New York State Department of Health
Wadsworth Center

Proficiency Testing Program

26-Apr-06

DIAGNOSTIC IMMUNOLOGY & HUMAN IMMUNODEFICIENCY VIRUS SUMMARY ANALYSIS

Proficiency Test Event
26-Apr-06

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 April 26, 2006 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 5.

Grading Criteria:

- When both qualitative and quantitative results were reported ten points were deducted for each incorrect result. When only qualitative OR quantitative results were reported twenty points were deducted for each incorrect result.
- 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, ratio, 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	Target value ± 2 dilutions or positive or negative
Antistreptolysin O	Target value ± 2 dilutions or positive or negative
Complement C’3, C’4	Target value ± 3 S.D.
Cytomegalovirus Antibody	Reactive / nonreactive
Hepatitis (HbsAg, anti-HBc, HBeAg, and HCAb)	Reactive / nonreactive
HIV 1 Ab, Ag	Reactive / nonreactive
HTLV 1 Ab (EIA Ab, WB)	Reactive / nonreactive
Lyme Disease Ab, WB IgG, IgM	Reactive / nonreactive
Immunoglobulin A, E, M	Target value ± 3 S.D.
Immunoglobulin G	Target value ± 25 %
Infectious Mononucleosis	Target value ± 2 dilutions or positive or negative
Rheumatoid Factor	Target value ± 2 dilutions or positive or negative
Rubella Ab, IgM	Target value ± 2 dilutions or positive or negative or Immune or nonimmune
Syphilis Reagin Antibody	Target value ± 1 dilution
Syphilis Treponemal Antibody	Reactive / nonreactive

Antinuclear Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		46				47				48				49				50			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**56**	**4**	**7%**	**52**	**93%**	**56**	**100%**	**0**	**0%**	**56**	**100%**	**0**	**0%**	**56**	**100%**	**0**	**0%**	**0**	**0%**	**56**	**100%**
Bio-Rad	15		0%	15	100%	15	100%		0%	15	100%		0%	15	100%		0%		0%	15	100%
Diamedix	11	1	9%	10	91%	11	100%		0%	11	100%		0%	11	100%		0%		0%	11	100%
Others	30	3	10%	27	90%	30	100%		0%	30	100%		0%	30	100%		0%		0%	30	100%
IFA	**76**	**1**	**1%**	**75**	**99%**	**75**	**99%**	**1**	**1%**	**76**	**100%**	**0**	**0%**	**76**	**100%**	**0**	**0%**	**0**	**0%**	**76**	**100%**
Bio-Rad	21		0%	21	100%	21	100%		0%	21	100%		0%	21	100%		0%		0%	21	100%
The Binding Site	13		0%	13	100%	12	92%	1	8%	13	100%		0%	13	100%		0%		0%	13	100%
Wampole/Zeus	23	1	4%	22	96%	23	100%		0%	23	100%		0%	23	100%		0%		0%	23	100%
Others	19		0%	19	100%	19	100%		0%	19	100%		0%	19	100%		0%		0%	19	100%
Other Methods	**10**		**0%**	**10**	**100%**	**10**	**100%**		**0%**	**10**	**100%**		**0%**	**10**	**100%**		**0%**	**1**	**10%**	**9**	**90%**
Analyte Total	**142**	**5**	**4%**	**137**	**96%**	**141**	**99%**	**1**	**1%**	**142**	**100%**	**0**	**0%**	**142**	**100%**	**0**	**0%**	**1**	**1%**	**141**	**99%**

Note: Of the 115 laboratories reporting staining patterns: 93% found test sample 46 to stain Homogenous, and 95% found test sample 50 to stain Speckled.

Antinuclear Antibody

The number of laboratories that reported titers is listed for positive test samples 46 and 50. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

		Sample 46						Sample 50							
Method	**No.**										**Titers**				
Manufacturer	**Labs**	**80**	**160**	**320**	**640**	**1280**	**2560**	**80**	**160**	**320**	**640**	**1280**	**2560**	**5120**	**10240**
IFA															
Bio-Rad	20	4	4	9	2			1	1	6	7	3			
Wampole/ Zeus	21	3	10	3	1	2	1		4	2	5	5	2	1	1
The Binding site	13	2	3	4	4					1	4	6	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.

Antistreptolysin O

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		16				17				18				19				20			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Hemagglutination	**10**	**10**	**100%**	**0**	**0%**	**0**	**0%**	**10**	**100%**	**10**	**100%**	**0**	**0%**	**0**	**0%**	**10**	**100%**	**10**	**100%**	**0**	**0%**
Wampole /Zues	10	10	100%		0%		0%	10	100%	10	100%		0%		0%	10	100%	10	100%		0%
Latex Agglutination	**86**	**86**	**100%**	**0**	**0%**	**1**	**1%**	**85**	**99%**	**86**	**100%**	**0**	**0%**	**0**	**0%**	**86**	**100%**	**86**	**100%**	**0**	**0%**
Behring	21	21	100%		0%		0%	21	100%	21	100%		0%		0%	21	100%	21	100%		0%
Fisher	26	26	100%		0%		0%	26	100%	26	100%		0%		0%	26	100%	26	100%		0%
Remel	14	14	100%		0%		0%	14	100%	14	100%		0%		0%	14	100%	14	100%		0%
Others	25	25	100%		0%	1	4%	24	96%	25	100%		0%		0%	25	100%	25	100%		0%
Nephelometry	**28**	**28**	**100%**	**0**	**0%**	**0**	**0%**	**28**	**100%**	**28**	**100%**	**0**	**0%**	**0**	**0%**	**28**	**100%**	**28**	**100%**	**0**	**0%**
Beckman	16	16	100%		0%		0%	16	100%	16	100%		0%		0%	16	100%	16	100%		0%
Behring	12	12	100%		0%		0%	12	100%	12	100%		0%		0%	12	100%	12	100%		0%
Turbidimetry	**17**	**17**	**100%**	**0**	**0%**	**0**	**0%**	**17**	**100%**	**16**	**94%**	**1**	**6%**	**0**	**0%**	**17**	**100%**	**17**	**100%**	**0**	**0%**
Roche Diagnostics	12	12	100%		0%		0%	12	100%	11	92%	1	8%		0%	12	100%	12	100%		0%
Others	5	5	100%		0%		0%	5	100%	5	100%		0%		0%	5	100%	5	100%		0%
Other Methods	**2**	**2**	**100%**		**0%**		**0%**	**2**	**100%**	**2**	**100%**		**0%**		**0%**	**2**	**100%**	**2**	**100%**		**0%**
Analyte Total	**143**	**143**	**100%**	**0**	**0%**	**1**	**1%**	**142**	**99%**	**142**	**99%**	**1**	**1%**	**0**	**0%**	**143**	**100%**	**143**	**100%**	**0**	**0%**

Antistreptolysin O
Latex Agglutination Procedures

The number of laboratories that reported titers is listed for positive test samples 17 and 19. Only testing systems with 10 or more laboratories reporting titers are listed in this table.

Method *Manufacturer*	No. Labs	Sample 17 Titers 100	200	400	800	1600	Sample 19 Titers 100	200	400	800	1600
Biokit/ Fisher	16		2	12	2				12	4	
Dade Behring [1]	18			12	2				6	8	
Remel	12		1	11				1	9	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

Results are summarized for positive test samples 17 and 19. The Mean values ± S.D. are given where 10 or more laboratories reported quantitative results. Outlier values are omitted.

Method	No.	IU/ml	
Manufacturer	**Labs**	**Sample 17**	**Sample 19**
Nephelometry			
Dade Behring Neph.	13	436 ± 34	553 ± 35
Beckman Coulter Immage	10	688 ± 69	751 ± 44
Turbidimetry			
Roche Diagnostics Cobas	10	698 ± 81	787 ± 36

Cytomegalovirus Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		11*				**12**				**13**				**14**				**15**			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**38**	**7**	**18%**	**27**	**71%**	**38**	**100%**	**1**	**3%**	**1**	**3%**	**37**	**97%**	**38**	**100%**	**0**	**0%**	**38**	**100%**	**0**	**0%**
Wampole /Zeus	17	2	12%	13	76%	17	100%		0%		0%	17	100%	17	100%		0%	17	100%		0%
Others	21	5	24%	14	67%	21	100%	1	5%	1	5%	20	95%	21	100%		0%	21	100%		0%
ELFA	**21**	**0**	**0%**	**21**	**100%**	**21**	**100%**	**0**	**0%**	**0**	**0%**	**21**	**100%**	**21**	**100%**	**0**	**0%**	**21**	**100%**	**0**	**0%**
bioMérieux Vidas	21		0%	21	100%	21	100%		0%		0%	21	100%	21	100%		0%	21	100%		0%
Chemiluminescence	**15**	**4**	**27%**	**9**	**60%**	**15**	**100%**	**0**	**0%**	**1**	**7%**	**14**	**93%**	**15**	**100%**	**0**	**0%**	**15**	**100%**	**0**	**0%**
Diagnostic Products	15	4	27%	9	60%	15	100%		0%	1	7%	14	93%	15	100%		0%	15	100%		0%
Hemagglutination	**12**	**0**	**0%**	**12**	**100%**	**12**	**100%**	**0**	**0%**	**0**	**0%**	**12**	**100%**	**12**	**100%**	**0**	**0%**	**12**	**100%**	**0**	**0%**
Olympus	12		0%	12	100%	12	100%		0%		0%	12	100%	12	100%		0%	12	100%		0%
Other Methods	**12**		**0%**	**12**	**100%**	**12**	**100%**		**0%**	**1**	**8%**	**11**	**92%**	**11**	**92%**	**1**	**8%**	**12**	**100%**		**0%**
Analyte Total	**98**	**11**	**11%**	**81**	**83%**	**98**	**100%**	**1**	**1%**	**3**	**3%**	**95**	**97%**	**97**	**99%**	**1**	**1%**	**98**	**100%**	**0**	**0%**

* Test sample #11 was not authenticated - A consensus agreement cannot be reached among participants, by regulation requirement, the sample cannot be graded (scored) and all participating laboratories get credit for this sample. 7 laboratories across multiple systems reported an equivocal or indeterminate result for sample #11.

Cytomegalovirus Antibody

Results are summarized for positive test samples 11 and 13. For the procedure indicated, the Mean values ± S.D. are given where 10 or more laboratories reported quantitative results.

Manufacturer	No. Labs	Units	Sample Number 11	Sample Number 13
EIA				
Wampole/ Zeus Scientific	12	Ratio	1.12 ± 0.19	2.58 ± 0.20
ELFA				
bioMerieux Vidas	14	AU/ml	6.38 ± 0.65	57 ± 6.6

Hepatitis B Core Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		6				7				8				9				10			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**68**	**0**	**0%**	**68**	**100%**	**68**	**100%**	**0**	**0%**	**0**	**0%**	**68**	**100%**	**1**	**1%**	**67**	**99%**	**0**	**0%**	**68**	**100%**
Bayer	18		0%	18	100%	18	100%		0%		0%	18	100%		0%	18	100%		0%	18	100%
Diagnostic Products	24		0%	24	100%	24	100%		0%		0%	24	100%	1	4%	23	96%		0%	24	100%
Ortho	26		0%	26	100%	26	100%		0%		0%	26	100%		0%	26	100%		0%	26	100%
EIA	**85**	**1**	**1%**	**84**	**99%**	**85**	**100%**	**0**	**0%**	**0**	**0%**	**85**	**100%**	**0**	**0%**	**85**	**100%**	**0**	**0%**	**85**	**100%**
Abbott	63	1	2%	62	98%	63	100%		0%		0%	63	100%		0%	63	100%		0%	63	100%
Ortho	12		0%	12	100%	12	100%		0%		0%	12	100%		0%	12	100%		0%	12	100%
Other	10		0%	10	100%	10	100%		0%		0%	10	100%		0%	10	100%		0%	10	100%
Other Methods	**2**		**0%**	**2**	**100%**	**2**	**100%**		**0%**		**0%**	**2**	**100%**		**0%**	**2**	**100%**		**0%**	**2**	**100%**
Analyte Total	**155**	**1**	**1%**	**154**	**99%**	**155**	**100%**	**0**	**0%**	**0**	**0%**	**155**	**100%**	**1**	**1%**	**154**	**99%**	**0**	**0%**	**155**	**100%**

Hepatitis B Surface Antigen

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		6				7				8				9				10			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**86**	**86**	**100%**	**0**	**0%**	**80**	**93%**	**4**	**5%**	**0**	**0%**	**86**	**100%**	**86**	**100%**	**0**	**0%**	**1**	**1%**	**85**	**99%**
Bayer	23	23	100%		0%	23	100%		0%		0%	23	100%	23	100%		0%		0%	23	100%
Diagnostic Products	28	28	100%		0%	28	100%		0%		0%	28	100%	28	100%		0%		0%	28	100%
Ortho [1]	35	35	100%		0%	29	83%	4	11%		0%	35	100%	35	100%		0%	1	3%	34	97%
EIA	**116**	**116**	**100%**	**0**	**0%**	**116**	**100%**	**0**	**0%**	**0**	**0%**	**116**	**100%**	**116**	**100%**	**0**	**0%**	**1**	**1%**	**115**	**99%**
Abbott	83	83	100%		0%	83	100%		0%		0%	83	100%	83	100%		0%	1	1%	82	99%
Bio-Rad	10	10	100%		0%	10	100%		0%		0%	10	100%	10	100%		0%		0%	10	100%
Roche	10	10	100%		0%	10	100%		0%		0%	10	100%	10	100%		0%		0%	10	100%
Other	13	13	100%		0%	13	100%		0%		0%	13	100%	13	100%		0%		0%	13	100%
Other Methods	**3**	**3**	**100%**		**0%**	**3**	**100%**		**0%**		**0%**	**3**	**100%**	**3**	**100%**		**0%**		**0%**	**3**	**100%**
Analyte Total	**205**	**205**	**100%**	**0**	**0%**	**199**	**97%**	**4**	**2%**	**0**	**0%**	**205**	**100%**	**205**	**100%**	**0**	**0%**	**2**	**1%**	**203**	**99%**

[1] An equivocal or borderline result on sample #7 was reported by 2 labs.

Hepatitis Be Antigen

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		66				67				68				69				70			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**31**	**31**	**100%**	**0**	**0%**	**0**	**0%**	**31**	**100%**	**31**	**100%**	**0**	**0%**	**1**	**3%**	**30**	**97%**	**31**	**100%**	**0**	**0%**
DiaSorin	30	30	100%		0%		0%	30	100%	30	100%		0%		0%	30	100%	30	100%		0%
Other	1	1	100%		0%		0%	1	100%	1	100%		0%	1	100%		0%	1	100%		0%
Other Methods	**4**	**4**	**100%**		**0%**		**0%**	**4**	**100%**	**4**	**100%**		**0%**		**0%**	**4**	**100%**	**4**	**100%**		**0%**
Analyte Total	**35**	**35**	**100%**	**0**	**0%**	**0**	**0%**	**35**	**100%**	**35**	**100%**	**0**	**0%**	**1**	**3%**	**34**	**97%**	**35**	**100%**	**0**	**0%**

Hepatitis C Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		71				72				73				74				75			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**62**	**62**	**100%**	**0**	**0%**	**62**	**100%**	**0**	**0%**	**0**	**0%**	**61**	**98%**	**62**	**100%**	**0**	**0%**	**0**	**0%**	**62**	**100%**
Bayer	27	27	100%		0%	27	100%		0%		0%	27	100%	27	100%		0%		0%	27	100%
Ortho [1]	35	35	100%		0%	35	100%		0%		0%	34	97%	35	100%		0%		0%	35	100%
EIA	**102**	**100**	**98%**	**2**	**2%**	**100**	**98%**	**2**	**2%**	**0**	**0%**	**102**	**100%**	**101**	**99%**	**1**	**1%**	**0**	**0%**	**102**	**100%**
Abbott	75	74	99%	1	1%	73	97%	2	3%		0%	75	100%	74	99%	1	1%		0%	75	100%
Ortho	27	26	96%	1	4%	27	100%		0%		0%	27	100%	27	100%		0%		0%	27	100%
Other Methods	**1**	**1**	**100%**		**0%**	**1**	**100%**		**0%**		**0%**	**1**	**100%**	**1**	**100%**		**0%**		**0%**	**1**	**100%**
Analyte Total	**165**	**163**	**99%**	**2**	**1%**	**163**	**99%**	**2**	**1%**	**0**	**0%**	**164**	**99%**	**164**	**99%**	**1**	**1%**	**0**	**0%**	**165**	**100%**

[1] An indeterminate result on sample #73 was reported by 1 labs.

HIV Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		31				32				33				34				35			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**129**	**129**	**100%**	**0**	**0%**	**0**	**0%**	**129**	**100%**	**129**	**100%**	**0**	**0%**	**0**	**0%**	**129**	**100%**	**129**	**100%**	**0**	**0%**
Abbott	68	68	100%		0%		0%	68	100%	68	100%		0%		0%	68	100%	68	100%		0%
bioMérieux	17	17	100%		0%		0%	17	100%	17	100%		0%		0%	17	100%	17	100%		0%
Bio-Rad	44	44	100%		0%		0%	44	100%	44	100%		0%		0%	44	100%	44	100%		0%
Rapid EIA	**95**	**95**	**100%**	**0**	**0%**	**0**	**0%**	**95**	**100%**	**95**	**100%**	**0**	**0%**	**0**	**0%**	**95**	**100%**	**95**	**100%**	**0**	**0%**
Orasure	95	95	100%		0%		0%	95	100%	95	100%		0%		0%	95	100%	95	100%		0%
Rapid Immunoassa	**39**	**39**	**100%**	**0**	**0%**	**0**	**0%**	**39**	**100%**	**39**	**100%**	**0**	**0%**	**0**	**0%**	**39**	**100%**	**39**	**100%**	**0**	**0%**
Medmira	26	26	100%		0%		0%	26	100%	26	100%		0%		0%	26	100%	26	100%		0%
Trinity	10	10	100%		0%		0%	10	100%	10	100%		0%		0%	10	100%	10	100%		0%
Other	3	3	100%		0%		0%	3	100%	3	100%		0%		0%	3	100%	3	100%		0%
Western Blot	**40**	**40**	**100%**	**0**	**0%**	**0**	**0%**	**40**	**100%**	**40**	**100%**	**0**	**0%**	**0**	**0%**	**40**	**100%**	**40**	**100%**	**0**	**0%**
Bio-Rad [1]	35	35	100%		0%		0%	35	100%	35	100%		0%		0%	35	100%	35	100%		0%
Other	5	5	100%		0%		0%	5	100%	5	100%		0%		0%	5	100%	5	100%		0%
Other Methods	**6**	**6**	**100%**		**0%**		**0%**	**6**	**100%**	**6**	**100%**		**0%**		**0%**	**6**	**100%**	**6**	**100%**		**0%**
Analyte Total	**309**	**309**	**100%**	**0**	**0%**	**0**	**0%**	**309**	**100%**	**309**	**100%**	**0**	**0%**	**0**	**0%**	**309**	**100%**	**309**	**100%**	**0**	**0%**

HIV p24 Antigen

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		61				62				63				64				65			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**4**	**4**	**100%**	**0**	**0%**	**4**	**100%**	**0**	**0%**	**4**	**100%**	**0**	**0%**	**0**	**0%**	**4**	**100%**	**4**	**100%**	**0**	**0%**
Beckman Coulter	4	4	100%		0%	4	100%		0%	4	100%		0%		0%	4	100%	4	100%		0%
Analyte Total	**4**	**4**	**100%**	**0**	**0%**	**4**	**100%**	**0**	**0%**	**4**	**100%**	**0**	**0%**	**0**	**0%**	**4**	**100%**	**4**	**100%**	**0**	**0%**

HTLV Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		36				37				38				39				40			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**46**	**46**	**100%**	**0**	**0%**	**0**	**0%**	**46**	**100%**	**46**	**100%**	**0**	**0%**	**46**	**100%**	**0**	**0%**	**0**	**0%**	**46**	**100%**
Abbott	29	29	100%		0%		0%	29	100%	29	100%		0%	29	100%		0%		0%	29	100%
bioMérieux	17	17	100%		0%		0%	17	100%	17	100%		0%	17	100%		0%		0%	17	100%
Analyte Total	**46**	**46**	**100%**	**0**	**0%**	**0**	**0%**	**46**	**100%**	**46**	**100%**	**0**	**0%**	**46**	**100%**	**0**	**0%**	**0**	**0%**	**46**	**100%**

Infectious Mononucleosis

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		26				27				28				29				30			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
CICA	**29**	**0**	**0%**	**29**	**100%**	**29**	**100%**	**0**	**0%**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**29**	**100%**	**29**	**100%**	**0**	**0%**
Cardinal Health SP	11		0%	11	100%	11	100%		0%	11	100%		0%		0%	11	100%	11	100%		0%
Others	18		0%	18	100%	18	100%		0%	18	100%		0%		0%	18	100%	18	100%		0%
Hemagglutination	**49**	**1**	**2%**	**48**	**98%**	**49**	**100%**	**0**	**0%**	**49**	**100%**	**0**	**0%**	**0**	**0%**	**49**	**100%**	**36**	**73%**	**13**	**27%**
Fisher	15		0%	15	100%	15	100%		0%	15	100%		0%		0%	15	100%	4	27%	11	73%
Wampole/Zeus	25	1	4%	24	96%	25	100%		0%	25	100%		0%		0%	25	100%	24	96%	1	4%
Others	9		0%	9	100%	9	100%		0%	9	100%		0%		0%	9	100%	8	89%	1	11%
Latex Agglutination	**152**	**1**	**1%**	**151**	**99%**	**151**	**99%**	**1**	**1%**	**152**	**100%**	**0**	**0%**	**1**	**1%**	**151**	**99%**	**151**	**99%**	**1**	**1%**
Fisher	53		0%	53	100%	53	100%		0%	53	100%		0%		0%	53	100%	53	100%		0%
Remel	22		0%	22	100%	22	100%		0%	22	100%		0%		0%	22	100%	22	100%		0%
Wampole/Zeus	55		0%	55	100%	55	100%		0%	55	100%		0%		0%	55	100%	55	100%		0%
Others	22	1	5%	21	95%	21	95%	1	5%	22	100%		0%	1	5%	21	95%	21	95%	1	5%
Solid Phase IA	**57**	**0**	**0%**	**57**	**100%**	**57**	**100%**	**0**	**0%**	**57**	**100%**	**0**	**0%**	**0**	**0%**	**57**	**100%**	**57**	**100%**	**0**	**0%**
Seradyn	21		0%	21	100%	21	100%		0%	21	100%		0%		0%	21	100%	21	100%		0%
Wampole/Zeus	27		0%	27	100%	27	100%		0%	27	100%		0%		0%	27	100%	27	100%		0%
Others	9		0%	9	100%	9	100%		0%	9	100%		0%		0%	9	100%	9	100%		0%
Other Methods	**3**		**0%**	**3**	**100%**	**3**	**100%**		**0%**	**3**	**100%**		**0%**		**0%**	**3**	**100%**	**3**	**100%**		**0%**
Analyte Total	**290**	**2**	**1%**	**288**	**99%**	**289**	**100%**	**1**	**0%**	**290**	**100%**	**0**	**0%**	**1**	**0%**	**289**	**100%**	**276**	**95%**	**14**	**5%**

Note: The expected result for sample #30 is negative. Laboratories who reported any other result than negative for this sample should critically examine their protocol and test kit/method.

Infectious Mononucleosis

Latex Agglutination Procedures

The number of laboratories that reported titers are summarized for positive test samples 26 and 29. The dilution schemes laboratories used are represented by the letter A and B. Only methods with 10 or more laboratories reporting titers are listed in this table.

Method	No. Labs		Sample 26 Titers 2 7	4 14	8 28	16 56	32	64	128	Sample 29 Titers 2 7	4 14	8 28	16 56	32	64
Latex Agglutination	19	A	2	1	2	6	1		2	2	1	3	5	2	1
		B	1	2	2						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.

Lyme Disease Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		41				42				43				44				45			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**66**	**66**	**100%**	**0**	**0%**	**66**	**100%**	**0**	**0%**	**65**	**98%**	**1**	**2%**	**0**	**0%**	**66**	**100%**	**1**	**2%**	**65**	**98%**
Immunetics	17	17	100%		0%	17	100%		0%	17	100%		0%		0%	17	100%		0%	17	100%
MarDx	12	12	100%		0%	12	100%		0%	12	100%		0%		0%	12	100%		0%	12	100%
Wampole /Zeus	30	30	100%		0%	30	100%		0%	29	97%	1	3%		0%	30	100%	1	3%	29	97%
Others	7	7	100%		0%	7	100%		0%	7	100%		0%		0%	7	100%		0%	7	100%
ELFA	**30**	**30**	**100%**	**0**	**0%**	**30**	**100%**	**0**	**0%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**0**	**0%**	**30**	**100%**
bioMérieux	30	30	100%		0%	30	100%		0%	30	100%		0%		0%	30	100%		0%	30	100%
Other Methods	**8**	**8**	**100%**		**0%**	**8**	**100%**		**0%**	**8**	**100%**		**0%**		**0%**	**8**	**100%**		**0%**	**8**	**100%**
Analyte Total	**104**	**104**	**100%**	**0**	**0%**	**104**	**100%**	**0**	**0%**	**103**	**99%**	**1**	**1%**	**0**	**0%**	**104**	**100%**	**1**	**1%**	**103**	**99%**

Lyme Western Blot IgG

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative; E = Equivocal/ Indeterminate																											
		41						42						43						44						45					
		N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%
Western Blot - IgG	**26**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**26**	**100%**	**1**	**4%**	**0**	**0%**	**25**	**96%**
MarDx	24	24	100%		0%		0%	24	100%		0%		0%	24	100%		0%		0%		0%		0%	24	100%	1	4%		0%	23	96%
Other	2	2	100%		0%		0%	2	100%		0%		0%	2	100%		0%		0%		0%		0%	2	100%		0%		0%	2	100%
Other Methods	**4**	**4**	**100%**		**0%**		**0%**	**4**	**100%**		**0%**		**0%**	**4**	**100%**		**0%**		**0%**		**0%**		**0%**	**4**	**100%**		**0%**		**0%**	**4**	**100%**
Analyte Total	**30**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**0**	**0%**	**30**	**100%**	**1**	**3%**	**0**	**0%**	**29**	**97%**

Lyme Western Blot IgM

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative; E = Equivocal/ Indeterminate																											
		41						42						43						44*						45					
		N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%	N	%	E	%	R	%
Western Blot - IgM	**26**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**11**	**42%**	**1**	**4%**	**14**	**54%**	**24**	**92%**	**2**	**8%**	**0**	**0%**
MarDx	24	24	100%		0%		0%	24	100%		0%		0%	24	100%		0%		0%	9	38%	1	4%	14	58%	22	92%	2	8%		0%
Other	2	2	100%		0%		0%	2	100%		0%		0%	2	100%		0%		0%	2	100%		0%		0%	2	100%		0%		0%
Other Methods	**3**	**3**	**100%**		**0%**		**0%**	**3**	**100%**		**0%**		**0%**	**3**	**100%**		**0%**		**0%**	**2**	**67%**		**0%**	**1**	**33%**	**3**	**100%**		**0%**		**0%**
Analyte Total	**29**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**29**	**100%**	**0**	**0%**	**0**	**0%**	**13**	**45%**	**1**	**3%**	**15**	**52%**	**27**	**93%**	**2**	**7%**	**0**	**0%**

* Test sample #44 was not authenticated - A consensus agreement cannot be reached among participants, by regulation requirement, 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				27				28				29				30			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**11**	**0**	**0%**	**11**	**100%**	**11**	**100%**	**0**	**0%**	**0**	**0%**	**11**	**100%**	**11**	**100%**	**0**	**0%**	**11**	**100%**	**0**	**0%**
Others	11		0%	11	100%	11	100%		0%		0%	11	100%	11	100%		0%	11	100%		0%
Latex Agglutination	**128**	**0**	**0%**	**128**	**100%**	**127**	**99%**	**1**	**1%**	**0**	**0%**	**128**	**100%**	**125**	**98%**	**3**	**2%**	**127**	**99%**	**1**	**1%**
Becton Dickinson	19		0%	19	100%	19	100%		0%		0%	19	100%	19	100%		0%	19	100%		0%
Fisher	47		0%	47	100%	47	100%		0%		0%	47	100%	47	100%		0%	47	100%		0%
Seradyn	12		0%	12	100%	12	100%		0%		0%	12	100%	12	100%		0%	12	100%		0%
Wampole/Zeus	13		0%	13	100%	12	92%	1	8%		0%	13	100%	11	85%	2	15%	12	92%	1	8%
Others	37		0%	37	100%	37	100%		0%		0%	37	100%	36	97%	1	3%	37	100%		0%
Nephelometry	**43**	**0**	**0%**	**43**	**100%**	**43**	**100%**	**0**	**0%**	**0**	**0%**	**43**	**100%**	**43**	**100%**	**0**	**0%**	**38**	**88%**	**0**	**0%**
Beckman Coulter [1]	22		0%	22	100%	22	100%		0%		0%	22	100%	22	100%		0%	17	77%		0%
Behring	21		0%	21	100%	21	100%		0%		0%	21	100%	21	100%		0%	21	100%		0%
Turbidimetry	**36**	**1**	**3%**	**35**	**97%**	**35**	**97%**	**1**	**3%**	**1**	**3%**	**35**	**97%**	**36**	**100%**	**0**	**0%**	**36**	**100%**	**0**	**0%**
Beckman Coulter	10	1	10%	9	90%	9	90%	1	10%	1	10%	9	90%	10	100%		0%	10	100%		0%
Roche	22		0%	22	100%	22	100%		0%		0%	22	100%	22	100%		0%	22	100%		0%
Others	4		0%	4	100%	4	100%		0%		0%	4	100%	4	100%		0%	4	100%		0%
Other Methods	**6**		**0%**	**6**	**100%**	**6**	**100%**		**0%**		**0%**	**6**	**100%**	**6**	**100%**		**0%**	**6**	**100%**		**0%**
Analyte Total	**224**	**1**	**0%**	**223**	**100%**	**222**	**99%**	**2**	**1%**	**1**	**0%**	**223**	**100%**	**221**	**99%**	**3**	**1%**	**218**	**97%**	**1**	**0%**

[1] Of 6 labs running the Beckman Coulter Array, 5 of them reported an "unstable reaction" on sample #30.

Rheumatoid Factor
Latex Agglutination Procedure

The number of laboratories that reported titers is listed for positive test samples 26 and 28. The dilution schemes laboratories used are represented by the letter A (IU/ml) and B (titer), testing systems with 10 or more laboratories reporting titers are listed in this table.

			Sample 26 Titers						Sample 28 Titers						
	No.	A	160	320	640	1280	2560	5120	80	160	320	640	1280	2560	5120
Manufacturer	**Labs**	**B**	**16**	**32**	**64**	**128**	**256**	**512**	**8**	**16**	**32**	**64**	**128**	**256**	**512**
Fisher	36	A		3	1	11	3			1	7	11	1		
		B		1	3	9			1		3	8		1	
Becton Dickson	15	A	2	4	6	3			2	5	6	1	1		
		B													

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

Results are summarized for positive test samples 26 and 28. The Mean values ± S.D. are given where 10 or more laboratories reported quantitative results. Outlier values are omitted.

Method *Manufacturer*	No. Labs	IU/ml Sample 26	IU/ml Sample 28
Nephelometry			
Beckman Coulter IMMAGE	16	1212 ± 66	652 ± 82
Turbidimetry			
Roche Diag. Cobas	13	694 ± 58	326 ± 16

Rubella IgG Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		11				12				13				14				15			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
Chemiluminescence	**59**	**0**	**0%**	**59**	**100%**	**59**	**100%**	**0**	**0%**	**1**	**2%**	**58**	**98%**	**59**	**100%**	**0**	**0%**	**59**	**100%**	**0**	**0%**
Bayer	27		0%	27	100%	27	100%		0%		0%	27	100%	27	100%		0%	27	100%		0%
Beckman	11		0%	11	100%	11	100%		0%		0%	11	100%	11	100%		0%	11	100%		0%
Diagnostic Products	21		0%	21	100%	21	100%		0%	1	5%	20	95%	21	100%		0%	21	100%		0%
EIA	**63**	**2**	**3%**	**61**	**97%**	**63**	**100%**	**0**	**0%**	**1**	**2%**	**62**	**98%**	**63**	**100%**	**0**	**0%**	**63**	**100%**	**0**	**0%**
Abbott	27	1	4%	26	96%	27	100%		0%		0%	27	100%	27	100%		0%	27	100%		0%
Diamedix	14	1	7%	13	93%	14	100%		0%	1	7%	13	93%	14	100%		0%	14	100%		0%
Wampole/Zeus	12		0%	12	100%	12	100%		0%		0%	12	100%	12	100%		0%	12	100%		0%
Others	10		0%	10	100%	10	100%		0%		0%	10	100%	10	100%		0%	10	100%		0%
ELFA	**34**	**0**	**0%**	**34**	**100%**	**33**	**97%**	**1**	**3%**	**0**	**0%**	**34**	**100%**	**33**	**97%**	**1**	**3%**	**34**	**100%**	**0**	**0%**
bioMérieux Vidas	34		0%	34	100%	33	97%	1	3%		0%	34	100%	33	97%	1	3%	34	100%		0%
Latex Agglutination	**38**	**1**	**3%**	**37**	**97%**	**38**	**100%**	**0**	**0%**	**0**	**0%**	**38**	**100%**	**38**	**100%**	**0**	**0%**	**38**	**100%**	**0**	**0%**
Fisher	15	1	7%	14	93%	15	100%		0%		0%	15	100%	15	100%		0%	15	100%		0%
Others	23		0%	23	100%	23	100%		0%		0%	23	100%	23	100%		0%	23	100%		0%
Other Methods	**8**		**0%**	**8**	**100%**	**8**	**100%**		**0%**		**0%**	**8**	**100%**	**8**	**100%**		**0%**	**8**	**100%**		**0%**
Analyte Total	**202**	**3**	**1%**	**199**	**99%**	**201**	**100%**	**1**	**0%**	**2**	**1%**	**200**	**99%**	**201**	**100%**	**1**	**0%**	**202**	**100%**	**0**	**0%**

Rubella IgG Antibody

Results are summarized for positive test samples 11 and 13. 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 13
Chemiluminescence				
Bayer	22	IU/ml	110 ± 13	194 ± 22
Diagnostic Products	18	IU/ml	15 ± 2.3	75 ± 9
EIA				
Abbott AxSYM	11	IU/ml	19 ± 2.5	70 ± 4.3

Rubella IgM Specific

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		56				57				58				59				60			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**14**	**14**	**100%**	**0**	**0%**	**0**	**0%**	**14**	**100%**	**14**	**100%**	**0**	**0%**	**14**	**100%**	**0**	**0%**	**12**	**86%**	**1**	**7%**
Other [1]	14	14	100%		0%		0%	14	100%	14	100%		0%	14	100%		0%	12	86%	1	7%
Other Methods	**7**	**7**	**100%**		**0%**		**0%**	**7**	**100%**	**7**	**100%**		**0%**	**7**	**100%**		**0%**	**7**	**100%**		**0%**
Analyte Total	**21**	**21**	**100%**	**0**	**0%**	**0**	**0%**	**21**	**100%**	**21**	**100%**	**0**	**0%**	**21**	**100%**	**0**	**0%**	**19**	**90%**	**1**	**5%**

[1] An equivocal or borderline result on sample #60 was reported by 1 lab.

Syphilis - Reagin Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number — R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		1				2				3*				4				5			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
RPR	**276**	**2**	**1%**	**274**	**99%**	**275**	**100%**	**1**	**0%**	**234**	**85%**	**42**	**15%**	**275**	**100%**	**1**	**0%**	**1**	**0%**	**275**	**100%**
ASI	36		0%	36	100%	36	100%		0%	32	89%	4	11%	36	100%		0%		0%	36	100%
Becton Dickinson	140		0%	140	100%	140	100%		0%	112	80%	28	20%	140	100%		0%		0%	140	100%
Fisher	48	2	4%	46	96%	47	98%	1	2%	41	85%	7	15%	47	98%	1	2%	1	2%	47	98%
True Medix	16		0%	16	100%	16	100%		0%	16	100%		0%	16	100%		0%		0%	16	100%
Wampole/Zeus	22		0%	22	100%	22	100%		0%	22	100%		0%	22	100%		0%		0%	22	100%
Others	14		0%	14	100%	14	100%		0%	11	79%	3	21%	14	100%		0%		0%	14	100%
Other Methods	**1**		**0%**	**1**	**100%**	**1**	**100%**		**0%**	**1**	**100%**		**0%**	**1**	**100%**		**0%**		**0%**	**1**	**100%**
Analyte Total	**277**	**2**	**1%**	**275**	**99%**	**276**	**100%**	**1**	**0%**	**235**	**85%**	**42**	**15%**	**276**	**100%**	**1**	**0%**	**1**	**0%**	**276**	**100%**

* Test sample #3 was not authenticated - A consensus agreement cannot be reached among participants, by regulation requirement, the sample cannot be graded (scored) and all participating laboratories get credit for this sample.

Syphilis - Reagin Antibody

RPR Procedures

The number of laboratories that reported titers is listed for positive test samples 1 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 1 Titers 2	4	8	16	32	64	Sample 5 Titers 2	4	8	16	32	64
Becton Dickinson	126		17	80	28		1	2	36	82	4	1	
Fisher	47		11	23	8	1			22	19	16		
Wampole/ Zeus	22	1	3	16	2			1	12	8			
ASI	24		7	14	3				14	10			
True Medix	16	1	6	6	3				7	7	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.

Syphilis - Treponemal Antibody

Method / Manufacturer	No. Labs	Participant Results/ Sample Number R = Reactive/ Positive; N = Non-Reactive/ Negative																			
		1				2				3*				4				5			
		N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%	N	%	R	%
EIA	**10**	**0**	**0%**	**10**	**100%**	**10**	**100%**	**0**	**0%**	**10**	**100%**	**0**	**0%**	**10**	**100%**	**0**	**0%**	**0**	**0%**	**10**	**100%**
Other	10		0%	10	100%	10	100%		0%	10	100%		0%	10	100%		0%		0%	10	100%
Gel. Part. Agglut.	**34**	**0**	**0%**	**34**	**100%**	**34**	**100%**	**0**	**0%**	**33**	**97%**	**1**	**3%**	**33**	**97%**	**1**	**3%**	**1**	**3%**	**33**	**97%**
Fujirebio	34		0%	34	100%	34	100%		0%	33	97%	1	3%	33	97%	1	3%	1	3%	33	97%
IFA	**26**	**0**	**0%**	**26**	**100%**	**26**	**100%**	**0**	**0%**	**25**	**96%**	**1**	**4%**	**26**	**100%**	**0**	**0%**	**0**	**0%**	**26**	**100%**
Wampole/Zeus	26		0%	26	100%	26	100%		0%	25	96%	1	4%	26	100%		0%		0%	26	100%
MHA	**12**	**0**	**0%**	**12**	**100%**	**12**	**100%**	**0**	**0%**	**2**	**17%**	**10**	**83%**	**12**	**100%**	**0**	**0%**	**0**	**0%**	**12**	**100%**
Olympus	12		0%	12	100%	12	100%		0%	2	17%	10	83%	12	100%		0%		0%	12	100%
Other Methods	**7**		**0%**	**7**	**100%**	**7**	**100%**		**0%**	**7**	**100%**		**0%**	**7**	**100%**		**0%**		**0%**	**7**	**100%**
Analyte Total	**89**	**0**	**0%**	**89**	**100%**	**89**	**100%**	**0**	**0%**	**77**	**87%**	**12**	**13%**	**88**	**99%**	**1**	**1%**	**1**	**1%**	**88**	**99%**

* Test sample #3 was not authenticated - A consensus agreement cannot be reached among participants, by regulation requirement, the sample cannot be graded (scored) and all participating laboratories get credit for this sample.

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/*Beckman Coulter IMMAGE*	12	12 ± 1.5	412 ± 20	415 ± 14	< 10	169 ± 7.1
Nephelometry/Behring Nephelometer	19	18 ± 1.1	490 ± 59	483 ± 54	< 17	167 ± 8.5
Nephelometry/ *Total*	33	16 ± 3.1	451 ± 49	444 ± 33	< 17	168 ± 8.7
Turbidimetry/ *Total*	7	< 36	438 ± 20	445 ± 33	< 36	153 ± 6.4
Complement C'3		76	77	78	79	80
Nephelometry/*Beckman Coulter IMMAGE*	20	45 ± 1.7	437 ± 24	434 ± 17	50 ± 2.1	194 ± 11
Nephelometry/*Behring Nephelometer*	18	46 ± 3.5	491 ± 27	495 ± 29	52 ± 3.8	203 ± 12
Turbidimetry/*Roche Cobas Integra*	12	44 ± 2.0	477 ± 16	472 ± 22	48 ± 1.7	195 ± 6.6
Nephelometry/ *Total*	54	45 ± 1.8	460 ± 35	461 ± 37	50 ± 2.4	195 ± 7.3
Turbidimetry/ *Total*	42	46 ± 3.5	461 ± 46	470 ± 33	50 ± 3.6	191 ± 12
Complement C'4		76	77	78	79	80
Nephelometry/*Beckman Coulter IMMAGE*	20	5.1 ± 0.2	118 ± 5.3	118 ± 5.3	4.9 ± 0.2	34 ± 2.0
Nephelometry/*Behring Nephelometer*	16	4.8 ± 0.2	100 ± 6.6	102 ± 8.6	4.3 ± 0.4	30 ± 1.7
Turbidimetry/*Roche Cobas Integra*	11	< 6	99 ± 2.6	100 ± 2.5	< 6	30 ± 1.0
Nephelometry/ *Total*	54	< 10	107 ± 11	108 ± 11	< 10	32 ± 2.6
Turbidimetry/ *Total*	40	< 16	100 ± 11	101 ± 11	< 16	29 ± 2.3

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 Array*	11	751 ± 31	281 ± 13	270 ± 7.6	104 ± 3.4	595 ± 9.5
Nephelometry/*Beckman Coulter IMMAGE*	21	708 ± 23	279 ± 6.7	257 ± 12	99 ± 3.5	613 ± 25
Nephelometry/*Behring Nephelometer*	22	729 ± 31	279 ± 10	274 ± 6.5	101 ± 5.2	633 ± 25
Turbidimetry/*Roche Cobas Integra*	13	842 ± 60	263 ± 5.2	240 ± 4.2	90 ± 3.4	559 ± 34
Nephelometry/ *Total*	67	723 ± 37	277 ± 10	267 ± 13	100 ± 4.5	614 ± 34
Turbidimetry/ *Total*	46	737 ± 92	271 ± 11	244 ± 11	93 ± 6.2	571 ± 49
Immunoglobulin E (IU/ml)						
Chemiluminescence/Bayer	10	849 ± 77	282 ± 17	292 ± 18	21 ± 1.3	434 ± 30
Chemiluminescence/*Diag. Prod. Co.*	29	811 ± 65	276 ± 13	290 ± 23	28 ± 1.9	405 ± 25
FEIA/*Pharmacia*	10	778 ± 114	265 ± 41	275 ± 34	30 ± 2.1	427 ± 26
Chemiluminescence/ *Total*	44	824 ± 75	275 ± 17	287 ± 23	26 ± 3.4	413 ± 31
FEIA/ *Total*	17	780 ± 89	268 ± 32	276 ± 28	30 ± 3.1	415 ± 37
Nephelometry/ *Total*	14	857 ± 67	270 ± 13	295 ± 28	25 ± 2.9	428 ± 33
Immunoglobulin G (mg/dl)						
Nephelometry/*Beckman Coulter Array*	10	1366 ± 62	1400 ± 53	1153 ± 46	619 ± 25	2342 ± 151
Nephelometry/*Beckman Coulter IMMAGE*	21	1399 ± 53	1449 ± 48	1198 ± 42	630 ± 32	2425 ± 87
Nephelometry/*Behring Nephelometer*	23	1514 ± 73	1550 ± 85	1258 ± 51	671 ± 26	3051 ± 166
Turbidimetry/*Roche Cobas Integra*	13	1354 ± 30	1433 ± 31	1130 ± 21	608 ± 11	2552 ± 66
Nephelometry/ *Total*	67	1445 ± 86	1488 ± 88	1214 ± 65	647 ± 35	2700 ± 348
Turbidimetry/ *Total*	45	1350 ± 74	1413 ± 66	1130 ± 54	592 ± 28	2468 ± 200
Immunoglobulin M (mg/dl)						
Nephelometry/*Beckman Coulter Array*	10	173 ± 8.2	92 ± 4.5	771 ± 39	47 ± 1.2	233 ± 13
Nephelometry/*Beckman Coulter IMMAGE*	21	153 ± 6.9	93 ± 3.6	687 ± 56	43 ± 1.7	214 ± 6.7
Nephelometry/*Behring Nephelometer*	22	234 ± 17	95 ± 3.9	840 ± 52	43 ± 2.8	315 ± 19
Turbidimetry/*Roche Cobas Integra*	14	144 ± 2.9	90 ± 3.4	901 ± 19	36 ± 2.0	176 ± 4.1
Nephelometry/ *Total*	65	198 ± 49	93 ± 3.3	770 ± 83	44 ± 3.0	260 ± 49
Turbidimetry/ *Total*	45	143 ± 5.7	92 ± 5.6	819 ± 89	38 ± 3.0	197 ± 27

Acceptable Response (April 26, 2006 PT Event)
Quantitative Tests Results (Acceptable Range)

Analytes **Method/ Manufacture**	**Sample NO.**				
Alpha-1-Antitrypsin	76	77	78	79	80
Nephelometry/*Beckman Coulter Immage*	7 - 17	352 - 472	373 - 457	< 10	147 - 191
Nephelometry/*Dade Behring Neph.*	14 - 22	313 - 666	322 - 645	< 17	141 - 193
Nephelometry/ *Total*	6 - 26	303 - 598	343 - 544	< 17	142 - 195
Turbidimetry/ *Total*	< 36	378 - 497	347 - 544	< 36	133 - 172
Complement C'3	76	77	78	79	80
Nephelometry/*Beckman Coulter Immage*	40 - 51	366 - 509	384 - 484	43 - 57	161 - 226
Nephelometry/*Dade Behring Neph.*	35 - 56	411 - 572	406- 583	40- 64	168 - 239
Turbidimetry/*Roche Cobas Integra*	37 - 50	428 - 525	403 - 540	42 - 54	175 - 215
Nephelometry/ *Total*	39 - 51	356 - 564	351 - 571	42 - 58	172 - 217
Turbidimetry/ *Total*	35 - 57	323 - 600	371 - 571	39 - 61	157 - 227
Complement C'4	76	77	78	79	80
Nephelometry/*Beckman Coulter Immage*	4 - 6	102 - 134	102 - 134	4 - 6	28 - 41
Nephelometry/*Dade Behring Neph.*	4 - 6	80 - 120	75 - 127	3 - 6	24 - 36
Turbidimetry/*Roche Cobas Integra*	< 6	91 - 107	92 - 107	< 6	27 - 31
Nephelometry/ *Total*	< 10	72 - 142	74 - 141	< 10	23 - 40
Turbidimetry/ *Total*	< 16	67 - 133	68 - 133	< 16	22 - 37
Immunoglobulin A	81	82	83	84	85
Nephelometry/*Beckman Coulter Array*	656 - 846	242 - 319	246 - 293	93 - 115	566 - 625
Nephelometry/*Beckman Coulter Immage*	640 - 776	259 - 300	219 - 294	88 - 110	537 - 688
Nephelometry/*Dade Behring Neph .*	635 - 823	248 - 309	255 - 294	85 - 117	557 - 709
Turbidimetry/*Roche Cobas Integra*	662 - 1021	247 - 279	227 - 252	79 - 100	456 - 662
Nephelometry/ *Total*	613 - 834	247 - 308	228 - 306	87 - 114	511 - 717
Turbidimetry/ *Total*	462 - 1013	237 - 305	210 - 277	74 - 112	422 - 720
Immunoglobulin E	81	82	83	84	85
Chemiluminescence/*Bayer Advia Centaur*	618 - 1081	232 - 333	237 - 345	17 - 26	344 - 524
Chemiluminescence/*Diag.Prod. Immulite*	616 - 1005	237 - 314	222 - 357	22 - 33	329 - 480
FEIA/*Pharmacia Immunocap*	437 - 1120	141 - 389	172 - 378	24 - 37	349 - 505
Nephelometry/*Dade Behring Neph.*	719 - 1050	220 - 315	215 - 365	20 - 30	357 - 545
Chemiluminescence/ *Total*	598 - 1049	222 - 328	218 - 355	15 - 36	321 - 506
FEIA/ *Total*	511 - 1049	172 - 365	191 - 360	20 - 39	305 - 525
Nephelometry/ *Total*	656 - 1057	230 - 310	211 - 380	15 - 33	328 - 528
Immunoglobulin G	81	82	83	84	85
Nephelometry/*Beckman Coulter Array*	1024 - 1708	1050 - 1750	864 - 1442	464 - 774	1756 - 2927
Nephelometry/*Beckman Coulter Immage*	1049 - 1749	1086 - 1811	898 - 1498	472 - 787	1819 - 3032
Nephelometry/*Dade Behring Neph .*	1135 - 1892	1162 - 1938	943 - 1573	503 - 839	2288 - 3814
Turbidimetry/*Roche Cobas Integra*	1015 - 1693	1074 - 1792	848 - 1413	456 - 761	1913 - 3190
Nephelometry/ *Total*	1083 - 1806	1116 - 1859	911 - 1516	485 - 809	2025 - 3376
Turbidimetry/ *Total*	1012 - 1688	1059 - 1766	847 - 1412	443 - 740	1851 - 3086
Immunoglobulin M	81	82	83	84	85
Nephelometry/*Beckman Coulter Array*	148 - 198	77 - 106	654 - 887	43 - 52	192 - 273
Nephelometry/*Beckman Coulter Immage*	132 - 174	82 - 104	518 - 856	38 - 50	193 - 234
Nephelometry/*Dade Behring Neph .*	181 - 286	83 - 107	683 - 998	34 - 52	259 - 371
Turbidimetry/*Roche Cobas Integra*	134 - 153	79 - 100	845 - 957	30 - 43	163 - 189
Nephelometry/ *Total*	51 - 345	83 - 103	520 - 1021	34 - 53	114 - 407
Turbidimetry/ *Total*	126 - 161	74 - 109	551 - 1087	29 - 48	115 - 280

Acceptable Response (April 26, 2006 PT Event)
Qualitative / Quantitative Tests Results

Analytes	Sample NO.				
	1	**2**	**3**	**4**	**5**
Syphilis - Reagin Ab	R	N	N*	N	R
RPR Titer	4 - 16				2 - 16
Syphilis - Treponemal	R	N	N*	N	R
	6	**7**	**8**	**9**	**10**
HBcAb	R	N	R	R	R
HBsAg	N	N	R	N	R
	11	**12**	**13**	**14**	**15**
CMV	R*	N	R	N	N
Rubella Ab	R	N	R	N	N
	16	**17**	**18**	**19**	**20**
ASO	N	R	N	R	N
Latex Agglutination as IU/ml		100 - 1600		100 - 1600	
	26	**27**	**28**	**29**	**30**
Infectious Mono.	R	N	N	R	N
Latex Agglutination Titer	4 - 64			2 - 64	
Rheumatoid Factor	R	N	R	N	N
Latex Agglutination Titer	16 - 512		8 - 256		
Latex Agglutination as IU/ml	160 - 5120		80 - 2560		
	31	**32**	**33**	**34**	**35**
HIV Ab Screening/Confirmation	N	R	N	R	N
	36	**37**	**38**	**39**	**40**
HTLV 1 Ab	N	R	N	N	R
	41	**42**	**43**	**44**	**45**
LYME Disease Ab	N	N	N	R	R
LYME Disease Ab WB IgG	N	N	N	R	R
LYME Disease Ab WB IgM	N	N	N	R*	N
	46	**47**	**48**	**49**	**50**
ANA	R	N	N	N	R
EIA Titer	40 - 640				160 - 2560
IFA Titer	40 - 1280				160 - 5120
	56	**57**	**58**	**59**	**60**
Rubella IgM	N	R	N	N	N
	61	**62**	**63**	**64**	**65**
HIV p24 Ag	N	N	N	R	N
	66	**67**	**68**	**69**	**70**
HBeAg	N	R	N	R	N
	71	**72**	**73**	**74**	**75**
Hepatitis C Ab	N	N	R	N	R

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

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