New York State Department of Health
Wadsworth Center

Proficiency Testing Program

10-Sep-08

DIAGNOSTIC IMMUNOLOGY & HUMAN IMMUNODEFICIENCY VIRUS SUMMARY ANALYSIS

Proficiency Test Event
10-Sep-08

Diagnostic Immunology & Human Immunodeficiency Virus
Summary Report

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The data summarized in this report were tabulated from test results and accompanying information submitted by laboratories that participated in the September 10, 2008 Diagnostic Immunology and Human Immunodeficiency Virus proficiency test events. Participants are encouraged to review the data and to compare results and test kit performances.

Laboratories were evaluated on the basis of their responses for each analyte and on overall performance for all the analytes tested in the permit category. Appropriate responses were determined by participant consensus requiring 80% agreement in each test.

Qualitative/quantitative results were graded in relation to results given by participants for specific test kits. When the number of participants that used a specific test kit was less than 10, results were graded considering results given for the method used. Target values and acceptable ranges were determined as indicated in Page 4.

Grading Criteria:

- For each separate analyte where results were reported, qualitative or quantitative, twenty points were deducted for each incorrect answer. For Syphilis-Reagin (RPR), where both qualitative and quantitative results are reported under one analyte, ten points were deducted for each incorrect quantitative or qualitative result. Titering of positive Syphilis-Reagin samples is mandatory for all Diagnostic Services laboratories who perform this test, unless given an exemption. Failure to titer the positive samples to the endpoint will result in failure for the Syphilis-Reagin analyte.
- For **Diagnostic Services** failure to attain an overall testing score of at least 80% is unsatisfactory performance
- For **Donor Services** failure to attain an overall testing score of 100% is unsatisfactory performance.
- For **HIV** failure to attain an overall testing score of 100% is unsatisfactory performance.
- Laboratories failing two out of three consecutive proficiency test events for an analyte or for the permit category will fail the proficiency testing program for the analyte or for the permit category and may be required to cease patient testing for that analyte/category.

Summary Tables

Test kit manufacturer names are in *italics* . In some tables, test kits are grouped under test methods shown in bold letters. In all tables, test methods and test kit manufacturer names are listed in alphabetic order. Only the testing systems used by 10 or more laboratories are listed in this report.

For qualitative tests, results are summarized as the number of laboratories that reported a test sample as reactive to the number that reported it as non-reactive. In addition, where test results depend on a quantitative value (e.g. titer, IU/ml) the values reported are given in separate tables. They are expressed, where applicable, as the Mean ± S.D. when ten or more laboratories reported data.

For quantitative tests, values reported variously as mg/dl, IU/ml, etc. are given as the Mean ± S.D. when ten or more laboratories reported results. Titers are given as endpoint titers.

Disclaimer

The use of brand and/or trade names in this report does not constitute an endorsement of the products on the part of the Wadsworth Center or the New York State Department of Health.

Determination of Acceptable Responses

Analyte or Test	Criteria
Alpha-1 Antitrypsin	Target value ± 3 S.D.
Antinuclear Antibody	Positive or negative
Antinuclear Antibody Quantitative (IFA systems only)	Target value ± 2 dilutions
Antistreptolysin O	Positive or negative
Antistreptolysin O Quantitative	Target value ± 2 dilutions or Target value ± 3 S.D.
Complement C'3, C'4	Target value ± 3 S.D.
Cytomegalovirus Antibody	Positive or negative
Hepatitis (HbsAg, anti-HBc, HBeAg, and HCAb)	Reactive or nonreactive
HIV 1 Ab, Ag	Reactive or nonreactive
HTLV 1 Ab	Positive or negative
Lyme Disease Ab, WB IgG, IgM	Positive or negative
Immunoglobulin A, E, M	Target value ± 3 S.D.
Immunoglobulin G	Target value ± 25 %
Infectious Mononucleosis	Positive or negative
Rheumatoid Factor	Positive or negative
Rheumatoid Factor Quantitative	Target value ± 2 dilutions or Target value ± 3 S.D.
Rubella Ab, IgM	Positive or negative or Immune or nonimmune
Rubella Ab Quantitative	Target value ± 3 S.D.
Syphilis Reagin Antibody	Reactive or nonreactive Target value ± 1 dilution
Syphilis Treponemal Antibody	Reactive or nonreactive

Antinuclear Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		46 N				**47 N**				**48 N**				**49 R**				**50 N**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**42**	**42**	**100%**	**0**	**0%**	**42**	**100%**	**0**	**0%**	**42**	**100%**	**0**	**0%**	**0**	**0%**	**42**	**100%**	**42**	**100%**	**0**	**0%**
Bio-Rad	11	11	100%		0%	11	100%		0%	11	100%		0%		0%	11	100%	11	100%		0%
Others	31	31	100%		0%	31	100%		0%	31	100%		0%		0%	31	100%	31	100%		0%
IFA	**65**	**65**	**100%**	**0**	**0%**	**65**	**100%**	**0**	**0%**	**63**	**97%**	**2**	**3%**	**2**	**3%**	**63**	**97%**	**65**	**100%**	**0**	**0%**
Bio-Rad	18	18	100%		0%	18	100%		0%	17	94%	1	6%	1	6%	17	94%	18	100%		0%
The Binding Site	10	10	100%		0%	10	100%		0%	9	90%	1	10%	1	10%	9	90%	10	100%		0%
Wampole/Zeus	18	18	100%		0%	18	100%		0%	18	100%		0%		0%	18	100%	18	100%		0%
Others	19	19	100%		0%	19	100%		0%	19	100%		0%		0%	19	100%	19	100%		0%
Muliplexed Bead	16	16	100%		0%	16	100%		0%	16	100%		0%		0%	16	100%	16	100%		0%
Other Methods	4	3	75%	1	25%	3	75%	1	25%	4	100%		0%		0%	4	100%	4	100%		0%
Analyte Total	**127**	**126**	**99%**	**1**	**1%**	**126**	**99%**	**1**	**1%**	**125**	**98%**	**2**	**2%**	**2**	**2%**	**125**	**98%**	**127**	**100%**	**0**	**0%**

Antinuclear Antibody Quantitative (IFA systems only)

The number of laboratories that reported titers is listed for positive test sample 49. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

Method		No.	Sample 49 Titer							
Manufacturer		**Labs**	**40**	**80**	**160**	**320**	**640**	**1280**	**2560**	**5120**
IFA	***Total***	95	3	5	34	28	19		2	
	Bio-Rad	25	1	3	11	6	2			
	Immuno	13			2	4	6		1	
	The Binding site	17			7	2	6			
	Wampole/ Zeus	22	1	1	7	7	4		1	

Note: The number of labs reporting specific titers may not add up to the total number of labs for that system because some labs are not reporting endpoint titers.

Antinuclear Antibody Staining Patterns

	Sample 49	
Staining Pattern	#	%
Homogenous	91	97%
Nucleolar		
Peripheral		
Speckled	3	3%

The reporting of a staining pattern here is for informational purposes only and is not used for grading.

Antistreptolysin O

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		16 R				**17 R**				**18 N**				**19 N**				**20 N**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Latex Agglutination	**74**	**0**	**0%**	**74**	**100%**	**0**	**0%**	**74**	**100%**	**74**	**100%**	**0**	**0%**	**74**	**100%**	**0**	**0%**	**74**	**100%**	**0**	**0%**
Dade Behring	18		0%	18	100%		0%	18	100%	18	100%		0%	18	100%		0%	18	100%		0%
Fisher	18		0%	18	100%		0%	18	100%	18	100%		0%	18	100%		0%	18	100%		0%
Remel	15		0%	15	100%		0%	15	100%	15	100%		0%	15	100%		0%	15	100%		0%
Others	23		0%	23	100%		0%	23	100%	23	100%		0%	23	100%		0%	23	100%		0%
Nephelometry	**10**	**0**	**0%**	**10**	**100%**	**0**	**0%**	**10**	**100%**	**10**	**100%**	**0**	**0%**	**10**	**100%**	**0**	**0%**	**10**	**100%**	**0**	**0%**
Others	10		0%	10	100%		0%	10	100%	10	100%		0%	10	100%		0%	10	100%		0%
Hemagglutination	**11**	**0**	0%	**11**	100%	**0**	0%	**11**	100%	**11**	100%	**0**	0%	**11**	100%	**0**	0%	**11**	100%	**0**	0%
Wampole/Zeus	11		0%	11	100%		0%	11	100%	11	100%		0%	11	100%		0%	11	100%		0%
Turbidimetry	**10**	**0**	**0%**	**10**	**100%**	**0**	**0%**	**10**	**100%**	**10**	**100%**	**0**	**0%**	**10**	**100%**	**0**	**0%**	**10**	**100%**	**0**	**0%**
Others	10		0%	10	100%		0%	10	100%	10	100%		0%	10	100%		0%	10	100%		0%
Other Methods	1		0%	1	100%		0%	1	100%	1	100%		0%	1	100%		0%	1	100%		0%
Analyte Total	**106**	**0**	**0%**	**106**	**100%**	**0**	**0%**	**106**	**100%**	**106**	**100%**	**0**	**0%**	**106**	**100%**	**0**	**0%**	**106**	**100%**	**0**	**0%**

Antistreptolysin O Quantitative
Latex Agglutination Procedures

The number of laboratories that reported titers is listed for positive test samples 16 and 17. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

		Sample 16 Titer						Sample 17 Titer					
Method ***Manufacturer***	**No. Labs**	**200**	**400**	**800**	**1600**	**3200**	**6400**	**200**	**400**	**800**	**1600**	**3200**	**6400**
Latex ***Total***	55	1	23	19	1				22	20			
Dade Behring	16		5	4					7	4			
Fisher	14		8	5					6	7			
Remel	13		6	6					5	6			

Note: The number of labs reporting specific titers may not add up to the total number of labs for that system because some labs are not reporting endpoint titers.

Antistreptolysin O Quantitative

Nephelometry & Turbidimetry Procedures

Results are summarized for positive test samples 16 and 17. The Mean values ± S.D. are given where 10 or more laboratories reported quantitative results. Outlier values are omitted.

Method / ***Manufacturer***	**No. Labs**	**Unit**	**Sample 16**	**Sample 17**
Nephelometry ***Total***	24	IU/ml	690 ± 169	667 ± 176
Beckman Immage	10	IU/ml	525 ± 37	506 ± 31
Dade Behring Neph.	11	IU/ml	841 ± 104	829 ± 122
Turbidimetry ***Total***	29	IU/ml	740 ± 127	714 ± 134
Roche Diagnostics Cobas	18	IU/ml	743 ± 50	715 ± 55

Cytomegalovirus Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		11 N				**12 N**				**13 N**				**14 N**				**15 R**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**39**	**39**	**100%**	**0**	**0%**	**39**	**100%**	**0**	**0%**	**38**	**97%**	**1**	**3%**	**39**	**100%**	**0**	**0%**	**0**	**0%**	**39**	**100%**
Wampole /Zeus	17	17	100%		0%	17	100%		0%	17	100%		0%	17	100%		0%		0%	17	100%
Others	22	22	100%		0%	22	100%		0%	21	95%	1	5%	22	100%		0%		0%	22	100%
ELFA	**20**	**20**	**100%**	**0**	**0%**	**20**	**100%**	**0**	**0%**	**20**	**100%**	**0**	**0%**	**20**	**100%**	**0**	**0%**	**0**	**0%**	**20**	**100%**
bioMérieux Vidas	20	20	100%		0%	20	100%		0%	20	100%		0%	20	100%		0%		0%	20	100%
Chemiluminescence	**14**	**13**	**93%**	**1**	**7%**	**14**	**100%**	**0**	**0%**	**14**	**100%**	**0**	**0%**	**14**	**100%**	**0**	**0%**	**0**	**0%**	**14**	**100%**
Diagnostic Products	12	11	92%	1	8%	12	100%		0%	12	100%		0%	12	100%		0%		0%	**12**	100%
Others	2	2	100%		0%	2	100%		0%	2	100%		0%	2	100%		0%		0%	2	100%
Hemagglutination	**11**	**11**	**100%**	**0**	**0%**	**11**	**100%**	**0**	**0%**	**11**	**100%**	**0**	**0%**	**11**	**100%**	**0**	**0%**	**0**	**0%**	**11**	**100%**
Olympus	11	11	100%		0%	11	100%		0%	11	100%		0%	11	100%		0%		0%	11	100%
Other Methods	8	8	100%		0%	7	88%	1	13%	7	88%	1	13%	7	88%	1	13%		0%	8	100%
Analyte Total	**92**	**91**	**99%**	**1**	**1%**	**91**	**99%**	**1**	**1%**	**90**	**98%**	**2**	**2%**	**91**	**99%**	**1**	**1%**	**0**	**0%**	**92**	**100%**

Hepatitis B Core Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		6 N				7 N				8 R				9 N				10 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**103**	**103**	**100%**	**0**	**0%**	**103**	**100%**	**0**	**0%**	**1**	**1%**	**102**	**99%**	**103**	**100%**	**0**	**0%**	**103**	**100%**	**0**	**0%**
Abbott	14	14	100%		0%	14	100%		0%		0%	14	100%	14	100%		0%	14	100%		0%
Bayer	40	40	100%		0%	40	100%		0%		0%	40	100%	40	100%		0%	40	100%		0%
Diagnostic Products	19	19	100%		0%	19	100%		0%	1	5%	18	95%	19	100%		0%	19	100%		0%
Ortho	30	30	100%		0%	30	100%		0%		0%	30	100%	30	100%		0%	30	100%		0%
EIA	**44**	**44**	**100%**	**0**	**0%**	**25**	**57%**	**14**	**32%**	**0**	**0%**	**44**	**100%**	**44**	**100%**	**0**	**0%**	**43**	**98%**	**1**	**2%**
Abbott Axsym [1]	22	22	100%		0%	3	14%	14	64%		0%	22	100%	22	100%		0%	22	100%		0%
DiaSorin	10	10	100%		0%	10	100%		0%		0%	10	100%	10	100%		0%	10	100%		0%
Other	12	12	100%		0%	12	100%		0%		0%	12	100%	12	100%		0%	11	92%	1	8%
Analyte Total	**147**	**147**	**100%**	**0**	**0%**	**128**	**87%**	**14**	**10%**	**1**	**1%**	**146**	**99%**	**147**	**100%**	**0**	**0%**	**146**	**99%**	**1**	**1%**

[1] Five laboratories reported an equivocal result on sample #7.

Hepatitis B Surface Antigen

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		6 N				7 R *				8 N				9 N				10 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**133**	**133**	**100%**	**0**	**0%**	**116**	**87%**	**17**	**13%**	**99**	**74%**	**27**	**20%**	**133**	**100%**	**0**	**0%**	**133**	**100%**	**0**	**0%**
Abbott	14	14	100%		0%		0%	14	100%	14	100%		0%	14	100%		0%	14	100%		0%
Bayer	52	52	100%		0%	51	98%	1	2%	51	98%	1	2%	52	100%		0%	52	100%		0%
Diagnostic Products	18	18	100%		0%	18	100%		0%	17	94%	1	6%	18	100%		0%	18	100%		0%
Ortho [1]	38	38	100%		0%	36	95%	2	5%	6	16%	25	66%	38	100%		0%	38	100%		0%
Roche	11	11	100%		0%	11	100%		0%	11	100%		0%	11	100%		0%	11	100%		0%
EIA	**55**	**55**	**100%**	**0**	**0%**	**20**	**36%**	**35**	**64%**	**54**	**98%**	**1**	**2%**	**55**	**100%**	**0**	**0%**	**55**	**100%**	**0**	**0%**
Abbott Axsym	26	26	100%		0%		0%	26	100%	26	100%		0%	26	100%		0%	26	100%		0%
Bio-Rad	16	16	100%		0%	15	94%	1	6%	16	100%		0%	16	100%		0%	16	100%		0%
Other	13	13	100%		0%	5	38%	8	62%	12	92%	1	8%	13	100%		0%	13	100%		0%
Confirmation	**119**	**118**	**99%**	**1**	**1%**	**116**	**97%**	**3**	**3%**	**115**	**97%**	**4**	**3%**	**119**	**100%**	**0**	**0%**	**119**	**100%**	**0**	**0%**
Abbott Axsym	14	14	100%		0%	14	100%		0%	14	100%		0%	14	100%		0%	14	100%		0%
Bayer/Siemens	35	35	100%		0%	34	97%	1	3%	34	97%	1	3%	35	100%		0%	35	100%		0%
Diagnostic Products	10	10	100%		0%	10	100%		0%	10	100%		0%	10	100%		0%	10	100%		0%
Ortho	27	27	100%		0%	27	100%		0%	24	89%	3	11%	27	100%		0%	27	100%		0%
Other	33	32	97%	1	3%	31	94%	2	6%	33	100%		0%	33	100%		0%	33	100%		0%
Other Methods	5	5	100%		0%	1	20%	4	80%	5	100%		0%	5	100%		0%	5	100%		0%
Analyte Total	**312**	**311**	**100%**	**1**	**0%**	**253**	**81%**	**59**	**19%**	**273**	**88%**	**32**	**10%**	**312**	**100%**	**0**	**0%**	**312**	**100%**	**0**	**0%**

***** Samples #7 is not authenticated, the expected result is reactive. When a consensus agreement cannot be reached among participants, by regulation requirements, the sample cannot be graded (scored) and all participating laboratories get credit for this sample.

[1] Seven laboratories reported a result of equivocal on sample # 8.

Hepatitis Be Antigen

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		66 R				67 N				68 N				69 N				70 R			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**27**	**0**	**0%**	**27**	**100%**	**27**	**100%**	**0**	**0%**	**27**	**100%**	**0**	**0%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**27**	**100%**
DiaSorin	26		0%	26	100%	26	100%		0%	26	100%		0%	26	100%		0%		0%	26	100%
Other	1		0%	1	100%	1	100%		0%	1	100%		0%	1	100%		0%		0%	1	100%
Other Methods	5		0%	5	100%	5	100%		0%	5	100%		0%	5	100%		0%		0%	5	100%
Analyte Total	**32**	**0**	**0%**	**32**	**100%**	**32**	**100%**	**0**	**0%**	**32**	**100%**	**0**	**0%**	**32**	**100%**	**0**	**0%**	**0**	**0%**	**32**	**100%**

Hepatitis C Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		71 N				72 N				73 R				74 N				75 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**96**	**95**	**99%**	**0**	**0%**	**95**	**99%**	**0**	**0%**	**1**	**1%**	**94**	**98%**	**95**	**99%**	**0**	**0%**	**95**	**99%**	**0**	**0%**
Bayer	51	51	100%		0%	51	100%		0%		0%	51	100%	51	100%		0%	51	100%		0%
Ortho	38	38	100%		0%	38	100%		0%		0%	38	100%	38	100%		0%	38	100%		0%
Other [1]	7	6	86%		0%	6	86%		0%	1	14%	5	71%	6	86%		0%	6	86%		0%
EIA	**68**	**68**	**100%**	**0**	**0%**	**68**	**100%**	**0**	**0%**	**0**	**0%**	**68**	**100%**	**68**	**100%**	**0**	**0%**	**68**	**100%**	**0**	**0%**
Abbott	42	42	100%		0%	42	100%		0%		0%	42	100%	42	100%		0%	42	100%		0%
Ortho	25	25	100%		0%	25	100%		0%		0%	25	100%	25	100%		0%	25	100%		0%
Other	1	1	100%		0%	1	100%		0%		0%	1	100%	1	100%		0%	1	100%		0%
Confirmation	**26**	**25**	**96%**	**0**	**0%**	**25**	**96%**	**0**	**0%**	**0**	**0%**	**25**	**96%**	**25**	**96%**	**0**	**0%**	**25**	**96%**	**0**	**0%**
Chiron	20	20	100%		0%	20	100%		0%		0%	20	100%	20	100%		0%	20	100%		0%
Other [1]	6	5	83%		0%	5	83%		0%		0%	5	83%	5	83%		0%	5	83%		0%
Other Methods	6	6	100%		0%	6	100%		0%		0%	6	100%	6	100%		0%	6	100%		0%
Analyte Total	**196**	**194**	**99%**	**0**	**0%**	**194**	**99%**	**0**	**0%**	**1**	**1%**	**193**	**98%**	**194**	**99%**	**0**	**0%**	**194**	**99%**	**0**	**0%**

[1] One laboratory reported an unstable reaction on all 5 samples.

HIV Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		31 N				32 R				33 N				34 R				35 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**22**	**22**	**100%**	**0**	**0%**	**0**	**0%**	**22**	**100%**	**22**	**100%**	**0**	**0%**	**0**	**0%**	**22**	**100%**	**22**	**100%**	**0**	**0%**
Bayer	22	22	100%		0%		0%	22	100%	22	100%		0%		0%	22	100%	22	100%		0%
EIA	**97**	**97**	**100%**	**0**	**0%**	**0**	**0%**	**97**	**100%**	**97**	**100%**	**0**	**0%**	**0**	**0%**	**97**	**100%**	**97**	**100%**	**0**	**0%**
Abbott	43	43	100%		0%		0%	43	100%	43	100%		0%		0%	43	100%	43	100%		0%
Bio-Rad	53	53	100%		0%		0%	53	100%	53	100%		0%		0%	53	100%	53	100%		0%
Others	1	1	100%		0%		0%	1	100%	1	100%		0%		0%	1	100%	1	100%		0%
Rapid EIA	**100**	**100**	**100%**	**0**	**0%**	**0**	**0%**	**100**	**100%**	**100**	**100%**	**0**	**0%**	**0**	**0%**	**100**	**100%**	**100**	**100%**	**0**	**0%**
Orasure	100	100	100%		0%		0%	100	100%	100	100%		0%		0%	100	100%	100	100%		0%
Rapid Immunoassay	**54**	**54**	**100%**	**0**	**0%**	**0**	**0%**	**54**	**100%**	**54**	**100%**	**0**	**0%**	**0**	**0%**	**54**	**100%**	**54**	**100%**	**0**	**0%**
Medmira	15	15	100%		0%		0%	15	100%	15	100%		0%		0%	15	100%	15	100%		0%
Trinity	26	26	100%		0%		0%	26	100%	26	100%		0%		0%	26	100%	26	100%		0%
Other	13	13	100%		0%		0%	13	100%	13	100%		0%		0%	13	100%	13	100%		0%
Western Blot	**48**	**48**	**100%**	**0**	**0%**	**0**	**0%**	**48**	**100%**	**48**	**100%**	**0**	**0%**	**0**	**0%**	**48**	**100%**	**48**	**100%**	**0**	**0%**
Bio-Rad	41	41	100%		0%		0%	41	100%	41	100%		0%		0%	41	100%	41	100%		0%
Others	7	7	100%		0%		0%	7	100%	7	100%		0%		0%	7	100%	7	100%		0%
Other Methods	8	8	100%		0%		0%	8	100%	8	100%		0%		0%	8	100%	8	100%		0%
Analyte Total	**329**	**329**	**100%**	**0**	**0%**	**0**	**0%**	**329**	**100%**	**329**	**100%**	**0**	**0%**	**0**	**0%**	**329**	**100%**	**329**	**100%**	**0**	**0%**

HTLV Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number **R = Reactive/ Positive; N = Non-Reactive/ Negative**																			
		36 N				**37 N**				**38 R**				**39 N**				**40 N**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**40**	**39**	**98%**	**1**	**3%**	**40**	**100%**	**0**	**0%**	**0**	**0%**	**40**	**100%**	**39**	**98%**	**1**	**3%**	**40**	**100%**	**0**	**0%**
Abbott	24	24	100%		0%	24	100%		0%		0%	24	100%	24	100%		0%	24	100%		0%
Other Methods	16	15	94%	1	6%	16	100%		0%		0%	16	100%	15	94%	1	6%	16	100%		0%
Analyte Total	**40**	**39**	**98%**	**1**	**3%**	**40**	**100%**	**0**	**0%**	**0**	**0%**	**40**	**100%**	**39**	**98%**	**1**	**3%**	**40**	**100%**	**0**	**0%**

Infectious Mononucleosis

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		26 N				27 R				28 N				29 N				30 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
CICA	**18**	**18**	**100%**	**0**	**0%**	**0**	**0%**	**18**	**100%**	**18**	**100%**	**0**	**0%**	**18**	**100%**	**0**	**0%**	**18**	**100%**	**0**	**0%**
Others	18	18	100%		0%		0%	18	100%	18	100%		0%	18	100%		0%	18	100%		0%
Hemagglutination	**49**	**48**	**98%**	**1**	**2%**	**0**	**0%**	**49**	**100%**	**47**	**96%**	**2**	**4%**	**47**	**96%**	**2**	**4%**	**45**	**92%**	**4**	**8%**
Fisher	20	20	100%		0%		0%	20	100%	20	100%		0%	19	95%	1	5%	19	95%	1	5%
Wampole/Zeus	20	20	100%		0%		0%	20	100%	19	95%	1	5%	20	100%		0%	19	95%	1	5%
Others	9	8	89%	1	11%		0%	9	100%	8	89%	1	11%	8	89%	1	11%	7	78%	2	22%
Latex Agglutination	**138**	**138**	**100%**	**0**	**0%**	**0**	**0%**	**138**	**100%**	**138**	**100%**	**0**	**0%**	**138**	**100%**	**0**	**0%**	**138**	**100%**	**0**	**0%**
Fisher	42	42	100%		0%		0%	42	100%	42	100%		0%	42	100%		0%	42	100%		0%
Remel	25	25	100%		0%		0%	25	100%	25	100%		0%	25	100%		0%	25	100%		0%
Wampole/Zeus	51	51	100%		0%		0%	51	100%	51	100%		0%	51	100%		0%	51	100%		0%
Others	20	20	100%		0%		0%	20	100%	20	100%		0%	20	100%		0%	20	100%		0%
Solid Phase IA	**62**	**61**	**98%**	**1**	**2%**	**0**	**0%**	**62**	**100%**	**62**	**100%**	**0**	**0%**	**62**	**100%**	**0**	**0%**	**62**	**100%**	**0**	**0%**
Inverness	30	30	100%		0%		0%	30	100%	30	100%		0%	30	100%		0%	30	100%		0%
Seradyn	26	25	96%	1	4%		0%	26	100%	26	100%		0%	26	100%		0%	26	100%		0%
Others	6	6	100%		0%		0%	6	100%	6	100%		0%	6	100%		0%	6	100%		0%
Other Methods	4	3	75%	1	25%		0%	4	100%	3	75%	1	25%	3	75%	1	25%	3	75%	1	25%
Analyte Total	**271**	**268**	**99%**	**3**	**1%**	**0**	**0%**	**271**	**100%**	**268**	**99%**	**3**	**1%**	**268**	**99%**	**3**	**1%**	**266**	**98%**	**5**	**2%**

Lyme Disease Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		41 N				42 R				43 N				44 N				45 R			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**60**	**60**	**100%**	**0**	**0%**	**0**	**0%**	**60**	**100%**	**60**	**100%**	**0**	**0%**	**60**	**100%**	**0**	**0%**	**0**	**0%**	**60**	**100%**
Immunetics	16	16	100%		0%		0%	16	100%	16	100%		0%	16	100%		0%		0%	16	100%
Wampole /Zeus	32	32	100%		0%		0%	32	100%	32	100%		0%	32	100%		0%		0%	32	100%
Others	12	12	100%		0%		0%	12	100%	12	100%		0%	12	100%		0%		0%	12	100%
ELFA	**28**	**28**	**100%**	**0**	**0%**	**0**	**0%**	**28**	**100%**	**28**	**100%**	**0**	**0%**	**28**	**100%**	**0**	**0%**	**0**	**0%**	**28**	**100%**
bioMérieux	28	28	100%		0%		0%	28	100%	28	100%		0%	28	100%		0%		0%	28	100%
Other Methods	9	9	100%		0%		0%	9	100%	9	100%		0%	9	100%		0%		0%	9	100%
Analyte Total	**97**	**97**	**100%**	**0**	**0%**	**0**	**0%**	**97**	**100%**	**97**	**100%**	**0**	**0%**	**97**	**100%**	**0**	**0%**	**0**	**0%**	**97**	**100%**

Lyme Western Blot IgG

Participant Results/ Sample Number

R = Reactive/ Positive; N = Non-Reactive/ Negative; E = Equivocal/ Indeterminate

Method / *Manufacturer*	No. Labs	41 N						42 R						43 N						44 N						45 R					
		N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%
Western Blot - IgG	**27**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**27**	**100%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**27**	**100%**
MarDx	24	24	100%		0%		0%		0%		0%	24	100%	24	100%		0%		0%	24	100%		0%		0%		0%		0%	24	100%
Other	3	3	100%		0%		0%		0%		0%	3	100%	3	100%		0%		0%	3	100%		0%		0%		0%		0%	3	100%
Other Methods	3	3	100%		0%		0%		0%		0%	3	100%	3	100%		0%		0%	3	100%		0%		0%		0%		0%	3	100%
Analyte Total	**30**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**30**	**100%**

Lyme Western Blot IgM

Participant Results/ Sample Number

R = Reactive/ Positive; N = Non-Reactive/ Negative; E = Equivocal/ Indeterminate

Method / *Manufacturer*	No. Labs	41 N						42 R *						43 N						44 N						45 R *					
		N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%
Western Blot - IgM	**27**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**21**	**78%**	**3**	**11%**	**3**	**11%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**12**	**44%**	**1**	**4%**	**14**	**52%**
MarDx	24	24	100%		0%		0%	20	83%	3	13%	1	4%	24	100%		0%		0%	24	100%		0%		0%	10	42%	1	4%	13	54%
Other	3	3	100%		0%		0%	1	33%		0%	2	67%	3	100%		0%		0%	3	100%		0%		0%	2	67%		0%	1	33%
Other Methods	2	2	100%		0%		0%		0%		0%	2	100%	2	100%		0%		0%	2	100%		0%		0%		0%		0%	2	100%
Analyte Total	**29**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**21**	**72%**	**3**	**10%**	**5**	**17%**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**12**	**41%**	**1**	**3%**	**16**	**55%**

***** Samples #42 and 45 are not authenticated, the expected result is positive. When a consensus agreement cannot be reached among participants, by regulation requirements, the sample cannot be graded (scored) and all participating laboratories get credit for this sample.

Rheumatoid Factor

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		26 N				27 R				28 N				29 N				30 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Latex Agglutination	**106**	**103**	**97%**	**3**	**3%**	**9**	**8%**	**97**	**92%**	**106**	**100%**	**0**	**0%**	**104**	**98%**	**2**	**2%**	**104**	**98%**	**2**	**2%**
Becton Dickinson	19	18	95%	1	5%	3	16%	16	84%	19	100%		0%	19	100%		0%	18	95%	1	5%
Fisher	39	38	97%	1	3%	1	3%	38	97%	39	100%		0%	39	100%		0%	39	100%		0%
Wampole/Zeus	12	11	92%	1	8%	4	33%	8	67%	12	100%		0%	11	92%	1	8%	11	92%	1	8%
Others	36	36	100%		0%	1	3%	35	97%	36	100%		0%	35	97%	1	3%	36	100%		0%
Nephelometry	**20**	**20**	**100%**	**0**	**0%**	**1**	**5%**	**19**	**95%**	**20**	**100%**	**0**	**0%**	**20**	**100%**	**0**	**0%**	**20**	**100%**	**0**	**0%**
Beckman	10	10	100%		0%		0%	10	100%	10	100%		0%	10	100%		0%	10	100%		0%
Behring	10	10	100%		0%	1	10%	9	90%	10	100%		0%	10	100%		0%	10	100%		0%
Turbidimetry	**19**	**19**	**100%**	**0**	**0%**	**0**	**0%**	**19**	**100%**	**19**	**100%**	**0**	**0%**	**19**	**100%**	**0**	**0%**	**19**	**100%**	**0**	**0%**
Roche	11	11	100%		0%		0%	11	100%	11	100%		0%	11	100%		0%	11	100%		0%
Others	8	8	100%		0%		0%	8	100%	8	100%		0%	8	100%		0%	8	100%		0%
Other Methods	7	6	86%	1	14%		0%	7	100%	7	100%		0%	7	100%		0%	7	100%		0%
Analyte Total	**152**	**148**	**97%**	**4**	**3%**	**10**	**7%**	**142**	**93%**	**152**	**100%**	**0**	**0%**	**150**	**99%**	**2**	**1%**	**150**	**99%**	**2**	**1%**

Rheumatoid Factor Quantitative
Latex Agglutination Procedure

The number of laboratories that reported titers is listed for positive test sample 27. The dilution schemes laboratories used are represented by the letter A and B, testing systems with 10 or more laboratories reporting titers are listed in this table.

			Sample 27 Titer						
	No.	A	10	20	40	80	160	320	640
Manufacturer	**Labs**	**B**	**1**	**2**	**4**	**8**	**16**	**32**	**64**
Total	78	A	2	8	23	8	1		
		B		8	6	6	2		
Becton Dickenson	15	A		7	3	2			
		B							
Fisher	28	A		1	13	3			
		B		1	5	4			

Note: The number of labs reporting specific titers may not add up to the total number of labs for that system because some labs are not reporting endpoint titers.

Rheumatoid Factor Quantitative

Nephelometry & Turbidimetry Procedures

Results are summarized for positive test sample 27. The Mean values ± S.D. are given where 10 or more laboratories reported quantitative results. Outlier values are omitted.

Method *Manufacturer*	**No. Labs**	**Unit**	**Sample 27**
Nephelometry ***Total***	35	IU/ml	44 ± 5.4
Beckman Coulter IMMAGE	13	IU/ml	47 ± 3.9
Dade Behring Nephelometer	19	IU/ml	42 ± 4.8
Turbidimetry ***Total***	60	IU/ml	45 ± 8.9
Roche Diag. Cobas	16	IU/ml	42 ± 0.9

Rubella Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		11 N				12 N				13 N				14 N				15 R			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**56**	**55**	**98%**	**1**	**2%**	**55**	**98%**	**1**	**2%**	**55**	**98%**	**1**	**2%**	**54**	**96%**	**2**	**4%**	**1**	**2%**	**54**	**96%**
Bayer	27	27	100%		0%	27	100%		0%	27	100%		0%	26	96%	1	4%	1	4%	26	96%
Beckman [1]	13	12	92%	1	8%	12	92%	1	8%	12	92%	1	8%	12	92%	1	8%		0%	12	92%
Diagnostic Products	12	12	100%		0%	12	100%		0%	12	100%		0%	12	100%		0%		0%	12	100%
Others	4	4	100%		0%	4	100%		0%	4	100%		0%	4	100%		0%		0%	4	100%
EIA	**55**	**55**	**100%**	**0**	**0%**	**55**	**100%**	**0**	**0%**	**55**	**100%**	**0**	**0%**	**55**	**100%**	**0**	**0%**	**0**	**0%**	**54**	**98%**
Abbott	19	19	100%		0%	19	100%		0%	19	100%		0%	19	100%		0%		0%	19	100%
Diamedix [1]	10	10	100%		0%	10	100%		0%	10	100%		0%	10	100%		0%		0%	9	90%
Wampole/Zeus	15	15	100%		0%	15	100%		0%	15	100%		0%	15	100%		0%		0%	15	100%
Others	11	11	100%		0%	11	100%		0%	11	100%		0%	11	100%		0%		0%	11	100%
Latex Agglutination	**37**	**37**	**100%**	**0**	**0%**	**37**	**100%**	**0**	**0%**	**36**	**97%**	**1**	**3%**	**36**	**97%**	**1**	**3%**	**1**	**3%**	**36**	**97%**
Fisher	22	22	100%		0%	22	100%		0%	21	95%	1	5%	21	95%	1	5%	1	5%	21	95%
Others	15	15	100%		0%	15	100%		0%	15	100%		0%	15	100%		0%		0%	15	100%
Other Methods	11	11	100%		0%	11	100%		0%	10	91%	1	9%	11	100%		0%	1	9%	10	91%
Analyte Total	**159**	**158**	**99%**	**1**	**1%**	**158**	**99%**	**1**	**1%**	**156**	**98%**	**3**	**2%**	**156**	**98%**	**3**	**2%**	**3**	**2%**	**154**	**97%**

[1] One laboratory reported an equivocal result on sample #15

Rubella Antibody Quantitative

Results are summarized for positive test sample 15. The Mean values ± S.D. are given where 10 or more laboratories reported quantitative results. Outlier values are omitted.

Method ***Manufacturer***	**No. Labs**	**Unit**	**Sample 15**
Chemiluminescence Total	55	IU/ml	15 ± 2.2
Bayer	27	IU/ml	118 ± 12
Diagnostic Products	16	IU/ml	15 ± 1.0
EIA Total	16	IU/ml	18 ± 4.1

Rubella IgM Specific

Method / *Manufacturer*	No. Labs	Participant Results/ Sample Number **R = Reactive/ Positive; N = Non-Reactive/ Negative**																			
		56 R				**57 N**				**58 R**				**59 N**				**60 N**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**8**		0%	8	100%	8	100%		0%		0%	8	100%	8	100%		0%	8	100%		0%
Chemiluminescence	**10**		0%	10	100%	10	100%		0%		0%	10	100%	10	100%		0%	10	100%		0%
Analyte Total	**18**	**0**	**0%**	**18**	**100%**	**18**	**100%**	**0**	**0%**	**0**	**0%**	**18**	**100%**	**18**	**100%**	**0**	**0%**	**18**	**100%**	**0**	**0%**

Syphilis - Reagin Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		1 N				2 N				3 R *				4 N				5 R *			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
RPR	**256**	**256**	**100%**	**0**	**0%**	**256**	**100%**	**0**	**0%**	**80**	**31%**	**173**	**68%**	**254**	**99%**	**2**	**1%**	**210**	**82%**	**43**	**17%**
ASI	38	38	100%		0%	38	100%		0%	12	32%	26	68%	38	100%		0%	30	79%	8	21%
Becton Dickenson [1]	124	124	100%		0%	124	100%		0%	32	26%	90	73%	123	99%	1	1%	107	86%	16	13%
Fisher [2]	47	47	100%		0%	47	100%		0%	22	47%	24	51%	46	98%	1	2%	42	89%	5	11%
True Medix [3]	17	17	100%		0%	17	100%		0%	5	29%	12	71%	17	100%		0%	10	59%	5	29%
Wampole/Zeus	21	21	100%		0%	21	100%		0%	6	29%	15	71%	21	100%		0%	15	71%	6	29%
Others	9	9	100%		0%	9	100%		0%	3	33%	6	67%	9	100%		0%	6	67%	3	33%
Analyte Total	**256**	**256**	**100%**	**0**	**0%**	**256**	**100%**	**0**	**0%**	**80**	**31%**	**173**	**68%**	**254**	**99%**	**2**	**1%**	**210**	**82%**	**43**	**17%**

***** Samples #3 and #5 are not authenticated, the expected result is reactive. When a consensus agreement cannot be reached among participants, by regulation requirements, the sample cannot be graded (scored) and all participating laboratories get credit for this sample.

[1] Two laboratories reported equivocal on #3 and one laboratory reported equivocal on #5.

[2] One laboratory reported an equivocal on #3.

[3] Two laboratories reported an equivocal on #5.

Syphilis - Reagin Antibody

RPR Procedures

The number of laboratories that reported titers is listed for positive test samples 3 and 5 for the RPR procedure. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

Method / *Manufacturer*	No. Labs	Sample 3 Titer 1	2	4	8	16	32	Sample 5 Titer 1	2	4	8	16	32
Total	156	117	29	5	1			36	6				
ASI	16	13	2					7	1				
Becton Dickenson	83	67	13		1			15					
Fisher	25	18	5	1				3	2				
True Medix	12	7	4	1				5					
Wampole/ Zeus	15	10	3	2				4	2				

Note: The number of labs reporting specific titers may not add up to the total number of labs for that system because some labs are not reporting endpoint titers, or they reported the sample as nonreactive.

Syphilis - Treponemal Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		1 N				2 N				3 R				4 N				5 R			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**20**	**20**	**100%**	**0**	**0%**	**20**	**100%**	**0**	**0%**	**0**	**0%**	**20**	**100%**	**20**	**100%**	**0**	**0%**	**1**	**5%**	**19**	**95%**
Trinity Biotech	10	10	100%		0%	10	100%		0%		0%	10	100%	10	100%		0%	1	10%	9	90%
Others	10	10	100%		0%	10	100%		0%		0%	10	100%	10	100%		0%		0%	10	100%
Gel. Part. Agglut.	**32**	**32**	**100%**	**0**	**0%**	**32**	**100%**	**0**	**0%**	**0**	**0%**	**32**	**100%**	**32**	**100%**	**0**	**0%**	**0**	**0%**	**32**	**100%**
Fujirebio	32	32	100%		0%	32	100%		0%		0%	32	100%	32	100%		0%		0%	32	100%
IFA	**21**	**21**	**100%**	**0**	**0%**	**21**	**100%**	**0**	**0%**	**0**	**0%**	**21**	**100%**	**21**	**100%**	**0**	**0%**	**0**	**0%**	**19**	**90%**
Wampole/Zeus [1]	21	21	100%		0%	21	100%		0%		0%	21	100%	21	100%		0%		0%	19	90%
Other Methods	13	4	31%	9	69%	4	31%	9	69%	4	31%	9	69%	4	31%	9	69%	1	8%	12	92%
Analyte Total	**86**	**77**	**90%**	**9**	**10%**	**77**	**90%**	**9**	**10%**	**4**	**5%**	**82**	**95%**	**77**	**90%**	**9**	**10%**	**2**	**2%**	**82**	**95%**

[1] Two laboratories reported an equivocal response on sample #5.

AAT, C'3, and C'4

The Mean mg/dl ± S.D. is given where 10 or more laboratoies reported values. Outlier values are omitted.

Analytes		**Sample NO.**				
	No.					
Alpha-1-Antitrypsin	**Labs**	76	77	78	79	80
Nephelometry/*Behring Nephelometer*	19	24 ± 1.4	140 ± 7.7	17 ± 1.0	74 ± 4.2	98 ± 5.1
Nephelometry/ *Total*	27	25 ± 2.5	141 ± 8.0	17 ± 2.1	74 ± 7.0	93 ± 12
All Method/ *Total*	39	25 ± 2.7	145 ± 14	17 ± 2.2	78 ± 10	93 ± 12
Complement C'3		76	77	78	79	80
Nephelometry/*Beckman Coulter IMMAGE*	16	40 ± 1.8	173 ± 8.1	23 ± 1.8	127 ± 4.9	75 ± 2.5
Nephelometry/*Behring Nephelometer*	13	42 ± 2.2	194 ± 9.8	24 ± 1.4	132 ± 6.0	85 ± 3.3
Turbidimetry/*Roche Cobas Integra*	14	40 ± 1.8	164 ± 4.6	23 ± 0.9	125 ± 3.5	73 ± 2.2
Turbidimetry/Roche/Hitachi Modular	10	41 ± 1.6	161 ± 3.5	25 ± 1.5	120 ± 2.7	71 ± 2.3
Nephelometry/ *Total*	40	41 ± 2.2	183 ± 13	24 ± 1.8	130 ± 6.2	81 ± 5.6
Turbidimetry/ *Total*	60	40 ± 3.2	163 ± 9.2	24 ± 1.9	121 ± 6.1	72 ± 3.5
All Method/ *Total*	105	41 ± 2.9	171 ± 15	24 ± 2.0	125 ± 7.9	75 ± 6.6
Complement C'4		76	77	78	79	80
Nephelometry/*Beckman Coulter IMMAGE*	16	6.1 ± 0.4	31 ± 1.5	4.5 ± 0.3	32 ± 1.5	15 ± 0.7
Nephelometry/*Behring Nephelometer*	13	5.9 ± 0.2	30 ± 2.1	4.0 ± 0.1	30 ± 1.9	14 ± 0.6
Turbidimetry/*Roche Cobas Integra*	15	5.0 ± 0.0	23 ± 1.1	3.6 ± 0.5	26 ± 0.8	12 ± 0.7
Nephelometry/ *Total*	40	6.0 ± 0.0	31 ± 2.1	4.3 ± 0.4	31 ± 1.9	14 ± 0.9
Turbidimetry/ *Total*	50	5.3 ± 0.7	24 ± 1.9	3.6 ± 0.8	26 ± 2.7	12 ± 1.2
All Method/ *Total*	102	5.6 ± 0.7	27 ± 4.0	3.9 ± 0.6	28 ± 3.1	12.9 ± 1.6

IgA, IgE, IgG, and IgM

The Mean mg/dl (IU/ml for IgE) ± S.D. is given for IgA, IgE, and IgM and Mean mg/dl ± 25% is given for IgG where 10 or more laboratories reported values. Outlier values are omitted.

Analytes (Unit)	No.	**Sample NO.**				
Immunoglobulin A (mg/dl)	Labs	81	82	83	84	85
Nephelometry/*Beckman Coulter IMMAGE*	18	47 ± 2.6	64 ± 2.5	52 ± 2.2	190 ± 11	218 ± 13
Nephelometry/*Behring Nephelometer*	16	48 ± 2.7	68 ± 3.7	61 ± 1.7	209 ± 4.3	236 ± 9.9
Turbidimetry/ *Beckman Coulter Synchron*	10	50 ± 3.9	67 ± 6.9	57 ± 2.3	197 ± 5.5	217 ± 10.8
Turbidimetry/ *Roche Cobas Intergra*	14	46 ± 3.0	61 ± 4.3	48 ± 4.0	186 ± 7.2	214 ± 2.7
Turbidimetry/ *Roche/Hitachi Modular*	10	51 ± 0.9	64 ± 4.3	54 ± 4.1	185 ± 4.3	205 ± 4.3
Nephelometry/ *Total*	50	48 ± 2.9	67 ± 4.4	56 ± 5.2	201 ± 11	228 ± 15
Turbidimetry/ *Total*	59	49 ± 4.0	65 ± 5.1	55 ± 6.0	188 ± 8.9	213 ± 12
All Method/ *Total*	113	48 ± 3.5	66 ± 4.9	56 ± 6.0	194 ± 12	220 ± 16
Immunoglobulin E (IU/ml)						
Chemiluminescence/Bayer Advia	10	28 ± 1.4	426 ± 31	4.8 ± 1.6	172 ± 12	194 ± 12
Chemiluminescence/*Diag. Prod. Co.*	29	30 ± 1.7	396 ± 29	3.2 ± 0.4	175 ± 10	193 ± 17
FEIA/ *Pharmacia Immunocap*	12	28 ± 2.2	412 ± 21	4.4 ± 0.6	162 ± 7.3	194 ± 4.9
Chemiluminescence/ *Total*	48	29 ± 1.9	406 ± 30	3.2 ± 0.4	174 ± 10	192 ± 14
FEIA/ *Total*	18	28 ± 2.0	415 ± 19	4.7 ± 0.7	163 ± 12	195 ± 11
All Method/ *Total*	80	29 ± 2.2	409 ± 40	3.7 ± 0.8	169 ± 13	192 ± 13
Immunoglobulin G (mg/dl)						
Nephelometry/*Beckman Coulter IMMAGE*	17	257 ± 9.2	480 ± 21	289 ± 8.8	1058 ± 69	929 ± 65
Nephelometry/*Behring Nephelometer*	16	258 ± 17	510 ± 13	305 ± 15	1075 ± 52	1030 ± 58
Turbidimetry/*Roche Cobas Integra*	14	242 ± 18	472 ± 27	264 ± 21	1020 ± 32	931 ± 17
Turbidimetry/*Roche/Hitachi Modular*	10	238 ± 8.2	441 ± 15	279 ± 12	972 ± 15	877 ± 13
Nephelometry/ *Total*	49	255 ± 14	491 ± 31	293 ± 17	1062 ± 59	973 ± 75
Turbidimetry/ *Total*	55	236 ± 18	460 ± 28	274 ± 20	999 ± 39	906 ± 49
All Method/ *Total*	107	247 ± 21	476 ± 34	287 ± 24	1028 ± 66	939 ± 70
Immunoglobulin M (mg/dl)						
Nephelometry/*Beckman Coulter IMMAGE*	17	25 ± 2.0	23 ± 1.7	21 ± 1.5	100 ± 5.1	90 ± 5.5
Nephelometry/*Behring Nephelometer*	17	25 ± 1.1	22 ± 1.0	22 ± 1.2	112 ± 4.8	107 ± 4.6
Turbidimetry/*Roche Cobas Integra*	14	22 ± 2.7	20 ± 1.1	19 ± 1.7	91 ± 2.9	79 ± 2.7
Nephelometry/ *Total*	48	25 ± 1.7	23 ± 1.7	22 ± 1.6	106 ± 7.0	99 ± 9.6
Turbidimetry/ *Total*	55	26 ± 3.0	23 ± 3.2	23 ± 4.1	97 ± 8.0	88 ± 9.3
All Method/ *Total*	107	25 ± 2.3	23 ± 2.7	22 ± 2.6	101 ± 8.9	93 ± 11

Acceptable Response (September 10, 2008 PT Event)
Quantitative Tests Results (Acceptable Range)

Analytes Method/ Manufacture	Sample NO.				
Alpha-1-Antitrypsin	76	77	78	79	80
Nephelometry/*Dade Behring Neph.*	19 - 28	116 - 163	13 - 20	61 - 87	82 - 114
Nephelometry/ *Total*	17 - 33	116 - 165	10 - 24	52 - 95	56 - 129
All Method/ *Total*	16 - 33	101 - 189	10 - 24	47 - 109	57 - 129
Complement C'3	76	77	78	79	80
Nephelometry/*Beckman Coulter Immage*	34 - 46	148 - 197	17 - 29	112 - 142	67 - 83
Nephelometry/*Dade Behring Neph.*	35 - 49	164 - 224	19 - 28	114 - 150	74 - 95
Turbidimetry/*Roche Cobas Integra*	34 - 45	149 - 178	20 - 26	114 - 136	66 - 80
Turbidimetry/*Roche/Hitachi Modular*	35 - 46	151 - 172	19 - 30	112 - 128	63 - 78
Nephelometry/ *Total*	34 - 48	143 - 223	18 - 29	111 - 148	63 - 98
Turbidimetry/ *Total*	30 - 50	135 - 191	18 - 30	102 - 139	61 - 82
All Method/ *Total*	32 - 50	125 - 218	18 - 30	100 - 149	55 - 95
Complement C'4	76	77	78	79	80
Nephelometry/*Beckman Coulter Immage*	4 - 8	26 - 36	3 - 6	27 - 37	12 - 17
Nephelometry/*Dade Behring Neph.*	5 - 7	23 - 37	3 - 5	24 - 36	11 - 16
Turbidimetry/*Roche Cobas Integra*	4 - 6	20 - 27	2 - 6	23 - 29	9 - 14
Nephelometry/ *Total*	5 - 7	24 - 38	3 - 6	25 - 37	11 - 17
Turbidimetry/ *Total*	3 - 8	18 - 31	1 - 6	18 - 35	8 - 16
All Method/ *Total*	3 - 8	14 - 39	2 - 6	18 - 38	8 - 18
Immunoglobulin A	81	82	83	84	85
Nephelometry/*Beckman Coulter Immage*	39 - 55	56 - 72	45 - 59	156 - 224	178 - 259
Nephelometry/*Dade Behring Neph .*	40 - 57	56 - 80	55 - 66	195 - 222	206 - 266
Turbidimetry/ *Beckman Coulter Synch.*	38 - 62	46 - 88	50 - 65	180 - 214	184 - 250
Turbidimetry/ *Roche Cobas Integra*	37 - 56	48 - 75	36 - 61	165 - 209	205 - 222
Turbidimetry/ *Roche/Hitachi Modular*	48 - 54	50 - 77	42 - 67	172 - 198	192 - 218
Nephelometry/ *Total*	39 - 57	53 - 80	40 - 72	169 - 233	183 - 274
Turbidimetry/ *Total*	37 - 62	50 - 81	37 - 74	161 - 216	174 - 252
All Method/ *Total*	37 - 59	51 - 81	38 - 75	157 - 231	172 - 269
Immunoglobulin E	81	82	83	84	85
Chemiluminescence/*Bayer Advia*	24 - 33	333 - 522	1 - 10	135 - 209	158 - 229
Chemiluminescence/*Diag.Prod. Immulite*	24 - 35	310 - 482	2 - 5	144 - 206	140 - 246
FEIA/*Pharmacia Immunocap*	20 - 35	347 - 476	2 - 7	139 - 184	179 - 209
Chemiluminescence/ *Total*	23 - 35	315 - 497	2 - 5	143 - 206	150 - 233
FEIA/ *Total*	22 - 34	357 - 473	2 - 7	128 - 200	162 - 228
All Method/ *Total*	22 - 36	290 - 529	1 - 7	129 - 209	152 - 232
Immunoglobulin G	81	82	83	84	85
Nephelometry/*Beckman Coulter Immage*	193 - 322	360 - 601	217 - 362	793 - 1323	696 - 1161
Nephelometry/*Dade Behring Neph .*	193 - 322	382 - 638	228 - 382	806 - 1344	772 - 1288
Turbidimetry/*Roche Cobas Integra*	181 - 303	354 - 591	198 - 331	764 - 1275	698 - 1164
Turbidimetry/ *Roche/Hitachi Modular*	178 - 298	331 - 552	208 - 349	729 - 1216	657 - 1097
Nephelometry/ *Total*	191 - 319	368 - 614	220 - 367	796 - 1328	729 - 1216
Turbidimetry/ *Total*	176 - 295	354 - 576	205 - 343	749 - 1249	679 - 1133
All Method/ *Total*	185 - 309	356 - 595	215 - 359	772 - 1287	704 - 1175
Immunoglobulin M	81	82	83	84	85
Nephelometry/*Beckman Coulter Immage*	18 - 31	18 - 29	16 - 26	84 - 116	73 - 107
Nephelometry/*Dade Behring Neph .*	21 - 29	19 - 26	18 - 26	97 - 127	93 - 121
Turbidimetry/*Roche Cobas Integra*	14 - 31	17 - 24	13 - 24	83 - 100	71 - 87
Nephelometry/ *Total*	20 - 31	18 - 29	16 - 27	85 - 127	69 - 128
Turbidimetry/ *Total*	16 - 35	13 - 33	10 - 36	72 - 121	59 - 116
All Method/ *Total*	18 - 33	15 - 31	14 - 30	74 - 129	60 - 127

Acceptable Response (September 10, 2008 PT Event)
Qualitative / Quantitative Tests Results

Analytes	Sample NO.				
	1	**2**	**3**	**4**	**5**
Syphilis - Reagin	N	N	R*	N	R*
RPR Titer	< 1:1	< 1:1	1:1 - 1:4	< 1:1	1:1 - 1:2
Syphilis - Treponemal	N	N	R	N	R
	6	**7**	**8**	**9**	**10**
HBcAb	N	N	R	N	N
HBsAg	N	R*	N	N	N
HBsAg Confirmation	N	R	N	N	N
	11	**12**	**13**	**14**	**15**
CMV	N	N	N	N	R
Rubella Ab	N	N	N	N	R
Rubella Ab Quantitative *EIA IU/ml*	< 5	< 5	< 5	< 5	5 - 31
Chemiluminescent IU/ml	< 10	< 10	< 10	< 10	9 - 23
Advia Centaur IU/ml	< 10	< 10	< 10	< 10	81 - 155
	16	**17**	**18**	**19**	**20**
ASO	R	R	N	N	N
ASO Quantitative *Latex IU/ml*	100 - 1600	100 - 1600	< 200	< 200	< 200
Nephelometry IU/ml	357 - 1123	313 - 1115	< 60	< 60	< 60
Turbidimetry IU/ml	182 - 1199	137 - 1198	< 65	< 65	< 65
	26	**27**	**28**	**29**	**30**
Infectious Mono.	N	R	N	N	N
Rheumatoid Factor	N	R	N	N	N
RF Quantitative					
Latex (Diliution Scheme A)	< 10	10 - 160	< 10	< 10	< 10
Latex (Diliution Scheme B)	< 1:2	1:2 - 1:16	< 1:2	< 1:2	< 1:2
Nephelometry IU/ml	< 20	27 - 60	< 20	< 20	< 20
Turbidimetry IU/ml	< 20	18 - 73	< 20	< 20	< 20
	31	**32**	**33**	**34**	**35**
HIV Ab Screening/Confirmation	N	R	N	R	N
	36	**37**	**38**	**39**	**40**
HTLV 1 Ab	N	N	R	N	N
	41	**42**	**43**	**44**	**45**
LYME Disease Ab	N	R	N	N	R
LYME Disease Ab WB IgG	N	R	N	N	R
LYME Disease Ab WB IgM	N	R*	N	N	R*
	46	**47**	**48**	**49**	**50**
ANA	N	N	N	R	N
IFA Titer	< 80	< 80	< 80	40 - 640	< 80
	56	**57**	**58**	**59**	**60**
Rubella IgM	R	N	R	N	N
	66	**67**	**68**	**69**	**70**
Hepatitis Be Ag	R	N	N	N	R
	71	**72**	**73**	**74**	**75**
Hepatitis C Ab	N	N	R	N	N
Hepatitis C Ab Confirmation	N	N	R	N	N

Note: R = Reactive/ Positive; I = Indeterminate; N = Non-Reactive/ Negative

* This test sample was not authenticated, because a consensus of 80% agreement was not reached. All participating laboratories received credit for this sample.