

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Immunology
MLE – M3

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2004 Evaluation Criteria

The evaluation criteria used in the 2004 MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

Qualitative

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

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

Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each peer group consisting of 10 or more laboratories. Acceptable performance is established based on a target value \pm the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on pages 44-45 under the heading "Acceptable Ranges for Quantitative Results."

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

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

Infectious Mononucleosis

<u>Method</u>	Specimen IM-11		Specimen IM-12		Specimen IM-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	3	328	3	327	251	-
ABI SureStep Mono-whole blood	-	2	-	2	2	-
Applied Biotech SureStep	-	4	-	4	3	-
ASI	-	1	-	1	1	-
BioStar Acceava Mono Test	-	8	-	8	8	-
BioStar Acceava Mono-whole blood	1	16	-	17	8	-
Fisher HealthCare Sure-Vue	-	16	-	16	16	-
Fisher Sure-Vue Strep A-waived	-	1	-	1	-	-
Genzyme Contrast Mono	-	1	-	1	1	-
Genzyme Contrast Mono-whole blood	-	3	-	3	2	-
J&S Medical Assoc. Accutex	-	1	-	1	1	-
LifeSign UniStep Mono	-	1	-	1	1	-
Mainline Confirms	-	1	-	1	1	-
Meridian ImmunoCardSTAT-waived	-	1	-	1	-	-
Meridian Monospot (Latex)	-	1	-	1	1	-
Polymedco Poly stat	-	10	-	10	8	-
Polymedco Poly stat – waived	-	17	-	17	8	-
Quidel Quick Vue+	2	70	2	70	63	-
Quidel Quick Vue+ - waived	-	34	1	32	13	-
Remel RIM A.R.C.	-	1	-	1	1	-
Seradyn	-	31	-	31	30	-
Seradyn Color Q – (whole blood)	-	2	-	2	2	-
Stanbio	-	1	-	1	1	-
Wampole ColorCard	-	15	-	15	15	-
Wampole Mono-Latex	-	8	-	8	8	-
Wampole Mono-Plus	-	35	-	35	30	-
Wampole Mono-Plus (whole blood)	-	26	-	26	10	-
Wampole Mono-Test	-	10	-	10	10	-
Wyntek OSOM	-	4	-	4	2	-

<u>Method</u>	Specimen IM-14		Specimen IM-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	251	-	251	-
ABI SureStep Mono-whole blood	2	-	2	-
Applied Biotech SureStep	3	-	3	-
ASI	1	-	1	-
BioStar Acceava Mono Test	8	-	8	-
BioStar Acceava Mono-whole blood	8	-	8	-
Fisher HealthCare Sure-Vue	16	-	16	-
Genzyme Contrast Mono	1	-	1	-
Genzyme Contrast Mono-whole blood	2	-	2	-
J&S Medical Assoc. Accutex	1	-	1	-
LifeSign UniStep Mono	1	-	1	-
Mainline Confirms	1	-	1	-
Meridian Monospot (Latex)	1	-	1	-
Polymedco Poly stat	8	-	8	-
Polymedco Poly stat – waived	8	-	8	-

Infectious Mononucleosis (cont'd)

<u>Method</u>	Specimen IM-14		Specimen IM-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
Quidel Quick Vue+	63	-	63	-
Quidel Quick Vue+ - waived	13	-	13	-
Remel RIM A.R.C.	1	-	1	-
Seradyn	30	-	30	-
Seradyn Color Q – (whole blood)	2	-	2	-
Stanbio	1	-	1	-
Wampole ColorCard	15	-	15	-
Wampole Mono-Latex	8	-	8	-
Wampole Mono-Plus	30	-	30	-
Wampole Mono-Plus (whole blood)	10	-	10	-
Wampole Mono-Test	10	-	10	-
Wyntek OSOM	2	-	2	-

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-11		Specimen RF-12		Specimen RF-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	2	119	-	121	119	2
Ampcor	-	1	-	1	1	-
ASI	-	8	-	8	8	-
Beckman Array	-	2	-	2	2	-
Beckman Synchron	-	5	-	5	5	-
Becton Dickinson	-	1	-	1	1	-
Behring RapiTex-Plate method	-	4	-	4	4	-
Biokit Rheumajet	-	3	-	3	3	-
BMH 717	-	1	-	1	1	-
Fisher HealthCare Sure-Vue	-	8	-	8	8	-
Immunostics Inc.	-	2	-	2	2	-
J&S Medical Assoc. Accutex	-	3	-	3	3	-
Murex Latex Test	-	2	-	2	2	-
Pulse Scientific	-	2	-	2	2	-
Quidel Concise Plus	-	1	-	1	1	-
Seradyn	1	46	-	47	46	1
Stanbio	-	2	-	2	2	-
Sterling Diagnostics, Inc.	-	2	-	2	2	-
Wampole ColorCard	-	2	-	2	2	-
Wampole Rheumatex	-	7	-	7	7	-
Wampole Rheumaton	-	13	-	13	13	-

Rheumatoid Factor—Qualitative (cont'd)

<u>Method</u>	Specimen RF-14		Specimen RF-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	120	119	2
Ampcor	-	1	1	-
ASI	-	8	8	-
Beckman Array	-	2	2	-
Beckman Synchron	-	5	5	-
Becton Dickinson	-	1	1	-
Behring RapiTex-Plate method	-	4	4	-
Biokit Rheumajet	-	3	3	-
BMH 717	-	1	1	-
Fisher HealthCare Sure-View	-	8	8	-
Immunostics Inc.	-	2	2	-
J&S Medical Assoc. Accutex	-	3	3	-
Murex Latex Test	-	2	2	-
Pulse Scientific	-	2	2	-
Quidel Concise Plus	-	1	1	-
Seradyn	-	47	47	-
Stanbio	-	2	2	-
Sterling Diagnostics, Inc.	-	2	2	-
Wampole ColorCard	-	2	2	-
Wampole Rheumatex	-	7	7	-
Wampole Rheumaton	-	13	12	1

Rheumatoid Factor—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>2/</u>	<u>8/</u>	<u>16/</u>	<u>32/</u>	<u>64/</u>	<u>128/</u>	<u>256/</u>	<u>512/</u>	<u>1024/</u>	<u>2048/</u>	<u>>2560</u>
	<u>4</u>	<u>10</u>	<u>20</u>	<u>40</u>	<u>80</u>	<u>160</u>	<u>320</u>	<u>640</u>	<u>1280</u>	<u>2560</u>	
Specimen RF-11											
All Methods	19	5	2	1	2	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	-	1	-	-	-	-	-	-
Behring RapiTex - Plate method	-	1	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	2	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-View	5	-	-	-	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-	-	-
Seradyn	8	3	-	1	-	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (Titer) (cont'd)

<u>Specimen/Method</u>	<u>2/4</u>	<u>8/10</u>	<u>16/20</u>	<u>32/40</u>	<u>64/80</u>	<u>128/160</u>	<u>256/320</u>	<u>512/640</u>	<u>1024/1280</u>	<u>2048/2560</u>	<u>>2560</u>
Specimen RF-12											
All Methods	18	5	3	1	2	-	-	-	-	-	-
ASI	1	-	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	-	1	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	2	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	4	1	-	-	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Pulse Scientific	-	1	-	-	-	-	-	-	-	-	-
Seradyn	8	2	1	1	-	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

Specimen RF-14

All Methods	16	6	4	1	2	-	-	-	-	-	-
ASI	-	1	-	-	-	-	-	-	-	-	-
Beckman Synchron	-	-	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	-	1	-	-	-	-	-	-
Behring RapiTex - Plate method	1	-	-	-	-	-	-	-	-	-	-
Biokit Rheumajet	2	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	3	2	-	-	-	-	-	-	-	-	-
Murex Latex Test	1	-	-	-	-	-	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-	-	-
Seradyn	8	2	1	1	-	-	-	-	-	-	-
Sterling Diagnostics, Inc.	-	1	-	-	-	-	-	-	-	-	-
Wampole Rheumatex	-	-	2	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU)

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen RF-11							
All Methods	17	87.1	38.7	44.5	76	40	160
Beckman Synchron	5	127.8	17.9	14.0	134	96	139
Specimen RF-12							
All Methods	17	80.9	35.3	43.6	80	40	139
Beckman Synchron	5	127.2	20.9	16.4	137	90	139
Specimen RF-14							
All Methods	17	82.5	33.6	40.7	77	40	138
Beckman Synchron	5	127.4	17.9	14.0	135	96	138

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	6	-	-	6	-	6
Beckman Nephelometer	1	-	-	1	-	1
Behring RapiTex	2	-	-	2	-	2
Fisher HealthCare Sure-Vue	1	-	-	1	-	1
J&S Medical Assoc. Accutex	1	-	-	1	-	1
Wampole	1	-	-	1	-	1

<u>Method</u>	<u>Specimen AS-14</u>		<u>Specimen AS-15</u>	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	6	-	-	6
Beckman Nephelometer	1	-	-	1
Behring RapiTex	2	-	-	2
Fisher HealthCare Sure-Vue	1	-	-	1
J&S Medical Assoc. Accutex	1	-	-	1
Wampole	1	-	-	1

Anti-Streptolysin O (ASO)—Quantitative

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

<u>Specimen/Method</u>	<u>Todd Units / International Units</u>									<u>Streptozyme</u>	
	<u>≤50</u>	<u>100</u>	<u>125</u>	<u>166-200</u>	<u>250-300</u>	<u>333-400</u>	<u>500-600</u>	<u>800-833</u>	<u>≥2500</u>	<u>100-200</u>	<u>400-800</u>
Specimen AS-12											
All Methods	-	-	-	-	-	1	1	-	-	1	1
Behring RapiTex	-	-	-	-	-	-	1	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-	-
Wampole	-	-	-	-	-	-	-	-	-	1	-
Specimen AS-13											
All Methods	-	-	-	-	-	1	1	-	-	1	1
Behring RapiTex	-	-	-	-	-	-	1	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-	-
Wampole	-	-	-	-	-	-	-	-	-	1	-
Specimen AS-15											
All Methods	-	-	-	-	-	1	1	-	-	1	1
Behring RapiTex	-	-	-	-	-	-	1	-	-	-	1
Fisher HealthCare Sure-Vue	-	-	-	-	-	1	-	-	-	-	-
Wampole	-	-	-	-	-	-	-	-	-	1	-

Complement C3 (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen COM-11							
All Methods	10	31.8	4.5	14.2	32	25	38
DiaSorin (INCSTAR)	4	-	-	-	35	25	38
Specimen COM-12							
All Methods	12	129.7	13.5	10.4	126	116	150
DiaSorin (INCSTAR)	5	123.8	14.7	11.9	117	116	150
Specimen COM-13							
All Methods	12	81.1	5.2	6.4	80	70	89
DiaSorin (INCSTAR)	5	79.8	6.7	8.4	80	70	89
Specimen COM-14							
All Methods	12	58.2	4.7	8.0	58	49	66
DiaSorin (INCSTAR)	5	57.0	5.0	8.9	58	49	63
Specimen COM-15							
All Methods	12	125.2	10.5	8.4	125	109	144
DiaSorin (INCSTAR)	5	121.6	12.1	9.9	119	109	140

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>
Specimen COM-11							
All Methods	5	4.8	3.0	63.2	7	1	7
DiaSorin (INCSTAR)	3	-	-	-	7	1	7
Specimen COM-12							
All Methods	12	29.7	7.9	26.7	27	23	47
DiaSorin (INCSTAR)	5	27.4	1.5	5.5	27	26	29
Specimen COM-13							
All Methods	9	8.6	2.3	26.9	9	5	13
DiaSorin (INCSTAR)	5	8.4	1.5	18.1	9	6	10
Specimen COM-14							
All Methods	12	17.9	1.7	9.7	18	15	20
DiaSorin (INCSTAR)	5	18.8	1.6	8.7	19	16	20
Specimen COM-15							
All Methods	12	29.4	6.9	23.5	28	24	44
DiaSorin (INCSTAR)	5	27.4	1.5	5.5	28	25	29

Antinuclear Antibody (ANA)—Qualitative

<u>Method</u>	Specimen AN-11		Specimen AN-12		Specimen AN-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	1	4	5	-	2	3
Diagnostic Technology	-	3	3	-	1	2
Pulse Scientific	1	-	1	-	1	-
Wampole Impact	-	1	1	-	-	1

<u>Method</u>	Specimen AN-14		Specimen AN-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	4	1	1	4
Diagnostic Technology	2	1	1	2
Pulse Scientific	1	-	-	1
Wampole Impact	1	-	-	1

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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Specimen AN-11

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

Specimen AN-13

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

Specimen AN-15

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

Antinuclear Antibody (ANA)—Qualitative

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	4	16	4	16	19	1
ASI	4	-	4	-	4	-
Immuno Concepts	-	5	-	5	5	-
INOVA Diagnostics	-	2	-	2	2	-
Kallestad	-	5	-	5	4	1
Seradyn	-	1	-	1	1	-
Wampole Impact	-	1	-	1	1	-
Zeus	-	1	-	1	1	-

Antinuclear Antibody (ANA)—Qualitative (cont'd)

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	4	16	20	-
ASI	4	-	4	-
Immuno Concepts	-	5	5	-
INOVA Diagnostics	-	2	2	-
Kallestad	-	5	5	-
Seradyn	-	1	1	-
Wampole Impact	-	1	1	-
Zeus	-	1	1	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

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

C-Reactive Protein—Qualitative

<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	-	13	13	-
ASI	-	2	2	-
Behring RapiTex	-	1	1	-
Biokit Rheumajet	-	1	1	-
Dade Dimension/AR/ES/RxL/Xpand	-	1	1	-
Murex Latex Test	-	1	1	-
Pulse Scientific	-	2	2	-
Seradyn	-	1	1	-
Wampole	-	2	2	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>Low Value</u>	<u>High Value</u>
Specimen CR-5				
All Methods	29	6.00	0.21	22.00
Beckman Synchron	9	1.80	1.60	18.00
Dade Dimension/AR/ES/RxL/Xpand	8	19.50	1.97	21.00
DiaSorin (INCSTAR)	4	7.74	1.86	21.50
Roche Integra	3	2.19	0.21	22.00

Specimen CR-6

All Methods	4	0.06	0.01	3.00
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C-Reactive Protein—Quantitative (mg/dL), High Sensitivity

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Low Value</u>	<u>High Value</u>
Specimen CR-5							
All Methods	53	17.312	8.654	50.0	20.60	1.00	31.50
Dade Dimension High Sensi CRP	4	-	-	-	2.13	2.10	2.16
Kamiya Biomedical hs-CRP	5	10.220	7.116	69.6	10.00	1.00	21.00
Other High Sensitivity CRP method	9	19.663	7.257	36.9	22.61	2.06	26.10
Pointe Scientific CRP (HS)	4	-	-	-	21.95	9.10	23.00
Polymedco Full Range CRP	8	20.419	0.765	3.7	20.07	19.60	21.90
Polymedco Ultra CRP	6	13.443	6.257	46.5	13.85	3.72	20.46
Roche Cobas HS CRP	4	-	-	-	23.34	22.11	25.20
SDI Biomed, Inc.	4	-	-	-	29.50	6.67	31.50

Specimen CR-6

All Methods	43	0.209	0.168	80.6	0.20	0.02	0.71
Kamiya Biomedical hs-CRP	6	0.277	0.184	66.6	0.27	0.03	0.55
Other High Sensitivity CRP method	9	0.169	0.056	32.9	0.20	0.03	0.20
Polymedco Full Range CRP	6	0.208	0.102	49.0	0.20	0.10	0.40
Polymedco Ultra CRP	9	0.270	0.235	87.1	0.25	0.04	0.71
Roche Cobas HS CRP	4	-	-	-	0.10	0.02	0.20
SDI Biomed, Inc.	4	-	-	-	0.95	0.10	1.30

Rubella—Qualitative

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	-	12	12	-	-	12
Abbott AxSYM	-	3	3	-	-	3
Abbott IMx	-	1	1	-	-	1
Becton Dickinson	-	1	1	-	-	1
Biokit	-	1	1	-	-	1
bioMerieux Vitek, Mini Vidas	-	2	2	-	-	2
DPC Immulite/1000	-	1	1	-	-	1
Fisher HealthCare Sure-Vue	-	1	1	-	-	1
Seradyn	-	2	2	-	-	2
	Specimen RU-14		Specimen RU-15			
All Methods	12	-	-	12		
Abbott AxSYM	3	-	-	3		
Abbott IMx	1	-	-	1		
Becton Dickinson	1	-	-	1		
Biokit	1	-	-	1		
bioMerieux Vitek, Mini Vidas	2	-	-	2		
DPC Immulite/1000	1	-	-	1		
Fisher HealthCare Sure-Vue	1	-	-	1		
Seradyn	2	-	-	2		

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>
Specimen RU-11							
All Methods	3	-	-	-	24.1	23.4	25.0
Specimen RU-13							
All Methods	3	-	-	-	25.0	23.3	26.1
Specimen RU-15							
All Methods	3	-	-	-	25.8	24.0	26.0

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>
Specimen AL-11							
All Methods	8	384.9	27.4	7.1	392	345	418
bioMerieux Vitek, Mini Vidas	1	-	-	-	376	376	376
Hycor EIA	2	-	-	-	382	345	418
Pharmacia & Upjohn Unicap 100	5	388.0	24.8	6.4	394	346	410
Specimen AL-12							
All Methods	8	383.6	23.8	6.2	386	346	417
bioMerieux Vitek, Mini Vidas	1	-	-	-	380	380	380
Hycor EIA	2	-	-	-	382	346	417
Pharmacia & Upjohn Unicap 100	5	385.2	18.8	4.9	392	360	408
Specimen AL-13							
All Methods	8	34.6	7.2	20.7	34	23	49
bioMerieux Vitek, Mini Vidas	1	-	-	-	23	23	23
Hycor EIA	2	-	-	-	41	33	49
Pharmacia & Upjohn Unicap 100	5	34.4	1.8	5.3	35	32	36
Specimen AL-14							
All Methods	8	65.5	5.0	7.7	66	59	74
bioMerieux Vitek, Mini Vidas	1	-	-	-	59	59	59
Hycor EIA	2	-	-	-	68	62	74
Pharmacia & Upjohn Unicap 100	5	65.8	3.6	5.4	67	60	69
Specimen AL-15							
All Methods	8	66.1	5.8	8.7	68	56	74
bioMerieux Vitek, Mini Vidas	1	-	-	-	56	56	56
Hycor EIA	2	-	-	-	68	62	74
Pharmacia & Upjohn Unicap 100	5	67.4	3.3	4.9	68	62	71

Allergen Specific IgE Antibodies

Specimen AL-11

	Bermuda Grass Allergen							Cat Epithelium Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	5	7	-	-	-	-	3	7	4	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	-	1	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	1	2	-	-	-	-	-	3	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-	-	-	1	-	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	2	1	-	-	-	-	-	4	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	1	-	-	-	-	-	1	-	-	-	-

	Russian Thistle Allergen							Sage Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	2	2	-	-	-	-	-	-	-	-	-
Hycor EIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	1	1	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-

	White Oak Allergen							Meadow Grass, Kentucky Blue Grass, June Grass Allergen						
	CLASS RESULT							CLASS RESULT						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	4	8	-	-	-	-	-	-	3	4	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	1	1	-	-	-	-	-	-	1	1	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	4	-	-	-	-	-	-	-	2	-
Pharmacia Unicap 100 (KU/L)	-	-	-	1	-	-	-	-	-	-	-	-	-	-

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

Allergen Specific IgE Antibodies (cont'd)

Specimen AL-12

	House Dust Mite Allergen							Bermuda Grass Allergen						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	4	9	-	1	-	-	1	4	7	-	-
Hycor EIA	-	-	-	-	1	-	-	-	-	-	-	1	-	-
MAST Immunosystems (LU)	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	3	-	-	-	-	-	2	1	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	1	-	-	-	-	-	1	-	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	4	-	-	-	-	-	1	2	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	1	-	-	-	1	-	-	-
	Perennial Rye Allergen							Olive Allergen						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	3	3	-	-	-	-	2	-	-	-
Hycor EIA	-	-	-	-	-	1	-	-	-	-	-	-	-	-
MAST Immunosystems (LU)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	1	-	-	-	-	-	-	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	-	1	-	-	-	-	-	1	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	1	-	-	-	-	-	1	-	-	-
	Common Ragweed Allergen							English Plantain Allergen						
	<i>CLASS RESULT</i>							<i>CLASS RESULT</i>						
	0	1	2	3	4	5	6	0	1	2	3	4	5	6
All Methods	-	-	-	-	5	8	-	-	-	-	2	9	-	-
Hycor EIA	-	-	-	-	-	1	-	-	-	-	-	1	-	-
MAST Immunosystems (LU)	-	-	-	-	1	-	-	-	-	-	-	1	-	-
Pharmacia & Upjohn CAP (% ref)	-	-	-	-	1	2	-	-	-	-	-	3	-	-
Pharmacia & Upjohn CAP (KU/L)	-	-	-	-	1	-	-	-	-	-	1	-	-	-
Pharmacia & Upjohn UniCap 100	-	-	-	-	1	-	-	-	-	-	1	-	-	-
Pharmacia UniCap 100 (% ref)	-	-	-	-	-	4	-	-	-	-	-	3	-	-
Pharmacia Unicap 100 (KU/L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Dog Dander Allergen													
	<i>CLASS RESULT</i>													
	0	1	2	3	4	5	6							
All Methods	-	-	4	5	-	-	-							
Hycor EIA	-	-	-	1	-	-	-							
MAST Immunosystems (LU)	-	-	-	1	-	-	-							
Pharmacia & Upjohn CAP (% ref)	-	-	-	1	-	-	-							
Pharmacia & Upjohn CAP (KU/L)	-	-	1	-	-	-	-							
Pharmacia & Upjohn UniCap 100	-	-	1	-	-	-	-							
Pharmacia UniCap 100 (% ref)	-	-	1	2	-	-	-							
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>
Specimen IP-11							
All Methods	9	190.9	26.7	14.0	190	130	220
Specimen IP-12							
All Methods	9	121.9	11.7	9.6	120	104	144
Specimen IP-13							
All Methods	9	191.1	22.0	11.5	192	143	215
Specimen IP-14							
All Methods	9	176.4	12.9	7.3	171	163	198
Specimen IP-15							
All Methods	9	163.4	16.8	10.3	163	130	185

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>
Specimen IP-11							
All Methods	9	894.0	101.4	11.3	895	730	1092
Specimen IP-12							
All Methods	9	540.6	55.1	10.2	542	470	664
Specimen IP-13							
All Methods	7	2173.7	96.0	4.4	2147	2072	2360
Specimen IP-14							
All Methods	7	2439.3	134.7	5.5	2422	2330	2713
Specimen IP-15							
All Methods	9	930.2	118.5	12.7	937	670	1070

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>
Specimen IP-11							
All Methods	9	86.9	5.0	5.8	87	79	94
Specimen IP-12							
All Methods	9	44.6	5.1	11.3	46	38	51
Specimen IP-13							
All Methods	9	88.3	4.9	5.5	90	81	94
Specimen IP-14							
All Methods	7	407.1	12.6	3.1	409	389	421
Specimen IP-15							
All Methods	7	656.1	98.5	15.0	661	507	780

Syphilis Serology—Qualitative: RPR

<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	53	2	-	54	53	2
ASI	15	-	-	15	14	1
Becton Dickinson	29	1	-	29	30	-
Biokit	1	-	-	1	1	-
Fisher	1	-	-	1	1	-
Fisher HealthCare Sure-Vue	2	-	-	2	2	-
J&S Medical Assoc. Accutex	1	-	-	1	1	-
New Horizons	1	-	-	1	1	-
Scientific Products	-	1	-	1	-	1
Stanbio	1	-	-	1	1	-
Wampole Impact RPR	1	-	-	1	1	-
	Specimen SY-14		Specimen SY-15			
All Methods	-	54	52	3		
ASI	-	15	14	1		
Becton Dickinson	-	29	29	1		
Biokit	-	1	1	-		
Fisher	-	1	1	-		
Fisher HealthCare Sure-Vue	-	2	2	-		
J&S Medical Assoc. Accutex	-	1	1	-		
New Horizons	-	1	1	-		
Scientific Products	-	1	-	1		
Stanbio	-	1	1	-		
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>
Specimen SY-11							
All Methods	9	14	-	-	-	-	-
ASI	5	4	-	-	-	-	-
Becton Dickinson	3	7	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	1	-	-	-	-	-
New Horizons	-	1	-	-	-	-	-
Stanbio	-	1	-	-	-	-	-
Specimen SY-13							
All Methods	8	14	1	-	-	-	-
ASI	3	5	1	-	-	-	-
Becton Dickinson	3	7	-	-	-	-	-
Fisher HealthCare Sure-Vue	1	1	-	-	-	-	-
New Horizons	-	1	-	-	-	-	-
Stanbio	1	-	-	-	-	-	-
Specimen SY-15							
All Methods	17	6	-	-	-	-	-
ASI	7	2	-	-	-	-	-
Becton Dickinson	7	3	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-
New Horizons	-	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	-	208	208	-
Abbott FlexPack	-	1	1	-
Abbot Signify	-	3	3	-
Applied Biotech SureStep	-	18	18	-
BD LINK 2	-	4	4	-
Beckman Coulter FlexSure	-	31	31	-
Fisher HealthCare Sure-Vue	-	7	7	-
LifeSign Status	-	3	3	-
Meridian ImmunoCard	-	2	2	-
Meridian Premier	-	1	1	-
Polymedco Poly stat	-	32	32	-
Quidel QuickVue	-	98	98	-
Remel RIM A.R.C.	-	1	1	-
Wampole Clearview	-	2	2	-

Lyme Disease Serology

<u>Method</u>	<u>Specimen LY-5</u>		<u>Specimen LY-6</u>	
	<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	-	4	4	-

Mycoplasma Antibody

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

Viral Markers – Anti-HBc

<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	1	-	1	-	1	-
<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>	<u>Negative</u>	<u>Positive</u>
All Methods	1	-	1	-		

Viral Markers – Anti-HIV

<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	-	2	2	-	2	-
<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>	<u>Negative</u>	<u>Positive</u>
All Methods	2	-	2	-		

Viral Markers – HAV

<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	1	-	1	-	-	1
<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>	<u>Negative</u>	<u>Positive</u>
All Methods	1	-	1	-		

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

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

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

Specimen VM-14: IgG, Total and IgM are Negative.

Specimen VM-15: IgG is Positive; IgM and Total are Negative.

Viral Markers – HBeAg

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

Viral Markers – HBsAb

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

Viral Markers – Anti-HBsAg

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

Viral Markers – HCV

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

VIRAL MARKERS – INTERNATIONAL LABS

Viral Markers – Anti-HBc (International)

<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	7	8	1	8	-
Abbott AxSYM	-	2	2	-	2	-
Abbott AxSYM – IgM	1	-	1	-	1	-
Beckman (Sanofi) ACCESS	-	1	1	-	1	-
DPC Immulite/1000	1	-	1	-	1	-
Roche Cobas CORE	-	1	-	1	1	-
Roche Elecsys 1010/2010	-	1	1	-	1	-
VITROS Eci	-	1	1	-	1	-
	Specimen VM-14		Specimen VM-15			
All Methods	9	-	8	-		
Abbott AxSYM	2	-	2	-		
Abbott AxSYM – IgM	1	-	1	-		
Beckman (Sanofi) ACCESS	1	-	1	-		
DPC Immulite/1000	1	-	1	-		
Roche Cobas CORE	1	-	1	-		
Roche Elecsys 1010/2010	1	-	1	-		
VITROS Eci	1	-	1	-		

Viral Markers – Anti-HIV (International)

<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	-	9	10	-	10	-
Abbott AxSYM	-	3	3	-	3	-
Beckman (Sanofi) ACCESS	-	1	1	-	1	-
bioMerieux Vitek, Mini Vidas	-	-	1	-	1	-
Roche Cobas CORE	-	1	1	-	1	-
VITROS Eci	-	2	2	-	2	-
	Specimen VM-14		Specimen VM-15			
All Methods	9	-	9	-		
Abbott AxSYM	3	-	3	-		
Beckman (Sanofi) ACCESS	1	-	1	-		
bioMerieux Vitek, Mini Vidas	-	-	1	-		
Roche Cobas CORE	1	-	-	-		
VITROS Eci	2	-	2	-		

Viral Markers – HAV (International)

<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	4	2	5	-	7
Abbott AxSYM	2	-	-	2	-	2
Abbott AxSYM – IgM	-	1	1	-	-	1
bioMerieux Vidas	-	1	1	-	-	1
bioMerieux Vitek, Mini Vidas	-	-	-	1	-	1
Roche Elecsys 1010/2010	1	-	-	1	-	1
	Specimen VM-14		Specimen VM-15			
All Methods	7	-	2	4		
Abbott AxSYM	2	-	-	2		
Abbott AxSYM – IgM	1	-	1	-		
bioMerieux Vidas	1	-	1	-		
bioMerieux Vitek, Mini Vidas	1	-	-	-		
Roche Elecsys 1010/2010	1	-	-	1		

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

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

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

Specimen VM-14: IgG, Total and IgM are Negative.

Specimen VM-15: IgG is Positive; IgM and Total are Negative.

Viral Markers – HBeAg (International)

<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	5	-	5	-	-	5
Abbott AxSYM	2	-	2	-	-	2
Roche Elecsys 1010/2010	1	-	1	-	-	1
	Specimen VM-14		Specimen VM-15			
All Methods	5	-	5	-		
Abbott AxSYM	2	-	2	-		
Roche Elecsys 1010/2010	1	-	1	-		

Viral Markers – HBsAb (International)

<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	6	6	-	7	-
Abbott AxSYM	-	3	3	-	3	-
DPC Immulite/1000	-	1	-	-	1	-
Roche Elecsys 1010/2010	-	1	1	-	1	-
VITROS ECi	1	-	1	-	1	-
	Specimen VM-14		Specimen VM-15			
All Methods	7	-	-	6		
Abbott AxSYM	3	-	-	3		
DPC Immulite/1000	1	-	-	-		
Roche Elecsys 1010/2010	1	-	-	1		
VITROS ECi	1	-	-	1		

Viral Markers – Anti-HBsAg (International)

<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	8	2	11	-	2	8
Abbott AxSYM	2	2	4	-	-	4
Beckman (Sanofi) ACCESS	1	-	1	-	-	1
DPC Immulite/1000	-	-	1	-	-	-
Roche Cobas CORE	1	-	1	-	1	-
Roche Elecsys 1010/2010	1	-	1	-	-	1
VITROS Eci	1	-	1	-	1	-

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	11	-	11	-
Abbott AxSYM	4	-	4	-
Beckman (Sanofi) ACCESS	1	-	1	-
DPC Immulite/1000	1	-	1	-
Roche Cobas CORE	1	-	1	-
Roche Elecsys 1010/2010	1	-	1	-
VITROS Eci	1	-	1	-

Viral Markers – HCV (International)

<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	10	-	10	-	5	4
Abbott AxSYM	4	-	4	-	-	4
Roche Cobas CORE	1	-	1	-	1	-
VITROS Eci	2	-	2	-	2	-

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>
All Methods	9	-	1	9
Abbott AxSYM	4	-	-	4
Roche Cobas CORE	1	-	-	1
VITROS Eci	2	-	1	1

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