

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

Proficiency Testing Program

April 28, 2015

**DIAGNOSTIC IMMUNOLOGY
SUMMARY ANALYSIS**

**Diagnostic Immunology
Proficiency Test Event
April 28, 2015**

Summary Analysis

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The data summarized in this report were tabulated from proficiency test results and accompanying information submitted by laboratories that participated in the April 28, 2015 Diagnostic Immunology Proficiency Test event. 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. Titering of positive Syphilis-Reagin samples is mandatory for all Diagnostic Services laboratories who perform this test, unless given an exemption. Failure to titer the positive samples to the endpoint will result in failure for the Syphilis-Reagin analyte.
- * For **Diagnostic Services** failure to attain an overall testing score of at least 80% is unsatisfactory performance
- * For **Donor Services** failure to attain an overall testing score of 100% is unsatisfactory performance.
- * 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

In some tables, test kits are grouped under test methods shown in bold letters. In all tables, primary test kits are listed in alphabetic order.

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 ten or more laboratories reported data. 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 $\pm$ 3 S.D.
Antinuclear Antibody	Positive or negative
Antinuclear Antibody Quantitative (IFA titers only)	Target value $\pm$ 2 dilutions
Antistreptolysin O	Positive or negative
Antistreptolysin O Quantitative, Semi-Quant, and Titer	Target value $\pm$ 2 dilutions or Target value $\pm$ 3 S.D.
Complement C'3, C'4	Target value $\pm$ 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 $\pm$ 3 S.D.
Immunoglobulin G	Target value $\pm$ 25 %
Infectious Mononucleosis	Positive or negative
Rheumatoid Factor	Positive or negative
Rheumatoid Factor Quantitative, Semi-Quant. and Titer	Target value $\pm$ 2 dilutions or Target value $\pm$ 3 S.D.
Rubella Ab, IgM	Positive or negative or Immune or nonimmune
Rubella Ab Quantitative	Target value $\pm$ 3 S.D.
Syphilis Reagin Antibody	Reactive or nonreactive Target value $\pm$ 1 dilution
Syphilis Treponemal Antibody	Reactive or nonreactive

Qualitative Antinuclear Ab (ANA) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 46 - 93% of participants reported positive.			
All Labs	99	7	-
AESKULISA ANA	1	-	-
Bio-Rad Bioplex	8	-	-
BioRad EIA Systems (any)	8	-	-
BioRad/Kallestad IFA Systems (any)	19	-	-
DiaSorin ANA Screen EIA	1	1	-
Diamedix EIA Systems (any)	5	-	-
DiaSorin ANA IFA Systems	1	-	-
Hycor Autostat II EIA	1	-	-
Immuno Concepts IFA Systems (any)	5	2	-
IMMCO Diagnostics IFA	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	8	3	-
INOVA Novalite/Quanta Lite	7	-	-
Phadia/Pharmacia Immunocap/UniCap (all models)	4	-	-
RhiGene Fluor ANA IFA Test	2	-	-
Sanofi/Kallestad Quantifluor IFA Kit	1	-	-
Trinity Biotech ANA EIA Test	2	-	-
Wampole ANA EIA	3	-	-
Wampole/Zeus ANA IFA Hep-2	17	1	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	5	-	-

SAMPLE 47 - 98% of participants reported negative.

All Labs	1	104	-
AESKULISA ANA	-	1	-
Bio-Rad Bioplex	-	8	-
BioRad EIA Systems (any)	-	8	-
BioRad/Kallestad IFA Systems (any)	-	19	-
DiaSorin ANA Screen EIA	-	2	-
Diamedix EIA Systems (any)	1	4	-
DiaSorin ANA IFA Systems	-	1	-
Hycor Autostat II EIA	-	1	-
Immuno Concepts IFA Systems (any)	-	7	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	11	-
INOVA Novalite/Quanta Lite	-	7	-
Phadia/Pharmacia Immunocap/UniCap (all models)*	-	3	-
RhiGene Fluor ANA IFA Test	-	2	-
Sanofi/Kallestad Quantifluor IFA Kit	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	3	-
Wampole/Zeus ANA IFA Hep-2	-	18	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	5	-

*** One laboratory reported an invalid result.**

Qualitative Antinuclear Ab (ANA) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 48 - 99% of participants reported negative.			
All Labs	-	105	-
AESKULISA ANA	-	1	-
Bio-Rad Bioplex	-	8	-
BioRad EIA Systems (any)	-	8	-
BioRad/Kallestad IFA Systems (any)	-	19	-
DiaSorin ANA Screen EIA	-	2	-
Diamedix EIA Systems (any)	-	5	-
DiaSorin ANA IFA Systems	-	1	-
Hycor Autostat II EIA	-	1	-
Immuno Concepts IFA Systems (any)	-	7	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	11	-
INOVA Novalite/Quanta Lite	-	7	-
Phadia/Pharmacia Immunocap/UniCap (all models)*	-	3	-
RhiGene Fluor ANA IFA Test	-	2	-
Sanofi/Kallestad Quantifluor IFA Kit	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	3	-
Wampole/Zeus ANA IFA Hep-2	-	18	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	5	-
* One laboratory reported an invalid result.			

SAMPLE 49 - 99% of participants reported positive.			
All Labs	105	-	1
AESKULISA ANA	1	-	-
Bio-Rad Bioplex	8	-	-
BioRad EIA Systems (any)	8	-	-
BioRad/Kallestad IFA Systems (any)	19	-	-
DiaSorin ANA Screen EIA	2	-	-
Diamedix EIA Systems (any)	5	-	-
DiaSorin ANA IFA Systems	1	-	-
Hycor Autostat II EIA	1	-	-
Immuno Concepts IFA Systems (any)	7	-	-
IMMCO Diagnostics IFA	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	11	-	-
INOVA Novalite/Quanta Lite	6	-	1
Phadia/Pharmacia Immunocap/UniCap (all models)	4	-	-
RhiGene Fluor ANA IFA Test	2	-	-
Sanofi/Kallestad Quantifluor IFA Kit	1	-	-
Trinity Biotech ANA EIA Test	2	-	-
Wampole ANA EIA	3	-	-
Wampole/Zeus ANA IFA Hep-2	18	-	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	5	-	-

Qualitative Antinuclear Ab (ANA) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 50 - 99% of participants reported negative.			
All Labs	-	105	-
AESKULISA ANA	-	1	-
Bio-Rad Bioplex	-	8	-
BioRad EIA Systems (any)	-	8	-
BioRad/Kallestad IFA Systems (any)	-	19	-
DiaSorin ANA Screen EIA	-	2	-
Diamedix EIA Systems (any)	-	5	-
DiaSorin ANA IFA Systems	-	1	-
Hycor Autostat II EIA	-	1	-
Immuno Concepts IFA Systems (any)	-	7	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	11	-
INOVA Novalite/Quanta Lite	-	7	-
Phadia/Pharmacia Immunocap/UniCap (all models)*	-	3	-
RhiGene Fluor ANA IFA Test	-	2	-
Sanofi/Kallestad Quantifluor IFA Kit	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	3	-
Wampole/Zeus ANA IFA Hep-2	-	18	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	5	-

*** One laboratory reported an invalid result.**

Antinuclear Ab (ANA) IFA Titers - Diagnostic Services

The number of laboratories that reported titers is listed for positive test samples 46 and 49.

Primary Test Kit/Assay	No. Labs	Sample 46 Titers							
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280	≥ 1:2560
All Labs	79	5	2	3	12	24	20	9	4
Antibodies Inc. ANA IFA	1	-	-	-	-	1	-	-	-
BioRad/Kallestad IFA Systems (any)	25	-	-	-	1	10	10	4	-
DiaSorin ANA IFA Systems	1	-	1	-	-	-	-	-	-
Immuno Concepts IFA Systems (any)	8	2	-	-	2	1	2	1	-
IMMCO Diagnostics IFA	2	-	-	-	-	1	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	18	2	1	2	2	6	3	-	2
RhiGene Fluor ANA IFA Test	2	-	-	1	1	-	-	-	-
Sanofi/Kallestad Quantifluor IFA Kit	1	-	-	-	-	-	-	1	-
Wampole/Zeus ANA IFA Hep-2	21	1	-	-	6	5	4	3	2

Staining Pattern - A total of 72 labs reported a staining pattern, of those 65 labs (95%) reported speckled, 3 labs (4%) nucleolar, and 4 labs (6%) homogenous. The reporting of a staining pattern here is for informational purposes only and is not graded.

Primary Test Kit/Assay	No. Labs	Sample 49 Titers							
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280	≥ 1:2560
All Labs	79	-	-	6	20	26	23	2	2
Antibodies Inc. ANA IFA	1	-	-	-	-	1	-	-	-
BioRad/Kallestad IFA Systems (any)	25	-	-	2	8	11	4	-	-
DiaSorin ANA IFA Systems	1	-	-	-	-	1	-	-	-
Immuno Concepts IFA Systems (any)	8	-	-	1	1	1	3	1	1
IMMCO Diagnostics IFA	2	-	-	-	-	1	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	18	-	-	-	3	7	6	1	1
RhiGene Fluor ANA IFA Test	2	-	-	-	1	1	-	-	-
Sanofi/Kallestad Quantifluor IFA Kit	1	-	-	-	-	-	1	-	-
Wampole/Zeus ANA IFA Hep-2	21	-	-	3	7	3	8	-	-

Staining Pattern - 78 labs reported a staining pattern, of those 75 labs (96%) reported homogenous and 3 labs (4%) reported speckled. The reporting of a staining pattern here is for informational purposes only and is not graded.

Qualitative Antistreptolysin O - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16 - 100% of participants reported positive.		
All Labs	50	-
Aeroset-Muligent Quantia ASO	1	-
Arlington Scientific ASO Latex Test	3	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	1	-
BioKit Rheumajet ASO Latex Test	9	-
Fisher Sure-View ASO Latex Test	18	-
Remel Seratest ASO Latex Test	3	-
Siemens (Dade Behring) RapiTex Latex Test	10	-
True Medix Trutest Latex Test	3	-
Wampole Color Card ASO Latex Test	2	-

SAMPLE 17 - 100% of participants reported negative.		
All Labs	-	50
Aeroset-Muligent Quantia ASO	-	1
Arlington Scientific ASO Latex Test	-	3
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	1
BioKit Rheumajet ASO Latex Test	-	9
Fisher Sure-View ASO Latex Test	-	18
Remel Seratest ASO Latex Test	-	3
Siemens (Dade Behring) RapiTex Latex Test	-	10
True Medix Trutest Latex Test	-	3
Wampole Color Card ASO Latex Test	-	2

SAMPLE 18 - 100% of participants reported positive.		
All Labs	50	-
Aeroset-Muligent Quantia ASO	1	-
Arlington Scientific ASO Latex Test	3	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	1	-
BioKit Rheumajet ASO Latex Test	9	-
Fisher Sure-View ASO Latex Test	18	-
Remel Seratest ASO Latex Test	3	-
Siemens (Dade Behring) RapiTex Latex Test	10	-
True Medix Trutest Latex Test	3	-
Wampole Color Card ASO Latex Test	2	-

Qualitative Antistreptolysin O - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 19 - 100% of participants reported negative.		
All Labs	-	50
Aeroset-Muligent Quantia ASO	-	1
Arlington Scientific ASO Latex Test	-	3
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	1
BioKit Rheumajet ASO Latex Test	-	9
Fisher Sure-View ASO Latex Test	-	18
Remel Seratest ASO Latex Test	-	3
Siemens (Dade Behring) RapiTex Latex Test	-	10
True Medix Trutest Latex Test	-	3
Wampole Color Card ASO Latex Test	-	2

SAMPLE 20 - 100% of participants reported negative.		
All Labs	-	50
Aeroset-Muligent Quantia ASO	-	1
Arlington Scientific ASO Latex Test	-	3
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	1
BioKit Rheumajet ASO Latex Test	-	9
Fisher Sure-View ASO Latex Test	-	18
Remel Seratest ASO Latex Test	-	3
Siemens (Dade Behring) RapiTex Latex Test	-	10
True Medix Trutest Latex Test	-	3
Wampole Color Card ASO Latex Test	-	2

Antistreptolysin O (ASO) Titers - Diagnostic Services

The number of laboratories that reported titers for positive test samples 16 and 18.

Primary Test Kit/Assay	No. Labs	Sample 16 Titers					
		< 1:1	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	8	-	4	3	1	-	-
Arlington Scientific ASO Latex Test	2	-	1	-	1	-	-
BioKit Rheumajet ASO Latex Test	1	-	1	-	-	-	-
Fisher Sure-View ASO Latex Test	3	-	2	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	2	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 18 Titers					
		< 1:1	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	8	-	3	4	1	-	-
Arlington Scientific ASO Latex Test	2	-	-	1	1	-	-
BioKit Rheumajet ASO Latex Test	1	-	-	1	-	-	-
Fisher Sure-View ASO Latex Test	3	-	2	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	1	1	-	-	-

Semi-quantitative Antistreptolysin O (ASO) - Diagnostic Services

The number of laboratories that reported titers for positive test samples 16 and 18.

Primary Test Kit/Assay	No. Labs	Sample 16 Results (IU/ml)					
		< 200	200	400	800	1600	≥ 3200
All Labs	33	-	18	15	-	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	8	-	7	1	-	-	-
Fisher Sure-View ASO Latex Test	13	-	8	5	-	-	-
Remel Seratest ASO Latex Test	3	-	2	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	8	-	-	8	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 18 Results (IU/ml)					
		< 200	200	400	800	1600	≥ 3200
All Labs	33	-	15	18	-	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	8	-	5	3	-	-	-
Fisher Sure-View ASO Latex Test	13	-	6	7	-	-	-
Remel Seratest ASO Latex Test	3	-	2	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	8	-	1	7	-	-	-

Quantitative Antistreptolysin O (ASO) IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		59	59	126.36	503.80	315.08	62.91
Nephelometry Total		17	17	252.03	289.14	270.58	6.19
	Beckman Coulter Immage	3	3	-	-	191.67	-
	Siemens Dimension VISTA	7	7	-	-	270.29	-
	Siemens Nephelometer Systems (all models)	7	7	-	-	270.29	-
Turbidimetry Total		42	42	169.65	508.00	338.82	56.39
	Abbott Architect	2	2	-	-	242.65	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	3	-	-	228.40	-
	Beckman Coulter (formerly Olympus) AU System	12	12	375.59	398.05	386.82	3.74
	Roche Diagnostics Cobas (all systems)	15	15	231.51	447.81	339.66	36.05
	Roche/Hitachi Modular Systems (all models)	4	4	-	-	309.57	-
	Siemens ADVIA 1200/1650/1800/2400	6	6	-	-	359.78	-

Sample 17		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		59	44	0.00	100.00	50.00	16.67
Nephelometry Total		17	14	22.03	61.28	41.66	6.54
	Beckman Coulter Immage	3	3	-	-	30.07	-
	Siemens Dimension VISTA	7	5	-	-	45.92	-
	Siemens Nephelometer Systems (all models)	7	6	-	-	43.90	-
Turbidimetry Total		42	30	20.85	59.82	40.34	6.49
	Abbott Architect	2	0	-	-	-	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	2	-	-	4.45	-
	Beckman Coulter (formerly Olympus) AU System	12	4	-	-	29.30	-
	Roche Diagnostics Cobas (all systems)	15	15	37.04	52.17	44.61	2.52
	Roche/Hitachi Modular Systems (all models)	4	4	-	-	43.20	-
	Siemens ADVIA 1200/1650/1800/2400	6	5	-	-	34.06	-

Sample 18		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		59	59	200.26	692.17	446.21	81.98
Nephelometry Total		17	17	437.82	565.33	501.57	21.25
	Beckman Coulter Immage	3	3	-	-	272.00	-
	Siemens Dimension VISTA	7	7	-	-	495.86	-
	Siemens Nephelometer Systems (all models)	7	7	-	-	507.29	-
Turbidimetry Total		42	42	206.87	673.54	440.20	77.78
	Abbott Architect	2	2	-	-	266.85	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	3	-	-	276.50	-
	Beckman Coulter (formerly Olympus) AU System	12	12	387.96	434.06	411.01	7.68
	Roche Diagnostics Cobas (all systems)	15	15	414.56	587.14	500.85	28.76
	Roche/Hitachi Modular Systems (all models)	4	4	-	-	476.32	-
	Siemens ADVIA 1200/1650/1800/2400	6	6	-	-	467.22	-

Quantitative Antistreptolysin O (ASO) IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 19		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		59	45	0.00	100.00	50.00	16.67
Nephelometry Total		17	15	23.36	62.05	42.71	6.45
	Beckman Coulter Immage	3	3	-	-	32.90	-
	Siemens Dimension VISTA	7	6	-	-	46.95	-
	Siemens Nephelometer Systems (all models)	7	6	-	-	43.37	-
Turbidimetry Total		42	30	17.55	62.33	39.94	7.46
	Abbott Architect	2	0	-	-	-	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	2	-	-	14.20	-
	Beckman Coulter (formerly Olympus) AU System	12	4	-	-	29.35	-
	Roche Diagnostics Cobas (all systems)	15	15	35.83	53.97	44.90	3.02
	Roche/Hitachi Modular Systems (all models)	4	4	-	-	42.62	-
	Siemens ADVIA 1200/1650/1800/2400	6	5	-	-	35.14	-

Sample 20		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		59	44	0.00	100.00	50.00	16.67
Nephelometry Total		17	14	27.44	58.11	42.78	5.11
	Beckman Coulter Immage	3	3	-	-	34.37	-
	Siemens Dimension VISTA	7	5	-	-	46.54	-
	Siemens Nephelometer Systems (all models)	7	6	-	-	43.85	-
Turbidimetry Total		42	30	17.97	59.94	38.96	6.99
	Abbott Architect	2	0	-	-	-	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	2	-	-	11.30	-
	Beckman Coulter (formerly Olympus) AU System	12	4	-	-	29.55	-
	Roche Diagnostics Cobas (all systems)	15	15	36.39	50.00	43.19	2.27
	Roche/Hitachi Modular Systems (all models)	4	4	-	-	44.33	-
	Siemens ADVIA 1200/1650/1800/2400	6	5	-	-	33.04	-

Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 11 - 54% of participants reported negative. *			
All Labs	17	32	10
Bio-Rad CMV IgG EIA	-	3	-
Bio-Rad Bioplex Torc IgG	4	-	-
bioMerieux VIDAS/mini VIDAS Systems	8	-	6
Diamedix CMV EIA Systems (any)	2	-	-
DiaSorin Liaison CMV IgG	-	14	-
Immucor Capture CMV	1	-	-
Siemens Immulite Systems (all models)	2	1	3
Trinity Biotech CAPTIA CMV IgG EIA	-	2	-
Wampole Zeus Scientific CMV IgG ELISA	-	4	-
Zeus Scientific CMV IgG EIA	-	8	1

SAMPLE 12 - 54% of participants reported negative. *			
All Labs	18	32	9
Bio-Rad CMV IgG EIA	-	3	-
Bio-Rad Bioplex Torc IgG	4	-	-
bioMerieux VIDAS/mini VIDAS Systems	9	-	5
Diamedix CMV EIA Systems (any)	1	-	1
DiaSorin Liaison CMV IgG	-	14	-
Immucor Capture CMV	1	-	-
Siemens Immulite Systems (all models)	3	1	2
Trinity Biotech CAPTIA CMV IgG EIA	-	2	-
Wampole Zeus Scientific CMV IgG ELISA	-	4	-
Zeus Scientific CMV IgG EIA	-	8	1

SAMPLE 13 - 100% of participants reported negative.			
All Labs	-	59	-
Bio-Rad CMV IgG EIA	-	3	-
Bio-Rad Bioplex Torc IgG	-	4	-
bioMerieux VIDAS/mini VIDAS Systems	-	14	-
Diamedix CMV EIA Systems (any)	-	2	-
DiaSorin Liaison CMV IgG	-	14	-
Immucor Capture CMV	-	1	-
Siemens Immulite Systems (all models)	-	6	-
Trinity Biotech CAPTIA CMV IgG EIA	-	2	-
Wampole Zeus Scientific CMV IgG ELISA	-	4	-
Zeus Scientific CMV IgG EIA	-	9	-

Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 14 - 58% of participants reported negative. *			
All Labs	16	34	9
Bio-Rad CMV IgG EIA	-	3	-
Bio-Rad Bioplex Torc IgG	4	-	-
bioMerieux VIDAS/mini VIDAS Systems	9	-	5
Diamedix CMV EIA Systems (any)	1	1	-
DiaSorin Liaison CMV IgG	-	14	-
Immucor Capture CMV	1	-	-
Siemens Immulite Systems (all models)	1	2	3
Trinity Biotech CAPTIA CMV IgG EIA	-	2	-
Wampole Zeus Scientific CMV IgG ELISA	-	4	-
Zeus Scientific CMV IgG EIA	-	8	1

SAMPLE 15 - 100% of participants reported positive.			
All Labs	59	-	-
Bio-Rad CMV IgG EIA	3	-	-
Bio-Rad Bioplex Torc IgG	4	-	-
bioMerieux VIDAS/mini VIDAS Systems	14	-	-
Diamedix CMV EIA Systems (any)	2	-	-
DiaSorin Liaison CMV IgG	14	-	-
Immucor Capture CMV	1	-	-
Siemens Immulite Systems (all models)	6	-	-
Trinity Biotech CAPTIA CMV IgG EIA	2	-	-
Wampole Zeus Scientific CMV IgG ELISA	4	-	-
Zeus Scientific CMV IgG EIA	9	-	-

* Unable to validate samples #11, #12, and #14, the target result is negative. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.

Qualitative Cytomegalovirus Ab (CMV) - Donor Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 61 - 11% of participants reported negative. *			
All Labs	15	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	-	2
Immucor Capture CMV	6	-	-
Beckman Coulter (formerly Olympus) PK System	9	-	-
Siemens Immulite Systems (all models)	-	1	-
Other	-	1	-
SAMPLE 62 - 11% of participants reported negative. *			
All Labs	15	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	-	2
Immucor Capture CMV	6	-	-
Beckman Coulter (formerly Olympus) PK System	9	-	-
Siemens Immulite Systems (all models)	-	1	-
Other	-	1	-
SAMPLE 63 - 95% of participants reported negative.			
All Labs	1	18	-
bioMerieux VIDAS/mini VIDAS Systems	-	2	-
Immucor Capture CMV	1	5	-
Beckman Coulter (formerly Olympus) PK System	-	9	-
Siemens Immulite Systems (all models)	-	1	-
Other	-	1	-
SAMPLE 64 - 11% of participants reported negative. *			
All Labs	16	2	-
bioMerieux VIDAS/mini VIDAS Systems	1	-	1
Immucor Capture CMV	6	-	-
Beckman Coulter (formerly Olympus) PK System	9	-	-
Siemens Immulite Systems (all models)	-	1	-
Other	-	1	-
SAMPLE 65 - 100% of participants reported positive.			
All Labs	19	-	-
bioMerieux VIDAS/mini VIDAS Systems	2	-	-
Immucor Capture CMV	6	-	-
Beckman Coulter (formerly Olympus) PK System	9	-	-
Siemens Immulite Systems (all models)	1	-	-
Other	1	-	-

*** Unable to validate samples #61, #62, and #64, the target result is negative. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.**

Qualitative Hepatitis B core Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 06 - 99% of participants reported reactive.		
All Labs	131	1
Abbott Architect	26	-
BioRad MONOLISA HBc	3	-
DiaSorin ETI-AB Corek Plus	2	-
Ortho HBc ELISA	1	-
Ortho Vitros (all models)	28	-
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	1	-
Siemens ADVIA Centaur	65	1
Siemens Immulite Systems (all models)	5	-
SAMPLE 07 - 99% of participants reported nonreactive.		
All Labs	1	131
Abbott Architect	-	26
BioRad MONOLISA HBc	-	3
DiaSorin ETI-AB Corek Plus	-	2
Ortho HBc ELISA	-	1
Ortho Vitros (all models)	-	28
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	1	65
Siemens Immulite Systems (all models)	-	5
SAMPLE 08 - 99% of participants reported nonreactive.		
All Labs	1	131
Abbott Architect	-	26
BioRad MONOLISA HBc	-	3
DiaSorin ETI-AB Corek Plus	-	2
Ortho HBc ELISA	-	1
Ortho Vitros (all models)	-	28
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	1	65
Siemens Immulite Systems (all models)	-	5

Qualitative Hepatitis B core Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 09 - 100% of participants reported nonreactive.		
All Labs	-	132
Abbott Architect	-	26
BioRad MONOLISA HBc	-	3
DiaSorin ETI-AB Corek Plus	-	2
Ortho HBc ELISA	-	1
Ortho Vitros (all models)	-	28
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	-	66
Siemens Immulite Systems (all models)	-	5
SAMPLE 10 - 99% of participants reported reactive.		
All Labs	131	1
Abbott Architect	26	-
BioRad MONOLISA HBc	3	-
DiaSorin ETI-AB Corek Plus	2	-
Ortho HBc ELISA	1	-
Ortho Vitros (all models)	28	-
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	1	-
Siemens ADVIA Centaur	65	1
Siemens Immulite Systems (all models)	5	-

Qualitative Hepatitis B Core Ab - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 51 - 100% of participants reported reactive.		
All Labs	19	-
Abbott PRISM	9	-
BioRad MONOLISA HBc	1	-
Ortho HBc ELISA	8	-
Siemens ADVIA Centaur	1	-
SAMPLE 52 - 100% of participants reported nonreactive.		
All Labs	-	19
Abbott PRISM	-	9
BioRad MONOLISA HBc	-	1
Ortho HBc ELISA	-	8
Siemens ADVIA Centaur	-	1
SAMPLE 53 - 100% of participants reported nonreactive.		
All Labs	-	19
Abbott PRISM	-	9
BioRad MONOLISA HBc	-	1
Ortho HBc ELISA	-	8
Siemens ADVIA Centaur	-	1
SAMPLE 54 - 100% of participants reported nonreactive.		
All Labs	-	19
Abbott PRISM	-	9
BioRad MONOLISA HBc	-	1
Ortho HBc ELISA	-	8
Siemens ADVIA Centaur	-	1
SAMPLE 55 - 100% of participants reported reactive.		
All Labs	19	-
Abbott PRISM	9	-
BioRad MONOLISA HBc	1	-
Ortho HBc ELISA	8	-
Siemens ADVIA Centaur	1	-

Qualitative Hepatitis B surface Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 06 - 100% of participants reported reactive.		
All Labs	179	-
Abbott Architect	30	-
Bio-Rad GS HBsAg EIA	3	-
DiaSorin ETI MAK-2 Plus	3	-
Ortho Vitros (all models)	37	-
Roche Diagnostics Cobas (all systems)	7	-
Roche Diagnostics Elecsys Systems	8	-
Siemens ADVIA Centaur	87	-
Siemens Immulite Systems (all models)	4	-
SAMPLE 07 - 96% of participants reported nonreactive.		
All Labs	7	172
Abbott Architect	2	28
Bio-Rad GS HBsAg EIA	-	3
DiaSorin ETI MAK-2 Plus	-	3
Ortho Vitros (all models)	-	37
Roche Diagnostics Cobas (all systems)	-	7
Roche Diagnostics Elecsys Systems	-	8
Siemens ADVIA Centaur	5	82
Siemens Immulite Systems (all models)	-	4
SAMPLE 08 - 99% of participants reported nonreactive.		
All Labs	1	178
Abbott Architect	-	30
Bio-Rad GS HBsAg EIA	-	3
DiaSorin ETI MAK-2 Plus	-	3
Ortho Vitros (all models)	-	37
Roche Diagnostics Cobas (all systems)	-	7
Roche Diagnostics Elecsys Systems	-	8
Siemens ADVIA Centaur	1	86
Siemens Immulite Systems (all models)	-	4

Qualitative Hepatitis B surface Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 09 - 99% of participants reported nonreactive.		
All Labs	1	178
Abbott Architect	-	30
Bio-Rad GS HBsAg EIA	-	3
DiaSorin ETI MAK-2 Plus	-	3
Ortho Vitros (all models)	-	37
Roche Diagnostics Cobas (all systems)	-	7
Roche Diagnostics Elecsys Systems	-	8
Siemens ADVIA Centaur	1	86
Siemens Immulite Systems (all models)	-	4
SAMPLE 10 - 99% of participants reported reactive.		
All Labs	178	1
Abbott Architect	30	-
Bio-Rad GS HBsAg EIA	3	-
DiaSorin ETI MAK-2 Plus	3	-
Ortho Vitros (all models)	36	1
Roche Diagnostics Cobas (all systems)	7	-
Roche Diagnostics Elecsys Systems	8	-
Siemens ADVIA Centaur	87	-
Siemens Immulite Systems (all models)	4	-

Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 06 - 100% of participants reported reactive.		
All Labs	112	-
Abbott Architect	20	-
Abbott HBsAg Confirmatory Assay	2	-
Bio-Rad GS HBsAg Confirmatory Assay	1	-
DiaSorin ETI MAK-2 Plus	2	-
Ortho Vitros (all models)	21	-
Roche Diagnostics Cobas (all systems)	4	-
Roche Diagnostics Elecsys Systems	3	-
Siemens ADVIA Centaur	59	-
SAMPLE 07 - 96% of participants reported nonreactive.		
All Labs	5	107
Abbott Architect	2	18
Abbott HBsAg Confirmatory Assay	-	2
Bio-Rad GS HBsAg Confirmatory Assay	-	1
DiaSorin ETI MAK-2 Plus	-	2
Ortho Vitros (all models)	-	21
Roche Diagnostics Cobas (all systems)	-	4
Roche Diagnostics Elecsys Systems	1	2
Siemens ADVIA Centaur	3	56
SAMPLE 08 - 100% of participants reported nonreactive.		
All Labs	-	112
Abbott Architect	-	20
Abbott HBsAg Confirmatory Assay	-	2
Bio-Rad GS HBsAg Confirmatory Assay	-	1
DiaSorin ETI MAK-2 Plus	-	2
Ortho Vitros (all models)	-	21
Roche Diagnostics Cobas (all systems)	-	4
Roche Diagnostics Elecsys Systems	-	3
Siemens ADVIA Centaur	-	59

Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 09 - 100% of participants reported nonreactive.		
All Labs	-	112
Abbott Architect	-	20
Abbott HBsAg Confirmatory Assay	-	2
Bio-Rad GS HBsAg Confirmatory Assay	-	1
DiaSorin ETI MAK-2 Plus	-	2
Ortho Vitros (all models)	-	21
Roche Diagnostics Cobas (all systems)	-	4
Roche Diagnostics Elecsys Systems	-	3
Siemens ADVIA Centaur	-	59
SAMPLE 10 - 100% of participants reported reactive.		
All Labs	112	-
Abbott Architect	20	-
Abbott HBsAg Confirmatory Assay	2	-
Bio-Rad GS HBsAg Confirmatory Assay	1	-
DiaSorin ETI MAK-2 Plus	2	-
Ortho Vitros (all models)	21	-
Roche Diagnostics Cobas (all systems)	4	-
Roche Diagnostics Elecsys Systems	3	-
Siemens ADVIA Centaur	59	-

Qualitative Hepatitis B Surface Antigen - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 51 - 100% of participants reported reactive.		
All Labs	20	-
Abbott Architect	1	-
Abbott PRISM	9	-
Genetic Systems HBsAg EIA 3.0	10	-
SAMPLE 52 - 95% of participants reported nonreactive.		
All Labs	1	19
Abbott Architect	-	1
Abbott PRISM	-	9
Genetic Systems HBsAg EIA 3.0	1	9
SAMPLE 53 - 65% of participants nonreported nonreactive. *		
All Labs	7	13
Abbott Architect	1	-
Abbott PRISM	2	7
Genetic Systems HBsAg EIA 3.0	4	6
SAMPLE 54 - 70% of participants reported nonreactive. *		
All Labs	6	14
Abbott Architect	1	-
Abbott PRISM	2	7
Genetic Systems HBsAg EIA 3.0	3	7
SAMPLE 55 - 100% of participants reported reactive.		
All Labs	20	-
Abbott Architect	1	-
Abbott PRISM	9	-
Genetic Systems HBsAg EIA 3.0	10	-

* Unable to validate samples #53, and #54, the target result is nonreactive. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.

Qualitative Hepatitis B Surface Ag Confirmation - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 51 - 100% of participants reported reactive.		
All Labs	15	-
Abbott Architect	1	-
Abbott PRISM	6	-
Genetic Systems HBsAg EIA 3.0	8	-
SAMPLE 52 - 93% of participants reported nonreactive.		
All Labs	1	14
Abbott Architect	-	1
Abbott PRISM	-	6
Genetic Systems HBsAg EIA 3.0	1	7
SAMPLE 53 - 53% of participants reported nonreactive. *		
All Labs	7	8
Abbott Architect	1	-
Abbott PRISM	2	4
Genetic Systems HBsAg EIA 3.0	4	4
SAMPLE 54 - 60% of participants reported nonreactive. *		
All Labs	6	9
Abbott Architect	1	-
Abbott PRISM	2	4
Genetic Systems HBsAg EIA 3.0	3	5
SAMPLE 55 - 100% of participants reported reactive.		
All Labs	15	-
Abbott Architect	1	-
Abbott PRISM	6	-
Genetic Systems HBsAg EIA 3.0	8	-

* Unable to validate samples #53, and #54, the target result is nonreactive. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.

Qualitative Hepatitis Be Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 66 - 100% of participants reported nonreactive.		
All Labs	-	24
DiaSorin ELX 800 Microplate Reader	-	2
DiaSorin ETI-EBK Plus	-	8
DiaSorin ETI MAK 3000	-	2
Ortho Vitros (all models)	-	8
Siemens ADVIA Centaur	-	4
SAMPLE 67 - 100% of participants reported nonreactive.		
All Labs	-	24
DiaSorin ELX 800 Microplate Reader	-	2
DiaSorin ETI-EBK Plus	-	8
DiaSorin ETI MAK 3000	-	2
Ortho Vitros (all models)	-	8
Siemens ADVIA Centaur	-	4
SAMPLE 68 - 100% of participants reported reactive.		
All Labs	24	-
DiaSorin ELX 800 Microplate Reader	2	-
DiaSorin ETI-EBK Plus	8	-
DiaSorin ETI MAK 3000	2	-
Ortho Vitros (all models)	8	-
Siemens ADVIA Centaur	4	-
SAMPLE 69 - 100% of participants reported nonreactive.		
All Labs	-	24
DiaSorin ELX 800 Microplate Reader	-	2
DiaSorin ETI-EBK Plus	-	8
DiaSorin ETI MAK 3000	-	2
Ortho Vitros (all models)	-	8
Siemens ADVIA Centaur	-	4
SAMPLE 70 - 100% of participants reported reactive.		
All Labs	24	-
DiaSorin ELX 800 Microplate Reader	2	-
DiaSorin ETI-EBK Plus	8	-
DiaSorin ETI MAK 3000	2	-
Ortho Vitros (all models)	8	-
Siemens ADVIA Centaur	4	-

Qualitative Hepatitis C Virus Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 71 - 100% of participants reported nonreactive.		
All Labs	-	164
Abbott Architect	-	33
HCV Ortho Version 3.0 ELISA	-	8
Ortho Vitros (all models)	-	35
Roche Diagnostics Elecsys Systems	-	7
Siemens ADVIA Centaur	-	81
SAMPLE 72 - 99% of participants reported reactive.		
All Labs	162	2
Abbott Architect	33	-
HCV Ortho Version 3.0 ELISA	8	-
Ortho Vitros (all models)	35	-
Roche Diagnostics Elecsys Systems	7	-
Siemens ADVIA Centaur	79	2
SAMPLE 73 - 100% of participants reported nonreactive.		
All Labs	-	164
Abbott Architect	-	33
HCV Ortho Version 3.0 ELISA	-	8
Ortho Vitros (all models)	-	35
Roche Diagnostics Elecsys Systems	-	7
Siemens ADVIA Centaur	-	81

Qualitative Hepatitis C Virus Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 74 - 99% of participants reported nonreactive.		
All Labs	2	162
Abbott Architect	-	33
HCV Ortho Version 3.0 ELISA	-	8
Ortho Vitros (all models)	-	35
Roche Diagnostics Elecsys Systems	-	7
Siemens ADVIA Centaur	2	79

SAMPLE 75 - 99% of participants reported reactive.		
All Labs	163	1
Abbott Architect	33	-
HCV Ortho Version 3.0 ELISA	8	-
Ortho Vitros (all models)	35	-
Roche Diagnostics Elecsys Systems	7	-
Siemens ADVIA Centaur	80	1

Qualitative Hepatitis C Ab - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 91 - 100% of participants reported nonreactive.		
All Labs	-	20
Abbott PRISM	-	9
Ortho HCV Version 3.0 ELISA	-	10
Siemens ADVIA Centaur	-	1
SAMPLE 92 - 100% of participants reported reactive.		
All Labs	20	-
Abbott PRISM	9	-
Ortho HCV Version 3.0 ELISA	10	-
Siemens ADVIA Centaur	1	-
SAMPLE 93 - 100% of participants reported nonreactive.		
All Labs	-	20
Abbott PRISM	-	9
Ortho HCV Version 3.0 ELISA	-	10
Siemens ADVIA Centaur	-	1
SAMPLE 94 - 100% of participants reported nonreactive.		
All Labs	-	20
Abbott PRISM	-	9
Ortho HCV Version 3.0 ELISA	-	10
Siemens ADVIA Centaur	-	1
SAMPLE 95 - 100% of participants reported reactive.		
All Labs	20	-
Abbott PRISM	9	-
Ortho HCV Version 3.0 ELISA	10	-
Siemens ADVIA Centaur	1	-

Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 31 - 99% of participants reported nonreactive.		
All Labs	1	262
Architect HIV Ag/Ab Combo Assay (Abbott)	-	43
Abbott PRISM HIV O Plus (Abbott)	-	1
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	45
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	1	23
Avioq HIV-1 Microelisa System (Avioq)	-	2
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	7
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	10
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	2
Clearview HIV 1/2 Stat-Pak (Alere)	-	12
Reveal Rapid HIV-1 Antibody Test (MedMira)	-	2
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	85
Vitros Anti-HIV 1+2 (Ortho)	-	18
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	12
SAMPLE 32 - 100% of participants reported nonreactive.		
All Labs	-	263
Architect HIV Ag/Ab Combo Assay (Abbott)	-	43
Abbott PRISM HIV O Plus (Abbott)	-	1
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	45
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	24
Avioq HIV-1 Microelisa System (Avioq)	-	2
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	7
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	10
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	2
Clearview HIV 1/2 Stat-Pak (Alere)	-	12
Reveal Rapid HIV-1 Antibody Test (MedMira)	-	2
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	85
Vitros Anti-HIV 1+2 (Ortho)	-	18
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	12
SAMPLE 33 - 100% of participants reported reactive.		
All Labs	263	-
Architect HIV Ag/Ab Combo Assay (Abbott)	43	-
Abbott PRISM HIV O Plus (Abbott)	1	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	45	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	24	-
Avioq HIV-1 Microelisa System (Avioq)	2	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	7	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	10	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	2	-
Clearview HIV 1/2 Stat-Pak (Alere)	12	-
Reveal Rapid HIV-1 Antibody Test (MedMira)	2	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	85	-
Vitros Anti-HIV 1+2 (Ortho)	18	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	12	-

Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 34 - 100% of participants reported reactive.		
All Labs	263	-
Architect HIV Ag/Ab Combo Assay (Abbott)	43	-
Abbott PRISM HIV O Plus (Abbott)	1	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	45	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	24	-
Avioq HIV-1 Microelisa System (Avioq)	2	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	7	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	10	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	2	-
Clearview HIV 1/2 Stat-Pak (Alere)	12	-
Reveal Rapid HIV-1 Antibody Test (MedMira)	2	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	85	-
Vitros Anti-HIV 1+2 (Ortho)	18	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	12	-

SAMPLE 35 - 100% of participants reported nonreactive.

All Labs	-	263
Architect HIV Ag/Ab Combo Assay (Abbott)	-	43
Abbott PRISM HIV O Plus (Abbott)	-	1
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	45
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	24
Avioq HIV-1 Microelisa System (Avioq)	-	2
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	7
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	10
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	2
Clearview HIV 1/2 Stat-Pak (Alere)	-	12
Reveal Rapid HIV-1 Antibody Test (MedMira)	-	2
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	85
Vitros Anti-HIV 1+2 (Ortho)	-	18
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	12

Qualitative HIV-1 Ab - Supplemental/Confirmation Tests

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 31 - 100% of participants reported nonreactive.		
All Labs	-	52
GS HIV-1 Western Blot (Bio-Rad)	-	11
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	37
Laboratory developed assay/Other	-	2
Cambridge Biotech HIV-1 WB (Maxim Biomedical)	-	1
Fluorognost IFA HIV-1 (Sanochemias)	-	1
SAMPLE 32 - 100% of participants reported nonreactive.		
All Labs	-	52
GS HIV-1 Western Blot (Bio-Rad)	-	11
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	37
Laboratory developed assay/Other	-	2
Cambridge Biotech HIV-1 WB (Maxim Biomedical)	-	1
Fluorognost IFA HIV-1 (Sanochemias)	-	1
SAMPLE 33 - 100% of participants reported reactive.		
All Labs	52	-
GS HIV-1 Western Blot (Bio-Rad)	11	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	37	-
Laboratory developed assay/Other	2	-
Cambridge Biotech HIV-1 WB (Maxim Biomedical)	1	-
Fluorognost IFA HIV-1 (Sanochemias)	1	-
SAMPLE 34 - 100% of participants reported reactive.		
All Labs	52	-
GS HIV-1 Western Blot (Bio-Rad)	11	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	37	-
Laboratory developed assay/Other	2	-
Cambridge Biotech HIV-1 WB (Maxim Biomedical)	1	-
Fluorognost IFA HIV-1 (Sanochemias)	1	-
SAMPLE 35 - 100% of participants reported nonreactive.		
All Labs	-	52
GS HIV-1 Western Blot (Bio-Rad)	-	11
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	37
Laboratory developed assay/Other	-	2
Cambridge Biotech HIV-1 WB (Maxim Biomedical)	-	1
Fluorognost IFA HIV-1 (Sanochemias)	-	1

Qualitative HIV Ab Screening - Donor Tests

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 96 - 100% of participants reported nonreactive.		
All Labs	-	19
PRISM HIV O Plus (Abbott)	-	8
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	10
Other	-	1
SAMPLE 97 - 100% of participants reported nonreactive.		
All Labs	-	19
PRISM HIV O Plus (Abbott)	-	8
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	10
Other	-	1
SAMPLE 98 - 100% of participants reported reactive.		
All Labs	19	-
PRISM HIV O Plus (Abbott)	8	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	10	-
Other	1	-
SAMPLE 99 - 100% of participants reported reactive.		
All Labs	19	-
PRISM HIV O Plus (Abbott)	8	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	10	-
Other	1	-
SAMPLE 100 - 100% of participants reported nonreactive.		
All Labs	-	19
PRISM HIV O Plus (Abbott)	-	8
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	10
Other	-	1

Qualitative HIV-1 Ab Supplemental/Confirmation - Donor Tests

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 96 - 100% of participants reported nonreactive.		
All Labs	-	9
GS HIV-1 Western Blot (Bio-Rad)	-	6
Fluorognost IFA HIV-1 (Sanochemias)	-	2
Other	-	1
SAMPLE 97 - 100% of participants reported nonreactive.		
All Labs	-	9
GS HIV-1 Western Blot (Bio-Rad)	-	6
Fluorognost IFA HIV-1 (Sanochemias)	-	2
Other	-	1
SAMPLE 98 - 100% of participants reported reactive.		
All Labs	9	-
GS HIV-1 Western Blot (Bio-Rad)	6	-
Fluorognost IFA HIV-1 (Sanochemias)	2	-
Other	1	-
SAMPLE 99 - 100% of participants reported reactive.		
All Labs	9	-
GS HIV-1 Western Blot (Bio-Rad)	6	-
Fluorognost IFA HIV-1 (Sanochemias)	2	-
Other	1	-
SAMPLE 100 - 100% of participants reported nonreactive.		
All Labs	-	9
GS HIV-1 Western Blot (Bio-Rad)	-	6
Fluorognost IFA HIV-1 (Sanochemias)	-	2
Other	-	1

Qualitative HTLV-1 Ab - Diagnostic Services

	Participant Results	
	Positive	Negative
SAMPLE 36 - 100% of participants reported negative.		
All Labs	-	4
Abbott PRISM	-	1
Avioq HTLV I/II Microelisa System	-	3
SAMPLE 37 - 100% of participants reported positive.		
All Labs	4	-
Abbott PRISM	1	-
Avioq HTLV I/II Microelisa System	3	-
SAMPLE 38 - 100% of participants reported negative.		
All Labs	-	4
Abbott PRISM	-	1
Avioq HTLV I/II Microelisa System	-	3
SAMPLE 39 - 100% of participants reported negative.		
All Labs	-	4
Abbott PRISM	-	1
Avioq HTLV I/II Microelisa System	-	3
SAMPLE 40 - 100% of participants reported negative.		
All Labs	-	4
Abbott PRISM	-	1
Avioq HTLV I/II Microelisa System	-	3

Qualitative HTLV-1 Ab - Donor Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 86 - 100% of participants reported negative.		
All Labs	-	17
Abbott PRISM	-	10
Avioq HTLV I/II Microelisa System	-	7
SAMPLE 87 - 100% of participants reported positive.		
All Labs	17	-
Abbott PRISM	10	-
Avioq HTLV I/II Microelisa System	7	-
SAMPLE 88 - 100% of participants reported negative.		
All Labs	-	17
Abbott PRISM	-	10
Avioq HTLV I/II Microelisa System	-	7
SAMPLE 89 - 100% of participants reported negative.		
All Labs	-	17
Abbott PRISM	-	10
Avioq HTLV I/II Microelisa System	-	7
SAMPLE 90 - 100% of participants reported negative.		
All Labs	-	17
Abbott PRISM	-	10
Avioq HTLV I/II Microelisa System	-	7

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 26 - 100% of participants reported negative.			
All Labs	-	229	-
Alere Acceava Mono Cassette (Inverness)	-	4	-
Arlington Scientific Mono Tests	-	3	-
Beckman Coulter ICON Mono	-	7	-
Biokit Monogen Latex	-	11	-
Cardinal Health Color Mono Latex	-	4	-
Cardinal Health SP Brand Rapid Mono Test	-	7	-
Clearview Mono	-	30	-
Fisher Sure-View Color Mono Latex Test Kit	-	5	-
Fisher Sure-View Mono Latex	-	65	-
Fisher Sure-View Signature Mono Test Kit	-	10	-
Inverness BioStar Acceava Mono/Mono II Test	-	9	-
Inverness Signify MONO TEST	-	1	-
Meridian MonoSpot Latex	-	5	-
Meridian ImmunoCard Mono	-	5	-
Nova Scientific Infectious Mono Latex Assay	-	1	-
OSOM Mono Test	-	4	-
Polymedco PolyStat Mono	-	2	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	-	19	-
Remel Mono-Lex Test	-	8	-
Remel SeraTest MONO	-	5	-
Seradyn Color Slide II Mononucleosis	-	4	-
Wampole Color Card MONO	-	16	-
Wampole Mono-Latex	-	2	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 27 - 100% of participants reported positive.			
All Labs	229	-	-
Alere Acceava Mono Cassette (Inverness)	4	-	-
Arlington Scientific Mono Tests	3	-	-
Beckman Coulter ICON Mono	7	-	-
Biokit Monogen Latex	11	-	-
Cardinal Health Color Mono Latex	4	-	-
Cardinal Health SP Brand Rapid Mono Test	7	-	-
Clearview Mono	30	-	-
Fisher Sure-View Color Mono Latex Test Kit	5	-	-
Fisher Sure-View Mono Latex	65	-	-
Fisher Sure-View Signature Mono Test Kit	10	-	-
Inverness BioStar Acceava Mono/Mono II Test	9	-	-
Inverness Signify MONO TEST	1	-	-
Meridian MonoSpot Latex	5	-	-
Meridian ImmunoCard Mono	5	-	-
Nova Scientific Infectious Mono Latex Assay	1	-	-
OSOM Mono Test	4	-	-
Polymedco PolyStat Mono	2	-	-
Rapid Response BTNX	2	-	-
Remel Color Slide II Mononucleosis	19	-	-
Remel Mono-Lex Test	8	-	-
Remel SeraTest MONO	5	-	-
Seradyn Color Slide II Mononucleosis	4	-	-
Wampole Color Card MONO	16	-	-
Wampole Mono-Latex	2	-	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 28 - 99% of participants reported positive.			
All Labs	227	1	-
Alere Acceava Mono Cassette (Inverness)	4	-	-
Arlington Scientific Mono Tests	3	-	-
Beckman Coulter ICON Mono	7	-	-
Biokit Monogen Latex	11	-	-
Cardinal Health Color Mono Latex	4	-	-
Cardinal Health SP Brand Rapid Mono Test	7	-	-
Clearview Mono	29	1	-
Fisher Sure-View Color Mono Latex Test Kit	5	-	-
Fisher Sure-View Mono Latex	65	-	-
Fisher Sure-View Signature Mono Test Kit	10	-	-
Inverness BioStar Acceava Mono/Mono II Test	9	-	-
Inverness Signify MONO TEST	1	-	-
Meridian MonoSpot Latex	5	-	-
Meridian ImmunoCard Mono	5	-	-
Nova Scientific Infectious Mono Latex Assay	1	-	-
OSOM Mono Test	4	-	-
Polymedco PolyStat Mono	2	-	-
Rapid Response BTNX	2	-	-
Remel Color Slide II Mononucleosis	19	-	-
Remel Mono-Lex Test	8	-	-
Remel SeraTest MONO	5	-	-
Seradyn Color Slide II Mononucleosis	4	-	-
Wampole Color Card MONO	15	-	1
Wampole Mono-Latex	2	-	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 29 - 99% of participants reported negative.			
All Labs	1	228	-
Alere Acceava Mono Cassette (Inverness)	-	4	-
Arlington Scientific Mono Tests	-	3	-
Beckman Coulter ICON Mono	-	7	-
Biokit Monogen Latex	-	11	-
Cardinal Health Color Mono Latex	-	4	-
Cardinal Health SP Brand Rapid Mono Test	-	7	-
Clearview Mono	1	29	-
Fisher Sure-View Color Mono Latex Test Kit	-	5	-
Fisher Sure-View Mono Latex	-	65	-
Fisher Sure-View Signature Mono Test Kit	-	10	-
Inverness BioStar Acceava Mono/Mono II Test	-	9	-
Inverness Signify MONO TEST	-	1	-
Meridian MonoSpot Latex	-	5	-
Meridian ImmunoCard Mono	-	5	-
Nova Scientific Infectious Mono Latex Assay	-	1	-
OSOM Mono Test	-	4	-
Polymedco PolyStat Mono	-	2	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	-	19	-
Remel Mono-Lex Test	-	8	-
Remel SeraTest MONO	-	5	-
Seradyn Color Slide II Mononucleosis	-	4	-
Wampole Color Card MONO	-	16	-
Wampole Mono-Latex	-	2	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 30 - 100% of participants reported negative.			
All Labs	-	229	-
Alere Acceava Mono Cassette (Inverness)	-	4	-
Arlington Scientific Mono Tests	-	3	-
Beckman Coulter ICON Mono	-	7	-
Biokit Monogen Latex	-	11	-
Cardinal Health Color Mono Latex	-	4	-
Cardinal Health SP Brand Rapid Mono Test	-	7	-
Clearview Mono	-	30	-
Fisher Sure-View Color Mono Latex Test Kit	-	5	-
Fisher Sure-View Mono Latex	-	65	-
Fisher Sure-View Signature Mono Test Kit	-	10	-
Inverness BioStar Acceava Mono/Mono II Test	-	9	-
Inverness Signify MONO TEST	-	1	-
Meridian MonoSpot Latex	-	5	-
Meridian ImmunoCard Mono	-	5	-
Nova Scientific Infectious Mono Latex Assay	-	1	-
OSOM Mono Test	-	4	-
Polymedco PolyStat Mono	-	2	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	-	19	-
Remel Mono-Lex Test	-	8	-
Remel SeraTest MONO	-	5	-
Seradyn Color Slide II Mononucleosis	-	4	-
Wampole Color Card MONO	-	16	-
Wampole Mono-Latex	-	2	-

Qualitative Lyme Disease Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 41 - 100% of participants reported positive.			
All Labs	94	-	-
Bio-Rad Evolis	1	-	-
Bio-Rad Platelia Lyme IgG/IgM	2	-	-
bioMerieux VIDAS/mini VIDAS Systems	26	-	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	8	-	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	25	-	-
Immunetics C6 B. burgdorferi EIA Test	8	-	-
Laboratory developed assay	2	-	-
MarDx Lyme Disease EIA (IgM & IgG)	4	-	-
Trinity Biotech B. burgdorferi IgG/IgM	2	-	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	16	-	-
SAMPLE 42 - 99% of participants reported negative.			
All Labs	1	93	-
Bio-Rad Evolis	-	1	-
Bio-Rad Platelia Lyme IgG/IgM	-	2	-
bioMerieux VIDAS/mini VIDAS Systems	1	25	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	8	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	25	-
Immunetics C6 B. burgdorferi EIA Test	-	8	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease EIA (IgM & IgG)	-	4	-
Trinity Biotech B. burgdorferi IgG/IgM	-	2	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	16	-
SAMPLE 43 - 100% of participants reported negative.			
All Labs	-	94	-
Bio-Rad Evolis	-	1	-
Bio-Rad Platelia Lyme IgG/IgM	-	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	26	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	8	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	25	-
Immunetics C6 B. burgdorferi EIA Test	-	8	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease EIA (IgM & IgG)	-	4	-
Trinity Biotech B. burgdorferi IgG/IgM	-	2	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	16	-

Qualitative Lyme Disease Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 44 - 100% of participants reported negative.			
All Labs	-	94	-
Bio-Rad Evolis	-	1	-
Bio-Rad Platelia Lyme IgG/IgM	-	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	26	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	8	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	25	-
Immunetics C6 B. burgdorferi EIA Test	-	8	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease EIA (IgM & IgG)	-	4	-
Trinity Biotech B. burgdorferi IgG/IgM	-	2	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	16	-
SAMPLE 45 - 100% of participants reported negative.			
All Labs	-	94	-
Bio-Rad Evolis	-	1	-
Bio-Rad Platelia Lyme IgG/IgM	-	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	26	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	8	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	25	-
Immunetics C6 B. burgdorferi EIA Test	-	8	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease EIA (IgM & IgG)	-	4	-
Trinity Biotech B. burgdorferi IgG/IgM	-	2	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	16	-

Qualitative Lyme Western Blot IgG - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 41 - 79% of participants reported positive. *			
All Labs	30	8	-
Borrelia B31 ViraStrip IgG (Viramed)	1	5	-
B. burgdoferi B31 IgG Line Blot Test (Gold Standard)	2	1	-
Laboratory developed assay	3	-	-
MarDx Lyme Disease (IgG) Marblot Strip Test	24	2	-
SAMPLE 42 - 100% of participants reported negative.			
All Labs	-	38	-
Borrelia B31 ViraStrip IgG (Viramed)	-	6	-
B. burgdoferi B31 IgG Line Blot Test (Gold Standard)	-	3	-
Laboratory developed assay	-	3	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	26	-
SAMPLE 43 - 100% of participants reported negative.			
All Labs	-	38	-
Borrelia B31 ViraStrip IgG (Viramed)	-	6	-
B. burgdoferi B31 IgG Line Blot Test (Gold Standard)	-	3	-
Laboratory developed assay	-	3	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	26	-
SAMPLE 44 - 100% of participants reported negative.			
All Labs	-	38	-
Borrelia B31 ViraStrip IgG (Viramed)	-	6	-
B. burgdoferi B31 IgG Line Blot Test (Gold Standard)	-	3	-
Laboratory developed assay	-	3	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	26	-
SAMPLE 45 - 100% of participants reported negative.			
All Labs	-	38	-
Borrelia B31 ViraStrip IgG (Viramed)	-	6	-
B. burgdoferi B31 IgG Line Blot Test (Gold Standard)	-	3	-
Laboratory developed assay	-	3	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	26	-

*** Unable to validate sample #41, the target result is positive. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.**

Qualitative Lyme Western Blot IgM - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 41 - 97% of participants reported positive.			
All Labs	36	1	-
Borrelia B31 ViraStrip IgM (Viramed)	6	-	-
B. burgdoferi B31 IgM Line Blot Test (Gold Standard)	3	-	-
Laboratory developed assay	2	-	-
MarDx Lyme Disease (IgM) Marblot Strip Test	25	1	-
SAMPLE 42 - 100% of participants reported negative.			
All Labs	-	37	-
Borrelia B31 ViraStrip IgM (Viramed)	-	6	-
B. burgdoferi B31 IgM Line Blot Test (Gold Standard)	-	3	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	26	-
SAMPLE 43 - 100% of participants reported negative.			
All Labs	-	37	-
Borrelia B31 ViraStrip IgM (Viramed)	-	6	-
B. burgdoferi B31 IgM Line Blot Test (Gold Standard)	-	3	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	26	-
SAMPLE 44 - 100% of participants reported negative.			
All Labs	-	37	-
Borrelia B31 ViraStrip IgM (Viramed)	-	6	-
B. burgdoferi B31 IgM Line Blot Test (Gold Standard)	-	3	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	26	-
SAMPLE 45 - 100% of participants reported negative.			
All Labs	-	37	-
Borrelia B31 ViraStrip IgM (Viramed)	-	6	-
B. burgdoferi B31 IgM Line Blot Test (Gold Standard)	-	3	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	26	-

Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 26 - 99% of participants reported negative.		
All Labs	1	85
Arlington Scientific RF Latex Test	-	5
Beckman Coulter Immage	-	3
Biokit Rheumajet RF Latex	-	12
Cardinal Health SP RF Latex	-	3
Diamedix RF EIA Systems	-	2
Elia RF IgM FEIA (Phadia)	-	1
Fisher Sure-Vue RF Latex	1	33
Beckman Coulter (formerly Olympus) AU System	-	2
Ortho Vitros (all models)	-	2
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2
Remel Seratest RF Latex Test	-	3
Roche Diagnostics Cobas (all systems)	-	2
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA 1200/1650/1800/2400	-	2
Siemens Dimension VISTA	-	2
Siemens Nephelometer Systems (all models)	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	4
True Medix Diagnostics Trutest RF	-	2
Wampole Colorcard RF	-	1
Wampole Rheumatex RF	-	2

SAMPLE 27 - 100% of participants reported positive.		
All Labs	86	-
Arlington Scientific RF Latex Test	5	-
Beckman Coulter Immage	3	-
Biokit Rheumajet RF Latex	12	-
Cardinal Health SP RF Latex	3	-
Diamedix RF EIA Systems	2	-
Elia RF IgM FEIA (Phadia)	1	-
Fisher Sure-Vue RF Latex	34	-
Beckman Coulter (formerly Olympus) AU System	2	-
Ortho Vitros (all models)	2	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	2	-
Remel Seratest RF Latex Test	3	-
Roche Diagnostics Cobas (all systems)	2	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA 1200/1650/1800/2400	2	-
Siemens Dimension VISTA	2	-
Siemens Nephelometer Systems (all models)	1	-
Siemens (Dade Behring) RapiTex Latex Test	4	-
True Medix Diagnostics Trutest RF	2	-
Wampole Colorcard RF	1	-
Wampole Rheumatex RF	2	-

Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 28 - 100% of participants reported positive.		
All Labs	86	-
Arlington Scientific RF Latex Test	5	-
Beckman Coulter Immage	3	-
Beckman Coulter AU System	12	-
Biokit Rheumajet RF Latex	3	-
Cardinal Health SP RF Latex	2	-
Diamedix RF EIA Systems	1	-
Elia RF IgM FEIA (Phadia)	34	-
Fisher Sure-Vue RF Latex	2	-
Ortho Vitros (all models)	2	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	2	-
Remel Seratest RF Latex Test	3	-
Roche Diagnostics Cobas (all systems)	2	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA 1200/1650/1800/2400	2	-
Siemens Dimension VISTA	2	-
Siemens Nephelometer Systems (all models)	1	-
Siemens (Dade Behring) RapiTex Latex Test	4	-
True Medix Diagnostics Trutest RF	2	-
Wampole Colorcard RF	1	-
Wampole Rheumatex RF	2	-

SAMPLE 29 - 100% of participants reported negative.

All Labs	-	86
Arlington Scientific RF Latex Test	-	5
Beckman Coulter Immage	-	3
Biokit Rheumajet RF Latex	-	12
Cardinal Health SP RF Latex	-	3
Diamedix RF EIA Systems	-	2
Elia RF IgM FEIA (Phadia)	-	1
Fisher Sure-Vue RF Latex	-	34
Beckman Coulter (formerly Olympus) AU System	-	2
Ortho Vitros (all models)	-	2
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2
Remel Seratest RF Latex Test	-	3
Roche Diagnostics Cobas (all systems)	-	2
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA 1200/1650/1800/2400	-	2
Siemens Dimension VISTA	-	2
Siemens Nephelometer Systems (all models)	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	4
True Medix Diagnostics Trutest RF	-	2
Wampole Colorcard RF	-	1
Wampole Rheumatex RF	-	2

Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 30 - 99% of participants reported negative.		
All Labs	1	85
Arlington Scientific RF Latex Test	-	5
Beckman Coulter Immage	-	3
Biokit Rheumajet RF Latex	-	12
Cardinal Health SP RF Latex	-	3
Diamedix RF EIA Systems	-	2
Elia RF IgM FEIA (Phadia)	-	1
Fisher Sure-View RF Latex	-	34
Beckman Coulter (formerly Olympus) AU System	-	2
Ortho Vitros (all models)	1	1
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2
Remel Seratest RF Latex Test	-	3
Roche Diagnostics Cobas (all systems)	-	2
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA 1200/1650/1800/2400	-	2
Siemens Dimension VISTA	-	2
Siemens Nephelometer Systems (all models)	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	4
True Medix Diagnostics Trutest RF	-	2
Wampole Colorcard RF	-	1
Wampole Rheumatex RF	-	2

Rheumatoid Factor Titers - Diagnostic Services

The number of laboratories that reported titers is listed for positive test samples 27 and 28.

Primary Test Kit/Assay	No. Labs	Sample 27 Titers					
		< 1:1	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	21	-	-	1	8	7	5
Arlington Scientific RF Latex Test	2	-	-	-	-	-	2
Biokit Rheumajet RF Latex	3	-	-	-	3	-	-
Cardinal Health SP RF Latex	1	-	-	-	-	-	1
Fisher Sure-Vue RF Latex	12	-	-	-	5	6	1
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	1	-	1	-
Wampole Rheumatex RF	1	-	-	-	-	-	1

Primary Test Kit/Assay	No. Labs	Sample 28 Titers					
		< 1:1	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	21	-	-	-	1	9	11
Arlington Scientific RF Latex Test	2	-	-	-	-	-	2
Biokit Rheumajet RF Latex	3	-	-	-	-	2	1
Cardinal Health SP RF Latex	1	-	-	-	-	-	1
Fisher Sure-Vue RF Latex	12	-	-	-	-	6	6
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	-	1	1	-
Wampole Rheumatex RF	1	-	-	-	-	-	1

Semi-Quantitative Rheumatoid Factor - Diagnostic Services

The number of laboratories reporting semi-quantitative results for positive samples 27 and 28.

Primary Test Kit/Assay	No. Labs	Sample 27 Results (IU/ml)					
		< 20	20	40	80	160	≥ 320
All Labs	29	-	1	19	9	-	-
Biokit Rheumajet RF Latex	7	-	-	3	4	-	-
Fisher Sure-Vue RF Latex	17	-	1	12	4	-	-
Remel Seratest RF Latex Test	2	-	-	2	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	1	1	-	-
Wampole Colorcard RF	1	-	-	1	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 28 Results (IU/ml)					
		< 20	20	40	80	160	≥ 320
All Labs	29	-	-	1	21	7	-
Biokit Rheumajet RF Latex	7	-	-	-	4	3	-
Fisher Sure-Vue RF Latex	17	-	-	-	14	3	-
Remel Seratest RF Latex Test	2	-	-	-	2	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	-	1	1	-
Wampole Colorcard RF	1	-	-	1	-	-	-

Quantitative Rheumatoid Factor (RF) IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 26		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		114	44	0.00	20.00	10.00	3.33
Chemiluminescence Total		1	0	-	-	-	-
	Abbott Architect	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		6	4	-	-	3.46	-
	Diamedix RF EIA Systems	3	3	-	-	3.02	-
	Elia RF IgM Flouorezymeimmunoassay (Phadia)	2	0	-	-	-	-
	IMMCO Diagnostics ImmuLisa Rheumatoid Factor - IgM	1	1	-	-	4.80	-
Nephelometry Total		36	0	-	-	-	-
	Beckman Coulter Immage	7	0	-	-	-	-
	Siemens Dimension VISTA	22	0	-	-	-	-
	Siemens Nephelometer Systems (all models)	7	0	-	-	-	-
Turbidimetry Total		71	40	0.00	16.58	8.21	2.79
	Abbott Architect	1	1	-	-	16.20	-
	Beckman Coulter Immage	1	0	-	-	-	-
	Kamiya Biomedical RF	2	2	-	-	6.20	-
	Beckman Coulter (formerly Olympus) AU System	16	6	-	-	9.30	-
	Ortho Vitros (all models)	6	2	-	-	10.05	-
	Roche Diagnostics Cobas (all systems)	21	12	0.51	14.66	7.58	2.36
	Roche Diagnostics RF II	2	1	-	-	10.00	-
	Roche/Hitachi Modular Systems (all models)	11	8	-	-	8.68	-
	Siemens ADVIA 1200/1650/1800/2400	11	8	-	-	8.57	-

Sample 27		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		114	113	22.07	59.01	40.54	6.16
Chemiluminescence Total		1	1	-	-	47.60	-
	Abbott Architect	1	1	-	-	47.60	-
ELISA Enzyme-linked Immunosorbent Assay Total		6	5	-	-	75.07	-
	Diamedix RF EIA Systems	3	3	-	-	98.79	-
	Elia RF IgM Flouorezymeimmunoassay (Phadia)	2	2	-	-	39.50	-
	IMMCO Diagnostics ImmuLisa Rheumatoid Factor - IgM	1	0	-	-	-	-
Nephelometry Total		36	36	25.94	36.98	31.46	1.84
	Beckman Coulter Immage	7	7	-	-	41.90	-
	Siemens Dimension VISTA	22	22	26.73	36.05	31.39	1.55
	Siemens Nephelometer Systems (all models)	7	7	-	-	30.54	-
Turbidimetry Total		71	71	36.69	51.62	44.16	2.49
	Abbott Architect	1	1	-	-	50.60	-
	Beckman Coulter Immage	1	1	-	-	40.90	-
	Kamiya Biomedical RF	2	2	-	-	39.45	-
	Beckman Coulter (formerly Olympus) AU System	16	16	38.25	49.91	44.08	1.94
	Ortho Vitros (all models)	6	6	-	-	40.86	-
	Roche Diagnostics Cobas (all systems)	21	21	40.82	47.41	44.11	1.10
	Roche Diagnostics RF II	2	2	-	-	41.05	-
	Roche/Hitachi Modular Systems (all models)	11	11	42.74	44.75	43.74	0.34
	Siemens ADVIA 1200/1650/1800/2400	11	11	44.16	51.27	47.72	1.18

Quantitative Rheumatoid Factor (RF) IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 28		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		114	113	50.77	97.12	73.94	7.73
Chemiluminescence Total		1	1	-	-	79.30	-
	<i>Abbott Architect</i>	1	1	-	-	79.30	-
ELISA Enzyme-linked Immunosorbent Assay Total		6	5	-	-	103.53	-
	<i>Diamedix RF EIA Systems</i>	3	3	-	-	123.21	-
	<i>Elia RF IgM Flouorezymeimmunoassay (Phadia)</i>	2	2	-	-	74.00	-
	<i>IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM</i>	1	0	-	-	-	-
Nephelometry Total		36	36	53.38	74.59	63.99	3.53
	<i>Beckman Coulter Immage</i>	7	7	-	-	102.91	-
	<i>Siemens Dimension VISTA</i>	22	22	54.64	74.71	64.67	3.34
	<i>Siemens Nephelometer Systems (all models)</i>	7	7	-	-	59.19	-
Turbidimetry Total		71	71	68.70	84.21	76.46	2.59
	<i>Abbott Architect</i>	1	1	-	-	82.00	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	104.00	-
	<i>Kamiya Biomedical RF</i>	2	2	-	-	75.75	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	16	16	70.77	85.19	77.98	2.40
	<i>Ortho Vitros (all models)</i>	6	6	-	-	72.10	-
	<i>Roche Diagnostics Cobas (all systems)</i>	21	21	71.72	81.48	76.60	1.63
	<i>Roche Diagnostics RF II</i>	2	2	-	-	74.90	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	11	11	72.27	79.47	75.87	1.20
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	11	11	38.94	156.52	97.73	19.60

Sample 29		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		114	46	0.00	20.00	10.00	3.33
Chemiluminescence Total		1	0	-	-	-	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		6	4	-	-	3.43	-
	<i>Diamedix RF EIA Systems</i>	3	3	-	-	3.07	-
	<i>Elia RF IgM Flouorezymeimmunoassay (Phadia)</i>	2	0	-	-	-	-
	<i>IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM</i>	1	1	-	-	4.50	-
Nephelometry Total		36	0	-	-	-	-
	<i>Beckman Coulter Immage</i>	7	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	22	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	7	0	-	-	-	-
Turbidimetry Total		71	42	2.36	14.66	8.51	2.05
	<i>Abbott Architect</i>	1	1	-	-	17.00	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Kamiya Biomedical RF</i>	2	1	-	-	3.60	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	16	6	-	-	8.85	-
	<i>Ortho Vitros (all models)</i>	6	2	-	-	9.50	-
	<i>Roche Diagnostics Cobas (all systems)</i>	21	12	2.77	13.66	8.22	1.81
	<i>Roche Diagnostics RF II</i>	2	2	-	-	10.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	11	9	-	-	9.38	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	11	9	-	-	9.67	-

Quantitative Rheumatoid Factor (RF) IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 30		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		114	49	0.00	20.00	10.00	3.33
Chemiluminescence Total		1	0	-	-	-	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		6	4	0.67	5.80	3.23	0.85
	<i>Diamedix RF EIA Systems</i>	3	3	0.63	5.26	2.95	0.77
	<i>Elia RF IgM Fluoroenzymeimmunoassay (Phadia)</i>	2	0	-	-	-	-
	<i>IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM</i>	1	1	4.10	4.10	4.10	0.00
Nephelometry Total		36	0	-	-	-	-
	<i>Beckman Coulter Immage</i>	7	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	22	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	7	0	-	-	-	-
Turbidimetry Total		71	45	2.22	16.73	9.47	2.42
	<i>Abbott Architect</i>	1	1	16.90	16.90	16.90	0.00
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Kamiya Biomedical RF</i>	2	1	8.30	8.30	8.30	0.00
	<i>Beckman Coulter (formerly Olympus) AU System</i>	16	8	0.00	16.60	8.07	2.84
	<i>Ortho Vitros (all models)</i>	6	3	5.70	14.99	10.35	1.55
	<i>Roche Diagnostics Cobas (all systems)</i>	21	13	2.68	15.35	9.02	2.11
	<i>Roche Diagnostics RF II</i>	2	1	13.80	13.80	13.80	0.00
	<i>Roche/Hitachi Modular Systems (all models)</i>	11	8	4.58	15.09	9.84	1.75
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	11	10	4.42	14.44	9.43	1.67

Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 11 - 100% of participants reported negative.		
All Labs	-	130
AtheNa Multi-Lyte MMRV IgG Plus (Zeus Sci.)	-	1
Beckman Coulter ACCESS	-	4
Beckman Coulter UniCel Dxl Systems (all models)	-	5
Bio-Rad Bioplex MMRV IgG	-	5
Bio-Rad Rubella IgG EIA	-	2
Bio-Rad Bioplex Torc IgG	-	1
bioMerieux VIDAS/mini VIDAS Systems	-	12
Clearview Rubella Plus	-	2
Diasorin Liaison Rubella IgG	-	19
Diasorin Rubella IgG ELISA	-	3
Diamedix Rubella EIA Systems IgG	-	2
Fisher Sure-View Rubella	-	8
Ortho Vitros (all models)	-	10
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	5
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	29
Siemens Immulite Systems (all models)	-	2
Trinity Biotech CAPTIA Rubella IgG EIA	-	3
Wampole IMPACT Rubella	-	2
Wampole Rubella IgG ELISA/ELISA II	-	1
Inverness/Wampole Rubella IgG EIA Systems	-	12
SAMPLE 12 - 100% of participants reported negative.		
All Labs	-	130
AtheNa Multi-Lyte MMRV IgG Plus (Zeus Sci.)	-	1
Beckman Coulter ACCESS	-	4
Beckman Coulter UniCel Dxl Systems (all models)	-	5
Bio-Rad Bioplex MMRV IgG	-	5
Bio-Rad Rubella IgG EIA	-	2
Bio-Rad Bioplex Torc IgG	-	1
bioMerieux VIDAS/mini VIDAS Systems	-	12
Clearview Rubella Plus	-	2
Diasorin Liaison Rubella IgG	-	19
Diasorin Rubella IgG ELISA	-	3
Diamedix Rubella EIA Systems IgG	-	2
Fisher Sure-View Rubella	-	8
Ortho Vitros (all models)	-	10
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	5
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	29
Siemens Immulite Systems (all models)	-	2
Trinity Biotech CAPTIA Rubella IgG EIA	-	3
Wampole IMPACT Rubella	-	2
Wampole Rubella IgG ELISA/ELISA II	-	1
Inverness/Wampole Rubella IgG EIA Systems	-	12

Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 13 - 99% of participants reported positive.		
All Labs	129	1
AtheNa Multi-Lyte MMRV IgG Plus (Zeus Sci.)	1	-
Beckman Coulter ACCESS	4	-
Beckman Coulter UniCel DxI Systems (all models)	5	-
Bio-Rad Bioplex MMRV IgG	5	-
Bio-Rad Rubella IgG EIA	2	-
Bio-Rad Bioplex Torc IgG	1	-
bioMerieux VIDAS/mini VIDAS Systems	12	-
Clearview Rubella Plus	2	-
Diasorin Liaison Rubella IgG	19	-
Diasorin Rubella IgG ELISA	3	-
Diamedix Rubella EIA Systems IgG	2	-
Fisher Sure-View Rubella	8	-
Ortho Vitros (all models)	10	-
Remel Ruba-Test	1	-
Roche Diagnostics Cobas (all systems)	5	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA Centaur	29	-
Siemens Immulite Systems (all models)	2	-
Trinity Biotech CAPTIA Rubella IgG EIA	3	-
Wampole IMPACT Rubella	2	-
Wampole Rubella IgG ELISA/ELISA II	1	-
Inverness/Wampole Rubella IgG EIA Systems	11	1
SAMPLE 14 - 99% of participants reported negative.		
All Labs	1	129
AtheNa Multi-Lyte MMRV IgG Plus (Zeus Sci.)	-	1
Beckman Coulter ACCESS	-	4
Beckman Coulter UniCel DxI Systems (all models)	-	5
Bio-Rad Bioplex MMRV IgG	-	5
Bio-Rad Rubella IgG EIA	-	2
Bio-Rad Bioplex Torc IgG	-	1
bioMerieux VIDAS/mini VIDAS Systems	-	12
Clearview Rubella Plus	-	2
Diasorin Liaison Rubella IgG	-	19
Diasorin Rubella IgG ELISA	-	3
Diamedix Rubella EIA Systems IgG	-	2
Fisher Sure-View Rubella	1	7
Ortho Vitros (all models)	-	10
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	5
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	29
Siemens Immulite Systems (all models)	-	2
Trinity Biotech CAPTIA Rubella IgG EIA	-	3
Wampole IMPACT Rubella	-	2
Wampole Rubella IgG ELISA/ELISA II	-	1
Inverness/Wampole Rubella IgG EIA Systems	-	12

Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 15 - 99% of participants reported positive.		
All Labs	129	1
AtheNa Multi-Lyte MMRV IgG Plus (Zeus Sci.)	1	-
Beckman Coulter ACCESS	4	-
Beckman Coulter UniCel Dxl Systems (all models)	5	-
Bio-Rad Bioplex MMRV IgG	5	-
Bio-Rad Rubella IgG EIA	2	-
Bio-Rad Bioplex Torc IgG	1	-
bioMerieux VIDAS/mini VIDAS Systems	12	-
Clearview Rubella Plus	2	-
Diasorin Liaison Rubella IgG	19	-
Diasorin Rubella IgG ELISA	3	-
Diamedix Rubella EIA Systems IgG	2	-
Fisher Sure-View Rubella	8	-
Ortho Vitros (all models)	10	-
Remel Ruba-Test	1	-
Roche Diagnostics Cobas (all systems)	4	1
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA Centaur	29	-
Siemens Immulite Systems (all models)	2	-
Trinity Biotech CAPTIA Rubella IgG EIA	3	-
Wampole IMPACT Rubella	2	-
Wampole Rubella IgG ELISA/ELISA II	1	-
Inverness/Wampole Rubella IgG EIA Systems	12	-

Quantitative Rubella Ab IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 11		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		59	12	0.00	0.95	0.27	0.23
Chemiluminescence Total		55	9	-	-	0.34	-
	Beckman Coulter ACCESS	1	0	-	-	-	-
	Beckman Coulter UniCel DxI Systems (all models)	5	4	-	-	0.35	-
	DiaSorin Liaison Rubella IgG Chemiluminescent Assay	4	0	-	-	-	-
	Ortho Vitros (all models)	6	3	-	-	0.22	-
	Roche Diagnostics Cobas (all systems)	3	0	-	-	-	-
	Roche/Hitachi Modular Systems (all models)	2	0	-	-	-	-
	Siemens ADVIA Centaur	31	2	-	-	0.50	-
	Siemens Immulite Systems (all models)	3	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	0.11	-
	Trinity Biotech CAPTIA Rubella IgG EIA	1	1	-	-	0.11	-
Enzyme Linked Fluorescent Assay (ELFA) Total		2	2	-	-	0.00	-
	bioMerieux VIDAS/mini VIDAS Systems	2	2	-	-	0.00	-
Multiplexed Bead Assay Total		1	0	-	-	-	-
	Bio-Rad Bioplex Torc IgG	1	0	-	-	-	-

Sample 12		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		59	14	0.00	1.07	0.28	0.26
Chemiluminescence Total		55	11	0.00	1.12	0.35	0.25
	Beckman Coulter ACCESS	1	0	-	-	-	-
	Beckman Coulter UniCel DxI Systems (all models)	5	4	-	-	0.35	-
	DiaSorin Liaison Rubella IgG Chemiluminescent Assay	4	0	-	-	-	-
	Ortho Vitros (all models)	6	3	-	-	0.18	-
	Roche Diagnostics Cobas (all systems)	3	0	-	-	-	-
	Roche/Hitachi Modular Systems (all models)	2	0	-	-	-	-
	Siemens ADVIA Centaur	31	4	-	-	99.45	-
	Siemens Immulite Systems (all models)	3	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	0.09	-
	Trinity Biotech CAPTIA Rubella IgG EIA	1	1	-	-	0.09	-
Enzyme Linked Fluorescent Assay (ELFA) Total		2	2	-	-	0.00	-
	bioMerieux VIDAS/mini VIDAS Systems	2	2	-	-	0.00	-
Multiplexed Bead Assay Total		1	0	-	-	-	-
	Bio-Rad Bioplex Torc IgG	1	0	-	-	-	-

Quantitative Rubella Ab IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 13		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		59	16	0.00	667.37	265.67	133.90
Chemiluminescence Total		55	12	0.00	674.82	303.34	123.83
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	357.90	-
	<i>Beckman Coulter UniCel DxI Systems (all models)</i>	5	5	-	-	396.48	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	4	4	-	-	168.00	-
	<i>Ortho Vitros (all models)</i>	6	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	0	-	-	-	-
	<i>Siemens ADVIA Centaur</i>	31	1	-	-	247.80	-
	<i>Siemens Immulite Systems (all models)</i>	3	1	-	-	380.00	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	3.58	-
	<i>Trinity Biotech CAPTIA Rubella IgG EIA</i>	1	1	-	-	3.58	-
Enzyme Linked Fluorescent Assay (ELFA) Total		2	2	-	-	187.50	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	2	-	-	187.50	-
Multiplexed Bead Assay Total		1	1	-	-	232.00	-
	<i>Bio-Rad Bioplex Torc IgG</i>	1	1	-	-	232.00	-

Sample 14		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		59	14	0.00	1.24	0.34	0.30
Chemiluminescence Total		55	11	0.00	1.28	0.43	0.28
	<i>Beckman Coulter ACCESS</i>	1	0	-	-	-	-
	<i>Beckman Coulter UniCel DxI Systems (all models)</i>	5	4	-	-	0.38	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	4	0	-	-	-	-
	<i>Ortho Vitros (all models)</i>	6	3	-	-	0.26	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	0	-	-	-	-
	<i>Siemens ADVIA Centaur</i>	31	4	-	-	5.29	-
	<i>Siemens Immulite Systems (all models)</i>	3	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	0.09	-
	<i>Trinity Biotech CAPTIA Rubella IgG EIA</i>	1	1	-	-	0.09	-
Enzyme Linked Fluorescent Assay (ELFA) Total		2	2	-	-	0.00	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	2	-	-	0.00	-
Multiplexed Bead Assay Total		1	0	-	-	-	-
	<i>Bio-Rad Bioplex Torc IgG</i>	1	0	-	-	-	-

Quantitative Rubella Ab IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 15		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		59	59	0.00	236.44	87.48	49.65
Chemiluminescence Total		55	55	0.00	236.21	92.19	48.01
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	41.30	-
	<i>Beckman Coulter UniCel DxI Systems (all models)</i>	5	5	-	-	43.76	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	4	4	-	-	21.35	-
	<i>Ortho Vitros (all models)</i>	6	6	-	-	47.45	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	182.23	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	160.20	-
	<i>Siemens ADVIA Centaur</i>	31	31	86.04	141.11	113.58	9.18
	<i>Siemens Immulite Systems (all models)</i>	3	3	-	-	34.63	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	2.83	-
	<i>Trinity Biotech CAPTIA Rubella IgG EIA</i>	1	1	-	-	2.83	-
Enzyme Linked Fluorescent Assay (ELFA) Total		2	2	-	-	29.50	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	2	-	-	29.50	-
Multiplexed Bead Assay Total		1	1	-	-	29.00	-
	<i>Bio-Rad Bioplex Torc IgG</i>	1	1	-	-	29.00	-

Qualitative Rubella IgM Specific - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 56 - 100% of participants reported negative.		
All Labs	-	14
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	2
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
Zeus Rubella IgM EIA	-	1
Rubella IgM EIA Systems	-	1
SAMPLE 57 - 100% of participants reported negative.		
All Labs	-	14
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	2
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
Zeus Rubella IgM EIA	-	1
Rubella IgM EIA Systems	-	1
SAMPLE 58 - 100% of participants reported negative.		
All Labs	-	14
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	2
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
Zeus Rubella IgM EIA	-	1
Rubella IgM EIA Systems	-	1
SAMPLE 59 - 100% of participants reported negative.		
All Labs	-	14
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	2
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
Zeus Rubella IgM EIA	-	1
Rubella IgM EIA Systems	-	1
SAMPLE 60 - 100% of participants reported positive.		
All Labs	14	-
DiaSorin Liaison Rubella IgM	3	-
Diamedix Rubella EIA Systems IgM	2	-
Siemens ADVIA Centaur	3	-
Siemens Immulite Systems (all models)	4	-
Zeus Rubella IgM EIA	1	-
Rubella IgM EIA Systems	1	-

Qualitative Syphilis Reagin Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 01 - 99% of participants reported nonreactive.		
All Labs	1	200
Ampcor RPR Card Test	-	3
ASI RPR Card Test for Syphilis	1	40
Becton Dickenson Macro-vue RPR	-	89
Fisher Sure-Vue RPR	-	39
Stanbio Syphilis (RPR) Quicktest	-	1
True Medix Diagnostics Trutest RPR	-	13
Wampole IMPACT RPR	-	15
SAMPLE 02 - 99% of participants reported reactive.		
All Labs	200	1
Ampcor RPR Card Test	3	-
ASI RPR Card Test for Syphilis	40	1
Becton Dickenson Macro-vue RPR	89	-
Fisher Sure-Vue RPR	39	-
Stanbio Syphilis (RPR) Quicktest	1	-
True Medix Diagnostics Trutest RPR	13	-
Wampole IMPACT RPR	15	-
SAMPLE 03 - 99% of participants reported nonreactive.		
All Labs	2	199
Ampcor RPR Card Test	-	3
ASI RPR Card Test for Syphilis	1	40
Becton Dickenson Macro-vue RPR	1	88
Fisher Sure-Vue RPR	-	39
Stanbio Syphilis (RPR) Quicktest	-	1
True Medix Diagnostics Trutest RPR	-	13
Wampole IMPACT RPR	-	15

Qualitative Syphilis Reagin Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 04 - 99% of participants reported reactive.		
All Labs	199	2
Ampcor RPR Card Test	3	-
ASI RPR Card Test for Syphilis	40	1
Becton Dickenson Macro-vue RPR	88	1
Fisher Sure-Vue RPR	39	-
Stanbio Syphilis (RPR) Quicktest	1	-
True Medix Diagnostics Trutest RPR	13	-
Wampole IMPACT RPR	15	-
SAMPLE 05 - 99% of participants reported nonreactive.		
All Labs	1	200
Ampcor RPR Card Test	-	3
ASI RPR Card Test for Syphilis	-	41
Becton Dickenson Macro-vue RPR	1	88
Fisher Sure-Vue RPR	-	1
Stanbio Syphilis (RPR) Quicktest	-	39
True Medix Diagnostics Trutest RPR	-	13
Wampole IMPACT RPR	-	15

Syphilis Reagin Ab (RPR) Titers - Diagnostic Services

The number of laboratories that reported titers is listed for reactive test samples 02 and 04.

Primary Test Kit/Assay	No. Labs	Sample 02 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	190	1	-	24	142	21	1	1
Ampcor RPR Card Test	3	-	-	1	2	-	-	-
ASI RPR Card Test for Syphilis	33	1	-	2	21	9	-	-
Becton Dickinson Macro-vue RPR	88	-	-	8	70	8	1	1
Fisher Sure-Vue RPR	37	-	-	8	26	3	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-	-	1	-	-	-
True Medix Diagnostics Trutest RPR	13	-	-	-	12	1	-	-
Wampole IMPACT RPR	15	-	-	5	10	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 04 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	190	1	21	134	25	7	2	-
Ampcor RPR Card Test	3	-	-	3	-	-	-	-
ASI RPR Card Test for Syphilis	33	1	4	19	8	1	-	-
Becton Dickinson Macro-vue RPR	88	-	5	64	11	6	2	-
Fisher Sure-Vue RPR	37	-	7	26	4	-	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-	1	-	-	-	-
True Medix Diagnostics Trutest RPR	13	-	-	11	2	-	-	-
Wampole IMPACT RPR	15	-	5	10	-	-	-	-

Qualitative Syphilis Reagin Ab - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 21 - 100% of participants reported nonreactive.		
All Labs	-	15
ASI RPR Card Test for Syphilis	-	8
Becton Dickenson Macro-vue RPR	-	7
SAMPLE 22 - 100% of participants reported reactive.		
All Labs	15	-
ASI RPR Card Test for Syphilis	8	-
Becton Dickenson Macro-vue RPR	7	-
SAMPLE 23 - 100% of participants reported nonreactive.		
All Labs	-	15
ASI RPR Card Test for Syphilis	-	8
Becton Dickenson Macro-vue RPR	-	7
SAMPLE 24 - 100% of participants reported reactive.		
All Labs	15	-
ASI RPR Card Test for Syphilis	8	-
Becton Dickenson Macro-vue RPR	7	-
SAMPLE 25 - 100% of participants reported nonreactive.		
All Labs	-	15
ASI RPR Card Test for Syphilis	-	8
Becton Dickenson Macro-vue RPR	-	7

Qualitative Syphilis Treponemal Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Equivocal
SAMPLE 01 - 88% of participants reported nonreactive.			
All Labs	11	83	-
Bio-Rad Bioplex	-	9	-
Bio-Rad Evolis	-	1	-
DiaSorin Liaison Treponemal Assay	-	20	-
Fujirebio Serodia-TP-PA	-	23	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	6	2	-
Scimedx FTA-ABS Test System	-	1	-
Siemens ADVIA Centaur SYPH Assay	-	5	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	1	11	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	10	-
SAMPLE 02 - 100% of participants reported reactive.			
All Labs	94	-	-
Bio-Rad Bioplex	9	-	-
Bio-Rad Evolis	1	-	-
DiaSorin Liaison Treponemal Assay	20	-	-
Fujirebio Serodia-TP-PA	23	-	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	8	-	-
Scimedx FTA-ABS Test System	1	-	-
Siemens ADVIA Centaur SYPH Assay	5	-	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	12	-	-
Wampole IMPACT IFA	1	-	-
Zeus Scientific FTA-ABS	10	-	-
SAMPLE 03 - 88% of participants reported nonreactive.			
All Labs	11	83	-
Bio-Rad Bioplex	-	9	-
Bio-Rad Evolis	-	1	-
DiaSorin Liaison Treponemal Assay	-	20	-
Fujirebio Serodia-TP-PA	-	23	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	6	2	-
Scimedx FTA-ABS Test System	-	1	-
Siemens ADVIA Centaur SYPH Assay	-	5	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	1	11	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	10	-

Qualitative Syphilis Treponemal Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Equivocal
SAMPLE 04 - 100% of participants reported reactive.			
All Labs	94	-	-
Bio-Rad Bioplex	9	-	-
Bio-Rad Evolis	1	-	-
DiaSorin Liaison Treponemal Assay	20	-	-
Fujirebio Serodia-TP-PA	23	-	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	8	-	-
Scimedx FTA-ABS Test System	1	-	-
Siemens ADVIA Centaur SYPH Assay	5	-	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	12	-	-
Wampole IMPACT IFA	1	-	-
Zeus Scientific FTA-ABS	10	-	-
SAMPLE 05 - 87% of participants reported nonreactive.			
All Labs	11	82	-
Bio-Rad Bioplex	-	9	-
Bio-Rad Evolis	-	1	-
DiaSorin Liaison Treponemal Assay	-	20	-
Fujirebio Serodia-TP-PA	-	23	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	6	2	-
Scimedx FTA-ABS Test System	-	1	-
Siemens ADVIA Centaur SYPH Assay	-	5	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	1	11	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	9	1

Qualitative Syphilis Treponemal Ab - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 21 - 100% of participants reported nonreactive.		
All Labs	-	19
DiaSorin Liaison Treponemal Assay	-	1
Fujirebio Serodia-TP-PA	-	3
Beckman Coulter (formerly Olympus) PK-TP System	-	10
Scimedx FTA-ABS Test System	-	3
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	2
SAMPLE 22 - 100% of participants reported reactive.		
All Labs	19	-
DiaSorin Liaison Treponemal Assay	1	-
Fujirebio Serodia-TP-PA	3	-
Beckman Coulter (formerly Olympus) PK-TP System	10	-
Scimedx FTA-ABS Test System	3	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	2	-
SAMPLE 23 - 100% of participants reported nonreactive.		
All Labs	-	19
DiaSorin Liaison Treponemal Assay	-	1
Fujirebio Serodia-TP-PA	-	3
Beckman Coulter (formerly Olympus) PK-TP System	-	10
Scimedx FTA-ABS Test System	-	3
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	2
SAMPLE 24 - 100% of participants reported reactive.		
All Labs	19	-
DiaSorin Liaison Treponemal Assay	1	-
Fujirebio Serodia-TP-PA	3	-
Beckman Coulter (formerly Olympus) PK-TP System	10	-
Scimedx FTA-ABS Test System	3	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	2	-
SAMPLE 25 - 100% of participants reported nonreactive.		
All Labs	-	19
DiaSorin Liaison Treponemal Assay	-	1
Fujirebio Serodia-TP-PA	-	3
Beckman Coulter (formerly Olympus) PK-TP System	-	10
Scimedx FTA-ABS Test System	-	3
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	2

Quantitative Alpha-1 Antitrypsin (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 76		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	37	57.31	163.13	110.22	17.64
Nephelometry Total		23	23	105.86	146.58	126.22	6.79
	Beckman Coulter Immage	4	4	-	-	79.80	-
	Siemens Dimension VISTA	4	4	-	-	117.75	-
	Siemens Nephelometer Systems (all models)	15	15	104.91	148.56	126.73	7.27
Turbidimetry Total		14	14	92.05	106.08	99.06	2.34
	Abbott Architect	1	1	-	-	98.00	-
	Beckman Coulter (formerly Olympus) AU System	2	2	-	-	101.50	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	100.00	-
	Roche/Hitachi Modular Systems (all models)	7	7	-	-	97.99	-

Sample 77		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	4	0.00	11.33	3.30	1.10
Nephelometry Total		23	1	-	-	5.00	-
	Beckman Coulter Immage	4	0	-	-	-	-
	Siemens Dimension VISTA	4	0	-	-	-	-
	Siemens Nephelometer Systems (all models)	15	1	-	-	5.00	-
Turbidimetry Total		14	3	-	-	2.73	-
	Abbott Architect	1	0	-	-	-	-
	Beckman Coulter (formerly Olympus) AU System	2	1	-	-	6.00	-
	Roche Diagnostics Cobas (all systems)	4	1	-	-	2.00	-
	Roche/Hitachi Modular Systems (all models)	7	1	-	-	0.20	-

Sample 78		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	37	53.13	244.39	148.76	31.88
Nephelometry Total		23	23	142.69	211.41	177.05	11.45
	Beckman Coulter Immage	4	4	-	-	96.12	-
	Siemens Dimension VISTA	4	4	-	-	183.00	-
	Siemens Nephelometer Systems (all models)	15	15	146.87	204.06	175.47	9.53
Turbidimetry Total		14	14	115.96	134.84	125.40	3.15
	Abbott Architect	1	1	-	-	128.00	-
	Beckman Coulter (formerly Olympus) AU System	2	2	-	-	130.00	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	125.75	-
	Roche/Hitachi Modular Systems (all models)	7	7	-	-	123.51	-

Quantitative Alpha-1 Antitrypsin (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 79		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	37	65.03	276.60	170.82	35.26
Nephelometry Total		23	23	173.87	228.35	201.11	9.08
	Beckman Coulter Immage	4	4	-	-	115.00	-
	Siemens Dimension VISTA	4	4	-	-	216.00	-
	Siemens Nephelometer Systems (all models)	15	15	181.87	213.41	197.64	5.26
Turbidimetry Total		14	14	128.75	158.42	143.59	4.95
	Abbott Architect	1	1	-	-	149.00	-
	Beckman Coulter (formerly Olympus) AU System	2	2	-	-	146.50	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	146.00	-
	Roche/Hitachi Modular Systems (all models)	7	7	-	-	142.33	-

Sample 80		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	37	45.79	194.06	119.92	24.71
Nephelometry Total		23	23	113.13	170.13	141.63	9.50
	Beckman Coulter Immage	4	4	-	-	81.75	-
	Siemens Dimension VISTA	4	4	-	-	149.00	-
	Siemens Nephelometer Systems (all models)	15	15	114.94	164.40	139.67	8.24
Turbidimetry Total		14	14	90.45	115.42	102.94	4.16
	Abbott Architect	1	1	-	-	110.00	-
	Beckman Coulter (formerly Olympus) AU System	2	2	-	-	109.00	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	96.50	-
	Roche/Hitachi Modular Systems (all models)	7	7	-	-	100.74	-

Quantitative Complement C3 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 76		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		100	100	106.11	135.72	120.92	4.94
Nephelometry Total		30	30	107.50	139.43	123.47	5.32
	<i>Beckman Coulter Immage</i>	6	6	-	-	117.33	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	1	1	-	-	125.00	-
	<i>Siemens Dimension VISTA</i>	12	12	113.19	136.98	125.08	3.96
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	110.31	139.51	124.91	4.87
Turbidimetry Total		70	70	106.78	132.80	119.79	4.34
	<i>Abbott Architect</i>	5	5	-	-	123.80	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	108.90	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	118.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	20	20	108.57	124.87	116.72	2.72
	<i>Ortho Vitros (all models)</i>	4	4	-	-	122.25	-
	<i>Roche Diagnostics Cobas (all systems)</i>	18	18	110.69	134.81	122.75	4.02
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	110.17	129.37	119.77	3.20
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	112.35	126.41	119.38	2.34

Sample 77		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		100	76	8.51	21.45	14.98	2.16
Nephelometry Total		30	28	12.00	20.21	16.10	1.37
	<i>Beckman Coulter Immage</i>	6	6	-	-	13.57	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	1	1	-	-	28.00	-
	<i>Siemens Dimension VISTA</i>	12	10	14.77	17.71	16.24	0.49
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	14.28	20.54	17.41	1.04
Turbidimetry Total		70	48	8.91	19.04	13.98	1.69
	<i>Abbott Architect</i>	5	5	-	-	18.60	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	10.70	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	16.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	20	12	9.62	18.88	14.25	1.54
	<i>Ortho Vitros (all models)</i>	4	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	18	10	8.66	16.98	12.82	1.39
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	9	-	-	14.49	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	9	-	-	14.61	-

Quantitative Complement C3 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 78		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		100	100	91.38	123.13	107.25	5.29
Nephelometry Total		30	30	89.36	129.38	109.37	6.67
	<i>Beckman Coulter Immage</i>	6	6	-	-	98.53	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	1	1	-	-	115.00	-
	<i>Siemens Dimension VISTA</i>	12	12	98.71	123.62	111.17	4.15
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	107.46	119.54	113.50	2.01
Turbidimetry Total		70	70	95.67	117.05	106.36	3.56
	<i>Abbott Architect</i>	5	5	-	-	108.40	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	99.90	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	104.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	20	20	99.95	107.46	103.71	1.25
	<i>Ortho Vitros (all models)</i>	4	4	-	-	110.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	18	18	95.54	122.78	109.16	4.54
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	96.77	116.29	106.53	3.25
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	99.38	112.02	105.70	2.11

Sample 79		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		100	100	93.05	117.52	105.28	4.08
Nephelometry Total		30	30	94.56	120.06	107.31	4.25
	<i>Beckman Coulter Immage</i>	6	6	-	-	99.17	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	1	1	-	-	110.00	-
	<i>Siemens Dimension VISTA</i>	12	12	99.66	116.01	107.83	2.72
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	101.67	117.60	109.64	2.66
Turbidimetry Total		70	70	94.19	115.01	104.60	3.47
	<i>Abbott Architect</i>	5	5	-	-	105.20	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	96.30	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	104.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	20	20	97.54	108.11	102.82	1.76
	<i>Ortho Vitros (all models)</i>	4	4	-	-	106.75	-
	<i>Roche Diagnostics Cobas (all systems)</i>	18	18	95.35	118.16	106.76	3.80
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	98.04	110.82	104.43	2.13
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	95.32	113.98	104.65	3.11

Quantitative Complement C3 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 80		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		100	100	76.38	100.83	88.61	4.07
Nephelometry Total		30	30	73.82	105.48	89.65	5.28
	<i>Beckman Coulter Immage</i>	6	6	-	-	81.70	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	1	1	-	-	90.00	-
	<i>Siemens Dimension VISTA</i>	12	12	82.45	101.29	91.87	3.14
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	78.95	104.14	91.55	4.20
Turbidimetry Total		70	70	80.74	95.63	88.18	2.48
	<i>Abbott Architect</i>	5	5	-	-	87.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	80.55	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	84.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	20	20	83.15	90.81	86.98	1.28
	<i>Ortho Vitros (all models)</i>	4	4	-	-	90.50	-
	<i>Roche Diagnostics Cobas (all systems)</i>	18	18	80.15	100.54	90.34	3.40
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	83.20	94.66	88.93	1.91
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	82.31	93.71	88.01	1.90

Quantitative Complement C4 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 76		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		98	98	17.55	26.61	22.08	1.51
Nephelometry Total		28	28	20.63	24.91	22.77	0.71
	<i>Beckman Coulter Immage</i>	6	6	-	-	22.50	-
	<i>Siemens Dimension VISTA</i>	11	11	21.31	24.49	22.90	0.53
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	22.41	23.47	22.94	0.18
Turbidimetry Total		70	70	17.00	26.62	21.81	1.60
	<i>Abbott Architect</i>	5	5	-	-	22.56	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	21.00	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	25.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	21	19.45	27.51	23.48	1.34
	<i>Ortho Vitros (all models)</i>	4	4	-	-	22.12	-
	<i>Roche Diagnostics Cobas (all models)</i>	17	17	18.17	23.14	20.66	0.83
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	18.44	22.94	20.69	0.75
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	18.74	22.70	20.72	0.66

Sample 77		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		98	21	0.00	2.80	0.86	0.65
Nephelometry Total		28	0	-	-	-	-
	<i>Beckman Coulter Immage</i>	6	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	11	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	11	0	-	-	-	-
Turbidimetry Total		70	21	0.00	2.80	0.86	0.65
	<i>Abbott Architect</i>	5	0	-	-	-	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	0	-	-	-	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	2.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	7	-	-	0.00	-
	<i>Ortho Vitros (all models)</i>	4	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all models)</i>	17	3	-	-	1.17	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	2	-	-	1.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	8	-	-	1.19	-

Quantitative Complement C4 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 78		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		98	98	22.25	34.47	28.36	2.04
Nephelometry Total		28	28	25.99	32.67	29.33	1.11
	<i>Beckman Coulter Immage</i>	6	6	-	-	28.50	-
	<i>Siemens Dimension VISTA</i>	11	11	27.47	31.40	29.44	0.65
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	26.26	33.08	29.67	1.14
Turbidimetry Total		70	70	21.40	34.55	27.97	2.19
	<i>Abbott Architect</i>	5	5	-	-	28.30	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	26.25	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	32.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	21	27.80	33.64	30.72	0.97
	<i>Ortho Vitros (all models)</i>	4	4	-	-	28.35	-
	<i>Roche Diagnostics Cobas (all models)</i>	17	17	24.72	29.07	26.90	0.73
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	23.77	28.97	26.37	0.87
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	23.92	27.84	25.88	0.65

Sample 79		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		98	98	16.75	25.00	20.87	1.37
Nephelometry Total		28	28	19.77	23.87	21.82	0.68
	<i>Beckman Coulter Immage</i>	6	6	-	-	21.52	-
	<i>Siemens Dimension VISTA</i>	11	11	20.09	23.73	21.91	0.61
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	19.94	23.86	21.90	0.65
Turbidimetry Total		70	70	16.29	24.70	20.50	1.40
	<i>Abbott Architect</i>	5	5	-	-	20.82	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	19.50	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	23.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	21	18.42	25.54	21.98	1.19
	<i>Ortho Vitros (all models)</i>	4	4	-	-	20.98	-
	<i>Roche Diagnostics Cobas (all models)</i>	17	17	17.42	21.63	19.52	0.70
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	17.76	21.68	19.72	0.65
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	17.98	20.82	19.40	0.47

Quantitative Complement C4 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 80		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		98	98	12.68	19.76	16.22	1.18
Nephelometry Total		28	28	15.53	18.80	17.17	0.54
	<i>Beckman Coulter Immage</i>	6	6	-	-	16.92	-
	<i>Siemens Dimension VISTA</i>	11	11	16.59	18.49	17.54	0.32
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	15.22	18.65	16.94	0.57
Turbidimetry Total		70	70	12.39	19.29	15.84	1.15
	<i>Abbott Architect</i>	5	5	-	-	16.64	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	14.95	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	18.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	21	13.58	19.94	16.76	1.06
	<i>Ortho Vitros (all models)</i>	4	4	-	-	16.57	-
	<i>Roche Diagnostics Cobas (all models)</i>	17	17	15.00	15.00	15.00	0.00
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	14.03	16.53	15.28	0.42
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	13.54	16.80	15.17	0.54

Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 81		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		107	106	110.58	194.02	152.30	13.91
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
Nephelometry Total		36	36	103.36	207.25	155.31	17.31
	Beckman Coulter Immage	9	9	-	-	135.25	-
	The Binding Site MININEPH	2	2	-	-	146.50	-
	Siemens Dimension/Vista/Xpand (all models)	13	13	151.81	184.35	168.08	5.42
	Siemens Nephelometer Systems (all models)	12	12	137.46	184.21	160.83	7.79
Turbidimetry Total		70	70	115.89	185.62	150.75	11.62
	Abbott Architect	5	5	-	-	152.94	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	140.50	-
	Kamiya Biomedical K-Assay IgA	1	1	-	-	155.00	-
	Beckman Coulter (formerly Olympus) AU System	19	19	145.73	169.52	157.62	3.96
	Ortho Vitros (all models)	4	4	-	-	157.27	-
	Roche Diagnostics Cobas (all systems)	16	16	122.62	154.14	138.38	5.25
	Roche/Hitachi Modular Systems (all models)	10	10	121.99	159.41	140.70	6.24
	Siemens ADVIA 1200/1650/1800/2400	10	10	153.73	178.67	166.20	4.16
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	165.00	-
	SPAplus IgA Kit (The Binding Site)	2	2	-	-	143.00	-

Sample 82		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		107	99	17.99	49.70	33.84	5.28
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
Nephelometry Total		36	35	21.84	48.02	34.93	4.36
	Beckman Coulter Immage	9	8	-	-	27.76	-
	The Binding Site MININEPH	2	2	-	-	36.35	-
	Siemens Dimension/Vista/Xpand (all models)	13	13	32.37	39.01	35.69	1.11
	Siemens Nephelometer Systems (all models)	12	12	33.42	43.88	38.65	1.74
Turbidimetry Total		70	64	16.24	50.26	33.25	5.67
	Abbott Architect	5	5	-	-	38.70	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	36.00	-
	Kamiya Biomedical K-Assay IgA	1	1	-	-	41.00	-
	Beckman Coulter (formerly Olympus) AU System	19	19	31.06	40.88	35.97	1.64
	Ortho Vitros (all models)	4	2	-	-	32.50	-
	Roche Diagnostics Cobas (all systems)	16	15	10.72	43.02	26.87	5.38
	Roche/Hitachi Modular Systems (all models)	10	9	-	-	31.67	-
	Siemens ADVIA 1200/1650/1800/2400	10	8	-	-	34.50	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	36.00	-
	SPAplus IgA Kit (The Binding Site)	2	2	-	-	43.50	-

Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 83		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		107	106	113.52	194.68	154.10	13.53
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
Nephelometry Total		36	36	113.43	207.02	160.23	15.60
	Beckman Coulter Immage	9	9	-	-	136.78	-
	The Binding Site MININEPH	2	2	-	-	151.60	-
	Siemens Dimension/Vista/Xpand (all models)	13	13	156.12	186.34	171.23	5.04
	Siemens Nephelometer Systems (all models)	12	12	147.13	187.53	167.33	6.73
Turbidimetry Total		70	70	117.36	184.53	150.95	11.20
	Abbott Architect	5	5	-	-	153.28	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	144.00	-
	Kamiya Biomedical K-Assay IgA	1	1	-	-	154.00	-
	Beckman Coulter (formerly Olympus) AU System	19	19	149.28	166.76	158.02	2.91
	Ortho Vitros (all models)	4	4	-	-	150.58	-
	Roche Diagnostics Cobas (all systems)	16	16	123.83	159.96	141.89	6.02
	Roche/Hitachi Modular Systems (all models)	10	10	124.12	155.68	139.90	5.26
	Siemens ADVIA 1200/1650/1800/2400	10	10	150.40	183.80	167.10	5.57
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	170.00	-
	SPAplus IgA Kit (The Binding Site)	2	2	-	-	142.00	-

Sample 84		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		107	106	83.84	151.98	117.91	11.36
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
Nephelometry Total		36	36	83.15	160.75	121.95	12.93
	Beckman Coulter Immage	9	9	-	-	104.06	-
	The Binding Site MININEPH	2	2	-	-	105.85	-
	Siemens Dimension/Vista/Xpand (all models)	13	13	116.48	145.06	130.77	4.76
	Siemens Nephelometer Systems (all models)	12	12	107.23	149.77	128.50	7.09
Turbidimetry Total		70	70	86.06	145.61	115.83	9.93
	Abbott Architect	5	5	-	-	121.44	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	110.00	-
	Kamiya Biomedical K-Assay IgA	1	1	-	-	122.00	-
	Beckman Coulter (formerly Olympus) AU System	19	19	109.50	133.38	121.44	3.98
	Ortho Vitros (all models)	4	4	-	-	114.67	-
	Roche Diagnostics Cobas (all systems)	16	16	84.57	130.38	107.47	7.63
	Roche/Hitachi Modular Systems (all models)	10	10	92.67	120.93	106.80	4.71
	Siemens ADVIA 1200/1650/1800/2400	10	10	116.92	141.08	129.00	4.03
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	127.00	-
	SPAplus IgA Kit (The Binding Site)	2	2	-	-	106.00	-

Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 85		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		107	106	80.13	142.79	111.46	10.44
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		36	36	79.88	150.36	115.12	11.75
	<i>Beckman Coulter Immage</i>	9	9	-	-	97.51	-
	<i>The Binding Site MININEPH</i>	2	2	-	-	107.8	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	13	13	114.37	133.32	123.85	3.157
	<i>Siemens Nephelometer Systems (all models)</i>	12	12	107.59	132.58	120.08	4.167
Turbidimetry Total		70	70	81.85	137.29	109.57	9.24
	<i>Abbott Architect</i>	5	5	-	-	114.82	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	103.5	-
	<i>Kamiya Biomedical K-Assay IgA</i>	1	1	-	-	112	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	19	107.82	123.54	115.68	2.62
	<i>Ortho Vitros (all models)</i>	4	4	-	-	106.98	-
	<i>Roche Diagnostics Cobas (all systems)</i>	16	16	79.29	125.43	102.36	7.69
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	87.02	114.18	100.6	4.527
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	108.05	132.35	120.2	4.05
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	122	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	103.5	-

Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 81		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		78	78	84.16	150.62	117.39	11.08
Chemiluminescence Total		44	44	87.09	151.70	119.39	10.77
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	120.74	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	5	5	-	-	111.97	-
	<i>Roche Diagnostics Cobas (all models)</i>	5	5	-	-	117.34	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	5	5	-	-	118.26	-
	<i>Siemens ADVIA Centaur</i>	11	11	92.06	125.67	108.86	5.60
	<i>Siemens Immulite Systems (all models)</i>	17	17	100.33	166.30	133.31	11.00
ELISA Enzyme-linked Immunosorbent Assay (EIA)		3	3	-	-	130.53	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	140.45	-
Fluoroenzyme Immunoassay (FEIA) Total		25	25	81.45	145.51	113.48	10.68
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	23	23	80.57	145.49	113.03	10.82
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	111.50	-
Nephelometry Total		6	6	-	-	113.08	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	111.88	-
	<i>Siemens Nephelometer Systems (all models)</i>	2	2	-	-	115.50	-

Sample 82		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		78	70	1.10	5.79	3.45	0.78
Chemiluminescence Total		44	44	1.72	4.36	3.04	0.44
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	2.78	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	5	5	-	-	2.80	-
	<i>Roche Diagnostics Cobas (all models)</i>	5	5	-	-	3.11	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	5	5	-	-	3.05	-
	<i>Siemens ADVIA Centaur</i>	11	11	0.57	7.01	3.79	1.07
	<i>Siemens Immulite Systems (all models)</i>	17	17	1.76	4.20	2.98	0.41
ELISA Enzyme-linked Immunosorbent Assay (EIA)		3	2	-	-	-	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	0	-	-	-	-
Fluoroenzyme Immunoassay (FEIA) Total		25	24	4.00	4.00	4.00	0.00
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	23	23	4.00	4.00	4.00	0.00
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	0	-	-	-	-
Nephelometry Total		6	0	-	-	-	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	2	0	-	-	-	-

Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 83		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		78	78	12.33	30.67	21.50	3.06
Chemiluminescence Total		44	44	8.95	33.02	20.98	4.01
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	20.63	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	5	5	-	-	21.38	-
	<i>Roche Diagnostics Cobas (all models)</i>	5	5	-	-	21.75	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	5	5	-	-	21.92	-
	<i>Siemens ADVIA Centaur</i>	11	11	11.50	18.87	15.18	1.23
	<i>Siemens Immulite Systems (all models)</i>	17	17	16.89	31.93	24.41	2.51
ELISA Enzyme-linked Immunosorbent Assay (EIA)		3	3	-	-	30.25	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	46.55	-
Fluoroenzyme Immunoassay (FEIA) Total		25	25	16.09	26.94	21.51	1.81
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	23	23	16.29	26.94	21.61	1.77
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	18.60	-
Nephelometry Total		6	6	-	-	22.47	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	22.62	-
	<i>Siemens Nephelometer Systems (all models)</i>	2	2	-	-	22.15	-

Sample 84		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		78	78	235.18	379.20	307.19	24.00
Chemiluminescence Total		44	44	227.92	413.58	320.75	30.94
	<i>Beckman Coulter ACCESS</i>	3	3	-	-	292.56	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	5	5	-	-	297.31	-
	<i>Roche Diagnostics Cobas (all models)</i>	5	5	-	-	306.66	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	5	5	-	-	313.46	-
	<i>Siemens ADVIA Centaur</i>	11	11	261.10	369.90	315.50	18.13
	<i>Siemens Immulite Systems (all models)</i>	17	17	229.79	454.59	342.19	37.47
ELISA Enzyme-linked Immunosorbent Assay (EIA)		3	3	-	-	316.39	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	313.49	-
Fluoroenzyme Immunoassay (FEIA) Total		25	25	231.89	361.05	296.47	21.53
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	23	23	231.25	358.71	294.98	21.24
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	297.00	-
Nephelometry Total		6	6	-	-	299.33	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	304.50	-
	<i>Siemens Nephelometer Systems (all models)</i>	2	2	-	-	289.00	-

Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 85		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		78	78	90.19	133.17	111.68	7.16
Chemiluminescence Total		44	44	83.69	152.82	118.25	11.52
	<i>Beckman Coulter ACCESS</i>	3	3	-	-	112.98	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	5	5	-	-	108.83	-
	<i>Roche Diagnostics Cobas (all models)</i>	5	5	-	-	113.11	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	5	5	-	-	115.02	-
	<i>Siemens ADVIA Centaur</i>	11	11	91.85	125.46	108.65	5.60
	<i>Siemens Immulite Systems (all models)</i>	16	16	107.39	154.24	130.81	7.81
ELISA Enzyme-linked Immunosorbent Assay (EIA)		3	3	-	-	111.74	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	97.55	-
Fluoroenzyme Immunoassay (FEIA) Total		25	25	85.78	131.24	108.51	7.58
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	23	23	84.66	131.71	108.19	7.84
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	113.10	-
Nephelometry Total		6	6	-	-	110.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	111.25	-
	<i>Siemens Nephelometer Systems (all models)</i>	2	2	-	-	107.50	-

Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 81		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		104	104	552.98	921.63	737.30	61.44
Nephelometry Total		34	34	573.92	956.54	765.23	63.77
	Beckman Coulter Immage	8	8	-	-	760.50	-
	The Binding Site MININEPH	1	1	-	-	831.80	-
	Siemens Dimension/Vista/Xpand (all models)	13	13	557.65	929.42	743.54	61.96
	Siemens Nephelometer Systems (all models)	12	12	589.75	982.92	786.33	65.53
Turbidimetry Total		70	70	544.85	908.08	726.46	60.54
	Abbott Architect	4	4	-	-	727.25	-
	Beckman Coulter Synchron LX/Unicel Systems	2	2	-	-	728.50	-
	Laboratory developed assay	1	1	-	-	797.79	-
	Beckman Coulter (formerly Olympus) AU System	19	19	546.76	911.27	729.02	60.75
	Ortho Vitros (all models)	4	4	-	-	869.41	-
	Roche Diagnostics Cobas (all systems)	15	15	558.80	931.33	745.07	62.09
	Roche/Hitachi Modular Systems (all models)	12	12	530.70	884.50	707.60	58.97
	Siemens ADVIA 1200/1650/1800/2400	10	10	538.95	898.25	718.60	59.88
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	764.00	-
	SPAplus IgG Kit (The Binding Site)	2	2	-	-	731.00	-

Sample 82		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		104	93	116.39	193.98	155.18	12.93
Nephelometry Total		34	33	125.18	208.64	166.91	13.91
	Beckman Coulter Immage	8	7	-	-	174.17	-
	The Binding Site MININEPH	1	1	-	-	197.20	-
	Siemens Dimension/Vista/Xpand (all models)	13	13	122.83	204.71	163.77	13.65
	Siemens Nephelometer Systems (all models)	12	12	123.12	205.21	164.17	13.68
Turbidimetry Total		70	60	111.70	186.16	148.93	12.41
	Abbott Architect	4	4	-	-	144.00	-
	Beckman Coulter Synchron LX/Unicel Systems	2	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
	Beckman Coulter (formerly Olympus) AU System	19	19	104.04	173.39	138.72	11.56
	Ortho Vitros (all models)	4	1	-	-	185.00	-
	Roche Diagnostics Cobas (all systems)	15	14	118.79	197.98	158.38	13.20
	Roche/Hitachi Modular Systems (all models)	12	11	118.97	198.28	158.62	13.22
	Siemens ADVIA 1200/1650/1800/2400	10	8	-	-	143.38	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	166.00	-
	SPAplus IgG Kit (The Binding Site)	2	2	-	-	172.50	-

Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 83		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		104	104	406.49	677.48	541.98	45.17
Nephelometry Total		34	34	423.95	706.59	565.27	47.11
	Beckman Coulter Immage	8	8	-	-	545.25	-
	The Binding Site MININEPH	1	1	-	-	676.60	-
	Siemens Dimension/Vista/Xpand (all models)	13	13	422.71	704.52	563.62	46.97
	Siemens Nephelometer Systems (all models)	12	12	435.31	725.52	580.42	48.37
Turbidimetry Total		70	70	399.13	665.22	532.18	44.35
	Abbott Architect	4	4	-	-	527.75	-
	Beckman Coulter Synchron LX/Unicel Systems	2	2	-	-	543.50	-
	Laboratory developed assay	1	1	-	-	567.09	-
	Beckman Coulter (formerly Olympus) AU System	19	19	392.98	654.96	523.97	43.66
	Ortho Vitros (all models)	4	4	-	-	562.65	-
	Roche Diagnostics Cobas (all systems)	15	15	409.70	682.83	546.27	45.52
	Roche/Hitachi Modular Systems (all models)	12	12	382.94	638.23	510.58	42.55
	Siemens ADVIA 1200/1650/1800/2400	10	10	396.53	660.88	528.70	44.06
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	601.00	-
	SPAplus IgG Kit (The Binding Site)	2	2	-	-	532.00	-

Sample 84		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		104	104	427.00	711.67	569.34	47.44
Nephelometry Total		34	34	446.34	743.91	595.12	49.59
	Beckman Coulter Immage	8	8	-	-	578.75	-
	The Binding Site MININEPH	1	1	-	-	682.50	-
	Siemens Dimension/Vista/Xpand (all models)	13	13	447.63	746.06	596.85	49.74
	Siemens Nephelometer Systems (all models)	12	12	453.75	756.25	605.00	50.42
Turbidimetry Total		70	70	417.44	695.74	556.59	46.38
	Abbott Architect	4	4	-	-	547.25	-
	Beckman Coulter Synchron LX/Unicel Systems	2	2	-	-	575.00	-
	Laboratory developed assay	1	1	-	-	600.61	-
	Beckman Coulter (formerly Olympus) AU System	19	19	414.43	690.72	552.57	46.05
	Ortho Vitros (all models)	4	4	-	-	593.16	-
	Roche Diagnostics Cobas (all systems)	15	15	428.95	714.92	571.93	47.66
	Roche/Hitachi Modular Systems (all models)	12	12	399.30	665.50	532.40	44.37
	Siemens ADVIA 1200/1650/1800/2400	10	10	415.20	692.00	553.60	46.13
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	604.00	-
	SPAplus IgG Kit (The Binding Site)	2	2	-	-	562.00	-

Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 85		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		104	104	314.70	524.50	419.60	34.97
Nephelometry Total		34	34	330.70	551.17	440.94	36.74
	<i>Beckman Coulter Immage</i>	8	8	-	-	438.00	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	513.40	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	13	13	331.21	552.02	441.62	36.80
	<i>Siemens Nephelometer Systems (all models)</i>	12	12	331.62	552.71	442.17	36.85
Turbidimetry Total		70	70	306.15	510.25	408.20	34.02
	<i>Abbott Architect</i>	4	4	-	-	406.75	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	2	2	-	-	427.00	-
	<i>Laboratory developed assay</i>	1	1	-	-	443.77	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	19	301.58	502.64	402.11	33.51
	<i>Ortho Vitros (all models)</i>	4	4	-	-	430.31	-
	<i>Roche Diagnostics Cobas (all systems)</i>	15	15	312.48	520.80	416.64	34.72
	<i>Roche/Hitachi Modular Systems (all models)</i>	12	12	289.94	483.23	386.58	32.22
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	306.90	511.50	409.20	34.10
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	454.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	433.50	-

Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 81		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		102	102	42.37	65.48	53.93	3.85
Nephelometry Total		33	33	47.70	65.95	56.83	3.04
	<i>Beckman Coulter Immage</i>	8	8	-	-	54.91	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	13	13	50.14	66.55	58.34	2.73
	<i>Siemens Nephelometer Systems (all models)</i>	12	12	47.43	65.74	56.58	3.05
Turbidimetry Total		69	69	42.28	62.84	52.56	3.43
	<i>Abbott Architect</i>	4	4	-	-	55.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	54.50	-
	<i>Laboratory developed assay</i>	1	1	-	-	60.90	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	19	46.27	56.45	51.36	1.70
	<i>Ortho Vitros (all models)</i>	4	4	-	-	52.91	-
	<i>Roche Diagnostics Cobas (all systems)</i>	16	16	42.16	58.98	50.57	2.80
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	41.83	62.09	51.96	3.38
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	49.08	63.81	56.44	2.46
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	57.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	50.50	-

Sample 82		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		102	73	4.17	28.07	16.12	3.98
Nephelometry Total		33	29	7.43	29.16	18.29	3.62
	<i>Beckman Coulter Immage</i>	8	7	-	-	13.59	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	13	12	17.66	24.04	20.85	1.06
	<i>Siemens Nephelometer Systems (all models)</i>	12	10	7.70	29.34	18.52	3.61
Turbidimetry Total		69	44	3.98	25.40	14.69	3.57
	<i>Abbott Architect</i>	4	3	-	-	16.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	1	-	-	16.40	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	7	-	-	17.00	-
	<i>Ortho Vitros (all models)</i>	4	1	-	-	21.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	16	12	6.43	17.58	12.01	1.86
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	9	-	-	11.43	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	8	-	-	16.88	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	19.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	18.50	-

Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 83		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		102	101	27.52	43.80	35.66	2.71
Nephelometry Total		33	33	28.63	44.47	36.55	2.64
	<i>Beckman Coulter Immage</i>	8	8	-	-	34.85	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	13	13	29.76	43.58	36.67	2.30
	<i>Siemens Nephelometer Systems (all models)</i>	12	12	30.86	44.24	37.55	2.23
Turbidimetry Total		69	68	26.81	43.88	35.35	2.85
	<i>Abbott Architect</i>	4	4	-	-	36.75	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	36.00	-
	<i>Laboratory developed assay</i>	1	1	-	-	39.40	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	19	34.76	38.43	36.59	0.61
	<i>Ortho Vitros (all models)</i>	4	4	-	-	35.15	-
	<i>Roche Diagnostics Cobas (all systems)</i>	16	15	27.07	41.52	34.29	2.41
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	25.26	39.69	32.48	2.41
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	26.86	46.94	36.90	3.35
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	36.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	32.00	-

Sample 84		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		102	102	71.62	101.05	86.34	4.91
Nephelometry Total		33	33	77.40	102.38	89.89	4.16
	<i>Beckman Coulter Immage</i>	8	8	-	-	86.31	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	13	13	80.92	101.42	91.17	3.42
	<i>Siemens Nephelometer Systems (all models)</i>	12	12	81.92	98.19	90.05	2.71
Turbidimetry Total		69	69	71.72	97.56	84.64	4.31
	<i>Abbott Architect</i>	4	4	-	-	87.25	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	82.50	-
	<i>Laboratory developed assay</i>	1	1	-	-	85.30	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	19	74.41	86.96	80.68	2.09
	<i>Ortho Vitros (all models)</i>	4	4	-	-	83.44	-
	<i>Roche Diagnostics Cobas (all systems)</i>	16	16	76.54	98.80	87.67	3.71
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	71.96	94.70	83.33	3.79
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	80.79	93.87	87.33	2.18
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	87.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	85.00	-

Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

Sample 85		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		102	102	39.86	59.98	49.92	3.35
Nephelometry Total		33	33	42.68	62.32	52.50	3.27
	<i>Beckman Coulter Immage</i>	8	8	-	-	48.86	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	13	13	48.53	58.87	53.70	1.72
	<i>Siemens Nephelometer Systems (all models)</i>	12	12	43.94	63.29	53.62	3.23
Turbidimetry Total		69	69	41.29	55.80	48.54	2.42
	<i>Abbott Architect</i>	4	4	-	-	51.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	48.50	-
	<i>Laboratory developed assay</i>	1	1	-	-	51.90	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	19	43.53	52.35	47.94	1.47
	<i>Ortho Vitros (all models)</i>	4	4	-	-	47.38	-
	<i>Roche Diagnostics Cobas (all systems)</i>	16	16	42.01	54.34	48.17	2.05
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	39.26	56.43	47.84	2.86
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	10	44.42	56.47	50.44	2.01
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	53.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	45.50	-