

# **MEDICAL LABORATORY EVALUATION**

## **PARTICIPANT SUMMARY**

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

Immunology  
MLE – M1

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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

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



**Infectious Mononucleosis (cont'd)**

<b><u>Method</u></b>	<b>Specimen IM-4</b>		<b>Specimen IM-5</b>	
	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
Quidel Quick Vue+	1	48	48	1
Quidel Quick Vue+ - waived	-	12	12	-
Remel RIM A.R.C.	-	2	2	-
Seradyn	-	32	32	-
Seradyn Color Q – (whole blood)	-	1	1	-
Stanbio	-	1	1	-
Wampole ColorCard	-	13	13	-
Wampole Mono-Latex	1	3	4	-
Wampole Mono-Plus	-	22	22	-
Wampole Mono-Plus (whole blood)	-	8	8	-
Wampole Mono-Test	6	4	10	-

**Rheumatoid Factor—Qualitative**

<b><u>Method</u></b>	<b>Specimen RF-1</b>		<b>Specimen RF-2</b>		<b>Specimen RF-3</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	1	118	-	119	119	-
Ampcor	-	1	-	1	1	-
ASI	-	7	-	7	7	-
Beckman Array	-	1	-	1	1	-
Beckman Synchron	-	1	-	1	1	-
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-View	-	9	-	9	9	-
Gamma	-	1	-	1	1	-
Immunostics Inc.	-	3	-	3	3	-
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	-	53	-	53	53	-
Stanbio	-	2	-	2	2	-
Sterling Diagnostics, Inc.	-	3	-	3	3	-
Wampole ColorCard	-	1	-	1	1	-
Wampole Rheumatex	-	7	-	7	7	-
Wampole Rheumaton	1	10	-	11	11	-

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

<b><u>Method</u></b>	<b>Specimen RF-4</b>		<b>Specimen RF-5</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
Ampcor	1	-	-	1
ASI	7	-	-	7
Beckman Array	1	-	-	1
Beckman Synchron	1	-	-	1
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	9	-	-	9
Gamma	1	-	-	1
Immunostics Inc.	3	-	-	3
J&S Medical Assoc. Accutex	3	-	-	3
Murex Latex Test	1	-	-	1
Pulse Scientific	1	-	-	1
Roche Integra	1	-	-	1
Seradyn	53	-	-	53
Stanbio	2	-	-	2
Sterling Diagnostics, Inc.	3	-	-	3
Wampole ColorCard	1	-	-	1
Wampole Rheumatex	7	-	-	7
Wampole Rheumaton	11	-	-	11

## 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-1</b>											
All Methods	11	9	3	4	1	-	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumagen	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	2	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	2	-	1	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Seradyn	6	6	-	-	1	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	-	1	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-
<b>Specimen RF-2</b>											
All Methods	10	10	3	4	1	-	-	-	-	-	-
ASI	-	-	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumagen	-	-	-	1	-	-	-	-	-	-	-
Biokit Rheumajet	2	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	2	-	1	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Seradyn	5	7	-	-	1	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	-	1	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-
<b>Specimen RF-5</b>											
All Methods	9	11	4	1	3	-	-	-	-	-	-
ASI	-	-	1	-	-	-	-	-	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-	-	-	-
Biokit Rheumagen	-	-	-	-	1	-	-	-	-	-	-
Biokit Rheumajet	1	1	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	2	-	-	1	-	-	-	-	-	-
Murex Latex Test	-	1	-	-	-	-	-	-	-	-	-
Seradyn	6	6	-	-	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-1</b>							
All Methods	20	114.1	59.1	51.9	95	54	256
Beckman Synchron	6	161.2	40.3	25.0	180	109	200
Seradyn	3	-	-	-	80	54	160
<b>Specimen RF-2</b>							
All Methods	19	114.1	61.5	53.9	80	55	256
Beckman Synchron	5	173.2	35.9	20.7	184	111	202
Seradyn	3	-	-	-	80	62	160
<b>Specimen RF-3</b>							
All Methods	5	9.2	11.1	120.9	4	3	29
<b>Specimen RF-4</b>							
All Methods	6	10.8	10.6	97.4	5	3	28
<b>Specimen RF-5</b>							
All Methods	20	104.6	51.0	48.7	94	40	198
Beckman Synchron	6	160.3	39.8	24.8	178	110	198
Seradyn	3	-	-	-	80	56	160

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

<u>Method</u>	Specimen AS-1		Specimen AS-2		Specimen AS-3	
	<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-4		Specimen AS-5	
	<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-3

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

#### Specimen AS-4

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-1</b>							
All Methods	11	154.6	11.4	7.4	154	137	169
DiaSorin (INCSTAR)	4	-	-	-	165	137	169
<b>Specimen COM-2</b>							
All Methods	12	77.6	7.8	10.0	77	60	90
DiaSorin (INCSTAR)	5	76.6	10.9	14.2	78	60	90
<b>Specimen COM-3</b>							
All Methods	11	118.0	7.5	6.4	115	105	130
DiaSorin (INCSTAR)	4	-	-	-	124	115	130
<b>Specimen COM-4</b>							
All Methods	12	92.8	7.2	7.8	93	76	105
DiaSorin (INCSTAR)	5	92.4	10.6	11.5	93	76	105
<b>Specimen COM-5</b>							
All Methods	11	206.4	10.6	5.1	207	190	229
DiaSorin (INCSTAR)	4	-	-	-	211	207	215

**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-1</b>							
All Methods	12	30.0	4.4	14.6	29	22	39
DiaSorin (INCSTAR)	5	30.2	6.5	21.6	29	22	39
<b>Specimen COM-2</b>							
All Methods	12	16.0	2.1	13.3	16	12	19
DiaSorin (INCSTAR)	5	16.8	2.9	17.6	18	12	19
<b>Specimen COM-3</b>							
All Methods	12	23.1	2.8	12.3	22	19	28
DiaSorin (INCSTAR)	5	23.8	3.8	16.1	24	19	28
<b>Specimen COM-4</b>							
All Methods	12	18.9	2.6	14.0	18	16	24
DiaSorin (INCSTAR)	5	19.6	3.6	18.3	20	16	24
<b>Specimen COM-5</b>							
All Methods	12	40.7	4.8	11.7	40	34	47
DiaSorin (INCSTAR)	5	41.8	6.3	15.1	45	34	47

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

<u>Method</u>	Specimen AN-1		Specimen AN-2		Specimen AN-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	9	-	9	-	4	5
Alpha Scientific Medical, Inc.	3	-	3	-	3	-
Diagnostic Technology	3	-	3	-	-	3
GenBio ImmunoDOT	1	-	1	-	-	1
Pulse Scientific	1	-	1	-	1	-
Wampole	1	-	1	-	-	1

<u>Method</u>	Specimen AN-4		Specimen AN-5	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	4	5	9	-
Alpha Scientific Medical, Inc.	3	-	3	-
Diagnostic Technology	-	3	3	-
GenBio ImmunoDOT	-	1	1	-
Pulse Scientific	1	-	1	-
Wampole	-	1	1	-

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

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<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>	Specimen AE-4		Specimen AE-5	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	12	12	-
Immuno Concepts	-	6	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>
<b>Specimen AE-3</b>											
All Methods	-	-	-	2	3	2	-	-	-	-	-
Immuno Concepts	-	-	-	2	2	1	-	-	-	-	-
Kallestad	-	-	-	-	1	1	-	-	-	-	-
<b>Specimen AE-4</b>											
All Methods	-	-	-	1	1	5	-	-	-	-	-
Immuno Concepts	-	-	-	1	-	4	-	-	-	-	-
Kallestad	-	-	-	-	1	1	-	-	-	-	-

## C-Reactive Protein—Qualitative

<u>Method</u>	<u>Specimen CR-1</u>		<u>Specimen CR-2</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	11	-	-	10
ASI	2	-	-	2
Behring RapiTex	1	-	-	1
Chemicon	1	-	-	1
Dade Dimension/AR/ES/RxL/Xpand	1	-	-	1
Gamma	1	-	-	1
Immunosits Inc.	2	-	-	2
Wampole	2	-	-	2

## C-Reactive Protein—Quantitative (mg/dL), Regular

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>
<b>Specimen CR-1</b>					
All Methods mg/dL - units	12	0.195	0.219	112.3	0.12
All Immunology Methods mg/L - units	4	-	-	-	0.34
Polymedco CRP	4	-	-	-	0.09
All Immunology Methods	8	0.483	0.958	198.5	0.11
<b>Specimen CR-2</b>					
All Methods mg/dL - units	40	5.604	6.735	120.2	1.96
Beckman Synchron	7	1.543	0.172	11.1	1.60
Dade Dimension/AR/ES/RxL/Xpa	6	1.805	0.110	6.1	1.80
Roche Integra	4	-	-	-	1.99
All Immunology Methods mg/L - units	23	1.742	0.293	16.8	1.70
Polymedco CRP	4	-	-	-	17.69
All Immunology Methods	10	16.673	3.486	20.9	17.74

**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-1</b>					
All Methods mg/dL - units	51	1.683	0.973	57.8	2.15
Dade Dimension High Sensi CR	7	0.166	0.063	38.0	0.16
All Immunology Methods	13	0.212	0.075	35.3	0.23
mg/L - units					
Kamiya Biomedical hs-CRP	3	-	-	-	2.44
Polymedco Full Range CRP	3	-	-	-	2.10
Polymedco Ultra CRP	4	-	-	-	2.21
Roche Cobas HS CRP	4	-	-	-	2.59
All Immunology Methods	33	2.284	0.331	14.5	2.28
<b>Specimen HCR-2</b>					
All Methods mg/dL - units	48	9.149	5.327	58.2	11.49
Dade Dimension High Sensi CR	7	1.190	0.072	6.0	1.18
All Immunology Methods	13	1.139	0.301	26.5	1.18
mg/L - units					
Kamiya Biomedical hs-CRP	3	-	-	-	12.48
Polymedco Full Range CRP	3	-	-	-	11.50
Roche Cobas HS CRP	5	13.106	1.352	10.3	12.34
All Immunology Methods	31	12.508	1.446	11.6	12.30

## Rubella—Qualitative

<u>Method</u>	<b>Specimen RU-1</b>		<b>Specimen RU-2</b>		<b>Specimen RU-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	10	-	10	10	-
Abbott AxSYM	-	1	-	1	1	-
Abbott IMx	-	1	-	1	1	-
Becton Dickinson	-	1	-	1	1	-
Biokit	-	1	-	1	1	-
bioMerieux Vitek, Mini Vidas	-	3	-	3	3	-
Seradyn	-	2	-	2	2	-
Wampole Rubella – Plus	-	1	-	1	1	-
	<b>Specimen RU-4</b>		<b>Specimen RU-5</b>			
All Methods	-	10	10	-		
Abbott AxSYM	-	1	1	-		
Abbott IMx	-	1	1	-		
Becton Dickinson	-	1	1	-		
Biokit	-	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-1</b>							
All Methods	3	-	-	-	233.3	4.2	304.2
<b>Specimen RU-2</b>							
All Methods	3	-	-	-	225.7	4.1	283.5
<b>Specimen RU-4</b>							
All Methods	3	-	-	-	261.2	4.1	327.0

**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-1</b>							
All Methods	8	271.1	25.2	9.3	273	242	318
bioMerieux Vitek, Mini Vidas	1	-	-	-	243	243	243
Hycor EIA	2	-	-	-	287	255	318
Pharmacia & Upjohn Unicap 100	5	270.6	17.4	6.4	275	242	289
<b>Specimen AL-2</b>							
All Methods	8	703.0	105.3	15.0	750	524	802
bioMerieux Vitek, Mini Vidas	1	-	-	-	748	748	748
Hycor EIA	2	-	-	-	557	524	589
Pharmacia & Upjohn Unicap 100	5	752.6	67.6	9.0	775	637	802
<b>Specimen AL-3</b>							
All Methods	9	95.3	14.2	14.8	93	75	117
bioMerieux Vitek, Mini Vidas	1	-	-	-	83	83	83
Hycor EIA	2	-	-	-	102	88	116
Pharmacia & Upjohn Unicap 100	6	95.2	13.9	14.6	96	75	117
<b>Specimen AL-4</b>							
All Methods	9	94.1	11.9	12.7	92	79	118
bioMerieux Vitek, Mini Vidas	1	-	-	-	82	82	82
Hycor EIA	2	-	-	-	95	92	98
Pharmacia & Upjohn Unicap 100	6	95.8	13.8	14.4	96	79	118
<b>Specimen AL-5</b>							
All Methods	9	28.7	5.2	18.0	29	19	37
bioMerieux Vitek, Mini Vidas	1	-	-	-	19	19	19
Hycor EIA	2	-	-	-	31	28	33
Pharmacia & Upjohn Unicap 100	6	29.7	4.4	14.7	29	25	37

# Allergen Specific IgE Antibodies

## Specimen AL-1

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

	Common Ragweed Allergen <i>CLASS RESULT</i>							White Oak Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	1	4	7	-	-	-	3	6	2	-	-
Hycor EIA	-	-	-	-	1	1	-	-	-	-	1	1	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	1	-	-	-	1	-	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	5	-	-	-	-	5	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	1	-	-	-	-	1	-	-	-	-

	Bermuda Grass 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	-	-	1	7	3	-	-	-	-	1	2	9	-	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	-	2	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	2	-	-	-	-	-	-	-	2	-	-
Pharmacia & Upjohn UniCap 100	-	-	1	-	-	-	-	-	-	-	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	4	-	-	-	-	-	-	-	4	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	1	-	-	-

	Dog Dander Allergen <i>CLASS RESULT</i>						
	0	1	2	3	4	5	6
All Methods	-	-	-	-	7	2	-
Hycor EIA	-	-	-	-	1	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	2	2	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	1	-	-

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

**Specimen AL-2**

	<b>Bermuda Grass Allergen</b>							<b>Russian Thistle Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	2	9	-	-	-	-	-	-	2	-	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	1	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	4	-	-	-	-	-	-	1	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	<b>Perennial Rye Allergen</b>							<b>Cat Epithelium Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	5	-	-	-	-	-	2	11	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	-	2	-	-
MAST Immunosystems (LU)	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	-	-	-	-	-	-	2	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	1	-	-	-	-	-	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	2	-	-	-	-	-	-	5	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	1	-	-	-
	<b>White Oak Allergen</b>							<b>Meadow, Kentucky Blue and June Grass Allergen</b>						
	<b>CLASS RESULT</b>							<b>CLASS RESULT</b>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	6	5	-	-	-	-	-	-	2	3	-
Hycor EIA	-	-	-	-	2	-	-	-	-	-	-	-	1	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	3	2	-	-	-	-	-	-	-	2	-
Pharmacia Unicap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-
	<b>Sage Allergen</b>													
	<b>CLASS RESULT</b>													
	0	1	2	3	4	5	6							
All Methods	-	-	-	-	-	-	-							
Hycor EIA	-	-	-	-	-	-	-							
MAST Immunosystems (LU)	-	-	-	-	-	-	-							
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	-	-	-							
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-							
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	-	-							
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-							

**IgA (mg/dL)**

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
<b>Specimen IP-1</b>							
All Methods	11	222.4	22.1	9.9	222	165	251
<b>Specimen IP-2</b>							
All Methods	11	108.8	13.4	12.3	110	86	131
<b>Specimen IP-3</b>							
All Methods	10	170.4	17.7	10.4	171	130	200
<b>Specimen IP-4</b>							
All Methods	11	135.1	14.4	10.6	136	101	159
<b>Specimen IP-5</b>							
All Methods	11	299.4	24.8	8.3	301	247	334

**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-1</b>							
All Methods	9	1109.9	40.9	3.7	1112	1029	1166
<b>Specimen IP-2</b>							
All Methods	10	534.8	27.4	5.1	526	499	600
<b>Specimen IP-3</b>							
All Methods	9	801.9	46.3	5.8	813	700	851
<b>Specimen IP-4</b>							
All Methods	11	641.9	60.8	9.5	644	508	731
<b>Specimen IP-5</b>							
All Methods	10	1457.1	96.5	6.6	1479	1265	1574

**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-1</b>							
All Methods	11	104.2	11.5	11.1	103	95	135
<b>Specimen IP-2</b>							
All Methods	11	52.0	6.9	13.3	53	37	61
<b>Specimen IP-3</b>							
All Methods	11	76.9	7.4	9.6	78	60	85
<b>Specimen IP-4</b>							
All Methods	11	61.3	5.7	9.2	63	50	68
<b>Specimen IP-5</b>							
All Methods	11	133.0	13.6	10.2	130	103	156

**Syphilis Serology—Qualitative: RPR**

<u>Method</u>	<b>Specimen SY-1</b>		<b>Specimen SY-2</b>		<b>Specimen SY-3</b>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	1	54	53	2	-	55
ASI	-	16	15	1	-	16
Becton Dickinson	-	27	26	1	-	27
Biokit	1	2	3	-	-	3
Fisher HealthCare Sure-Vue	-	3	3	-	-	3
J&S Medical Assoc. Accutex	-	1	1	-	-	1
New Horizons	-	1	1	-	-	1
Stanbio	-	2	2	-	-	2
Wampole Impact RPR	-	1	1	-	-	1
<b>Specimen SY-4</b>						
All Methods	54	1	-	55		
ASI	15	1	-	16		
Becton Dickinson	27	-	-	27		
Biokit	3	-	-	3		
Fisher HealthCare Sure-Vue	3	-	-	3		
J&S Medical Assoc. Accutex	1	-	-	1		
New Horizons	1	-	-	1		
Stanbio	2	-	-	2		
Wampole Impact RPR	1	-	-	1		
<b>Specimen SY-5</b>						
All Methods	54	1	-	55		
ASI	15	1	-	16		
Becton Dickinson	27	-	-	27		
Biokit	3	-	-	3		
Fisher HealthCare Sure-Vue	3	-	-	3		
J&S Medical Assoc. Accutex	1	-	-	1		
New Horizons	1	-	-	1		
Stanbio	2	-	-	2		
Wampole Impact RPR	1	-	-	1		

## Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>
<b>Specimen SY-2</b>							
All Methods	14	7	-	-	-	-	-
ASI	6	3	-	-	-	-	-
Becton Dickinson	5	3	-	-	-	-	-
Biokit	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	-	-	-	-	-	-
New Horizons	-	1	-	-	-	-	-
Stanbio	1	-	-	-	-	-	-

## Specimen SY-4

All Methods	17	4	-	-	-	-	-
ASI	8	1	-	-	-	-	-
Becton Dickinson	7	1	-	-	-	-	-
Biokit	1	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	-	-	-	-	-
New Horizons	-	1	-	-	-	-	-
Stanbio	1	-	-	-	-	-	-

## H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-1</u>		<u>Specimen HP-2</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	17	196	134	79
Abbott FlexPack	-	1	1	-
Abbot Signify	-	1	1	-
Applied Biotech SureStep	4	8	11	1
BD LINK 2	-	4	4	-
Beckman Coulter FlexSure	-	27	27	-
BioWhittaker FAST Plus	1	-	1	-
DPC Immulite/1000	-	1	1	-
Fisher HealthCare Sure-Vue	4	5	9	-
LifeSign Status	-	3	3	-
Meridian ImmunoCard	-	2	1	1
Meridian Premier	-	1	1	-
Polymedco Poly stat	7	26	33	-
Quidel QuickVue	-	102	25	77
Remel RIM A.R.C.	-	1	1	-
Wampole Clearview	-	4	4	-

## Lyme Disease Serology

<u>Method</u>	Specimen LY-1		Specimen LY-2	
	<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 PreVue	-	4	4	-

## Mycoplasma Antibody

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

## Viral Markers – Anti-HBc

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<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-4		Specimen VM-5			
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	-	1	-		

## Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	2	1	1	1	1
<u>Method</u>	Specimen VM-4		Specimen VM-5			
	<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>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<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-4		Specimen VM-5			
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	1	1	-		

Specimen VM-1: Total is Positive; IgM is Negative.

Specimen VM-2: Total is Positive; IgM is Negative.

Specimen VM-3: Total is Positive; IgM is Negative.

Specimen VM-4: Total and IgM are Positive.

Specimen VM-5: Total is Positive; IgM is Negative.

### Viral Markers – HBeAg

The vendor assay for specimens VM-1 through VM-5 are: Negative, Negative, Negative, Negative and Positive respectively.

### Viral Markers – HBsAb

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<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-4		Specimen VM-5			
All Methods	1	-	1	-		

### Viral Markers – Anti-HBsAg

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	3	3	-	3	-
Abbott Quantum	-	2	2	-	2	-
VITROS Eci	-	1	1	-	1	-
	Specimen VM-4		Specimen VM-5			
All Methods	3	-	-	3		
Abbott Quantum	2	-	-	2		
VITROS Eci	1	-	-	1		

### Viral Markers – HCV

The vendor assay for specimens VM-1 through VM-5 are: Negative, Positive, Negative, Negative and Negative, respectively.

## INTERNATIONAL LABS

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

<u>Method</u>	Specimen SY-1			Specimen SY-2			Specimen SY-3		
	<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	-	-	7	3	1	-	-	-	6
Becton Dickinson	-	-	1	-	1	-	-	-	1
Wiener Lab	-	-	1	1	-	-	-	-	-
	Specimen SY-4			Specimen SY-5					
All Methods	3	-	-	-	-	7			
Becton Dickinson	1	-	-	-	-	1			
Wiener Lab	-	-	-	-	-	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-2</b>								
All Methods	4	1	1	-	-	-	-	-
Wiener Lab	-	1	-	-	-	-	-	-
<b>Specimen SY-4</b>								
All Methods	2	2	1	-	-	-	-	-
Wiener Lab	-	-	-	-	-	-	-	-

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

<u>Method</u>	<u>Specimen SY-1</u>		<u>Specimen SY-2</u>		<u>Specimen SY-3</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	
Biokit	-	1	1	-	-	1	
Serodia	-	2	2	-	-	2	
		<u>Specimen SY-4</u>		<u>Specimen SY-5</u>			
All Methods	3	-	-	3			
Biokit	1	-	-	1			
Serodia	2	-	-	2			

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

<u>Method</u>	<u>Specimen SY-1</u>		<u>Specimen SY-2</u>		<u>Specimen SY-3</u>		
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	
All Methods	-	2	2	-	-	2	
		<u>Specimen SY-4</u>		<u>Specimen SY-5</u>			
All Methods	2	-	-	2			

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

<u>Method</u>	<u>Specimen SY-1</u>		<u>Specimen SY-2</u>		<u>Specimen SY-3</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	-	17	12	4	-	18
Abbott Syfacard-R	-	4	3	1	-	4
BD ProbeTec	-	1	-	1	-	1
Becton Dickinson	-	1	1	-	-	1
BioSystems	-	3	1	1	-	3
Immunostics Inc.	-	1	1	-	-	1
Omega Diagnostics	-	3	3	-	-	3
Serodia	-	1	1	-	-	1
Wiener Lab	-	1	1	-	-	1

**Syphilis Serology—Qualitative: RPR (International Labs) (cont'd)**

<u>Method</u>	<u>Specimen SY-4</u>		<u>Specimen SY-5</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
All Methods	13	4	-	16
Abbott Syfacard-R	3	1	-	4
BD ProbeTec	-	1	-	1
Becton Dickinson	1	-	-	1
BioSystems	1	1	-	2
Immunostics Inc.	1	-	-	1
Omega Diagnostics	3	-	-	3
Serodia	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-2</b>								
All Methods	6	2	-	-	-	-	-	2
Abbott Syfacard-R	2	1	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-
Omega Diagnostics	-	1	-	-	-	-	-	1
Serodia	-	-	-	-	-	-	-	1
Wiener Lab	1	-	-	-	-	-	-	-
<b>Specimen SY-4</b>								
All Methods	5	4	-	-	-	-	-	2
Abbott Syfacard-R	1	2	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-
Omega Diagnostics	1	-	-	-	-	-	-	1
Serodia	-	-	-	-	-	-	-	1
Wiener Lab	-	1	-	-	-	-	-	-

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

<u>Method</u>	<u>Specimen VM-1</u>		<u>Specimen VM-2</u>		<u>Specimen VM-3</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	11	2	12	1	11	1
Abbott AxSYM	4	1	5	-	5	-
Abbott AxSYM – IgM	1	-	1	-	1	-
Dade Behring PEP 2000	-	1	-	1	-	1
DPC Immulite/1000	1	-	1	-	1	-
Roche Cobas CORE	1	-	1	-	1	-
Roche Modular Analytics	1	-	1	-	1	-
VITROS ECi	1	-	1	-	1	-
Wiener Lab	1	-	1	-	1	-

**Viral Markers – Anti-HBc (International) (cont'd)**

<b><u>Method</u></b>	<b>Specimen VM-4</b>		<b>Specimen VM-5</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	1	11
Abbott AxSYM	5	-	-	5
Abbott AxSYM – IgM	1	-	1	-
Dade Behring PEP 2000	-	1	-	1
DPC Immulite/1000	1	-	-	1
Roche Cobas CORE	1	-	-	1
Roche Modular Analytics	1	-	-	1
VITROS ECi	1	-	-	1
Wiener Lab	1	-	-	1

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

<b><u>Method</u></b>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</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	-	18	19	-	19	-
Abbott AxSYM	-	6	6	-	6	-
Abbott AxSYM – IgM	-	1	1	-	1	-
Abbott AxSYM – Total	-	1	1	-	1	-
Beckman (Sanofi) ACCESS	-	1	1	-	1	-
bioMerieux Vidas - IgM	-	1	1	-	1	-
bioMerieux Vitek, Mini Vidas	-	-	1	-	1	-
Roche Cobas CORE	-	1	1	-	1	-
Roche Elecsys 1010/2010	-	2	2	-	2	-
VITROS ECi	-	2	2	-	2	-
Wiener Lab	-	1	1	-	1	-
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
All Methods	18	-	19			
Abbott AxSYM	6	-	6			
Abbott AxSYM – IgM	1	-	1			
Abbott AxSYM – Total	1	-	1			
Beckman (Sanofi) ACCESS	1	-	1			
bioMerieux Vidas - IgM	1	-	1			
bioMerieux Vitek, Mini Vidas	-	-	1			
Roche Cobas CORE	1	-	1			
Roche Elecsys 1010/2010	2	-	2			
VITROS ECi	2	-	2			
Wiener Lab	1	-	1			

### Viral Markers – HAV (International)

<u>Method</u>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	5	11	5	12	5	12
Abbott AxSYM	-	4	-	4	-	4
Abbott AxSYM – IgM	2	-	2	-	2	-
bioMerieux Vidas – IgM	2	-	2	-	2	-
bioMerieux Vitek, Mini Vidas	-	1	-	2	-	2
DiaSorin (INCSTAR)	-	1	-	1	-	1
Roche Elecsys 1010/2010	-	3	-	3	-	3
Roche Modular Analytics	-	1	-	1	-	1
VITROS Eci	1	-	1	-	1	-
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
All Methods	-	17	5	10		
Abbott AxSYM	-	4	-	3		
Abbott AxSYM – IgM	-	2	2	-		
bioMerieux Vidas – IgM	-	2	2	-		
bioMerieux Vitek, Mini Vidas	-	2	-	1		
DiaSorin (INCSTAR)	-	1	-	1		
Roche Elecsys 1010/2010	-	3	-	3		
Roche Modular Analytics	-	1	-	1		
VITROS Eci	-	1	1	-		

Specimen VM-1: Total is Positive; IgM is Negative.

Specimen VM-2: Total is Positive; IgM is Negative.

Specimen VM-3: Total is Positive; IgM is Negative.

Specimen VM-4: Total and IgM are Positive.

Specimen VM-5: Total is Positive; IgM is Negative.

### Viral Markers – HBeAg (International)

<u>Method</u>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	8	-	8	-	8	-
Abbott AxSYM	1	-	1	-	1	-
bioMerieux Vitek, Mini Vidas	1	-	1	-	1	-
Dade Behring PEP 200	1	-	1	-	1	-
Roche Elecsys 1010/2010	2	-	2	-	2	-
Roche Modular Analytics	1	-	1	-	1	-
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
All Methods	8	-	8	-		
Abbott AxSYM	1	-	1	-		
bioMerieux Vitek, Mini Vidas	1	-	1	-		
Dade Behring PEP 200	1	-	1	-		
Roche Elecsys 1010/2010	2	-	2	-		
Roche Modular Analytics	1	-	1	-		

### Viral Markers – HBsAb (International)

<u>Method</u>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	19		18	-	19	-
Abbott AxSYM	6		6	-	6	-
Beckman (Sanofi) ACCESS	1		1	-	1	-
bioMerieux Vidas - IgM	1		1	-	1	-
Dade Behring PEP 2000	1		1	-	1	-
DiaSorin (INCSTAR)	1		1	-	1	-
DPC Immulite/1000	1		-	-	1	-
Roche Elecsys 1010/2010	5		5	-	5	-
VITROS ECi	2		2	-	2	-
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
All Methods	19	-	18	-		
Abbott AxSYM	6	-	6	-		
Beckman (Sanofi) ACCESS	1	-	1	-		
bioMerieux Vidas - IgM	1	-	1	-		
Dade Behring PEP 2000	1	-	1	-		
DiaSorin (INCSTAR)	1	-	1	-		
DPC Immulite/1000	1	-	-	-		
Roche Elecsys 1010/2010	5	-	5	-		
VITROS ECi	2	-	2	-		

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

<u>Method</u>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	21	21	1	21	-
Abbott AxSYM	-	7	7	-	7	-
Abbott AxSYM – IgM	-	1	1	-	1	-
Beckman (Sanofi) ACCESS	-	1	1	-	1	-
bioMerieux Vidas – IgM	-	1	1	-	1	-
Dade Behring PEP 2000	-	1	-	1	1	-
DPC Immulite/1000	-	-	1	-	-	-
Roche Cobas CORE	-	1	1	-	1	-
Roche Elecsys 1010/2010	-	4	4	-	4	-
Roche Modular Analytics	-	1	1	-	1	-
VITROS ECi	-	2	2	-	2	-
Wiener Lab	-	1	1	-	1	-
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
All Methods	22	-	-	22		
Abbott AxSYM	7	-	-	7		
Abbott AxSYM – IgM	1	-	-	1		
Beckman (Sanofi) ACCESS	1	-	-	1		
bioMerieux Vidas – IgM	1	-	-	1		
Dade Behring PEP 2000	1	-	-	1		
DPC Immulite/1000	1	-	-	1		
Roche Cobas CORE	1	-	-	1		
Roche Elecsys 1010/2010	4	-	-	4		
Roche Modular Analytics	1	-	-	1		
VITROS ECi	2	-	-	2		
Wiener Lab	1	-	-	1		

## Viral Markers – HCV (International)

<u>Method</u>	<b>Specimen VM-1</b>		<b>Specimen VM-2</b>		<b>Specimen VM-3</b>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	18	-	-	18	16	1
Abbott AxSYM	7	-	-	7	7	-
Roche Cobas CORE	2	-	-	2	2	-
VITROS ECi	4	-	-	4	4	-
Wiener Lab	1	-	-	1	1	-
	<b>Specimen VM-4</b>		<b>Specimen VM-5</b>			
All Methods	17	-	18	-		
Abbott AxSYM	7	-	7	-		
Roche Cobas CORE	2	-	2	-		
VITROS ECi	4	-	4	-		
Wiener Lab	1	-	1	-		

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