total	3	-	3	-	-	3
bioMerieux Vidas – IgM	3	-	3	-	3	-
bioMerieux Vitek, Mini Vidas	3	-	3	-	1	2
Dade Behring PEP 2000	1	-	1	-	1	-
Roche Elecsys 1010/2010	3	-	3	-	-	3
Roche Modular Analytics	1	-	1	-	-	1
VITROS Eci	2	-	2	-	2	-

## Viral Markers – HAV (International)

<u>Method</u>	<b>Specimen VM-9</b>		<b>Specimen VM-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	22	23	-
Abbott AxSYM	-	3	3	-
Abbott AxSYM – IgM	-	3	3	-
Abbott AxSYM – Total	-	3	3	-
bioMerieux Vidas – IgM	-	3	3	-
bioMerieux Vitek, Mini Vidas	-	3	3	-
Dade Behring PEP 2000	-	1	1	-
Roche Elecsys 1010/2010	1	2	3	-
Roche Modular Analytics	-	1	1	-
VITROS ECi	-	2	2	-

Specimen VM-6: Total is Negative; IgM is Negative.

Specimen VM-7: Total is Negative; IgM is Negative.

Specimen VM-8: Total is Negative; IgM is Negative.

Specimen VM-9: Total and IgM are Positive.

Specimen VM-10: Total is Negative; IgM is Negative.

## Viral Markers – HBeAg (International)

<u>Method</u>	<b>Specimen VM-6</b>		<b>Specimen VM-7</b>		<b>Specimen VM-8</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	13	-	12	1	11	2
Abbott AxSYM – Total	3	-	3	-	1	2
bioMerieux Vidas – IgM	2	-	2	-	2	-
bioMerieux Vitek, Mini Vidas	2	-	1	1	2	-
Dade Behring PEP 2000	1	-	1	-	1	-
Roche Elecsys 1010/2010	1	-	1	-	1	-
Roche Modular Analytics	1	-	1	-	1	-
VITROS ECi	1	-	1	-	1	-

  

<u>Method</u>	<b>Specimen VM-9</b>		<b>Specimen VM-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	13	-	12	1
Abbott AxSYM – Total	3	-	3	-
bioMerieux Vidas – IgM	2	-	1	1
bioMerieux Vitek, Mini Vidas	2	-	2	-
Dade Behring PEP 2000	1	-	1	-
Roche Elecsys 1010/2010	1	-	1	-
Roche Modular Analytics	1	-	1	-
VITROS ECi	1	-	1	-

### Viral Markers – HBsAb (International)

<u>Method</u>	<b>Specimen VM-6</b>		<b>Specimen VM-7</b>		<b>Specimen VM-8</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	20	1	20	1	21	-
Abbott AxSYM	5	-	5	-	5	-
Abbott AxSYM – IgM	1	-	1	-	1	-
Abbott AxSYM – Total	2	-	2	-	2	-
Beckman (Sanofi) ACCESS	-	1	1	-	1	-
bioMerieux Vidas - IgM	1	-	1	-	1	-
bioMerieux Vitek, Mini Vidas	1	-	-	1	1	-
Dade Behring PEP 2000	1	-	1	-	1	-
Roche Elecsys 1010/2010	4	-	4	-	4	-
Roche Modular Analytics	1	-	1	-	1	-
VITROS ECi	3	-	3	-	3	-

<u>Method</u>	<b>Specimen VM-9</b>		<b>Specimen VM-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	20	1	19	2
Abbott AxSYM	5	-	5	-
Abbott AxSYM – IgM	1	-	1	-
Abbott AxSYM – Total	2	-	2	-
Beckman (Sanofi) ACCESS	-	1	1	-
bioMerieux Vidas - IgM	1	-	-	1
bioMerieux Vitek, Mini Vidas	1	-	-	1
Dade Behring PEP 2000	1	-	1	-
Roche Elecsys 1010/2010	4	-	4	-
Roche Modular Analytics	1	-	1	-
VITROS ECi	3	-	3	-

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

<u>Method</u>	<b>Specimen VM-6</b>		<b>Specimen VM-7</b>		<b>Specimen VM-8</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	29	22	8	20	10
Abbott AxSYM	-	6	4	2	1	5
Abbott AxSYM – IgM	-	1	1	-	-	1
Abbott AxSYM – Total	-	4	2	2	-	4
Beckman (Sanofi) ACCESS	-	1	1	-	1	-
bioMerieux Vidas – IgM	-	3	3	-	3	-
bioMerieux Vitek, Mini Vidas	-	2	2	-	2	-
Dade Behring PEP 2000	-	1	1	-	1	-
Roche Cobas CORE	-	2	2	-	2	-
Roche Elecsys 1010/2010	-	3	3	-	3	-
Roche Modular Analytics	-	2	2	-	2	-
VITROS ECi	-	4	-	4	4	-

## Viral Markers – Anti-HBsAg (International)

<u>Method</u>	<b>Specimen VM-9</b>		<b>Specimen VM-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	30	22	8
Abbott AxSYM	-	6	5	1
Abbott AxSYM – IgM	-	1	1	-
Abbott AxSYM – Total	-	4	2	2
Beckman (Sanofi) ACCESS	-	1	1	-
bioMerieux Vidas – IgM	-	3	3	-
bioMerieux Vitek, Mini Vidas	-	2	1	1
Dade Behring PEP 2000	-	1	1	-
Roche Cobas CORE	-	2	2	-
Roche Elecsys 1010/2010	-	3	3	-
Roche Modular Analytics	-	2	2	-
VITROS Eci	-	4	-	4

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

## Viral Markers – HCV (International)

<u>Method</u>	<b>Specimen VM-6</b>		<b>Specimen VM-7</b>		<b>Specimen VM-8</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	25	25	-	10	15
Abbott AxSYM	-	6	6	-	-	6
Abbott AxSYM – IgM	-	1	1	-	-	1
Abbott AxSYM – Total	-	3	3	-	-	3
Beckman (Sanofi) ACCESS	-	1	1	-	1	-
Bio-Rad Evolis	-	1	1	-	1	-
bioMerieux Vitek, Mini Vidas	-	1	1	-	1	-
Roche Cobas CORE	-	2	2	-	2	-
VITROS Eci	-	5	5	-	-	5

  

<u>Method</u>	<b>Specimen VM-9</b>		<b>Specimen VM-10</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	20	5	25	-
Abbott AxSYM	4	2	6	-
Abbott AxSYM – IgM	1	-	1	-
Abbott AxSYM – Total	-	3	3	-
Beckman (Sanofi) ACCESS	1	-	1	-
Bio-Rad Evolis	1	-	1	-
bioMerieux Vitek, Mini Vidas	1	-	1	-
Roche Cobas CORE	2	-	2	-
VITROS Eci	5	-	5	-

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