New York State Department of Health
Wadsworth Center

Proficiency Testing Program

13-May-09

DIAGNOSTIC IMMUNOLOGY & HUMAN IMMUNODEFICIENCY VIRUS SUMMARY ANALYSIS

Proficiency Test Event
13-May-09

Diagnostic Immunology & Human Immunodeficiency Virus
Summary Report

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Table of Contents

The data summarized in this report were tabulated from test results and accompanying information submitted by laboratories that participated in the May 13, 2009 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
- 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 R				**47 R**				**48 N**				**49 N**				**50 N**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**38**		**0%**	**38**	**100%**		**0%**	**38**	**100%**	**38**	**100%**		**0%**	**38**	**100%**		**0%**	**38**	**100%**		**0%**
IFA	**63**	**0**	**0%**	**63**	**100%**	**2**	**3%**	**61**	**97%**	**63**	**100%**	**0**	**0%**	**63**	**100%**	**0**	**0%**	**63**	**100%**	**0**	**0%**
Bio-Rad	19		0%	19	100%	1	5%	18	95%	19	100%		0%	19	100%		0%	19	100%		0%
Wampole/Zeus	16		0%	16	100%		0%	16	100%	16	100%		0%	16	100%		0%	16	100%		0%
Others	28		0%	28	100%	1	4%	27	96%	28	100%		0%	28	100%		0%	28	100%		0%
Muliplexed Bead [1]	17		0%	17	100%		0%	16	94%	17	100%		0%	17	100%		0%	17	100%		0%
Other Methods	7	1	14%	6	86%	1	14%	6	86%	6	86%	1	14%	6	86%	1	14%	6	86%	1	14%
Analyte Total	**125**	**1**	**1%**	**124**	**99%**	**3**	**2%**	**121**	**97%**	**124**	**99%**	**1**	**1%**	**124**	**99%**	**1**	**1%**	**124**	**99%**	**1**	**1%**

[1] One laboratory reported an equivocal result on sample #47.

Antinuclear Antibody Quantitative (IFA systems only)

The number of laboratories that reported titers is listed for positive test samples 46 and 47. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

Method / *Manufacturer*	No. Labs	Sample 46 Titer 40	80	160	320	640	1280	2560	5120	Sample 47 Titer 40	80	160	320	640	1280	2560	5120
IFA ***Total***	81			5	15	29	15	7	3	1	15	34	20	14	5		
Bio-Rad	22			4	5	9	2			1	6	12	2				
Immuno	10				1	2	2					2	2	5			
The Binding site	16				2	6	3	2	1		1	3	6	2	2		
Wampole/ Zeus	19				3	5	2	2	1		4	8	3	2	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.

Antinuclear Antibody Staining Patterns

Staining Pattern	Sample 46 #	Sample 46 %	Sample 47 #	Sample 47 %
Homogenous			91	96%
Nucleolar				
Peripheral				
Speckled	94	99%	1	1%

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 N**				**17 N**				**18 R**				**19 N**				**20 R**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Latex Agglutination	**68**	**68**	**100%**	**0**	**0%**	**68**	**100%**	**0**	**0%**	**1**	**1%**	**67**	**99%**	**68**	**100%**	**0**	**0%**	**1**	**1%**	**67**	**99%**
Dade Behring	17	17	100%		0%	17	100%		0%		0%	17	100%	17	100%		0%		0%	17	100%
Fisher	16	16	100%		0%	16	100%		0%		0%	16	100%	16	100%		0%		0%	16	100%
Remel	15	15	100%		0%	15	100%		0%		0%	15	100%	15	100%		0%		0%	15	100%
Others	20	20	100%		0%	20	100%		0%	1	5%	19	95%	20	100%		0%	1	5%	19	95%
Hemagglutination	**10**	**10**	**100%**	**0**	**0%**	**10**	**100%**	**0**	**0%**	**0**	**0%**	**10**	**100%**	**10**	**100%**	**0**	**0%**	**0**	**0%**	**10**	**100%**
Wampole/Zeus	10	10	100%		0%	10	100%		0%		0%	10	100%	10	100%		0%		0%	10	100%
Other Methods	15	15	100%		0%	15	100%		0%		0%	15	100%	15	100%		0%		0%	15	100%
Analyte Total	**93**	**93**	**100%**	**0**	**0%**	**93**	**100%**	**0**	**0%**	**1**	**1%**	**92**	**99%**	**93**	**100%**	**0**	**0%**	**1**	**1%**	**92**	**99%**

Antistreptolysin O Quantitative
Latex Agglutination Procedures

The number of laboratories that reported titers is listed for positive test samples 18 and 20. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

Method *Manufacturer*	No. Labs	Sample 18 Titer						Sample 20 Titer					
		200	400	800	1600	3200	6400	200	400	800	1600	3200	6400
Latex ***Total***	54		31	7					30	9			
Dade Behring	15		6	2					7	2			
Fisher	13		9	3					10	2			
Remel	13		11	1					10	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.

Antistreptolysin O Quantitative

Nephelometry & Turbidimetry Procedures

Results are summarized for positive test samples 18 and 20. 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 18**	**Sample 20**
Nephelometry ***Total***	16	IU/ml	524 ± 126	544 ± 139
Turbidimetry ***Total***	36	IU/ml	663 ± 127	668 ± 128
Roche Diagnostics Cobas	16	IU/ml	749 ± 29	751 ± 30

Cytomegalovirus Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		11 R				12 R				13 N				14 N				15 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**37**	**0**	**0%**	**37**	**100%**	**0**	**0%**	**36**	**97%**	**37**	**100%**	**0**	**0%**	**37**	**100%**	**0**	**0%**	**36**	**97%**	**0**	**0%**
Wampole /Zeus	18		0%	18	100%		0%	18	100%	18	100%		0%	18	100%		0%	18	100%		0%
Others [1]	19		0%	19	100%		0%	18	95%	19	100%		0%	19	100%		0%	18	95%		0%
ELFA	**19**	**0**	**0%**	**19**	**100%**	**0**	**0%**	**19**	**100%**	**19**	**100%**	**0**	**0%**	**19**	**100%**	**0**	**0%**	**19**	**100%**	**0**	**0%**
bioMérieux Vidas	19		0%	19	100%		0%	19	100%	19	100%		0%	19	100%		0%	19	100%		0%
Chemiluminescence	**12**	**0**	**0%**	**12**	**100%**	**0**	**0%**	**12**	**100%**	**12**	**100%**	**0**	**0%**	**12**	**100%**	**0**	**0%**	**12**	**100%**	**0**	**0%**
Diagnostic Products	10		0%	10	100%		0%	10	100%	10	100%		0%	10	100%		0%	10	100%		0%
Others	2		0%	2	100%		0%	2	100%	2	100%		0%	2	100%		0%	2	100%		0%
Hemagglutination	**11**	**0**	**0%**	**11**	**100%**	**0**	**0%**	**11**	**100%**	**11**	**100%**	**0**	**0%**	**11**	**100%**	**0**	**0%**	**11**	**100%**	**0**	**0%**
Olympus	11		0%	11	100%		0%	11	100%	11	100%		0%	11	100%		0%	11	100%		0%
Other Methods	9		0%	9	100%		0%	9	100%	9	100%		0%	9	100%		0%	9	100%		0%
Analyte Total	**88**	**0**	**0%**	**88**	**100%**	**0**	**0%**	**87**	**99%**	**88**	**100%**	**0**	**0%**	**88**	**100%**	**0**	**0%**	**87**	**99%**	**0**	**0%**

[1] One lab reported an equivocal on sample #12 and one lab reported an equivocal on sample #15.

Hepatitis B Core Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		6 N				7 N				8 N				9 R				10 R			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**103**	**103**	**100%**	**0**	**0%**	**103**	**100%**	**0**	**0%**	**103**	**100%**	**0**	**0%**	**0**	**0%**	**103**	**100%**	**2**	**2%**	**101**	**98%**
Abbott	13	13	100%		0%	13	100%		0%	13	100%		0%		0%	13	100%		0%	13	100%
Bayer	40	40	100%		0%	40	100%		0%	40	100%		0%		0%	40	100%		0%	40	100%
Diagnostic Products	18	18	100%		0%	18	100%		0%	18	100%		0%		0%	18	100%	1	6%	17	94%
Ortho	32	32	100%		0%	32	100%		0%	32	100%		0%		0%	32	100%	1	3%	31	97%
EIA	**44**	**44**	**100%**	**0**	**0%**	**44**	**100%**	**0**	**0%**	**44**	**100%**	**0**	**0%**	**0**	**0%**	**44**	**100%**	**1**	**2%**	**43**	**98%**
Abbott Axsym	23	23	100%		0%	23	100%		0%	23	100%		0%		0%	23	100%	1	4%	22	96%
DiaSorin	10	10	100%		0%	10	100%		0%	10	100%		0%		0%	10	100%		0%	10	100%
Ortho	9	9	100%		0%	9	100%		0%	9	100%		0%		0%	9	100%		0%	9	100%
Other	2	2	100%		0%	2	100%		0%	2	100%		0%		0%	2	100%		0%	2	100%
Analyte Total	**147**	**147**	**100%**	**0**	**0%**	**147**	**100%**	**0**	**0%**	**147**	**100%**	**0**	**0%**	**0**	**0%**	**147**	**100%**	**3**	**2%**	**144**	**98%**

Hepatitis B Surface Antigen

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		6 N				7 N				8 N				9 R				10 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**137**	**137**	**100%**	**0**	**0%**	**137**	**100%**	**0**	**0%**	**137**	**100%**	**0**	**0%**	**0**	**0%**	**137**	**100%**	**134**	**98%**	**3**	**2%**
Abbott	13	13	100%		0%	13	100%		0%	13	100%		0%		0%	13	100%	13	100%		0%
Bayer	53	53	100%		0%	53	100%		0%	53	100%		0%		0%	53	100%	53	100%		0%
Diagnostic Products	19	19	100%		0%	19	100%		0%	19	100%		0%		0%	19	100%	17	89%	2	11%
Ortho	42	42	100%		0%	42	100%		0%	42	100%		0%		0%	42	100%	41	98%	1	2%
Roche	10	10	100%		0%	10	100%		0%	10	100%		0%		0%	10	100%	10	100%		0%
EIA	**48**	**47**	**98%**	**1**	**2%**	**48**	**100%**	**0**	**0%**	**48**	**100%**	**0**	**0%**	**0**	**0%**	**48**	**100%**	**48**	**100%**	**0**	**0%**
Abbott Axsym	26	25	96%	1	4%	26	100%		0%	26	100%		0%		0%	26	100%	26	100%		0%
Bio-Rad	15	15	100%		0%	15	100%		0%	15	100%		0%		0%	15	100%	15	100%		0%
Other	7	7	100%		0%	7	100%		0%	7	100%		0%		0%	7	100%	7	100%		0%
Confirmation	**125**	**124**	**99%**	**1**	**1%**	**125**	**100%**	**0**	**0%**	**125**	**100%**	**0**	**0%**	**0**	**0%**	**125**	**100%**	**125**	**100%**	**0**	**0%**
Abbott Axsym	13	12	92%	1	8%	13	100%		0%	13	100%		0%		0%	13	100%	13	100%		0%
Bayer/Siemens	39	39	100%		0%	39	100%		0%	39	100%		0%		0%	39	100%	39	100%		0%
Diagnostic Products	10	10	100%		0%	10	100%		0%	10	100%		0%		0%	10	100%	10	100%		0%
Ortho	29	29	100%		0%	29	100%		0%	29	100%		0%		0%	29	100%	29	100%		0%
Other	34	34	100%		0%	34	100%		0%	34	100%		0%		0%	34	100%	34	100%		0%
Other Methods	6	6	100%		0%	6	100%		0%	6	100%		0%		0%	6	100%	6	100%		0%
Analyte Total	**316**	**314**	**99%**	**2**	**1%**	**316**	**100%**	**0**	**0%**	**316**	**100%**	**0**	**0%**	**0**	**0%**	**316**	**100%**	**313**	**99%**	**3**	**1%**

Note: If you do not have enough volume to complete testing, please call before the replacement deadline. If you call too late to have additional sample volume shipped and your reported results are different than the consensus results, your result will be marked incorrect.

Hepatitis Be Antigen

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		66 R				67 N				68 R				69 N				70 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**26**	**0**	**0%**	**26**	**100%**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**26**	**100%**	**26**	**100%**	**0**	**0%**	**26**	**100%**	**0**	**0%**
DiaSorin	25		0%	25	100%	25	100%		0%		0%	25	100%	25	100%		0%	25	100%		0%
Other	1		0%	1	100%	1	100%		0%		0%	1	100%	1	100%		0%	1	100%		0%
Other Methods	4		0%	4	100%	4	100%		0%		0%	4	100%	4	100%		0%	4	100%		0%
Analyte Total	**30**	**0**	**0%**	**30**	**100%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**30**	**100%**	**0**	**0%**	**30**	**100%**	**0**	**0%**

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 R			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**100**	**100**	**100%**	**0**	**0%**	**100**	**100%**	**0**	**0%**	**0**	**0%**	**100**	**100%**	**100**	**100%**	**0**	**0%**	**0**	**0%**	**100**	**100%**
Bayer	54	54	100%		0%	54	100%		0%		0%	54	100%	54	100%		0%		0%	54	100%
Ortho	40	40	100%		0%	40	100%		0%		0%	40	100%	40	100%		0%		0%	40	100%
Other	6	6	100%		0%	6	100%		0%		0%	6	100%	6	100%		0%		0%	6	100%
EIA	**62**	**62**	**100%**	**0**	**0%**	**62**	**100%**	**0**	**0%**	**0**	**0%**	**62**	**100%**	**62**	**100%**	**0**	**0%**	**0**	**0%**	**62**	**100%**
Abbott	40	40	100%		0%	40	100%		0%		0%	40	100%	40	100%		0%		0%	40	100%
Ortho	22	22	100%		0%	22	100%		0%		0%	22	100%	22	100%		0%		0%	22	100%
Confirmation	**26**	**26**	**100%**	**0**	**0%**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**26**	**100%**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**26**	**100%**
Chiron	22	22	100%		0%	22	100%		0%		0%	22	100%	22	100%		0%		0%	22	100%
Other	4	4	100%		0%	4	100%		0%		0%	4	100%	4	100%		0%		0%	4	100%
Other Methods	8	8	100%		0%	8	100%		0%		0%	8	100%	8	100%		0%		0%	8	100%
Analyte Total	**196**	**196**	**100%**	**0**	**0%**	**196**	**100%**	**0**	**0%**	**0**	**0%**	**196**	**100%**	**196**	**100%**	**0**	**0%**	**0**	**0%**	**196**	**100%**

HIV Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		31 R				32 N				33 N				34 N				35 R			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**39**	**0**	**0%**	**39**	**100%**	**39**	**100%**	**0**	**0%**	**39**	**100%**	**0**	**0%**	**39**	**100%**	**0**	**0%**	**0**	**0%**	**39**	**100%**
Bayer	26		0%	26	100%	26	100%		0%	26	100%		0%	26	100%		0%		0%	26	100%
Ortho	13		0%	13	100%	13	100%		0%	13	100%		0%	13	100%		0%		0%	13	100%
EIA	**89**	**0**	**0%**	**89**	**100%**	**89**	**100%**	**0**	**0%**	**89**	**100%**	**0**	**0%**	**89**	**100%**	**0**	**0%**	**0**	**0%**	**89**	**100%**
Abbott	39		0%	39	100%	39	100%		0%	39	100%		0%	39	100%		0%		0%	39	100%
Bio-Rad	50		0%	50	100%	50	100%		0%	50	100%		0%	50	100%		0%		0%	50	100%
Rapid EIA	**91**	**0**	**0%**	**91**	**100%**	**91**	**100%**	**0**	**0%**	**91**	**100%**	**0**	**0%**	**91**	**100%**	**0**	**0%**	**0**	**0%**	**91**	**100%**
Orasure	91		0%	91	100%	91	100%		0%	91	100%		0%	91	100%		0%		0%	91	100%
Rapid Immunoassay	**62**	**0**	**0%**	**62**	**100%**	**47**	**76%**	**0**	**0%**	**47**	**76%**	**0**	**0%**	**46**	**74%**	**1**	**2%**	**1**	**2%**	**61**	**98%**
Inverness	18		0%	18	100%	18	100%		0%	18	100%		0%	18	100%		0%		0%	18	100%
Medmira	15		0%	15	100%	15	100%		0%	15	100%		0%	15	100%		0%		0%	15	100%
Trinity [1]	25		0%	25	100%	10	40%		0%	10	40%		0%	9	36%	1	4%	1	4%	24	96%
Other	4		0%	4	100%	4	100%		0%	4	100%		0%	4	100%		0%		0%	4	100%
Western Blot	**42**	**0**	**0%**	**42**	**100%**	**42**	**100%**	**0**	**0%**	**42**	**100%**	**0**	**0%**	**42**	**100%**	**0**	**0%**	**0**	**0%**	**42**	**100%**
Bio-Rad	40		0%	40	100%	40	100%		0%	40	100%		0%	40	100%		0%		0%	40	100%
Others	2		0%	2	100%	2	100%		0%	2	100%		0%	2	100%		0%		0%	2	100%
Other Methods	6		0%	6	100%	6	100%		0%	6	100%		0%	6	100%		0%		0%	6	100%
Analyte Total	**329**	**0**	**0%**	**329**	**100%**	**314**	**95%**	**0**	**0%**	**314**	**95%**	**0**	**0%**	**313**	**95%**	**1**	**0%**	**1**	**0%**	**328**	**100%**

[1] 15 laboratories reported an "invalid" test on negative samples #32,33, and 34. Due to control line issue.

HTLV Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number **R = Reactive/ Positive; N = Non-Reactive/ Negative** **36 N**				**37 R**				**38 N**				**39 N**				**40 R**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**23**	**23**	**100%**	**0**	**0%**	**0**	**0%**	**23**	**100%**	**23**	**100%**	**0**	**0%**	**23**	**100%**	**0**	**0%**	**0**	**0%**	**22**	**96%**
Abbott [1]	22	22	100%		0%		0%	22	100%	22	100%		0%	22	100%		0%		0%	21	95%
Other	1	1	100%		0%		0%	1	100%	1	100%		0%	1	100%		0%		0%	1	100%
Abbott Prism	**13**	13	100%		0%		0%	13	100%	13	100%		0%	12	92%	1	8%		0%	13	100%
Analyte Total	**36**	**36**	**100%**	**0**	**0%**	**0**	**0%**	**36**	**100%**	**36**	**100%**	**0**	**0%**	**35**	**97%**	**1**	**3%**	**0**	**0%**	**35**	**97%**

[1] One laboratory reported an equivocal on sample #40.

Infectious Mononucleosis

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		26 N				27 N				28 R				29 R				30 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
CICA	**17**	**17**	**100%**	**0**	**0%**	**17**	**100%**	**0**	**0%**	**0**	**0%**	**17**	**100%**	**0**	**0%**	**17**	**100%**	**17**	**100%**	**0**	**0%**
Others	17	17	100%		0%	17	100%		0%		0%	17	100%		0%	17	100%	17	100%		0%
Hemagglutination	**44**	**43**	**98%**	**1**	**2%**	**43**	**98%**	**1**	**2%**	**0**	**0%**	**44**	**100%**	**0**	**0%**	**44**	**100%**	**41**	**93%**	**3**	**7%**
Fisher	16	15	94%	1	6%	15	94%	1	6%		0%	16	100%		0%	16	100%	14	88%	2	13%
Wampole/Zeus	20	20	100%		0%	20	100%		0%		0%	20	100%		0%	20	100%	19	95%	1	5%
Others	8	8	100%		0%	8	100%		0%		0%	8	100%		0%	8	100%	8	100%		0%
Latex Agglutination	**139**	**137**	**99%**	**1**	**1%**	**136**	**98%**	**3**	**2%**	**2**	**1%**	**137**	**99%**	**2**	**1%**	**137**	**99%**	**139**	**100%**	**0**	**0%**
Fisher [1]	44	43	98%		0%	43	98%	1	2%		0%	44	100%		0%	44	100%	44	100%		0%
Remel	25	25	100%		0%	25	100%		0%		0%	25	100%		0%	25	100%	25	100%		0%
Wampole/Zeus	51	51	100%		0%	50	98%	1	2%	1	2%	50	98%		0%	51	100%	51	100%		0%
Others	19	18	95%	1	5%	18	95%	1	5%	1	5%	18	95%	2	11%	17	89%	19	100%		0%
Solid Phase IA	**61**	**61**	**100%**	**0**	**0%**	**61**	**100%**	**0**	**0%**	**0**	**0%**	**61**	**100%**	**0**	**0%**	**61**	**100%**	**61**	**100%**	**0**	**0%**
Inverness	30	30	100%		0%	30	100%		0%		0%	30	100%		0%	30	100%	30	100%		0%
Seradyn	25	25	100%		0%	25	100%		0%		0%	25	100%		0%	25	100%	25	100%		0%
Others	6	6	100%		0%	6	100%		0%		0%	6	100%		0%	6	100%	6	100%		0%
Other Methods	4	4	100%	0	0%	4	100%		0%		0%	4	100%		0%	4	100%	4	100%		0%
Analyte Total	**265**	**262**	**99%**	**2**	**1%**	**261**	**98%**	**4**	**2%**	**2**	**1%**	**263**	**99%**	**2**	**1%**	**263**	**99%**	**262**	**99%**	**3**	**1%**

[1] One laboratory reported "not applicable" on sample #26.

Lyme Disease Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		41 R				42 N				43 N				44 N				45 R			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**57**	**0**	**0%**	**57**	**100%**	**57**	**100%**	**0**	**0%**	**57**	**100%**	**0**	**0%**	**57**	**100%**	**0**	**0%**	**0**	**0%**	**57**	**100%**
Immunetics	16		0%	16	100%	16	100%		0%	16	100%		0%	16	100%		0%		0%	16	100%
Wampole /Zeus	29		0%	29	100%	29	100%		0%	29	100%		0%	29	100%		0%		0%	29	100%
Others	12		0%	12	100%	12	100%		0%	12	100%		0%	12	100%		0%		0%	12	100%
ELFA	**29**	**0**	**0%**	**29**	**100%**	**29**	**100%**	**0**	**0%**	**29**	**100%**	**0**	**0%**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**29**	**100%**
bioMérieux	29		0%	29	100%	29	100%		0%	29	100%		0%	29	100%		0%		0%	29	100%
Other Methods	7		0%	7	100%	7	100%		0%	7	100%		0%	7	100%		0%		0%	7	100%
Analyte Total	**93**	**0**	**0%**	**93**	**100%**	**93**	**100%**	**0**	**0%**	**93**	**100%**	**0**	**0%**	**93**	**100%**	**0**	**0%**	**0**	**0%**	**93**	**100%**

Lyme Western Blot IgG

Participant Results/ Sample Number

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

Method / *Manufacturer*	No. Labs	41 R						42 N						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**	**0**	**0%**	**0**	**0%**	**27**	**100%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**1**	**4%**	**0**	**0%**	**26**	**96%**
MarDx	24		0%		0%	24	100%	24	100%		0%		0%	24	100%		0%		0%	24	100%		0%		0%	1	4%		0%	23	96%
Other	3		0%		0%	3	100%	3	100%		0%		0%	3	100%		0%		0%	3	100%		0%		0%		0%		0%	3	100%
Other Methods	3		0%		0%	3	100%	3	100%		0%		0%	3	100%		0%		0%	3	100%		0%		0%		0%		0%	3	100%
Analyte Total	**30**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**1**	**3%**	**0**	**0%**	**29**	**97%**

Lyme Western Blot IgM

Participant Results/ Sample Number

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

Method / *Manufacturer*	No. Labs	41 R*						42 N						43 N						44 N						45 N*					
		N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%
Western Blot - IgM	**27**	**15**	**56%**	**2**	**7%**	**10**	**37%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**27**	**100%**	**0**	**0%**	**0**	**0%**	**20**	**74%**	**3**	**11%**	**4**	**15%**
MarDx	24	14	58%	2	8%	8	33%	24	100%		0%		0%	24	100%		0%		0%	24	100%		0%		0%	18	75%	3	13%	3	13%
Other	3	1	33%		0%	2	67%	3	100%		0%		0%	3	100%		0%		0%	3	100%		0%		0%	2	67%		0%	1	33%
Other Methods	2		0%		0%	2	100%	2	100%		0%		0%	2	100%		0%		0%	2	100%		0%		0%	1	50%		0%	1	50%
Analyte Total	**29**	**15**	**52%**	**2**	**7%**	**12**	**41%**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**21**	**72%**	**3**	**10%**	**5**	**17%**

* Samples #41 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 N**				**28 R**				**29 R**				**30 N**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Latex Agglutination	**96**	**94**	**98%**	**2**	**2%**	**95**	**99%**	**1**	**1%**	**3**	**3%**	**93**	**97%**	**1**	**1%**	**95**	**99%**	**95**	**99%**	**1**	**1%**
Becton Dickinson	14	14	100%		0%	14	100%		0%		0%	14	100%		0%	14	100%	14	100%		0%
Fisher	39	39	100%		0%	39	100%		0%	2	5%	37	95%		0%	39	100%	38	97%	1	3%
Wampole/Zeus	11	10	91%	1	9%	11	100%		0%		0%	11	100%		0%	11	100%	11	100%		0%
Others	32	31	97%	1	3%	31	97%	1	3%	1	3%	31	97%	1	3%	31	97%	32	100%		0%
Nephelometry	**14**	**14**	**100%**	**0**	**0%**	**14**	**100%**	**0**	**0%**	**0**	**0%**	**14**	**100%**	**0**	**0%**	**14**	**100%**	**14**	**100%**	**0**	**0%**
Others	14	14	100%		0%	14	100%		0%		0%	14	100%		0%	14	100%	14	100%		0%
Turbidimetry	**17**	**17**	**100%**	**0**	**0%**	**17**	**100%**	**0**	**0%**	**0**	**0%**	**17**	**100%**	**0**	**0%**	**17**	**100%**	**17**	**100%**	**0**	**0%**
Others	17	17	100%		0%	17	100%		0%		0%	17	100%		0%	17	100%	17	100%		0%
Other Methods	11	10	91%	1	9%	10	91%	1	9%		0%	11	100%		0%	11	100%	10	91%	1	9%
Analyte Total	**138**	**135**	**98%**	**3**	**2%**	**136**	**99%**	**2**	**1%**	**3**	**2%**	**135**	**98%**	**1**	**1%**	**137**	**99%**	**136**	**99%**	**2**	**1%**

Rheumatoid Factor Quantitative
Latex Agglutination Procedure

The number of laboratories that reported titers is listed for positive test samples 28 and 29. 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 28 Titer								Sample 29 Titer							
Manufacturer	**No. Labs**	**A B**	**10 1**	**20 2**	**40 4**	**80 8**	**160 16**	**320 32**	**640 64**	**1280 128**	**10 1**	**20 2**	**40 4**	**80 8**	**160 16**	**320 32**	**640 64**	**1280 128**
Total	73	A			5	11	11	11	2			2	9	12	16	3		
		B			2	1	10	8	2				2	9	9	2	1	
Becton Dickenson	11	A			1	7	2	1				1	6	2	2			
		B																
Fisher	31	A			1	2	6	7					2	6	8	1		
		B			1		6	7					1	6	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.

Rheumatoid Factor Quantitative

Nephelometry & Turbidimetry Procedures

Results are summarized for positive test samples 28 and 29. 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 28**	**Sample 29**
Nephelometry ***Total***	25	IU/ml	220 ± 41	126 ± 28
Beckman Coulter IMMAGE	11	IU/ml	263 ± 10	156 ± 7.2
Dade Behring Nephelometer	14	IU/ml	188 ± 20	105 ± 15
Turbidimetry ***Total***	67	IU/ml	163 ± 76	110 ± 45
Beckman Unicel DxC	10	IU/ml	294 ± 22	174 ± 7.7
Roche Diag. Cobas	20	IU/ml	113 ± 4.4	81 ± 3.5
Roche Hitachi Modular (all models)	11	IU/ml	111 ± 1.7	79 ± 2.4

Rubella Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		11 R				12 R				13 N				14 N				15 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**55**	**0**	**0%**	**55**	**100%**	**2**	**4%**	**48**	**87%**	**55**	**100%**	**0**	**0%**	**55**	**100%**	**0**	**0%**	**55**	**100%**	**0**	**0%**
Bayer	25		0%	25	100%		0%	25	100%	25	100%		0%	25	100%		0%	25	100%		0%
Beckman [1]	13		0%	13	100%	2	15%	6	46%	13	100%		0%	13	100%		0%	13	100%		0%
Diagnostic Products	12		0%	12	100%		0%	12	100%	12	100%		0%	12	100%		0%	12	100%		0%
Others	5		0%	5	100%		0%	5	100%	5	100%		0%	5	100%		0%	5	100%		0%
EIA	**53**	**0**	**0%**	**53**	**100%**	**0**	**0%**	**51**	**96%**	**53**	**100%**	**0**	**0%**	**53**	**100%**	**0**	**0%**	**53**	**100%**	**0**	**0%**
Abbott [2]	19		0%	19	100%		0%	18	95%	19	100%		0%	19	100%		0%	19	100%		0%
Wampole/Zeus	16		0%	16	100%		0%	16	100%	16	100%		0%	16	100%		0%	16	100%		0%
Others [3]	18		0%	18	100%		0%	17	94%	18	100%		0%	18	100%		0%	18	100%		0%
Latex Agglutination	**31**	**0**	**0%**	**31**	**100%**	**1**	**3%**	**30**	**97%**	**31**	**100%**	**0**	**0%**	**31**	**100%**	**0**	**0%**	**30**	**97%**	**1**	**3%**
Fisher	19		0%	19	100%	1	5%	18	95%	19	100%		0%	19	100%		0%	18	95%	1	5%
Others	12		0%	12	100%		0%	12	100%	12	100%		0%	12	100%		0%	12	100%		0%
Other Methods	14		0%	14	100%		0%	14	100%	14	100%		0%	14	100%		0%	14	100%		0%
Analyte Total	**153**	**0**	**0%**	**153**	**100%**	**3**	**2%**	**143**	**93%**	**153**	**100%**	**0**	**0%**	**153**	**100%**	**0**	**0%**	**152**	**99%**	**1**	**1%**

[1] Five laboratories reported an equivocal result on sample #12
[2] One laboratory reported an equivocal result on sample #12
[3] One laboratory reported an equivocal result on sample #12

Rubella Antibody Quantitative

Results are summarized for positive test samples 11 and 12. 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 11**	**Sample 12**
Chemiluminescence Total	26	IU/ml	51 ± 7.2	15 ± 2.1
Diagnostic Products	16	IU/ml	49 ± 4.2	15 ± 1.3
Bayer(not included in total) *	25	IU/ml	496 ± 19	93 ± 11
EIA Total	17	IU/ml	45 ± 11	20 ± 5.6

* Results from Bayer Advia systems consistently run higher than all others.

Rubella IgM Specific

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		56 N				57 N				58 N				59 R				60 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**7**	7	100%		0%	7	100%		0%	7	100%		0%		0%	7	100%	6	86%	1	14%
Chemiluminescence	**9**	9	100%		0%	9	100%		0%	9	100%		0%		0%	9	100%	9	100%		0%
Analyte Total	**16**	**16**	**100%**	**0**	**0%**	**16**	**100%**	**0**	**0%**	**16**	**100%**	**0**	**0%**	**0**	**0%**	**16**	**100%**	**15**	**94%**	**1**	**6%**

Syphilis - Reagin Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		1 N				2 R				3 N				4 R				5 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
RPR	**245**	**245**	**100%**	**0**	**0%**	**0**	**0%**	**245**	**100%**	**245**	**100%**	**0**	**0%**	**0**	**0%**	**245**	**100%**	**245**	**100%**	**0**	**0%**
ASI	38	38	100%		0%		0%	38	100%	38	100%		0%		0%	38	100%	38	100%		0%
Becton Dickenson	117	117	100%		0%		0%	117	100%	117	100%		0%		0%	117	100%	117	100%		0%
Fisher	42	42	100%		0%		0%	42	100%	42	100%		0%		0%	42	100%	42	100%		0%
True Medix	16	16	100%		0%		0%	16	100%	16	100%		0%		0%	16	100%	16	100%		0%
Wampole/Zeus	20	20	100%		0%		0%	20	100%	20	100%		0%		0%	20	100%	20	100%		0%
Others	12	12	100%		0%		0%	12	100%	12	100%		0%		0%	12	100%	12	100%		0%
Analyte Total	**245**	**245**	**100%**	**0**	**0%**	**0**	**0%**	**245**	**100%**	**245**	**100%**	**0**	**0%**	**0**	**0%**	**245**	**100%**	**245**	**100%**	**0**	**0%**

Syphilis - Reagin Antibody

RPR Procedures

The number of laboratories that reported titers is listed for positive test samples 2 and 4 for the RPR procedure. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

Method *Manufacturer*	No. Labs	Sample 2 Titer 1	2	4	8	16	32	Sample 4 Titer 1	2	4	8	16	32
Total	222	63	134	24		1		3	85	113	19	2	
ASI	26	12	11	3				1	15	8	2		
Becton Dickenson	110	22	75	13					24	72	13	1	
Fisher	41	15	23	3				1	22	16	2		
True Medix	16	5	7	3		1		1	8	4	2	1	
Wampole/ Zeus	20	6	13	1					10	10			

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 R				3 N				4 R				5 N			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**18**	**18**	**100%**	**0**	**0%**	**0**	**0%**	**18**	**100%**	**18**	**100%**	**0**	**0%**	**0**	**0%**	**18**	**100%**	**18**	**100%**	**0**	**0%**
Others	18	18	100%		0%		0%	18	100%	18	100%		0%		0%	18	100%	18	100%		0%
Gel. Part. Agglut.	**30**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**30**	**100%**	**0**	**0%**
Fujirebio	30	30	100%		0%		0%	30	100%	30	100%		0%		0%	30	100%	30	100%		0%
FTA	**23**	**23**	**100%**	**0**	**0%**	**0**	**0%**	**23**	**100%**	**22**	**96%**	**1**	**4%**	**0**	**0%**	**23**	**100%**	**23**	**100%**	**0**	**0%**
Wampole/Zeus	18	18	100%		0%		0%	18	100%	18	100%		0%		0%	18	100%	18	100%		0%
Others	5	5	100%		0%		0%	5	100%	4	80%	1	20%		0%	5	100%	5	100%		0%
Other Methods	13	5	38%	8	62%		0%	13	100%	5	38%	8	62%		0%	13	100%	5	38%	8	62%
Analyte Total	**84**	**76**	**90%**	**8**	**10%**	**0**	**0%**	**84**	**100%**	**75**	**89%**	**9**	**11%**	**0**	**0%**	**84**	**100%**	**76**	**90%**	**8**	**10%**

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*	18	95 ± 5.9	36 ± 1.4	16 ± 0.7	6.1 ± 0.1	345 ± 25
Nephelometry/ *Total*	25	92 ± 7.4	36 ± 1.6	18 ± 2.3	6.1 ± 0.1	330 ± 33
All Method/ *Total*	36	91 ± 8.8	36 ± 2.2	18 ± 1.8	< 10	320 ± 32
Complement C'3		76	77	78	79	80
Nephelometry/*Beckman Coulter IMMAGE*	14	75 ± 3.4	34 ± 2.2	23 ± 1.4	29 ± 2.0	276 ± 15
Nephelometry/*Behring Nephelometer*	11	83 ± 5.2	36 ± 2.1	24 ± 0.9	30 ± 2.1	285 ± 19
Turbidimetry/*Roche Cobas Integra*	15	73 ± 2.85	35 ± 2.6	22 ± 0.8	29 ± 1.2	285 ± 5.1
Turbidimetry/*Roche/Hitachi Modular*	12	71 ± 1.8	36 ± 1.1	24 ± 0.9	31 ± 0.7	285 ± 6.2
Nephelometry/ *Total*	29	79 ± 5.4	35 ± 1.6	24 ± 1.1	30 ± 2.1	279 ± 17
Turbidimetry/ *Total*	65	72 ± 3.9	35 ± 2.7	23 ± 6.1	30 ± 2.3	283 ± 14
All Method/ *Total*	100	74 ± 5.2	35 ± 2.6	24 ± 1.9	30 ± 2.2	282 ± 15
Complement C'4		76	77	78	79	80
Nephelometry/*Beckman Coulter IMMAGE*	14	14 ± 0.5	8.0 ± 0.6	4.4 ± 0.4	3.5 ± 0.3	27 ± 1.1
Nephelometry/*Behring Nephelometer*	11	13 ± 0.7	7.6 ± 0.5	4.0 ± 0.1	3.3 ± 0.4	27 ± 1.9
Turbidimetry/*Roche Cobas Integra*	16	12 ± 0.9	6.8 ± 0.8	3.5 ± 0.5	3.2 ± 0.5	28 ± 0.9
Turbidimetry/*Roche/Hitachi Modular*	10	11 ± 0.2	6.1 ± 0.1	3.2 ± 0.4	3.0 ± 0.1	25 ± 0.4
Nephelometry/ *Total*	29	14 ± 0.8	7.9 ± 0.6	4.2 ± 0.4	3.5 ± 0.3	27 ± 1.7
Turbidimetry/ *Total*	63	12 ± 1.2	6.8 ± 0.8	3.5 ± 0.6	3.2 ± 0.5	27 ± 3.3
All Method/ *Total*	98	13 ± 1.3	7.2 ± 0.9	3.8 ± 0.6	3.2 ± 0.5	27 ± 2.8

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*	17	76 ± 3.9	109 ± 6.1	226 ± 11	181 ± 10	50 ± 3.2
Nephelometry/*Behring Nephelometer*	15	86 ± 3.8	120 ± 7.9	267 ± 16	209 ± 8.4	55 ± 4.2
Turbidimetry/ *Beckman Coulter Synchron*	11	85 ± 4.3	118 ± 1.8	244 ± 7.0	183 ± 7.4	62 ± 4.7
Turbidimetry/ *Roche Cobas Intergra*	16	76 ± 2.4	114 ± 5.0	240 ± 6.1	200 ± 5.9	50 ± 2.3
Turbidimetry/ *Roche/Hitachi Modular*	10	72 ± 8.2	104 ± 3.6	222 ± 3.9	184 ± 4.8	51 ± 1.1
Nephelometry/ *Total*	39	81 ± 6.5	114 ± 8.4	247 ± 24	195 ± 18	52 ± 4.7
Turbidimetry/ *Total*	63	80 ± 7.0	114 ± 7.1	236 ± 13	190 ± 12	54 ± 6.0
All Method/ *Total*	108	80 ± 7.0	115 ± 7.8	241 ± 18	193 ± 15	53 ± 5.3
Immunoglobulin E (IU/ml)						
Chemiluminescence/Bayer Advia	11	51 ± 3.0	647 ± 50	206 ± 9.5	33 ± 2.7	258 ± 16
Chemiluminescence/*Diag. Prod. Co.*	26	57 ± 6.0	728 ± 95	221 ± 14	40 ± 3.2	277 ± 31
FEIA/ *Pharmacia Immunocap*	13	50 ± 3.8	702 ± 77	195 ± 17	35 ± 2.4	245 ± 23
Chemiluminescence/ *Total*	46	55 ± 5.7	702 ± 87	217 ± 13	38 ± 4.6	269 ± 24
FEIA/ *Total*	18	51 ± 3.6	708 ± 71	198 ± 16	35 ± 2.2	247 ± 21
All Method/ *Total*	78	53 ± 5.5	707 ± 90	206 ± 21	37 ± 4.5	259 ± 28
Immunoglobulin G (mg/dl)						
Nephelometry/*Beckman Coulter IMMAGE*	16	407 ± 16	847 ± 36	1282 ± 55	966 ± 34	323 ± 12
Nephelometry/*Behring Nephelometer*	15	425 ± 25	866 ± 34	1363 ± 74	1002 ± 28	328 ± 16
Turbidimetry/ *Beckman Coulter Synchron*	10	394 ± 16	805 ± 18	1287 ± 10	926 ± 14	305 ± 15
Turbidimetry/*Roche Cobas Integra*	16	398 ± 11	826 ± 26	1282 ± 36	954 ± 20	307 ± 13
Turbidimetry/*Roche/Hitachi Modular*	10	361 ± 17	777 ± 14	1185 ± 29	898 ± 23	294 ± 13
Nephelometry/ *Total*	38	416 ± 21	853 ± 36	1315 ± 73	987 ± 39	323 ± 15
Turbidimetry/ *Total*	60	391 ± 21	807 ± 32	1257 ± 53	925 ± 38	307 ± 14
All Method/ *Total*	105	401 ± 24	825 ± 41	1278 ± 63	947 ± 52	313 ± 17
Immunoglobulin M (mg/dl)						
Nephelometry/*Beckman Coulter IMMAGE*	16	37 ± 2.2	41 ± 2.1	125 ± 6.1	31 ± 1.6	69 ± 1.8
Nephelometry/*Behring Nephelometer*	16	38 ± 2.7	37 ± 1.6	140 ± 6.1	30 ± 2.5	67 ± 1.8
Turbidimetry/ *Beckman Coulter Synchron*	10	39 ± 1.4	43 ± 1.2	119 ± 2.1	31 ± 1.2	64 ± 2.1
Turbidimetry/*Roche Cobas Integra*	16	36 ± 3.3	37 ± 3.9	120 ± 3.8	27 ± 3.1	66 ± 2.7
Turbidimetry/*Roche/Hitachi Modular*	10	36 ± 4.1	38 ± 4.7	118 ± 4.2	29 ± 2.9	68 ± 2.7
Nephelometry/ *Total*	37	38 ± 2.5	39 ± 3.7	133 ± 10	31 ± 2.3	67 ± 4.0
Turbidimetry/ *Total*	60	37 ± 3.7	41 ± 5.2	120 ± 6.3	30 ± 4.4	67 ± 4.6
All Method/ *Total*	104	38 ± 3.2	40 ± 4.9	127 ± 12	30 ± 2.9	67 ± 3.7

Acceptable Response (May 13, 2009 PT Event)
Quantitative Tests Results (Acceptable Range) - For groups of 10 labs or more.

Analytes Method/ Manufacture	Sample NO.				
Alpha-1-Antitrypsin	76	77	78	79	80
Nephelometry/*Dade Behring Neph.*	76 - 113	32 - 41	14 - 19	5 - 7	271 - 419
Nephelometry/ *Total*	69 - 115	31 - 42	10 - 25	5 - 7	231 - 429
All Method/ *Total*	64 - 118	28 - 43	12 - 23	< 10	223 - 418
Complement C'3	76	77	78	79	80
Nephelometry/*Beckman Coulter Immage*	65 - 86	27 - 41	18 - 28	23 - 36	230 - 322
Nephelometry/*Dade Behring Neph.*	67 - 99	29 - 43	21 - 27	24 - 37	229 - 342
Turbidimetry/*Roche Cobas Integra*	64 - 82	26 - 43	20 - 25	25 - 33	269 - 301
Turbidimetry/*Roche HitachiModular*	65 - 77	32 - 39	21 - 28	28 - 33	266 - 304
Nephelometry/ *Total*	62 - 96	30 - 40	20 - 28	23 - 36	228 - 330
Turbidimetry/ *Total*	60 - 84	27 - 44	15 - 31	22 - 37	241 - 324
All Method/ *Total*	58 - 90	27 - 44	18 - 30	23 - 37	237 - 327
Complement C'4	76	77	78	79	80
Nephelometry/*Beckman Coulter Immage*	12 - 16	6 - 10	3 - 6	2 - 5	23 - 31
Nephelometry/*Dade Behring Neph.*	10 - 16	6 - 10	3 - 5	2 - 5	21 - 33
Turbidimetry/*Roche Cobas Integra*	9 - 15	4 - 10	2 - 6	1 - 5	25 - 31
Turbidimetry/*Roche HitachiModular*	10 - 12	5 - 7	2 - 5	2 - 4	24 - 27
Nephelometry/ *Total*	11 - 17	6 - 10	3 - 6	2 - 5	22 - 33
Turbidimetry/ *Total*	8 - 16	4 - 10	1- 6	1 - 5	17 - 37
All Method/ *Total*	8 - 17	5 - 10	1- 6	1 - 5	18 - 36
Immunoglobulin A	81	82	83	84	85
Nephelometry/*Beckman Coulter Immage*	63 - 88	90 - 128	191 - 260	150 - 212	40 - 60
Nephelometry/*Dade Behring Neph .*	74 - 97	95 - 144	218 - 316	183 - 234	42 - 68
Turbidimetry/ *Beckman Coulter Synch.*	72 - 98	113 - 124	223 - 266	160 - 205	47 - 76
Turbidimetry/ *Roche Cobas Integra*	68 - 83	99 - 130	221 - 258	181 - 218	43 - 58
Turbidimetry/ *Roche/Hitachi Modular*	47 - 97	93 - 115	210 - 234	169 - 199	47 - 55
Nephelometry/ *Total*	60 - 101	89 - 140	176 - 319	142 - 248	37 - 66
Turbidimetry/ *Total*	58 - 101	92 - 136	197 - 275	154 - 226	35 - 72
All Method/ *Total*	59 - 102	91 - 138	187 - 294	148 - 237	36 - 69
Immunoglobulin E	81	82	83	84	85
Chemiluminescence/*Bayer Advia*	42 - 61	497 - 797	177 -235	25 - 42	210 - 305
Chemiluminescence/*Diag.Prod. Immulite*	38 - 76	441 - 1014	180 - 262	30 - 50	183 - 372
FEIA/*Pharmacia Immunocap*	38 - 62	470 - 935	144 - 246	27 - 43	176 - 315
Chemiluminescence/ *Total*	37 - 72	439 - 965	177 - 256	24 - 52	196 - 342
FEIA/ *Total*	39 - 62	494 - 922	149 - 247	28 - 42	184 - 310
All Method/ *Total*	36 - 70	437 - 977	142 - 270	23 - 51	175 - 344
Immunoglobulin G	81	82	83	84	85
Nephelometry/*Beckman Coulter Immage*	305 - 509	635 - 1059	961 - 1603	724 - 1207	241 - 404
Nephelometry/*Dade Behring Neph .*	319 - 532	649 - 1083	1022 - 1704	751 - 1253	246 - 411
Turbidimetry/ *Beckman Coulter Synch.*	295 - 493	603 - 1007	965 - 1609	694 - 1158	228 - 381
Turbidimetry/*Roche Cobas Integra*	297 - 497	619 - 1033	961 - 1603	715 - 1193	230 - 385
Turbidimetry/ *Roche/Hitachi Modular*	270 - 451	582 - 972	889 - 1482	673 - 1124	220 - 368
Nephelometry/ *Total*	312 - 521	639 - 1067	986 - 1645	740 - 1234	242 - 405
Turbidimetry/ *Total*	293 - 489	604 - 1009	942 - 1571	693 - 1157	229 - 384
All Method/ *Total*	300 - 502	618 - 1032	958 - 1598	710 - 1184	235 - 392
Immunoglobulin M	81	82	83	84	85
Nephelometry/*Beckman Coulter Immage*	30 - 45	34 - 48	107 - 144	26 - 36	63 - 75
Nephelometry/*Dade Behring Neph .*	30 - 47	31 - 42	122 - 159	22 - 38	61 - 73
Turbidimetry/ *Beckman Coulter Synch.*	34 - 43	39 - 48	112 - 125	27 - 35	57 - 71
Turbidimetry/*Roche Cobas Integra*	26 - 47	25 - 49	108 - 132	17 - 37	58 - 75
Turbidimetry/ *Roche/Hitachi Modular*	24 - 49	23 - 53	105 - 131	20 - 38	59 - 76
Nephelometry/ *Total*	30 - 46	27 - 50	103 - 164	24 - 38	55 - 80
Turbidimetry/ *Total*	26 - 49	25 - 57	100 - 139	16 - 44	53 - 81
All Method/ *Total*	28 - 48	25 - 55	91 - 163	21 - 39	55 - 79

Acceptable Response (May 13, 2009 PT Event)
Qualitative / Quantitative Tests Results

Analytes	Sample NO.				
	1	**2**	**3**	**4**	**5**
Syphilis - Reagin	N	R	N	R	N
RPR Titer	< 1	1 - 4	< 1	2 - 8	< 1
Syphilis - Treponemal	N	R	N	R	N
	6	**7**	**8**	**9**	**10**
HBcAb	N	N	N	R	R
HBsAg	N	N	N	R	N
HBsAg Confirmation	N	N	N	R	N
	11	**12**	**13**	**14**	**15**
CMV	R	R	N	N	N
Rubella Ab	R	R	N	N	N
Rubella Ab Quantitative *EIA IU/ml*	11 - 79	8 - 37	< 8	< 8	< 8
Chemiluminescent IU/ml	29 - 73	8 - 22	< 10	< 10	< 10
Advia Centaur IU/ml	440 - 552	58 - 128	< 5	< 5	< 5
	16	**17**	**18**	**19**	**20**
ASO	N	N	R	N	R
ASO Quantitative *Latex IU/ml*	< 200	< 200	200 - 1600	< 200	200 - 1600
Nephelometry IU/ml	< 100	< 100	147 - 902	< 100	127 - 961
Turbidimetry IU/ml	< 100	< 100	281 - 1045	< 100	283 - 1052
	26	**27**	**28**	**29**	**30**
Infectious Mono.	N	N	R	R	N
Rheumatoid Factor	N	N	R	R	N
RF Quantitative					
Latex (Diliution Scheme A)	< 20	< 20	40 - 640	20 - 640	< 20
Latex (Diliution Scheme B)	< 2	< 2	4 - 64	2 - 64	< 2
Nephelometry IU/ml	< 20	< 20	96 - 342	40 - 212	< 20
Turbidimetry IU/ml	< 20	< 20	99 - 362	70 - 197	< 20
	31	**32**	**33**	**34**	**35**
HIV Ab Screening/Confirmation	R	N	N	N	R
	36	**37**	**38**	**39**	**40**
HTLV 1 Ab	N	R	N	N	R
	41	**42**	**43**	**44**	**45**
LYME Disease Ab	R	N	N	N	R
LYME Disease Ab WB IgG	R	N	N	N	R
LYME Disease Ab WB IgM	R *	N	N	N	N *
	46	**47**	**48**	**49**	**50**
ANA	R	R	N	N	N
IFA Titer	160 - 2560	40 - 1280	< 40	< 40	< 40
	56	**57**	**58**	**59**	**60**
Rubella IgM	N	N	N	R	N
	66	**67**	**68**	**69**	**70**
Hepatitis Be Ag	R	N	R	N	N
	71	**72**	**73**	**74**	**75**
Hepatitis C Ab	N	N	R	N	R
Hepatitis C Ab Confirmation	N	N	R	N	R

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.