

**New York State Department of Health
Wadsworth Center**

Proficiency Testing Program

8-Sep-04

**DIAGNOSTIC IMMUNOLOGY &
HUMAN IMMUNODEFICIENCY VIRUS
SUMMARY ANALYSIS**

**Proficiency Test Event
8-Sep-04**

**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 8, 2004 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 6, 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 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 6 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 \pm S.D. when six or more laboratories reported data.

For quantitative tests, values reported variously as mg/dl, IU/ml, Enzyme activity, etc. are given as the Mean \pm S.D. when six 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	Mean value \pm 3 S.D.
Antinuclear Antibody	Mean value \pm 2 dilutions or positive or negative
Antistreptolysin O	Mean value \pm 3 S.D. or Mean value \pm 2 dilutions or positive or negative
Complement C'3, C'4	Mean value \pm 3 S.D.
Cytomegalovirus Antibody	Mean value \pm 3 S.D. or 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	Mean value \pm 3 S.D.
Immunoglobulin G	Mean value \pm 25 %
Infectious Mononucleosis	Mean value \pm 2 dilutions or positive or negative
Rheumatoid Factor	Mean value \pm 3 S.D. or Mean value \pm 2 dilutions or positive or negative
Rubella Ab, IgM	Mean value \pm 3 S.D. or Mean value \pm 2 dilutions or positive or negative or Immune or nonimmune
Syphilis Reagin Antibody	Mean value \pm 1 dilution
Syphilis Treponemal Antibody	Reactive / nonreactive

Antinuclear Antibody

Method <i>Manufacturer</i>	No. Labs	Participant Results/ Sample Number				
		46 N/R	47 N/R	48 N/R	49 N/R	50 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
EIA	50	50/0	0/50	50/0	0/50	0/50
<i>Bio-Rad</i>	13	13/0	0/13	13/0	0/13	0/13
<i>Diamedix</i>	11	11/0	0/11	11/0	0/11	0/11
<i>Wampole/ Zeus</i>	11	11/0	0/11	11/0	0/11	0/11
<i>Others</i>	15	15/0	0/15	15/0	0/15	0/15
IEA	5	5/0	0/5	5/0	0/5	0/5
IFA	95	95/0	1/94	95/0	1/94	0/95
<i>Bio-Rad</i>	32	32/0	0/32	32/0	0/32	0/32
<i>Immuno</i>	6	6/0	0/6	6/0	0/6	0/6
<i>The Binding site</i>	13	13/0	0/13	13/0	0/13	0/13
<i>Wampole/ Zeus</i>	28	28/0	1/27	28/0	0/28	0/28
<i>Others</i>	16	16/0	0/16	16/0	1/15	0/16

Note: Of the 127 laboratories reporting staining patterns: 98.4% found test sample 47 to stain Homogeneous, 93.7% found test sample 49 to stain Speckled, and 96.1% found test sample 50 to stain Homogeneous.

Antinuclear Antibody

The number of laboratories that reported titers is listed for positive test samples 47, 49, and 50. Only testing systems with 6 or more laboratories reporting titers are listed in this table.

Method Manufacturer	No. Labs	Sample 47 Titers							Sample 49 Titers						
		40	80	160	320	640	1280	2560	160	320	640	1280	2560	5120	10240
EIA															
<i>Bio-Rad</i> ^[1]	11	1	1	5	4				1	3	4		1		
<i>Diamedix</i>	7		1	4	1	1				1	4	1	1		
<i>Wampole/ Zeus</i> ^[2]	6	1	1	3		1				2	1	1			1
IFA															
<i>Bio-Rad</i> ^[3]	30		5	8	10	7			1	8	9	6	2		
<i>The Binding site</i> ^[4]	13	1	3	4	3	1	1		2	3	3	3			1
<i>Wampole/ Zeus</i> ^[5]	23		2	2	4	10	4	1		6	4	5	4		

Method Manufacturer	No. Labs	Sample 50 Titers				
		80	160	320	640	1280
EIA						
<i>Bio-Rad</i> ^[1]	11		3	5		1
<i>Diamedix</i>	7	1	1	2	3	
<i>Wampole/ Zeus</i> ^[2]	6		3	2	1	
IFA						
<i>Bio-Rad</i> ^[3]	30	3	4	8	12	1
<i>The Binding site</i> ^[4]	13	2	3	5	1	1
<i>Wampole/ Zeus</i> ^[5]	23	1	4	4	12	1

^[1] Two Laboratories did not report a titer for sample 49 and 50.

^[2] One laboratory did not report a titer for sample 49.

^[3] Four laboratories did not report a titer for sample 49 and two laboratories did not report a titer for sample 50.

^[4] One laboratory did not report a titer for sample 49 and 50.

^[5] Four laboratories did not report a titer for sample 49 and one laboratory did not report a titer for sample 50.

Antistreptolysin O

Participant Results/ Sample Number						
Method	No.	16	17	18	19	20
Manufacturer	Labs	N/R	N/R	N/R	N/R	N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
Hemagglutination	10	1/9	0/10	10/0	10/0	10/0
<i>Wampole/ Zeus</i>	10	1/9	0/10	10/0	10/0	10/0
Latex Agglutination	91	5/86	0/91	91/0	91/0	91/0
<i>Behring</i>	24	1/23	0/24	24/0	24/0	24/0
<i>Fisher</i>	29	1/28	0/29	29/0	29/0	29/0
<i>Remel</i>	13	0/13	0/13	13/0	13/0	13/0
<i>Wampole/ Zeus</i>	7	3/4	0/7	7/0	7/0	7/0
<i>Others</i>	25	0/25	0/25	25/0	25/0	25/0
Nephelometry	23	0/23	0/23	23/0	23/0	23/0
<i>Beckman</i>	12	0/12	0/12	12/0	12/0	12/0
<i>Behring</i>	11	0/11	0/11	11/0	11/0	11/0
Turbidimetry	25	1/24	0/25	25/0	25/0	25/0
<i>Beckman</i>	9	1/8	0/9	9/0	9/0	9/0
<i>Roche Diagnostics</i>	11	0/11	0/11	11/0	11/0	11/0
<i>Others</i>	5	0/5	0/5	5/0	5/0	5/0

Antistreptolysin O Hemagglutination Procedure

The number of laboratories reporting STZ units by the Wampole Streptozyme procedure for positive test samples 16 and 17.

STZ Units	Sample 16	Sample 17
200	4	1
400	1	3
600		1

Antistreptolysin O Latex Agglutination Procedures

The number of laboratories that reported titers is listed for positive test samples 16 and 17. Only testing systems with 6 or more laboratories reporting titers are listed in this table.

Method <i>Manufacturer</i>	No. Labs	A B	Sample 16 Titers				Sample 17 Titers				
			100 1	200 2	400 4	800	200 2	400 4	800	...	6400
<i>Behring</i>	18	A B		9	7	1	1 1	10	5		1
<i>Fisher</i>	23	A B	1 1	14 2	5		1 3	14	5		
<i>Remel</i>	9	A		8	1			6	3		

Antistreptolysin O

Results are summarized for positive test samples 16 and 17. The Mean values \pm S.D. are given where 6 or more laboratories reported quantitative results. Outlier values are omitted.

Method Manufacturer	No. Labs	IU/ml Sample 16	Sample 17
Nephelometry			
<i>Beckman</i>	12	175 \pm 11	435 \pm 29
<i>Behring</i>	11	268 \pm 28	637 \pm 59
Turbidimetry			
<i>Beckman</i>	6	179 \pm 7	475 \pm 35
<i>Roche Diagnostics</i>	10	266 \pm 9	557 \pm 18
Others	9	258 \pm 31	616 \pm 117
Total Mean \pm S.D.	48	230 \pm 47	536 \pm 95

Cytomegalovirus Antibody

Method <i>Manufacturer</i>	No. Labs	Participant Results/ Sample Number				
		11 N/R	12 N/R	13 N/R	14 N/R	15 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
Chemiluminescence	11	11/0	11/0	0/11	0/11	11/0
<i>Diagnostic Products</i>	11	11/0	11/0	0/11	0/11	11/0
EIA	38	38/0	38/0	0/38	0/38	38/0
<i>Diamedix</i>	8	8/0	8/0	0/8	0/8	8/0
<i>Wampole/ Zeus Scientific</i>	22	22/0	22/0	0/22	0/22	22/0
<i>Others</i>	8	8/0	8/0	0/8	0/8	8/0
ELFA	21	21/0	21/0	0/21	0/21	21/0
<i>bioMérieux Vitek</i>	21	21/0	21/0	0/21	0/21	21/0
Hemagglutination	12	12/0	12/0	0/12	0/12	12/0
<i>Olympus</i>	12	12/0	12/0	0/12	0/12	12/0
Latex Agglutination	17	17/0	17/0	0/17	0/17	17/0
<i>Becton Dickinson</i>	17	17/0	17/0	0/17	0/17	17/0
Solid Phase Immunoassay	5	5/0	5/0	0/5	0/5	4/1

Cytomegalovirus Antibody

For the procedure indicated, the Mean values \pm S.D. are given where 6 or more laboratories reported quantitative results.

Method	No.		Participant Results/ Sample Number	
Manufacturer	Labs	Units	13	14
EIA				
<i>Wampole/ Zeus Scientific</i>	17	ISR	2.7 ± 0.3	4.8 ± 0.9
ELFA				
<i>bioMerieux Vitek</i>	13	AU/ml	52.5 ± 5.6	149.1 ± 20.8

Hepatitis B Core Antibody

Participant Results/ Sample Number						
Method	No.	6	7 *	8	9	10
<i>Manufacturer</i>	<i>Labs</i>	N/R	N/R	N/R	N/R	N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
Chemiluminescence	29	0/29	29/0	29/0	0/29	0/29
<i>Diagnostic Prod.</i>	21	0/21	21/0	21/0	0/21	0/21
<i>Others</i>	8	0/8	8/0	8/0	0/8	0/8
EIA	123	0/123	38/85	122/1	1/122	1/122
<i>Abbott</i>	89	0/89	4/85	88/1	1/88	1/88
<i>DiaSorin</i>	18	0/18	18/0	18/0	0/18	0/18
<i>Ortho</i>	14	0/14	14/0	14/0	0/14	0/14
<i>Others</i>	2	0/2	2/0	2/0	0/2	0/2

* The expected result for sample # 7 is negative. Laboratories who reported this sample as positive should critically examine their protocol and test kit/method.

Hepatitis B Surface Antigen

Participant Results/ Sample Number						
Method	No.	6	7	8	9 *	10
<i>Manufacturer</i>	<i>Labs</i>	N/R	N/R	N/R	N/R	N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
Chemiluminescence	51	0/51	51/0	51/0	41/7	0/51
<i>Diagnostic Prod.</i>	27	0/27	27/0	27/0	27/0	0/27
<i>Ortho</i> ^[1]	24	0/24	24/0	24/0	14/7	0/24
EIA	152	0/152	151/1	152/0	152/0	0/152
<i>Abbott</i>	111	0/111	111/0	111/0	111/0	0/111
<i>Genetic System</i>	12	0/12	12/0	12/0	12/0	0/12
<i>DiaSorin</i>	11	0/11	11/0	11/0	11/0	0/11
<i>Ortho</i>	10	0/10	10/0	10/0	10/0	0/10
<i>Roche</i>	8	0/8	7/1	8/0	8/0	0/8

* The expected result for sample # 9 is negative. Laboratories who reported this sample as equivocal or positive should critically examine their protocol and test kit/method.

^[1] Three laboratories reported sample 9 as equivocal.

Hepatitis Be Antigen

Participant Results/ Sample Number						
Method	No.	66	67	68	69	70
Manufacturer	Labs	N/R	N/R	N/R	N/R	N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
EIA	37	0/37	0/37	37/0	37/0	0/37
<i>DiaSorin</i>	36	0/36	0/36	36/0	36/0	0/36
<i>Others</i>	1	0/1	0/1	1/0	1/0	0/1

Hepatitis C Antibody

Participant Results/ Sample Number						
Method	No.	71	72	73	74 *	75
Manufacturer	Labs	N/R	N/R	N/R	N/R	N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
Chemiluminescence	24	24/0	0/24	0/24	24/0	24/0
<i>Ortho</i>	24	24/0	0/24	0/24	24/0	24/0
EIA	150	150/0	1/149	1/149	103/47	150/0
<i>Abbott</i>	109	109/0	1/108	1/108	62/47	109/0
<i>Ortho</i>	40	40/0	0/40	0/40	40/0	40/0
<i>Others</i>	1	1/0	0/1	0/1	1/0	1/0

* Specimen 74 for Hepatitis C Ab produced discrepant results. Laboratories should be aware of the capabilities of their test kit. Kits by different manufacturers use different recombinant proteins and therefore detect antibodies to different portions of the virus. In addition, the fusion proteins vary, which can affect the detection phase. On this basis the sera can be expected to perform differently in the different test systems, since the antigens to which they are exposed vary in composition.

HIV Antibody

Participant Results/ Sample Number						
Method Manufacturer	No. Labs	31 N/R	32 N/R	33 N/R	34 N/R	35 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
EIA	134	134/0	0/134	134/0	0/134	134/0
<i>Abbott HIV-1/ HIV-2</i>	70	70/0	0/70	70/0	0/70	70/0
<i>bioMérieux HIV1</i>	23	23/0	0/23	23/0	0/23	23/0
<i>BioRad/ Genetic System HIV-1/ HIV-2</i>	25	25/0	0/25	25/0	0/25	25/0
<i>BioRad/ Genetic System rLAV EIA</i>	9	9/0	0/9	9/0	0/9	9/0
<i>Others</i>	7	7/0	0/7	7/0	0/7	7/0
Rapid EIA	71	71/0	0/71	71/0	0/71	71/0
<i>Orasure Oraquick Rapid HIV 1</i>	71	71/0	0/71	71/0	0/71	71/0
Rapid Immunoassay	34	34/0	0/34	34/0	0/34	34/0
<i>Medmira Reveal Rapid HIV 1</i>	34	34/0	0/34	34/0	0/34	34/0
IFA	2	2/0	0/2	2/0	0/2	2/0
Western Blot	43	43/0	0/43	43/0	0/43	42/1
<i>Bio-Rad/ Genetic System</i>	36	36/0	0/36	36/0	0/36	36/0
<i>Cambridge Biotech/ Calypte</i>	7	7/0	0/7	7/0	0/7	6/1

HIV p24 Antigen

Participant Results/ Sample Number						
Method Manufacturer	No. Labs	61 N/R	62 N/R	63 N/R	64 N/R	65 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
EIA	5	5/0	5/0	5/0	0/5	5/0
<i>Beckman Coulter</i>	5	5/0	5/0	5/0	0/5	5/0

HTLV Antibody

Method Manufacturer	No. Labs	Participant Results/ Sample Number				
		36 N/R	37 N/R	38 N/R	39 N/R	40 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
EIA	50	50/0	0/50	50/0	0/50	50/0
<i>Abbott HTLV-1/ HTLV-2</i>	30	30/0	0/30	30/0	0/30	30/0
<i>bioMérieux HTLV-I & II</i>	20	20/0	0/20	20/0	0/20	20/0

Infectious Mononucleosis

Method <i>Manufacturer</i>	No. Labs	Participant Results/ Sample Number				
		26 N/R	27 N/R	28 N/R	29 N/R	30 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
CICA	20	20/0	20/0	20/0	20/0	0/20
<i>BioStar</i>	6	6/0	6/0	6/0	6/0	0/6
<i>Polymedco</i>	11	11/0	11/0	11/0	11/0	0/11
<i>Others</i>	3	3/0	3/0	3/0	3/0	0/3
Hemagglutination	56	56/0	56/0	55/1	55/1	1/55
<i>Becton-Dickinson</i>	6	6/0	6/0	6/0	6/0	0/6
<i>Fisher</i>	11	11/0	11/0	11/0	11/0	0/11
<i>Wampole</i>	36	36/0	36/0	35/1	36/0	1/35
<i>Others</i>	3	3/0	3/0	3/0	2/1	0/3
Latex Agglutination	164	164/0	164/0	164/0	164/0	0/164
<i>Fisher</i>	54	54/0	54/0	54/0	54/0	0/54
<i>Meridian Bioscience</i>	6	6/0	6/0	6/0	6/0	0/6
<i>Murex</i>	12	12/0	12/0	12/0	12/0	0/12
<i>Remel</i>	11	11/0	11/0	11/0	11/0	0/11
<i>Wampole/ Zeus</i>	66	66/0	66/0	66/0	66/0	0/66
<i>Others</i>	15	15/0	15/0	15/0	15/0	0/15
Solid Phase Immunoassay	63	62/1	63/0	63/0	63/0	0/63
<i>Seradyn</i>	29	28/1	29/0	29/0	29/0	0/29
<i>Wampole/ Zeus</i>	24	24/0	24/0	24/0	24/0	0/24
<i>Others</i>	10	10/0	10/0	10/0	10/0	0/10

LYME Disease

Participant Results/ Sample Number						
Method Manufacturer	No. Labs	41 N/R	42 N/R	43 N/R	44 N/R	45 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
CICA	6	0/6	6/0	0/6	6/0	0/6
<i>Wampole/ Zeus</i>	6	0/6	6/0	0/6	6/0	0/6
EIA	74	0/74	74/0	1/73	74/0	1/73
<i>Diamedix</i>	16	0/16	16/0	0/16	16/0	0/16
<i>MarDx</i>	13	0/13	13/0	0/13	13/0	0/13
<i>Wampole/ Zeus</i>	32	0/32	32/0	1/31	32/0	1/31
<i>Other</i>	13	0/13	13/0	0/13	13/0	0/13
ELFA	34	1/33	33/1	1/33	32/2	0/34
<i>bioMerieux</i>	34	1/33	33/1	1/33	32/2	0/34
R = Reactive/ Positive; E = Equivocal; N = Non-Reactive/ Negative						
	No. Labs	41 N/E/R	42 N/R	43 N/E/R	44 N/R	45 N/E/R
Western Blot - IgG	32	2/0/30	32/0/0	0/0/32	32/0/0	0/0/32
<i>MarDx</i>	28	2/0/26	28/0/0	0/0/28	28/0/0	0/0/28
<i>Others</i>	4	0/0/4	4/0/0	0/0/4	4/0/0	0/0/4
Western Blot - IgM	31	25/3/3	31/0/0	6/2/23	31/0/0	7/2/22
<i>MarDx</i>	28	24/1/3	28/0/0	6/2/20	28/0/0	7/2/19
<i>Other</i>	3	1/2/0	3/0/0	0/0/3	3/0/0	0/0/3

Rheumatoid Factor

Method <i>Manufacturer</i>	No. Labs	Participant Results/ Sample Number				
		26 N/R	27 N/R	28 N/R	29 N/R	30 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
EIA	13	13/0	13/0	0/13	13/0	0/13
<i>Diamedix</i>	7	7/0	7/0	0/7	7/0	0/7
<i>Others</i>	6	6/0	6/0	0/6	6/0	0/6
Latex Agglutination	140	140/0	140/0	5/135	140/0	0/140
<i>Becton Dickson</i>	21	21/0	21/0	2/19	21/0	0/21
<i>Behring</i>	16	16/0	16/0	0/16	16/0	0/16
<i>Fisher</i>	47	47/0	47/0	0/47	47/0	0/47
<i>Remel</i>	6	6/0	6/0	0/6	6/0	0/6
<i>Seradyn</i>	14	14/0	14/0	0/14	14/0	0/14
<i>True Medix</i>	6	6/0	6/0	0/6	6/0	0/6
<i>Wampole/ Zeus</i>	20	20/0	20/0	3/17	20/0	0/20
<i>Others</i>	10	10/0	10/0	0/10	10/0	0/10
Nephelometry	49	49/0	49/0	0/49	48/1	0/49
<i>Beckman</i>	26	26/0	26/0	0/26	26/0	0/26
<i>Behring</i>	23	23/0	23/0	0/23	22/1	0/23
Turbidimetry	31	31/0	31/0	0/31	31/0	0/31
<i>Beckman</i>	7	7/0	7/0	0/7	7/0	0/7
<i>Roche</i>	17	17/0	17/0	0/17	17/0	0/17
<i>Others</i>	7	6/0	6/0	0/6	6/0	0/6

Rheumatoid Factor Latex Agglutination Procedure

The number of laboratories that reported titers is listed for positive test samples 28 and 30. The dilution schemes laboratories used are represented by the letter A and B. Only testing systems with 6 or more laboratories reporting titers are listed in this table.

<i>Manufacturer</i>	No. Labs	Sample 28 Titers										Sample 30 Titers									
		A	20	40	80	160	320	640	...	2560	20	40	80	160	320	640	1280	2560	512	2048	
<i>Becton Dickson</i> ^[1]	16	A	2	4	6	1	1	1					2	1	3	9	1				
<i>Behring</i> ^[1]	7	A			1	1	2								2	1		1			
		B		1		1							1			1	1				
<i>Biokit</i> ^[2]	14	B			3	10				1					1	6	6				
<i>Wampole/ Zeus</i>	11	A	6	3		2							1	2	3	3		2			
Following titers are expressed as IU/ml																					
<i>Biokit</i> ^[2]	19	A		2	5	11	1								2	4	11	1			

^[1] One laboratory did not report a titer for test sample 28.

^[2] One laboratory did not report a titer for test sample 30.

Rheumatoid Factor

Results are summarized for positive test sample 28 and 30. The Mean values \pm S.D. are given where 6 or more laboratories reported quantitative results. Outlier values are omitted.

Method	No.	IU/ml	
<i>Manufacturer</i>		Sample 28	Sample 30
EIA	11	126 \pm 13	138 \pm 21
Nephelometry			
<i>Beckman</i>	25	162 \pm 10	1223 \pm 70
<i>Behring</i>	23	192 \pm 17	1525 \pm 179
<i>Total</i>	48	176 \pm 20	1374 \pm 203
Turbidimetry			
<i>Beckman</i>	7	272 \pm 30	2355 \pm 92
<i>Roche Diagnostics</i>	17	98 \pm 4	730 \pm 64
<i>Total</i>	24	102 \pm 10	744 \pm 67

Rubella Antibody

Method Manufacturer	No. Labs	Participant Results/ Sample Number				
		11 N/R	12 N/R	13 N/R	14 N/R	15 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
Chemiluminescence	52	47/1	47/1	1/47	52/0	52/0
<i>Bayer</i> ^[1]	22	17/1	17/1	1/17	22/0	22/0
<i>Beckman</i>	13	13/0	13/0	0/13	13/0	13/0
<i>Diagnostic Products</i>	17	17/0	17/0	0/17	17/0	17/0
CICA	5	5/0	5/0	0/5	4/1	5/0
EIA	68	68/0	68/0	0/68	68/0	68/0
<i>Abbott AXSYM/ IMX</i>	30	30/0	30/0	0/30	30/0	30/0
<i>Diamedix</i>	13	13/0	13/0	0/13	13/0	13/0
<i>Wampole/ Zeus</i>	19	19/0	19/0	0/19	19/0	19/0
<i>Others</i>	6	6/0	6/0	0/6	6/0	6/0
ELFA	35	35/0	35/0	0/35	35/0	35/0
<i>bioMerieux</i>	35	35/0	35/0	0/35	35/0	35/0
Latex Agglutination	47	47/0	47/0	0/47	41/6	46/1
<i>Becton Dickson</i>	16	16/0	16/0	0/16	16/0	15/1
<i>Fisher</i>	12	12/0	12/0	0/12	11/1	12/0
<i>Murex</i>	7	7/0	7/0	0/7	7/0	7/0
<i>Wampole/ Zeus</i>	8	8/0	8/0	0/8	3/5	8/0
<i>Others</i>	4	4/0	4/0	0/4	4/0	4/0

^[1] Four laboratories reported equivocal for sample 11, 12, and 13.

Rubella Antibody

Results are summarized for positive test sample 13. The Mean values \pm S.D. are given where 6 or more laboratories reported quantitative results. Outlier values are omitted.

Method <i>Manufacturer</i>	No. Labs	IU/ml Sample 13
Chemiluminescence		
<i>Bayer</i>	18	155 \pm 14
<i>Beckman</i>	8	40 \pm 2
<i>Diagnostic Products</i>	15	43 \pm 5
<i>Total</i>	41	90 \pm 55
EIA		
<i>Abbott MEIA</i>	12	46 \pm 4
<i>Others</i>	11	45 \pm 4
<i>Total</i>	23	46 \pm 4

Rubella IgM

Method <i>Manufacturer</i>	No. Labs	Participant Results/ Sample Number				
		56 N/R	57 N/R	58 N/R	59 N/R	60 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
Chemiluminescence	6	6/0	6/0	0/6	6/0	0/6
EIA	18	18/0	18/0	0/18	18/0	0/18
<i>Abbott AXSYM/ IMX</i>	7	7/0	7/0	0/7	7/0	0/7
<i>Others</i>	11	11/0	11/0	0/11	11/0	0/11

Syphilis - Reagin Antibody

Participant Results/ Sample Number						
Method	No.	1	2	3	4	5
Manufacturer	Labs	N/R	N/R	N/R	N/R	N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
RPR	284	284/0	284/0	283/1	259/25	0/284
<i>ASI</i>	38	38/0	38/0	38/0	36/2	0/38
<i>Becton Dickinson</i>	149	149/0	149/0	148/1	134/15	0/149
<i>Fisher</i>	44	44/0	44/0	44/0	43/1	0/44
<i>Stanbio Syphilis</i>	6	6/0	6/0	6/0	4/2	0/6
<i>True Medix</i>	11	11/0	11/0	11/0	11/0	0/11
<i>Wampole/ Zeus</i>	24	24/0	24/0	24/0	19/5	0/24
<i>Others</i>	36	36/0	36/0	36/0	36/0	0/36

Syphilis - Reagin Antibody RPR Procedures

The number of laboratories that reported titers is listed for positive test sample 5 for the RPR procedure. Only testing systems with 6 or more laboratories reporting titers are listed in this table.

Method Manufacturer	No. Labs	Sample 5 Titers				
		1	2	4	8	16
<i>ASI</i>	28		21	7		
<i>Becton Dickinson</i>	133	1	101	26	5	
<i>Biokit</i>	43	3	30	10		
<i>True Medix</i> ^[1]	11		8	2		
<i>Wampole/ Zeus</i>	22	6	9	6	1	

^[1] One laboratory reported a titer of 40 for test sample 5.

Syphilis - Treponemal Antibody

Method <i>Manufacturer</i>	No. Labs	Participant Results/ Sample Number				
		1 N/R	2 N/R	3 N/R	4 N/R	5 N/R
R = Reactive/ Positive; N = Non-Reactive/ Negative						
EIA	5	5/0	5/0	5/0	5/0	0/5
<i>Trinity Biotech</i>	5	5/0	5/0	5/0	5/0	0/5
FTA	5	5/0	5/0	5/0	5/0	0/5
Gelatin Particle Agglutination	35	35/0	35/0	35/0	35/0	0/35
<i>Fujirebio Serodia</i>	35	35/0	35/0	35/0	35/0	0/35
IFA	34	34/0	34/0	34/0	34/0	0/34
<i>Wampole/ Zeus</i>	34	34/0	34/0	34/0	34/0	0/34
MHA	11	11/0	11/0	11/0	11/0	0/11
<i>Olympus</i>	11	11/0	11/0	11/0	11/0	0/11

AAT, C'3, and C'4

The Mean mg/dl \pm S.D. is given where 6 or more laboratories reported values. Outlier values are omitted.

Analytes	No. Labs	Sample NO.				
		76	77	78	79	80
Alpha-1-Antitrypsin						
Nephelometry/ <i>Beckman</i>	14	< 10	63 \pm 4	171 \pm 10	435 \pm 30	443 \pm 25
Nephelometry/ <i>Behring</i>	18	< 10	62 \pm 3	175 \pm 9	513 \pm 41	512 \pm 49
Nephelometry/ <i>Total</i>	32	< 10	62 \pm 3	173 \pm 9	479 \pm 53	482 \pm 53
Turbidimetry/ <i>Total</i>	9	< 30	61 \pm 9	157 \pm 17	419 \pm 47	417 \pm 46
Complement C'3						
Nephelometry/ <i>Beckman</i>	35	44 \pm 2	63 \pm 3	180 \pm 8	420 \pm 32	421 \pm 31
Nephelometry/ <i>Behring</i>	29	46 \pm 3	66 \pm 3	194 \pm 7	475 \pm 35	470 \pm 26
Nephelometry/ <i>Olympus</i>	6	44 \pm 1	61 \pm 1	170 \pm 5	363 \pm 7	366 \pm 8
Turbidimetry/ <i>Roche</i>	17	46 \pm 4	72 \pm 6	202 \pm 10	503 \pm 33	494 \pm 25
Nephelometry/ <i>Total</i>	65	45 \pm 3	64 \pm 3	186 \pm 11	445 \pm 43	443 \pm 38
Turbidimetry/ <i>Total</i>	30	45 \pm 3	68 \pm 7	191 \pm 16	459 \pm 63	454 \pm 56
Complement C'4						
Nephelometry/ <i>Beckman</i>	35	< 10	10 \pm 1	43 \pm 4	112 \pm 12	111 \pm 12
Nephelometry/ <i>Behring</i>	25	< 10	8 \pm 1	39 \pm 4	93 \pm 9	94 \pm 9
Turbidimetry/ <i>Behring</i>	6	< 10	8 \pm 1	36 \pm 1	85 \pm 1	85 \pm 1
Turbidimetry/ <i>Olympus</i>	6	< 10	< 19	42 \pm 3	93 \pm 5	94 \pm 4
Turbidimetry/ <i>Roche</i>	16	< 10	9 \pm 1	41 \pm 1	105 \pm 9	105 \pm 10
Nephelometry/ <i>Total</i>	61	< 10	9 \pm 1	41 \pm 4	105 \pm 14	104 \pm 13
Turbidimetry/ <i>Total</i>	34	< 10	< 19	39 \pm 7	97 \pm 11	96 \pm 9

IgA, IgE, IgG, and IgM

The Mean mg/dl (IU/ml for IgE) \pm S.D. is given for IgA, IgE, and IgM and Mean mg/dl \pm 25% is given for IgG where 6 or more laboratories reported values. Outlier values are omitted.

Analytes (Unit)	No. Labs	Sample NO.				
		81	82	83	84	85
Immunoglobulin A (mg/dl)						
Nephelometry/Beckman	39	456 \pm 20	470 \pm 20	297 \pm 13	93 \pm 3	509 \pm 22
Nephelometry/Behring	29	483 \pm 30	547 \pm 33	288 \pm 17	91 \pm 5	493 \pm 30
Turbidimetry/Beckman	6	403 \pm 30	447 \pm 36	293 \pm 15	92 \pm 4	407 \pm 33
Turbidimetry/Behring	6	417 \pm 17	459 \pm 21	286 \pm 12	84 \pm 4	493 \pm 20
Turbidimetry/Roche	18	421 \pm 26	458 \pm 30	295 \pm 17	86 \pm 6	511 \pm 27
Nephelometry/ Total	70	467 \pm 28	502 \pm 47	292 \pm 16	92 \pm 4	501 \pm 27
Turbidimetry/ Total	38	414 \pm 24	449 \pm 31	293 \pm 14	86 \pm 6	497 \pm 42
Immunoglobulin E (IU/ml)						
Chemiluminescence/Bayer	8	260 \pm 13	669 \pm 73	322 \pm 12	322 \pm 17	187 \pm 9
Chemiluminescence/Diag. Prod. Co.	30	259 \pm 17	648 \pm 44	296 \pm 19	296 \pm 17	181 \pm 11
EIA/Pharmacia	7	258 \pm 19	662 \pm 71	305 \pm 16	320 \pm 23	186 \pm 18
FEIA/Pharmacia	12	264 \pm 17	670 \pm 51	312 \pm 19	338 \pm 23	193 \pm 15
Nephelometry/Behring	7	280 \pm 25	843 \pm 64	339 \pm 31	417 \pm 41	211 \pm 17
Chemiluminescence/ Total	42	258 \pm 17	657 \pm 50	300 \pm 21	305 \pm 23	181 \pm 11
EIA/ Total	8	258 \pm 19	648 \pm 68	305 \pm 16	319 \pm 22	185 \pm 17
ELFA/ Total	6	248 \pm 37	622 \pm 47	298 \pm 59	323 \pm 21	163 \pm 12
FEIA/ Total	12	264 \pm 17	670 \pm 51	312 \pm 19	338 \pm 23	193 \pm 15
Nephelometry/ Total	10	275 \pm 24	803 \pm 84	314 \pm 49	398 \pm 50	196 \pm 27
Immunoglobulin G (mg/dl)						
Nephelometry/Beckman	39	2115 \pm 529	1938 \pm 484	1349 \pm 337	481 \pm 120	814 \pm 204
Nephelometry/Behring	26	2222 \pm 555	1999 \pm 500	1378 \pm 345	499 \pm 125	873 \pm 218
Turbidimetry/Behring	7	2233 \pm 558	1921 \pm 480	1330 \pm 333	464 \pm 116	823 \pm 206
Turbidimetry/Roche	18	2086 \pm 521	1882 \pm 471	1311 \pm 328	472 \pm 118	810 \pm 202
Nephelometry/ Total	70	2157 \pm 539	1958 \pm 489	1358 \pm 339	486 \pm 122	837 \pm 209
Turbidimetry/ Total	38	2127 \pm 532	1884 \pm 471	1322 \pm 330	466 \pm 117	815 \pm 204
Immunoglobulin M (mg/dl)						
Nephelometry/Beckman	39	248 \pm 7	289 \pm 11	100 \pm 5	49 \pm 3	65 \pm 3
Nephelometry/Behring	28	297 \pm 21	357 \pm 26	100 \pm 4	49 \pm 2	69 \pm 3
Turbidimetry/Behring	7	259 \pm 11	297 \pm 16	99 \pm 9	36 \pm 5	65 \pm 7
Turbidimetry/Roche	18	215 \pm 10	251 \pm 13	95 \pm 4	42 \pm 3	62 \pm 4
Nephelometry/ Total	68	268 \pm 29	315 \pm 36	100 \pm 6	49 \pm 3	67 \pm 4
Turbidimetry/ Total	38	225 \pm 24	258 \pm 25	98 \pm 7	43 \pm 6	64 \pm 5

Acceptable Response (September 8, 2004 PT Event)
Quantitative Tests Results (Acceptable Range)

Analytes/ Method/ Manufacture	Sample NO.				
	76	77	78	79	80
Alpha-1-Antitrypsin	76	77	78	79	80
Nephelometry/Beckman	< 10	51 - 74	141 - 201	346 - 523	368 - 519
Nephelometry/Behring	< 17	53 - 71	148 - 202	392 - 635	364 - 659
Nephelometry/ Total	< 17	52 - 72	145 - 202	319 - 638	323 - 640
Turbidimetry/ Total	< 30	33 - 88	107 - 207	278 - 561	279 - 556
Complement C'3	76	77	78	79	80
Nephelometry/Beckman	38 - 51	55 - 71	157 - 203	323 - 517	327 - 515
Nephelometry/Behring	38 - 55	58 - 74	172 - 216	368 - 581	390 - 549
Turbidimetry/Olympus	41 - 46	57 - 65	155 - 184	341 - 385	343 - 389
Turbidimetry/Roche	33 - 58	56 - 89	173 - 232	405 - 602	418 - 570
Nephelometry/ Total	37 - 53	55 - 73	152 - 219	315 - 574	328 - 558
Turbidimetry/ Total	35 - 55	48 - 88	144 - 239	269 - 649	285 - 622
Complement C'4	76	77	78	79	80
Nephelometry/Beckman	< 10	6.4 - 13.4	31 - 55	76 - 148	76 - 146
Nephelometry/Behring	< 10	4.9 - 10.6	26 - 52	66 - 120	66 - 122
Turbidimetry/Behring	< 10	5.3 - 10.1	31 - 40	81 - 89	82 - 89
Turbidimetry/Olympus	< 10	< 19	35 - 50	77 - 110	82 - 106
Turbidimetry/Roche	< 10	5.5 - 12.4	39 - 43	78 - 133	76 - 133
Nephelometry/ Total	< 10	4.5 - 13.5	29 - 53	62 - 147	63 - 144
Turbidimetry/ Total	< 10	< 19	18 - 59	64 - 130	68 - 123
Immunoglobulin A	81	82	83	84	85
Nephelometry/Beckman	395 - 516	410 - 530	258 - 335	83 - 103	442 - 576
Nephelometry/Behring	393 - 574	447 - 647	237 - 339	76 - 107	403 - 582
Turbidimetry/Beckman	314 - 492	339 - 554	248 - 338	79 - 105	307 - 508
Turbidimetry/Behring	364 - 471	398 - 521	250 - 321	72 - 95	433 - 552
Turbidimetry/Roche	342 - 500	368 - 548	244 - 347	68 - 103	428 - 593
Nephelometry/ Total	382 - 552	362 - 641	242 - 341	79 - 105	421 - 582
Turbidimetry/ Total	341 - 486	355 - 542	249 - 337	67 - 105	371 - 623
Immunoglobulin E	81	82	83	84	85
Chemiluminescence/Bayer	220 - 299	450 - 888	287 - 356	270 - 372	158 - 214
Chemiluminescence/Diag. Prod. Co.	207 - 311	515 - 781	240 - 352	244 - 348	148 - 214
EIA/Pharmacia	200 - 317	448 - 875	256 - 353	250 - 389	133 - 239
FEIA/Pharmacia	213 - 314	515 - 824	256 - 368	268 - 408	147 - 239
Nephelometry/Behring	205 - 356	651 - 1034	247 - 432	295 - 538	159 - 263
Chemiluminescence/ Total	207 - 309	505 - 807	238 - 362	235 - 375	147 - 215
EIA/ Total	200 - 317	445 - 851	256 - 354	254 - 384	135 - 235
ELFA/ Total	138 - 358	481 - 763	119 - 475	260 - 386	128 - 197
FEIA/ Total	214 - 314	515 - 824	256 - 368	268 - 408	147 - 239
Nephelometry/ Total	201 - 348	549 - 1056	168 - 460	249 - 547	115 - 277
Immunoglobulin G	81	82	83	84	85
Nephelometry/Beckman	1586 - 2643	1453 - 2422	1012 - 1686	360 - 601	610 - 1017
Nephelometry/Behring	1666 - 2777	1499 - 2499	1034 - 1723	374 - 624	655 - 1091
Turbidimetry/Behring	1675 - 2791	1440 - 2400	998 - 1662	348 - 580	617 - 1029
Turbidimetry/Roche	1564 - 2607	1412 - 2353	983 - 1638	354 - 590	607 - 1012
Nephelometry/ Total	1618 - 2696	1468 - 2447	1019 - 1698	365 - 608	628 - 1046
Turbidimetry/ Total	1595 - 2659	1413 - 2355	991 - 1652	350 - 583	611 - 1019
Immunoglobulin M	81	82	83	84	85
Nephelometry/Beckman	225 - 270	255 - 322	84 - 117	41 - 57	55 - 75
Nephelometry/Behring	234 - 360	280 - 434	88 - 112	43 - 55	60 - 79
Turbidimetry/Behring	226 - 292	248 - 345	74 - 125	22 - 50	45 - 85
Turbidimetry/Roche	185 - 246	212 - 289	85 - 106	33 - 51	50 - 74
Nephelometry/ Total	182 - 355	208 - 421	82 - 118	40 - 58	54 - 79
Turbidimetry/ Total	152 - 298	182 - 334	78 - 118	26 - 60	49 - 80

**Acceptable Response (September 8, 2004 PT Event)
Qualitative / Quantitative Tests Results**

Analytes	Sample NO.				
	1	2	3	4	5
Syphilis - Reagin Ab	N	N	N	N	R
<i>RPR Titer</i>					1 - 4
Syphilis - Treponemal	N	N	N	N	R
	6	7 *	8	9	10
HBcAb	R	N	N	R	R
HBsAg	R	N	N	N	R
	11	12	13	14	15
CMV	N	N	R	R	N
Rubella Ab	N	N	R	N	N
<i>EIA IU/ml</i>			32 - 59		
	16	17	18	19	20
ASO	R	R	N	N	N
<i>Latex Agglutination Titer</i>	100 - 800	100 - 1600			
<i>IU/ml</i>	88 - 372	250 - 820			
	26	27	28	29	30
Infectious Mono.	N	N	N	N	R
Rheumatoid Factor	N	N	R	N	R
<i>Latex Agglutination Titer</i>			20 - 640		80 - 2560
<i>Nephelometry IU/ml</i>			115 - 238		765 - 1983
<i>Turbidimetry IU/ml</i>			74 - 131		543 - 946
<i>EIA IU/ml</i>			88 - 165		75 - 199
	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	R	N
	41	42	43	44	45
LYME Disease Ab	R	N	R	N	R
LYME Disease Ab WB IgG	R	N	R	N	R
LYME Disease Ab WB IgM	N *	N	R *	N	N *
	46	47	48	49	50
ANA	N	R	N	R	R
<i>EIA Titer</i>		40 - 640		160 - 2560	80 - 1280
<i>IFA Titer</i>		40 - 2560		160 - 5120	80 - 2560
	56	57	58	59	60
Rubella IgM	N	N	R	N	R
	61	62	63	64	65
HIV p24 Ag	N	N	N	R	N
	66	67	68	69	70
HBeAg	R	R	N	N	R
	71	72	73	74 *	75
Hepatitis C Ab	N	R	R	N	N

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

* Test sample was not authenticated - A consensus of 80% agreement can not be reached among participants, by regulation requirement, the sample cannot be graded (scored) and all participating laboratories get credit for this sample.