

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

Proficiency Testing Program

September 9, 2015

**DIAGNOSTIC IMMUNOLOGY
SUMMARY ANALYSIS**

**Diagnostic Immunology
Proficiency Test Event
September 9, 2015**

Summary Analysis

Steven Bush M.S., Susan Wong Ph.D., and Mary Marchewka

Table of Contents

Review of Grading Policy	Page 5
Determination of Acceptable Responses	Page 6
Qualitative / Semi-quantitative Test Analytes	
Antinuclear Ab	Page 7 - 10
Antistreptolysin O	Page 11 - 15
Cytomegalovirus Ab	Page 16 - 18
Hepatitis B Core Ab	Page 19 - 21
Hepatitis B Surface Ag Screening/ Confirmation	Page 22 - 27
Hepatitis Be Ag	Page 28
Hepatitis C Ab	Page 29 - 31
HIV Ab Screening/ Confirmation	Page 32 - 36
HTLV-1 Ab	Page 37 - 38
Infectious Mononucleosis	Page 39 - 43
Lyme Disease (<u>Borrelia burgdorferi</u>) Ab	Page 44 - 47
Rheumatoid Factor	Page 48 - 54
Rubella Ab IgG	Page 55 - 60
Rubella IgM	Page 61
Syphilis-Reagin	Page 62 - 65
Syphilis-Treponemal Ab	Page 66 - 68
Quantitative Test Analytes	
Alpha-1 Antitrypsin	Page 69 - 70
Complement C'3	Page 71 - 73
Complement C'4	Page 74 - 76
Immunoglobulin A	Page 77 - 79
Immunoglobulin E	Page 80 - 82
Immunoglobulin G	Page 83 - 85
Immunoglobulin M	Page 86 - 88

The data summarized in this report were tabulated from proficiency test results and accompanying information submitted by laboratories that participated in the September 9, 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 - 100% of participants reported negative.			
All Labs	-	100	-
AESKULISA ANA	-	1	-
Bio-Rad Bioplex	-	8	-
BioRad EIA Systems (any)	-	7	-
BioRad/Kallestad IFA Systems (any)	-	18	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	3	-
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)	-	5	-
RhiGene Fluor ANA IFA Test	-	2	-
Sanofi/Kallestad Quantifluor IFA Kit	-	1	-
Trinity Biotech ANA EIA Test	-	3	-
Wampole ANA EIA	-	3	-
Wampole/Zeus ANA IFA Hep-2	-	17	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	3	-

SAMPLE 47 - 98% of participants reported positive.			
All Labs	98	2	-
AESKULISA ANA	1	-	-
Bio-Rad Bioplex	8	-	-
BioRad EIA Systems (any)	7	-	-
BioRad/Kallestad IFA Systems (any)	18	-	-
DiaSorin ANA Screen EIA	1	-	-
Diamedix EIA Systems (any)	3	-	-
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	9	2	-
INOVA Novalite/Quanta Lite	7	-	-
Phadia/Pharmacia Immunocap/UniCap (all models)	5	-	-
RhiGene Fluor ANA IFA Test	2	-	-
Sanofi/Kallestad Quantifluor IFA Kit	1	-	-
Trinity Biotech ANA EIA Test	3	-	-
Wampole ANA EIA	3	-	-
Wampole/Zeus ANA IFA Hep-2	17	-	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	3	-	-

Qualitative Antinuclear Ab (ANA) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 48 - 100% of participants reported positive.			
All Labs	100	-	-
AESKULISA ANA	1	-	-
Bio-Rad Bioplex	8	-	-
BioRad EIA Systems (any)	7	-	-
BioRad/Kallestad IFA Systems (any)	18	-	-
DiaSorin ANA Screen EIA	1	-	-
Diamedix EIA Systems (any)	3	-	-
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)	5	-	-
RhiGene Fluor ANA IFA Test	2	-	-
Sanofi/Kallestad Quantifluor IFA Kit	1	-	-
Trinity Biotech ANA EIA Test	3	-	-
Wampole ANA EIA	3	-	-
Wampole/Zeus ANA IFA Hep-2	17	-	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	3	-	-

SAMPLE 49 - 98% of participants reported negative.			
All Labs	-	98	2
AESKULISA ANA	-	1	-
Bio-Rad Bioplex	-	8	-
BioRad EIA Systems (any)	-	7	-
BioRad/Kallestad IFA Systems (any)	-	17	1
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	3	-
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)	-	4	1
RhiGene Fluor ANA IFA Test	-	2	-
Sanofi/Kallestad Quantifluor IFA Kit	-	1	-
Trinity Biotech ANA EIA Test	-	3	-
Wampole ANA EIA	-	3	-
Wampole/Zeus ANA IFA Hep-2	-	17	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	3	-

Qualitative Antinuclear Ab (ANA) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 50 - 98% of participants reported negative.			
All Labs	2	98	-
AESKULISA ANA	-	1	-
Bio-Rad Bioplex	-	8	-
BioRad EIA Systems (any)	-	7	-
BioRad/Kallestad IFA Systems (any)	-	18	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	3	-
DiaSorin ANA IFA Systems	-	1	-
Hycor Autostat II EIA	-	1	-
Immuno Concepts IFA Systems (any)	1	6	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	11	-
INOVA Novalite/Quanta Lite	-	7	-
Phadia/Pharmacia Immunocap/UniCap (all models)	1	4	-
RhiGene Fluor ANA IFA Test	-	2	-
Sanofi/Kallestad Quantifluor IFA Kit	-	1	-
Trinity Biotech ANA EIA Test	-	3	-
Wampole ANA EIA	-	3	-
Wampole/Zeus ANA IFA Hep-2	-	17	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	3	-

Antinuclear Ab (ANA) IFA Titers - Diagnostic Services

The number of laboratories that reported titers is listed for positive test samples 47 and 48.

Primary Test Kit/Assay	No. Labs	Sample 47 Titers							
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280	≥ 1:2560
All Labs	76	3	3	9	9	19	24	7	2
Antibodies Inc. ANA IFA	1	-	-	-	-	-	1	-	-
BioRad/Kallestad IFA Systems (any)	24	1	-	-	2	10	9	1	1
DiaSorin ANA IFA Systems	1	-	1	-	-	-	-	-	-
Immuno Concepts IFA Systems (any)	8	-	1	4	1	1	1	-	-
IMMCO Diagnostics IFA	2	-	-	1	-	-	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	17	2	1	2	2	2	4	4	-
RhiGene Fluor ANA IFA Test	2	-	-	-	2	-	-	-	-
Sanofi/Kallestad Quantifluor IFA Kit	1	-	-	-	-	-	-	1	-
Wampole/Zeus ANA IFA Hep-2	20	-	-	2	2	6	8	1	1

Staining Pattern - A total of 72 labs reported a staining pattern, of those 63 labs (88%) reported speckled, 5 labs (7%) nucleolar, and 4 labs (5%) homogenous. The reporting of a staining pattern here is for informational purposes only and is not graded.

Primary Test Kit/Assay	No. Labs	Sample 48 Titers							
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280	≥ 1:2560
All Labs	76	1	-	4	18	29	22	2	-
Antibodies Inc. ANA IFA	1	-	-	-	-	1	-	-	-
BioRad/Kallestad IFA Systems (any)	24	1	-	2	8	10	3	-	-
DiaSorin ANA IFA Systems	1	-	-	-	-	1	-	-	-
Immuno Concepts IFA Systems (any)	8	-	-	-	1	2	5	-	-
IMMCO Diagnostics IFA	2	-	-	-	-	2	-	-	-
INOVA IFA Systems/NOVA Lite Hep-2	17	-	-	-	2	5	9	1	-
RhiGene Fluor ANA IFA Test	2	-	-	-	1	1	-	-	-
Sanofi/Kallestad Quantifluor IFA Kit	1	-	-	-	-	1	-	-	-
Wampole/Zeus ANA IFA Hep-2	20	-	-	2	6	6	5	1	-

Staining Pattern - A total of 75 labs reported a staining pattern, of those 74 labs (95%) reported homogenous and 4 labs (5%) 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 - 98% of participants reported negative.		
All Labs	-	45
Aeroset-Muligent Quantia ASO	-	1
Arlington Scientific ASO Latex Test *	-	2
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	1
BioKit Rheumajet ASO Latex Test	-	9
Fisher Sure-Vue ASO Latex Test	-	17
Remel Seratest ASO Latex Test	-	2
Siemens (Dade Behring) RapiTex Latex Test	-	10
True Medix Trutest Latex Test	-	1
Wampole Color Card ASO Latex Test	-	1
* One Laboratory reported invalid		

SAMPLE 17 - 98% of participants reported positive.		
All Labs	45	-
Aeroset-Muligent Quantia ASO	1	-
Arlington Scientific ASO Latex Test *	2	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	1	-
BioKit Rheumajet ASO Latex Test	9	-
Fisher Sure-Vue ASO Latex Test	17	-
Remel Seratest ASO Latex Test	2	-
Siemens (Dade Behring) RapiTex Latex Test	10	-
True Medix Trutest Latex Test	1	-
Wampole Color Card ASO Latex Test	1	-
* One Laboratory reported invalid		

SAMPLE 18 - 98% of participants reported negative.		
All Labs	-	45
Aeroset-Muligent Quantia ASO	-	1
Arlington Scientific ASO Latex Test *	-	2
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	1
BioKit Rheumajet ASO Latex Test	-	9
Fisher Sure-Vue ASO Latex Test	-	17
Remel Seratest ASO Latex Test	-	2
Siemens (Dade Behring) RapiTex Latex Test	-	10
True Medix Trutest Latex Test	-	1
Wampole Color Card ASO Latex Test	-	1
* One Laboratory reported invalid		

Qualitative Antistreptolysin O - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 19 - 98% of participants reported positive.		
All Labs	45	-
Aeroset-Muligent Quantia ASO	1	-
Arlington Scientific ASO Latex Test *	2	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	1	-
BioKit Rheumajet ASO Latex Test	9	-
Fisher Sure-View ASO Latex Test	17	-
Remel Seratest ASO Latex Test	2	-
Siemens (Dade Behring) RapiTex Latex Test	10	-
True Medix Trutest Latex Test	1	-
Wampole Color Card ASO Latex Test	1	-
* One Laboratory reported invalid		

SAMPLE 20 - 98% of participants reported negative.		
All Labs	-	45
Aeroset-Muligent Quantia ASO	-	1
Arlington Scientific ASO Latex Test *	-	2
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	1
BioKit Rheumajet ASO Latex Test	-	9
Fisher Sure-View ASO Latex Test	-	17
Remel Seratest ASO Latex Test	-	2
Siemens (Dade Behring) RapiTex Latex Test	-	10
True Medix Trutest Latex Test	-	1
Wampole Color Card ASO Latex Test	-	1
* One Laboratory reported invalid		

Antistreptolysin O (ASO) Titers - Diagnostic Services

The number of laboratories that reported titers for positive test samples 17 and 19.

Primary Test Kit/Assay	No. Labs	Sample 17 Titers					
		< 1:1	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	8	-	1	5	2	-	-
Arlington Scientific ASO Latex Test	2	-	-	-	2	-	-
BioKit Rheumajet ASO Latex Test	1	-	1	-	-	-	-
Fisher Sure-Vue ASO Latex Test	3	-	-	3	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	2	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 19 Titers					
		< 1:1	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	8	-	1	6	-	1	-
Arlington Scientific ASO Latex Test	2	-	-	1	-	1	-
BioKit Rheumajet ASO Latex Test	1	-	-	1	-	-	-
Fisher Sure-Vue ASO Latex Test	3	-	-	3	-	-	-
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 17 and 19.

Primary Test Kit/Assay	No. Labs	Sample 17 Results (IU/ml)					
		< 200	200	400	800	1600	≥ 3200
All Labs	32	1	16	15	-	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	8	-	4	4	-	-	-
Fisher Sure-Vue ASO Latex Test	12	-	8	4	-	-	-
Remel Seratest ASO Latex Test	3	1	1	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	8	-	2	6	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 19 Results (IU/ml)					
		< 200	200	400	800	1600	≥ 3200
All Labs	32	1	16	14	1	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	8	-	2	5	1	-	-
Fisher Sure-Vue ASO Latex Test	12	-	7	5	-	-	-
Remel Seratest ASO Latex Test	3	1	1	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	8	-	5	3	-	-	-

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 *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		58	40	0.00	100.00	50.00	16.67
Nephelometry Total		18	14	36.54	49.97	43.25	2.24
	Beckman Coulter Immage	3	3	-	-	34.73	-
	Siemens Dimension VISTA	8	5	-	-	46.86	-
	Siemens Nephelometer Systems (all models)	7	6	-	-	43.02	-
Turbidimetry Total		40	26	21.09	57.25	39.17	6.03
	Abbott Architect	2	0	-	-	-	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	1	-	-	2.60	-
	Beckman Coulter (formerly Olympus) AU System	13	4	-	-	28.25	-
	Roche Diagnostics Cobas (all systems)	14	14	36.19	48.13	42.16	1.99
	Roche/Hitachi Modular Systems (all models)	3	3	-	-	40.70	-
	Siemens ADVIA 1200/1650/1800/2400	5	4	-	-	36.02	-

Sample 17		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		58	58	147.99	513.97	330.98	61.00
Nephelometry Total		18	18	274.55	324.78	299.67	8.37
	Beckman Coulter Immage	3	3	-	-	188.67	-
	Siemens Dimension VISTA	8	8	-	-	300.29	-
	Siemens Nephelometer Systems (all models)	7	7	-	-	296.29	-
Turbidimetry Total		40	40	190.16	516.63	353.39	54.41
	Abbott Architect	2	2	-	-	257.85	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	3	-	-	224.47	-
	Beckman Coulter (formerly Olympus) AU System	13	13	367.90	409.82	388.86	6.99
	Roche Diagnostics Cobas (all systems)	14	14	266.51	458.10	362.31	31.93
	Roche/Hitachi Modular Systems (all models)	3	3	-	-	336.87	-
	Siemens ADVIA 1200/1650/1800/2400	5	5	-	-	382.48	-

Sample 18		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		58	40	0.00	100.00	50.00	16.67
Nephelometry Total		18	15	39.69	47.26	43.48	1.26
	Beckman Coulter Immage	3	3	-	-	27.93	-
	Siemens Dimension VISTA	8	6	-	-	49.55	-
	Siemens Nephelometer Systems (all models)	7	6	-	-	43.43	-
Turbidimetry Total		40	25	21.41	58.91	40.16	6.25
	Abbott Architect	2	0	-	-	-	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	1	-	-	2.00	-
	Beckman Coulter (formerly Olympus) AU System	13	4	-	-	29.00	-
	Roche Diagnostics Cobas (all systems)	14	14	36.15	51.78	43.96	2.61
	Roche/Hitachi Modular Systems (all models)	3	3	-	-	42.40	-
	Siemens ADVIA 1200/1650/1800/2400	5	3	-	-	35.03	-

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		58	58	302.79	506.10	404.44	33.88
Nephelometry Total		18	18	377.13	454.07	415.60	12.82
	Beckman Coulter Immage	3	3	-	-	222.33	-
	Siemens Dimension VISTA	8	8	-	-	413.12	-
	Siemens Nephelometer Systems (all models)	7	7	-	-	418.43	-
Turbidimetry Total		40	40	180.50	577.61	379.05	66.18
	Abbott Architect	2	2	-	-	247.75	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	3	-	-	226.13	-
	Beckman Coulter (formerly Olympus) AU System	13	13	335.37	386.44	360.91	8.51
	Roche Diagnostics Cobas (all systems)	14	14	383.99	479.13	431.56	15.86
	Roche/Hitachi Modular Systems (all models)	3	3	-	-	420.20	-
	Siemens ADVIA 1200/1650/1800/2400	5	5	-	-	412.58	-

Sample 20		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		58	39	0.00	100.00	50.00	16.67
Nephelometry Total		18	13	40.50	45.25	42.88	0.79
	Beckman Coulter Immage	3	2	-	-	31.60	-
	Siemens Dimension VISTA	8	5	-	-	49.12	-
	Siemens Nephelometer Systems (all models)	7	6	-	-	42.77	-
Turbidimetry Total		40	26	20.51	59.86	40.19	6.56
	Abbott Architect	2	0	-	-	-	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	1	-	-	11.50	-
	Beckman Coulter (formerly Olympus) AU System	13	4	-	-	29.50	-
	Roche Diagnostics Cobas (all systems)	14	14	34.12	54.83	44.47	3.45
	Roche/Hitachi Modular Systems (all models)	3	3	-	-	41.17	-
	Siemens ADVIA 1200/1650/1800/2400	5	4	-	-	35.15	-

Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 11 - 98% of participants reported negative.			
All Labs	1	58	-
Bio-Rad CMV IgG EIA	-	2	-
Bio-Rad Bioplex Torc IgG	-	5	-
bioMerieux VIDAS/mini VIDAS Systems	-	14	-
Diamedix CMV EIA Systems (any)	-	2	-
DiaSorin Liaison CMV IgG	-	13	-
Immucor Capture CMV	1	-	-
Siemens Immulite Systems (all models)	-	7	-
Trinity Biotech CAPTIA CMV IgG EIA	-	2	-
Wampole Zeus Scientific CMV IgG ELISA	-	3	-
Zeus Scientific CMV IgG EIA	-	10	-

SAMPLE 12 - 100% of participants reported positive.			
All Labs	59	-	-
Bio-Rad CMV IgG EIA	2	-	-
Bio-Rad Bioplex Torc IgG	5	-	-
bioMerieux VIDAS/mini VIDAS Systems	14	-	-
Diamedix CMV EIA Systems (any)	2	-	-
DiaSorin Liaison CMV IgG	13	-	-
Immucor Capture CMV	1	-	-
Siemens Immulite Systems (all models)	7	-	-
Trinity Biotech CAPTIA CMV IgG EIA	2	-	-
Wampole Zeus Scientific CMV IgG ELISA	3	-	-
Zeus Scientific CMV IgG EIA	10	-	-

SAMPLE 13 - 98% of participants reported negative.			
All Labs	1	58	-
Bio-Rad CMV IgG EIA	-	2	-
Bio-Rad Bioplex Torc IgG	-	5	-
bioMerieux VIDAS/mini VIDAS Systems	-	14	-
Diamedix CMV EIA Systems (any)	-	2	-
DiaSorin Liaison CMV IgG	-	13	-
Immucor Capture CMV	1	-	-
Siemens Immulite Systems (all models)	-	7	-
Trinity Biotech CAPTIA CMV IgG EIA	-	2	-
Wampole Zeus Scientific CMV IgG ELISA	-	3	-
Zeus Scientific CMV IgG EIA	-	10	-

Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 14 - 100% of participants reported positive.			
All Labs	59	-	-
Bio-Rad CMV IgG EIA	2	-	-
Bio-Rad Bioplex Torc IgG	5	-	-
bioMerieux VIDAS/mini VIDAS Systems	14	-	-
Diamedix CMV EIA Systems (any)	2	-	-
DiaSorin Liaison CMV IgG	13	-	-
Immucor Capture CMV	1	-	-
Siemens Immulite Systems (all models)	7	-	-
Trinity Biotech CAPTIA CMV IgG EIA	2	-	-
Wampole Zeus Scientific CMV IgG ELISA	3	-	-
Zeus Scientific CMV IgG EIA	10	-	-
SAMPLE 15 - 98% of participants reported negative.			
All Labs	1	58	-
Bio-Rad CMV IgG EIA	-	2	-
Bio-Rad Bioplex Torc IgG	-	5	-
bioMerieux VIDAS/mini VIDAS Systems	-	14	-
Diamedix CMV EIA Systems (any)	-	2	-
DiaSorin Liaison CMV IgG	-	13	-
Immucor Capture CMV	1	-	-
Siemens Immulite Systems (all models)	-	7	-
Trinity Biotech CAPTIA CMV IgG EIA	-	2	-
Wampole Zeus Scientific CMV IgG ELISA	-	3	-
Zeus Scientific CMV IgG EIA	-	10	-

Qualitative Cytomegalovirus Ab (CMV) - Donor Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 61 - 100% of participants reported positive.			
All Labs	21	-	-
bioMerieux VIDAS/mini VIDAS Systems	2	-	-
Immucor Capture CMV	8	-	-
Beckman Coulter (formerly Olympus) PK System	10	-	-
Other	1	-	-
SAMPLE 62 - 86% of participants reported negative.			
All Labs	3	18	-
bioMerieux VIDAS/mini VIDAS Systems	-	2	-
Immucor Capture CMV	3	5	-
Beckman Coulter (formerly Olympus) PK System	-	10	-
Other	-	1	-
SAMPLE 63 - 100% of participants reported positive.			
All Labs	21	-	-
bioMerieux VIDAS/mini VIDAS Systems	2	-	-
Immucor Capture CMV	8	-	-
Beckman Coulter (formerly Olympus) PK System	10	-	-
Other	1	-	-
SAMPLE 64 - 76% of participants reported negative.			
All Labs	5	16	-
bioMerieux VIDAS/mini VIDAS Systems	-	2	-
Immucor Capture CMV	4	4	-
Beckman Coulter (formerly Olympus) PK System	1	9	-
Other	-	1	-
SAMPLE 65 - 81% of participants reported negative.			
All Labs	4	17	-
bioMerieux VIDAS/mini VIDAS Systems	-	2	-
Immucor Capture CMV	3	5	-
Beckman Coulter (formerly Olympus) PK System	1	9	-
Other	-	1	-

Qualitative Hepatitis B core Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 06 - 100% of participants reported nonreactive.		
All Labs	-	129
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	-	63
Siemens Immulite Systems (all models)	-	5
SAMPLE 07 - 100% of participants reported nonreactive.		
All Labs	-	129
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	-	63
Siemens Immulite Systems (all models)	-	1
		5
SAMPLE 08 - 100% of participants reported reactive.		
All Labs	129	-
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	63	-
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 reactive.		
All Labs	129	-
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	63	-
Siemens Immulite Systems (all models)	5	-
SAMPLE 10 - 100% of participants reported nonreactive.		
All Labs	-	129
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	-	63
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 nonreactive.		
All Labs	-	21
Abbott PRISM	-	10
BioRad MONOLISA HBc	-	2
Ortho HBc ELISA	-	9
SAMPLE 52 - 100% of participants reported reactive.		
All Labs	21	-
Abbott PRISM	10	-
BioRad MONOLISA HBc	2	-
Ortho HBc ELISA	9	-
SAMPLE 53 - 100% of participants reported nonreactive.		
All Labs	-	21
Abbott PRISM	-	10
BioRad MONOLISA HBc	-	2
Ortho HBc ELISA	-	9
SAMPLE 54 - 100% of participants reported reactive.		
All Labs	21	-
Abbott PRISM	10	-
BioRad MONOLISA HBc	2	-
Ortho HBc ELISA	9	-
SAMPLE 55 - 100% of participants reported nonreactive.		
All Labs	-	21
Abbott PRISM	-	10
BioRad MONOLISA HBc	-	2
Ortho HBc ELISA	-	9

Qualitative Hepatitis B surface Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 06 - 97% of participants reported nonreactive.		
All Labs	5	170
Abbott Architect	2	28
Bio-Rad GS HBsAg EIA	-	3
DiaSorin ETI MAK-2 Plus	-	3
Ortho Vitros (all models)	-	38
Roche Diagnostics Cobas (all systems)	-	7
Roche Diagnostics Elecsys Systems	-	8
Siemens ADVIA Centaur	3	79
Siemens Immulite Systems (all models)	-	4
SAMPLE 07 - 98% of participants reported nonreactive.		
All Labs	2	173
Abbott Architect	1	29
Bio-Rad GS HBsAg EIA	-	3
DiaSorin ETI MAK-2 Plus	-	3
Ortho Vitros (all models)	-	38
Roche Diagnostics Cobas (all systems)	-	7
Roche Diagnostics Elecsys Systems	-	8
Siemens ADVIA Centaur	1	81
Siemens Immulite Systems (all models)	-	4
SAMPLE 08 - 100% of participants reported reactive.		
All Labs	175	-
Abbott Architect	30	-
Bio-Rad GS HBsAg EIA	3	-
DiaSorin ETI MAK-2 Plus	3	-
Ortho Vitros (all models)	38	-
Roche Diagnostics Cobas (all systems)	7	-
Roche Diagnostics Elecsys Systems	8	-
Siemens ADVIA Centaur	82	-
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 reactive.		
All Labs	174	1
Abbott Architect	30	-
Bio-Rad GS HBsAg EIA	3	-
DiaSorin ETI MAK-2 Plus	3	-
Ortho Vitros (all models)	38	-
Roche Diagnostics Cobas (all systems)	7	-
Roche Diagnostics Elecsys Systems	8	-
Siemens ADVIA Centaur	81	1
Siemens Immulite Systems (all models)	4	-
SAMPLE 10 - 98% of participants reported nonreactive.		
All Labs	3	172
Abbott Architect	1	29
Bio-Rad GS HBsAg EIA	-	3
DiaSorin ETI MAK-2 Plus	-	3
Ortho Vitros (all models)	-	38
Roche Diagnostics Cobas (all systems)	-	7
Roche Diagnostics Elecsys Systems	-	8
Siemens ADVIA Centaur	2	80
Siemens Immulite Systems (all models)	-	4

Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 06 - 99% of participants reported nonreactive.		
All Labs	1	108
Abbott Architect	1	19
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	-	56
SAMPLE 07 - 99% of participants reported nonreactive.		
All Labs	1	108
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	1	55
SAMPLE 08 - 100% of participants reported reactive.		
All Labs	109	-
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	56	-

Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 09 - 99% of participants reported reactive.		
All Labs	108	1
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	55	1
SAMPLE 10 - 99% of participants reported nonreactive.		
All Labs	1	108
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	1	55

Qualitative Hepatitis B Surface Antigen - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 51 - 100% of participants reported nonreactive.		
All Labs	-	22
Abbott PRISM	-	10
Genetic Systems HBsAg EIA 3.0	-	12
SAMPLE 52 - 100% of participants reported reactive.		
All Labs	22	-
Abbott PRISM	10	-
Genetic Systems HBsAg EIA 3.0	12	-
SAMPLE 53 - 95% of participants reported nonreactive.		
All Labs	1	21
Abbott PRISM	-	10
Genetic Systems HBsAg EIA 3.0	1	11
SAMPLE 54 - 100% of participants reported reactive.		
All Labs	22	-
Abbott PRISM	10	-
Genetic Systems HBsAg EIA 3.0	12	-
SAMPLE 55 - 100% of participants reported nonreactive.		
All Labs	-	22
Abbott PRISM	-	10
Genetic Systems HBsAg EIA 3.0	-	12

Qualitative Hepatitis B Surface Ag Confirmation - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 51 - 100% of participants reported nonreactive.		
All Labs	-	17
Abbott PRISM	-	6
Genetic Systems HBsAg EIA 3.0	-	11
SAMPLE 52 - 100% of participants reported reactive.		
All Labs	17	-
Abbott PRISM	6	-
Genetic Systems HBsAg EIA 3.0	11	-
SAMPLE 53 - 94% of participants reported nonreactive.		
All Labs	1	16
Abbott PRISM	-	6
Genetic Systems HBsAg EIA 3.0	1	10
SAMPLE 54 - 100% of participants reported reactive.		
All Labs	17	-
Abbott PRISM	6	-
Genetic Systems HBsAg EIA 3.0	11	-
SAMPLE 55 - 100% of participants reported nonreactive.		
All Labs	-	17
Abbott PRISM	-	6
Genetic Systems HBsAg EIA 3.0	-	11

Qualitative Hepatitis Be Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 66 - 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 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 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 69 - 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 70 - 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

Qualitative Hepatitis C Virus Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 71 - 100% of participants reported nonreactive.		
All Labs	-	162
Abbott Architect	-	33
HCV Ortho Version 3.0 ELISA	-	8
Ortho Vitros (all models)	-	36
Roche Diagnostics Elecsys Systems	-	7
Siemens ADVIA Centaur	-	78
SAMPLE 72 - 100% of participants reported nonreactive.		
All Labs	-	162
Abbott Architect	-	33
HCV Ortho Version 3.0 ELISA	-	8
Ortho Vitros (all models)	-	36
Roche Diagnostics Elecsys Systems	-	7
Siemens ADVIA Centaur	-	78
SAMPLE 73 - 100% of participants reported reactive.		
All Labs	162	-
Abbott Architect	33	-
HCV Ortho Version 3.0 ELISA	8	-
Ortho Vitros (all models)	36	-
Roche Diagnostics Elecsys Systems	7	-
Siemens ADVIA Centaur	78	-

Qualitative Hepatitis C Virus Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 74 - 100% of participants reported reactive.		
All Labs	162	-
Abbott Architect	33	-
HCV Ortho Version 3.0 ELISA	8	-
Ortho Vitros (all models)	36	-
Roche Diagnostics Elecsys Systems	7	-
Siemens ADVIA Centaur	78	-
SAMPLE 75 - 100% of participants reported nonreactive.		
All Labs	-	162
Abbott Architect	-	33
HCV Ortho Version 3.0 ELISA	-	8
Ortho Vitros (all models)	-	36
Roche Diagnostics Elecsys Systems	-	7
Siemens ADVIA Centaur	-	78

Qualitative Hepatitis C Ab - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 91 - 100% of participants reported nonreactive.		
All Labs	-	22
Abbott PRISM	-	10
Ortho HCV Version 3.0 ELISA	-	12
SAMPLE 92 - 100% of participants reported reactive.		
All Labs	22	-
Abbott PRISM	10	-
Ortho HCV Version 3.0 ELISA	12	-
SAMPLE 93 - 100% of participants reported reactive.		
All Labs	22	-
Abbott PRISM	10	-
Ortho HCV Version 3.0 ELISA	12	-
SAMPLE 94 - 100% of participants reported nonreactive.		
All Labs	-	22
Abbott PRISM	-	10
Ortho HCV Version 3.0 ELISA	-	12
SAMPLE 95 - 100% of participants reported nonreactive.		
All Labs	-	22
Abbott PRISM	-	10
Ortho HCV Version 3.0 ELISA	-	12

Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 31 - 100% of participants reported nonreactive.		
All Labs	-	256
Architect HIV Ag/Ab Combo Assay (Abbott)	-	44
Abbott PRISM HIV O Plus (Abbott)	-	1
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	32
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	26
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 Complete HIV 1/2 (Alere)	-	10
Reveal Rapid HIV-1 Antibody Test (MedMira)	-	1
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	86
Vitros Anti-HIV 1+2 (Ortho)	-	18
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	13
SAMPLE 32 - 100% of participants reported reactive.		
All Labs	256	-
Architect HIV Ag/Ab Combo Assay (Abbott)	44	-
Abbott PRISM HIV O Plus (Abbott)	1	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	32	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	26	-
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)	10	-
Reveal Rapid HIV-1 Antibody Test (MedMira)	1	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	86	-
Vitros Anti-HIV 1+2 (Ortho)	18	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	13	-
SAMPLE 33 - 100% of participants reported nonreactive.		
All Labs	-	256
Architect HIV Ag/Ab Combo Assay (Abbott)	-	44
Abbott PRISM HIV O Plus (Abbott)	-	1
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	32
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	26
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)	-	10
Reveal Rapid HIV-1 Antibody Test (MedMira)	-	1
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	86
Vitros Anti-HIV 1+2 (Ortho)	-	18
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	13

Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 34 - 100% of participants reported nonreactive.		
All Labs	-	256
Architect HIV Ag/Ab Combo Assay (Abbott)	-	44
Abbott PRISM HIV O Plus (Abbott)	-	1
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	32
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	26
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)	-	10
Reveal Rapid HIV-1 Antibody Test (MedMira)	-	1
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	86
Vitros Anti-HIV 1+2 (Ortho)	-	18
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	13

SAMPLE 35 - 99% of participants reported reactive.

All Labs	254	2
Architect HIV Ag/Ab Combo Assay (Abbott)	44	-
Abbott PRISM HIV O Plus (Abbott)	1	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	31	1
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	26	-
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)	1	1
Clearview HIV 1/2 Stat-Pak (Alere)	10	-
Reveal Rapid HIV-1 Antibody Test (MedMira)	1	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	86	-
Vitros Anti-HIV 1+2 (Ortho)	18	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	13	-

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)	-	9
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	39
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 reactive.		
All Labs	52	-
GS HIV-1 Western Blot (Bio-Rad)	9	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	39	-
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 nonreactive.		
All Labs	-	52
GS HIV-1 Western Blot (Bio-Rad)	-	9
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	39
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 nonreactive.		
All Labs	-	52
GS HIV-1 Western Blot (Bio-Rad)	-	9
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	39
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 reactive.		
All Labs	52	-
GS HIV-1 Western Blot (Bio-Rad)	9	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	39	-
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 reactive.		
All Labs	22	-
PRISM HIV O Plus (Abbott)	9	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	12	-
Other	1	-
SAMPLE 97 - 100% of participants reported nonreactive.		
All Labs	-	22
PRISM HIV O Plus (Abbott)	-	9
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	12
Other	-	1
SAMPLE 98 - 100% of participants reported nonreactive.		
All Labs	-	22
PRISM HIV O Plus (Abbott)	-	9
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	12
Other	-	1
SAMPLE 99 - 100% of participants reported nonreactive.		
All Labs	-	22
PRISM HIV O Plus (Abbott)	-	9
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	12
Other	-	1
SAMPLE 100 - 100% of participants reported reactive.		
All Labs	22	-
PRISM HIV O Plus (Abbott)	9	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	12	-
Other	1	-

Qualitative HIV-1 Ab Supplemental/Confirmation - Donor Tests

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 96 - 100% of participants reported reactive.		
All Labs	11	-
GS HIV-1 Western Blot (Bio-Rad)	7	-
Fluorognost IFA HIV-1 (Sanochemias)	3	-
Other	1	-
SAMPLE 97 - 100% of participants reported nonreactive.		
All Labs	-	11
GS HIV-1 Western Blot (Bio-Rad)	-	7
Fluorognost IFA HIV-1 (Sanochemias)	-	3
Other	-	1
SAMPLE 98 - 100% of participants reported nonreactive.		
All Labs	-	11
GS HIV-1 Western Blot (Bio-Rad)	-	7
Fluorognost IFA HIV-1 (Sanochemias)	-	3
Other	-	1
SAMPLE 99 - 100% of participants reported nonreactive.		
All Labs	-	11
GS HIV-1 Western Blot (Bio-Rad)	-	7
Fluorognost IFA HIV-1 (Sanochemias)	-	3
Other	-	1
SAMPLE 100 - 100% of participants reported reactive.		
All Labs	11	-
GS HIV-1 Western Blot (Bio-Rad)	7	-
Fluorognost IFA HIV-1 (Sanochemias)	3	-
Other	1	-

Qualitative HTLV-1 Ab - Diagnostic Services

	Participant Results	
	Positive	Negative
SAMPLE 36 - 100% of participants reported positive.		
All Labs	4	-
Abbott PRISM	1	-
Avioq HTLV I/II Microelisa System	3	-
SAMPLE 37 - 100% of participants reported negative.		
All Labs	-	4
Abbott PRISM	-	1
Avioq HTLV I/II Microelisa System	-	3
SAMPLE 38 - 100% of participants reported positive.		
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 positive.		
All Labs	19	-
Abbott PRISM	11	-
Avioq HTLV I/II Microelisa System	8	-
SAMPLE 87 - 100% of participants reported negative.		
All Labs	-	19
Abbott PRISM	-	11
Avioq HTLV I/II Microelisa System	-	8
SAMPLE 88 - 100% of participants reported positive.		
All Labs	19	-
Abbott PRISM	11	-
Avioq HTLV I/II Microelisa System	8	-
SAMPLE 89 - 100% of participants reported negative.		
All Labs	-	19
Abbott PRISM	-	11
Avioq HTLV I/II Microelisa System	-	8
SAMPLE 90 - 100% of participants reported negative.		
All Labs	-	19
Abbott PRISM	-	11
Avioq HTLV I/II Microelisa System	-	8

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 26 - 100% of participants reported positive.			
All Labs	224	-	-
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	6	-	-
Cardinal Health SP Brand Rapid Mono Test	7	-	-
Clearview Mono	31	-	-
Fisher Sure-View Color Mono Latex Test Kit	6	-	-
Fisher Sure-View Mono Latex	63	-	-
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	-	-
Quidel Quickview Mono	1	-	-
Rapid Response BTNX	2	-	-
Remel Color Slide II Mononucleosis	17	-	-
Remel Mono-Lex Test	7	-	-
Remel SeraTest MONO	4	-	-
Seradyn Color Slide II Mononucleosis	3	-	-
Wampole Color Card MONO	13	-	-
Wampole Mono-Latex	2	-	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 27 - 100% of participants reported negative.			
All Labs	-	224	-
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	-	6	-
Cardinal Health SP Brand Rapid Mono Test	-	7	-
Clearview Mono	-	31	-
Fisher Sure-View Color Mono Latex Test Kit	-	6	-
Fisher Sure-View Mono Latex	-	63	-
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	-
Quidel Quickview Mono	-	1	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	-	17	-
Remel Mono-Lex Test	-	7	-
Remel SeraTest MONO	-	4	-
Seradyn Color Slide II Mononucleosis	-	3	-
Wampole Color Card MONO	-	13	-
Wampole Mono-Latex	-	2	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 28 - 99% of participants reported negative.			
All Labs	2	222	-
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	-	6	-
Cardinal Health SP Brand Rapid Mono Test	1	6	-
Clearview Mono	-	31	-
Fisher Sure-View Color Mono Latex Test Kit	-	6	-
Fisher Sure-View Mono Latex	-	63	-
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	-
Quidel Quickview Mono	-	1	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	-	17	-
Remel Mono-Lex Test	-	7	-
Remel SeraTest MONO	-	4	-
Seradyn Color Slide II Mononucleosis	-	3	-
Wampole Color Card MONO	-	13	-
Wampole Mono-Latex	1	1	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 29 - 60% of participants reported positive. *			
All Labs	134	89	1
Alere Acceava Mono Cassette (Inverness)	1	3	-
Arlington Scientific Mono Tests	3	-	-
Beckman Coulter ICON Mono	3	4	-
Biokit Monogen Latex	9	2	-
Cardinal Health Color Mono Latex	6	-	-
Cardinal Health SP Brand Rapid Mono Test	7	-	-
Clearview Mono	30	1	-
Fisher Sure-View Color Mono Latex Test Kit	-	6	-
Fisher Sure-View Mono Latex	24	39	-
Fisher Sure-View Signature Mono Test Kit	6	4	-
Inverness BioStar Acceava Mono/Mono II Test	7	2	-
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	-
Quidel Quickview Mono	-	1	-
Rapid Response BTNX	1	1	-
Remel Color Slide II Mononucleosis	11	6	-
Remel Mono-Lex Test	1	6	-
Remel SeraTest MONO	4	-	-
Seradyn Color Slide II Mononucleosis	3	-	-
Wampole Color Card MONO	2	10	1
Wampole Mono-Latex	-	2	-

*** Unable to validate sample #29, 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 Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 30 - 100% of participants reported negative.			
All Labs	-	224	-
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	-	6	-
Cardinal Health SP Brand Rapid Mono Test	-	7	-
Clearview Mono	-	31	-
Fisher Sure-View Color Mono Latex Test Kit	-	6	-
Fisher Sure-View Mono Latex	-	63	-
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	-
Quidel Quickview Mono	-	1	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	-	17	-
Remel Mono-Lex Test	-	7	-
Remel SeraTest MONO	-	4	-
Seradyn Color Slide II Mononucleosis	-	3	-
Wampole Color Card MONO	-	13	-
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 negative.			
All Labs	-	90	-
Bio-Rad Evolis	-	1	-
Bio-Rad Platelia Lyme IgG/IgM	-	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	26	-
Borrelia VIsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	8	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	23	-
Immunetics C6 B. burgdorferi EIA Test	-	8	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease EIA (IgM & IgG)	-	3	-
Trinity Biotech B. burgdorferi IgG/IgM	-	2	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	15	-
SAMPLE 42 - 100% of participants reported negative.			
All Labs	-	90	-
Bio-Rad Evolis	-	1	-
Bio-Rad Platelia Lyme IgG/IgM	-	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	26	-
Borrelia VIsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	8	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	23	-
Immunetics C6 B. burgdorferi E			

Qualitative Lyme Disease Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 44 - 100% of participants reported positive.			
All Labs	90	-	-
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	23	-	-
Immunetics C6 B. burgdorferi EIA Test	8	-	-
Laboratory developed assay	2	-	-
MarDx Lyme Disease EIA (IgM & IgG)	3	-	-
Trinity Biotech B. burgdorferi IgG/IgM	2	-	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	15	-	-
SAMPLE 45 - 100% of participants reported negative.			
All Labs	-	90	-
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	-	23	-
Immunetics C6 B. burgdorferi EIA Test	-		

Qualitative Lyme Western Blot IgG - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 41 - 100% of participants reported negative.			
All Labs	-	37	-
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	-	25	-
SAMPLE 42 - 100% of participants reported negative.			
All Labs	-	37	-
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	-	25	-
SAMPLE 43 - 100% of participants reported negative.			
All Labs	-	37	-
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	-	25	-
SAMPLE 44 - 81% of participants reported positive.			
All Labs	30	7	-

Qualitative Lyme Western Blot IgM - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 41 - 100% of participants reported negative.			
All Labs	-	36	-
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	-
SAMPLE 42 - 100% of participants reported negative.			
All Labs	-	36	-
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	-
SAMPLE 43 - 100% of participants reported negative.			
All Labs	-	36	-
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	-
SAMPLE 44 - 97% of participants reported positive.			
All Labs	35		

Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 26 - 100% of participants reported positive.		
All Labs	81	-
Arlington Scientific RF Latex Test	5	-
Beckman Coulter Immage	3	-
Biokit Rheumajet RF Latex	11	-
Cardinal Health SP RF Latex	3	-
Elia RF IgM FEIA (Phadia)	1	-
Fisher Sure-Vue RF Latex	35	-
Beckman Coulter (formerly Olympus) AU System	2	-
Ortho Vitros (all models)	3	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	2	-
Remel Seratest RF Latex Test	1	-
Roche Diagnostics Cobas (all systems)	1	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA 1200/1650/1800/2400	1	-
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 negative.		
All Labs	-	81
Arlington Scientific RF Latex Test	-	5
Beckman Coulter Immage	-	

Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 28 - 100% of participants reported negative.		
All Labs	-	81
Arlington Scientific RF Latex Test	-	5
Beckman Coulter Immage	-	3
Biokit Rheumajet RF Latex	-	11
Cardinal Health SP RF Latex	-	3
Elia RF IgM FEIA (Phadia)	-	1
Fisher Sure-Vue RF Latex	-	35
Beckman Coulter (formerly Olympus) AU System	-	2
Ortho Vitros (all models)	-	3
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2
Remel Seratest RF Latex Test	-	1
Roche Diagnostics Cobas (all systems)	-	1
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA 1200/1650/1800/2400	-	1
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 positive.

All Labs	81	-
Arlington Scientific RF Latex Test	5	-
Beckman Coulter Immage	3	-
Biokit Rheumajet RF Latex	11	-
Cardinal Health SP RF Latex	3	-
Elia RF IgM FEIA (Phadia)	1	-
Fisher Sure-Vue RF Latex	35	-
Beckman Coulter (formerly Olympus) AU System	2	-
Ortho Vitros (all models)	3	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	2	-
Remel Seratest RF Latex Test	1	-
Roche Diagnostics Cobas (all systems)	1	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA 1200/1650/1800/2400	1	-
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 - 100% of participants reported negative.		
All Labs	-	81
Arlington Scientific RF Latex Test	-	5
Beckman Coulter Immage	-	3
Biokit Rheumajet RF Latex	-	11
Cardinal Health SP RF Latex	-	3
Elia RF IgM FEIA (Phadia)	-	1
Fisher Sure-Vue RF Latex	-	35
Beckman Coulter (formerly Olympus) AU System	-	2
Ortho Vitros (all models)	-	3
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2
Remel Seratest RF Latex Test	-	1
Roche Diagnostics Cobas (all systems)	-	1
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA 1200/1650/1800/2400	-	1
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 26 and 29.

Primary Test Kit/Assay	No. Labs	Sample 26 Titers					
		< 1:1	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	21	-	-	2	3	10	6
Arlington Scientific RF Latex Test	2	-	-	-	-	-	2
Biokit Rheumajet RF Latex	3	-	-	-	1	2	-
Cardinal Health SP RF Latex	1	-	-	-	-	-	1
Fisher Sure-Vue RF Latex	12	-	-	1	1	8	2
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	1	1	-	-
Wampole Rheumatex RF	1	-	-	-	-	-	1

Primary Test Kit/Assay	No. Labs	Sample 29 Titers					
		< 1:1	1:16	1:32	1:64	1:128	≥ 1:256
All Labs	21	-	1	9	6	3	2
Arlington Scientific RF Latex Test	2	-	-	-	1	1	-
Biokit Rheumajet RF Latex	3	-	-	2	1	-	-
Cardinal Health SP RF Latex	1	-	-	-	-	-	1
Fisher Sure-Vue RF Latex	12	-	1	5	4	2	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	2	-	-	-
Wampole Rheumatex RF	1	-	-	-	-	-	1

Semi-Quantitative Rheumatoid Factor - Diagnostic Services

The number of laboratories reporting semi-quantitative results for positive samples 26 and 29.

Primary Test Kit/Assay	No. Labs	Sample 26 Results (IU/ml)					
		< 20	20	40	80	160	≥ 320
All Labs	29	1	-	10	15	3	-
Biokit Rheumajet RF Latex	6	-	-	-	5	1	-
Fisher Sure-Vue RF Latex	18	-	-	8	8	2	-
Remel Seratest RF Latex Test	2	1	-	-	1	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	1	1	-	-
Wampole Colorcard RF	1	-	-	1	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 29 Results (IU/ml)					
		< 20	20	40	80	160	≥ 320
All Labs	29	1	-	-	1	-	27
Biokit Rheumajet RF Latex	6	-	-	-	-	-	6
Fisher Sure-Vue RF Latex	18	-	-	-	-	-	18
Remel Seratest RF Latex Test	2	1	-	-	-	-	1
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	-	-	-	2
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		112	111	32.31	65.02	48.66	5.45
Chemiluminescence Total		1	1	-	-	50.30	-
	Abbott Architect	1	1	-	-	50.30	-
ELISA Enzyme-linked Immunosorbent Assay Total		4	3	-	-	68.90	-
	Diamedix RF EIA Systems	1	1	-	-	113.70	-
	Elia RF IgM Flouroenzymeimmunoassay (Phadia)	2	2	-	-	46.50	-
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	0	-	-	-	-
Nephelometry Total		37	37	36.48	49.12	42.80	2.11
	Beckman Coulter Immage	7	7	-	-	57.46	-
	Siemens Dimension VISTA	23	23	36.70	48.11	42.40	1.90
	Siemens Nephelometer Systems (all models)	7	7	-	-	41.01	-
Turbidimetry Total		70	70	41.44	60.16	50.80	3.12
	Abbott Architect	1	1	-	-	51.50	-
	Beckman Coulter Immage	1	1	-	-	57.10	-
	Kamiya Biomedical RF	2	2	-	-	50.05	-
	Beckman Coulter (formerly Olympus) AU System	18	18	45.93	54.67	50.30	1.46
	Ortho Vitros (all models)	7	7	-	-	46.10	-
	Roche Diagnostics Cobas (all systems)	19	19	44.51	56.92	50.72	2.07
	Roche Diagnostics RF II	2	2	-	-	49.40	-
	Roche/Hitachi Modular Systems (all models)	10	10	44.47	53.99	49.23	1.59
	Siemens ADVIA 1200/1650/1800/2400	10	10	52.54	59.40	55.97	1.14

Sample 27		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		112	14	0.00	10.79	3.61	2.39
Chemiluminescence Total		1	0	-	-	-	-
	Abbott Architect	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		4	2	-	-	6.50	-
	Diamedix RF EIA Systems	1	1	-	-	6.20	-
	Elia RF IgM Flouroenzymeimmunoassay (Phadia)	2	0	-	-	-	-
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	1	-	-	6.80	-
Nephelometry Total		37	1	-	-	0.00	-
	Beckman Coulter Immage	7	0	-	-	-	-
	Siemens Dimension VISTA	23	0	-	-	-	-
	Siemens Nephelometer Systems (all models)	7	0	-	-	-	-
Turbidimetry Total		70	11	0.00	9.71	3.41	2.10
	Abbott Architect	1	0	-	-	-	-
	Beckman Coulter Immage	1	0	-	-	-	-
	Kamiya Biomedical RF	2	1	-	-	3.60	-
	Beckman Coulter (formerly Olympus) AU System	18	2	-	-	3.45	-
	Ortho Vitros (all models)	7	0	-	-	-	-
	Roche Diagnostics Cobas (all systems)	19	6	-	-	4.33	-
	Roche Diagnostics RF II	2	0	-	-	-	-
	Roche/Hitachi Modular Systems (all models)	10	1	-	-	1.00	-
	Siemens ADVIA 1200/1650/1800/2400	10	1	-	-	0.00	-

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		112	13	0.00	11.72	3.44	2.76
Chemiluminescence Total		1	0	-	-	-	-
	Abbott Architect	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		4	2	-	-	4.60	-
	Diamedix RF EIA Systems	1	1	-	-	2.60	-
	Elia RF IgM Flouroenzymeimmunoassay (Phadia)	2	0	-	-	-	-
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	1	-	-	6.60	-
Nephelometry Total		37	1	-	-	0.00	-
	Beckman Coulter Immage	7	0	-	-	-	-
	Siemens Dimension VISTA	23	0	-	-	-	-
	Siemens Nephelometer Systems (all models)	7	0	-	-	-	-
Turbidimetry Total		70	10	0.00	11.85	3.55	2.77
	Abbott Architect	1	0	-	-	-	-
	Beckman Coulter Immage	1	0	-	-	-	-
	Kamiya Biomedical RF	2	1	-	-	6.30	-
	Beckman Coulter (formerly Olympus) AU System	18	2	-	-	3.40	-
	Ortho Vitros (all models)	7	0	-	-	-	-
	Roche Diagnostics Cobas (all systems)	19	5	-	-	4.48	-
	Roche Diagnostics RF II	2	0	-	-	-	-
	Roche/Hitachi Modular Systems (all models)	10	1	-	-	0.00	-
	Siemens ADVIA 1200/1650/1800/2400	10	1	-	-	0.00	-

Sample 29		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		112	108	278.90	385.44	332.17	17.76
Chemiluminescence Total		1	1	-	-	313.90	-
	Abbott Architect	1	1	-	-	313.90	-
ELISA Enzyme-linked Immunosorbent Assay Total		4	2	-	-	169.05	-
	Diamedix RF EIA Systems	1	1	-	-	159.10	-
	Elia RF IgM Flouroenzymeimmunoassay (Phadia)	2	1	-	-	179.00	-
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	0	-	-	-	-
Nephelometry Total		37	37	282.43	354.60	318.52	12.03
	Beckman Coulter Immage	7	7	-	-	571.43	-
	Siemens Dimension VISTA	23	23	287.90	351.27	319.59	10.56
	Siemens Nephelometer Systems (all models)	7	7	-	-	314.71	-
Turbidimetry Total		70	67	289.55	386.09	337.82	16.09
	Abbott Architect	1	1	-	-	311.00	-
	Beckman Coulter Immage	1	1	-	-	769.00	-
	Kamiya Biomedical RF	2	2	-	-	328.50	-
	Beckman Coulter (formerly Olympus) AU System	18	18	303.39	383.22	343.31	13.30
	Ortho Vitros (all models)	7	7	-	-	322.01	-
	Roche Diagnostics Cobas (all systems)	19	18	311.78	363.27	337.52	8.58
	Roche Diagnostics RF II	2	1	-	-	330.20	-
	Roche/Hitachi Modular Systems (all models)	10	10	305.12	346.24	325.68	6.85
	Siemens ADVIA 1200/1650/1800/2400	10	10	321.60	395.72	358.66	12.35

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		112	15	0.00	12.88	3.89	3.00
Chemiluminescence Total		1	0	-	-	-	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		4	2	-	-	5.00	-
	<i>Diamedix RF EIA Systems</i>	1	1	-	-	3.50	-
	<i>Elia RF IgM Flouorezymeimmunoassay (Phadia)</i>	2	0	-	-	-	-
	<i>IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM</i>	1	1	-	-	6.50	-
Nephelometry Total		37	1	-	-	0.00	-
	<i>Beckman Coulter Immage</i>	7	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	23	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	7	0	-	-	-	-
Turbidimetry Total		70	12	0.00	13.23	4.03	3.07
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Kamiya Biomedical RF</i>	2	1	-	-	1.50	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	18	2	-	-	3.45	-
	<i>Ortho Vitros (all models)</i>	7	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	19	6	-	-	5.15	-
	<i>Roche Diagnostics RF II</i>	2	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	2	-	-	4.50	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	10	1	-	-	0.00	-

Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 11 - 100% of participants reported negative.		
All Labs	-	125
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	-	6
Bio-Rad Rubella IgG EIA	-	2
Bio-Rad Bioplex Torc IgG	-	1
bioMerieux VIDAS/mini VIDAS Systems	-	11
Clearview Rubella Plus	-	2
Diasorin Liaison Rubella IgG	-	15
Diasorin Rubella IgG ELISA	-	2
Diamedix Rubella EIA Systems IgG	-	3
Fisher Sure-View Rubella	-	7
Ortho Vitros (all models)	-	12
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	4
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	27
Siemens Immulite Systems (all models)	-	2
Trinity Biotech CAPTIA Rubella IgG EIA	-	5
Wampole Rubella IgG ELISA/ELISA II	-	1
Inverness/Wampole Rubella IgG EIA Systems	-	13
SAMPLE 12 - 100% of participants reported positive.		
All Labs	125	-
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	6	-
Bio-Rad Rubella IgG EIA	2	-
Bio-Rad Bioplex Torc IgG	1	-
bioMerieux VIDAS/mini VIDAS Systems	11	-
Clearview Rubella Plus	2	-
Diasorin Liaison Rubella IgG	15	-
Diasorin Rubella IgG ELISA	2	-
Diamedix Rubella EIA Systems IgG	3	-
Fisher Sure-View Rubella	7	-
Ortho Vitros (all models)	12	-
Remel Ruba-Test	1	-
Roche Diagnostics Cobas (all systems)	4	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA Centaur	27	-
Siemens Immulite Systems (all models)	2	-
Trinity Biotech CAPTIA Rubella IgG EIA	5	-
Wampole Rubella IgG ELISA/ELISA II	1	-
Inverness/Wampole Rubella IgG EIA Systems	13	-
	-	-

Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 13 - 100% of participants reported negative.		
All Labs	-	125
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	-	6
Bio-Rad Rubella IgG EIA	-	2
Bio-Rad Bioplex Torc IgG	-	1
bioMerieux VIDAS/mini VIDAS Systems	-	11
Clearview Rubella Plus	-	2
Diasorin Liaison Rubella IgG	-	15
Diasorin Rubella IgG ELISA	-	2
Diamedix Rubella EIA Systems IgG	-	3
Fisher Sure-View Rubella	-	7
Ortho Vitros (all models)	-	12
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	4
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	27
Siemens Immulite Systems (all models)	-	2
Trinity Biotech CAPTIA Rubella IgG EIA	-	5
Wampole Rubella IgG ELISA/ELISA II	-	1
Inverness/Wampole Rubella IgG EIA Systems	-	13
	-	-
SAMPLE 14 - 100% of participants reported positive.		
All Labs	125	-
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	6	-
Bio-Rad Rubella IgG EIA	2	-
Bio-Rad Bioplex Torc IgG	1	-
bioMerieux VIDAS/mini VIDAS Systems	11	-
Clearview Rubella Plus	2	-
Diasorin Liaison Rubella IgG	15	-
Diasorin Rubella IgG ELISA	2	-
Diamedix Rubella EIA Systems IgG	3	-
Fisher Sure-View Rubella	7	-
Ortho Vitros (all models)	12	-
Remel Ruba-Test	1	-
Roche Diagnostics Cobas (all systems)	4	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA Centaur	27	-
Siemens Immulite Systems (all models)	2	-
Trinity Biotech CAPTIA Rubella IgG EIA	5	-
Wampole Rubella IgG ELISA/ELISA II	1	-
Inverness/Wampole Rubella IgG EIA Systems	13	-
	-	-

Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 15 - 100% of participants reported negative.		
All Labs	-	125
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	-	6
Bio-Rad Rubella IgG EIA	-	2
Bio-Rad Bioplex Torc IgG	-	1
bioMerieux VIDAS/mini VIDAS Systems	-	11
Clearview Rubella Plus	-	2
Diasorin Liaison Rubella IgG	-	15
Diasorin Rubella IgG ELISA	-	2
Diamedix Rubella EIA Systems IgG	-	3
Fisher Sure-View Rubella	-	7
Ortho Vitros (all models)	-	12
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	4
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	27
Siemens Immulite Systems (all models)	-	2
Trinity Biotech CAPTIA Rubella IgG EIA	-	5
Wampole Rubella IgG ELISA/ELISA II	-	1
Inverness/Wampole Rubella IgG EIA Systems	-	13
	-	-

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	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		58	26	0.00	1.40	0.37	0.34
Chemiluminescence Total		54	22	0.00	1.46	0.41	0.35
	Beckman Coulter ACCESS	3	1	-	-	0.20	-
	Beckman Coulter UniCel DxI Systems (all models)	4	3	-	-	0.77	-
	DiaSorin Liaison Rubella IgG Chemiluminescent Assay	4	0	-	-	-	-
	Ortho Vitros (all models)	7	4	-	-	0.00	-
	Roche Diagnostics Cobas (all systems)	2	1	-	-	0.19	-
	Roche/Hitachi Modular Systems (all models)	2	1	-	-	0.20	-
	Siemens ADVIA Centaur	30	12	0.00	1.39	0.51	0.30
	Siemens Immulite Systems (all models)	2	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	0.14	-
	Trinity Biotech CAPTIA Rubella IgG EIA	1	1	-	-	0.14	-
Enzyme Linked Fluorescent Assay (ELFA) Total		2	2	-	-	0.10	-
	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	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		58	57	0.00	247.70	94.46	51.08
Chemiluminescence Total		54	52	0.00	247.40	100.62	48.93
	Beckman Coulter ACCESS	3	2	-	-	38.70	-
	Beckman Coulter UniCel DxI Systems (all models)	4	4	-	-	48.15	-
	DiaSorin Liaison Rubella IgG Chemiluminescent Assay	4	4	-	-	25.93	-
	Ortho Vitros (all models)	7	7	-	-	61.89	-
	Roche Diagnostics Cobas (all systems)	2	2	-	-	190.90	-
	Roche/Hitachi Modular Systems (all models)	2	2	-	-	155.50	-
	Siemens ADVIA Centaur	30	29	93.31	160.21	126.76	11.15
	Siemens Immulite Systems (all models)	2	2	-	-	38.50	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	3.23	-
	Trinity Biotech CAPTIA Rubella IgG EIA	1	1	-	-	3.23	-
Enzyme Linked Fluorescent Assay (ELFA) Total		2	2	-	-	37.13	-
	bioMerieux VIDAS/mini VIDAS Systems	2	2	-	-	35.50	-
Multiplexed Bead Assay Total		1	1	-	-	31.00	-
	Bio-Rad Bioplex Torc IgG	1	1	-	-	31.00	-

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	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		58	23	0.00	1.71	0.41	0.43
Chemiluminescence Total		54	19	0.00	1.81	0.47	0.45
	Beckman Coulter ACCESS	3	1	-	-	0.30	-
	Beckman Coulter UniCel DxI Systems (all models)	4	3	-	-	0.77	-
	DiaSorin Liaison Rubella IgG Chemiluminescent Assay	4	0	-	-	-	-
	Ortho Vitros (all models)	7	4	-	-	0.00	-
	Roche Diagnostics Cobas (all systems)	2	1	-	-	0.18	-
	Roche/Hitachi Modular Systems (all models)	2	0	-	-	-	-
	Siemens ADVIA Centaur	30	10	0.00	1.95	0.60	0.45
	Siemens Immulite Systems (all models)	2	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	-	-	0.10	-
	bioMerieux VIDAS/mini VIDAS Systems	2	2	-	-	0.00	-
Multiplexed Bead Assay Total		1	0	-	-	-	-
	Bio-Rad Bioplex Torc IgG	1	0	-	-	-	-

Sample 14		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		58	57	0.00	105.60	52.09	17.84
Chemiluminescence Total		54	52	19.65	93.85	56.75	12.37
	Beckman Coulter ACCESS	3	2	-	-	37.70	-
	Beckman Coulter UniCel DxI Systems (all models)	4	4	-	-	41.73	-
	DiaSorin Liaison Rubella IgG Chemiluminescent Assay	4	4	-	-	26.65	-
	Ortho Vitros (all models)	7	7	-	-	64.91	-
	Roche Diagnostics Cobas (all systems)	2	2	-	-	148.10	-
	Roche/Hitachi Modular Systems (all models)	2	2	-	-	104.40	-
	Siemens ADVIA Centaur	30	29	37.79	84.46	61.12	7.78
	Siemens Immulite Systems (all models)	2	2	-	-	38.80	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	3.03	-
	Trinity Biotech CAPTIA Rubella IgG EIA	1	1	-	-	3.03	-
Enzyme Linked Fluorescent Assay (ELFA) Total		2	2	-	-	34.33	-
	bioMerieux VIDAS/mini VIDAS Systems	2	2	-	-	33.00	-
Multiplexed Bead Assay Total		1	1	-	-	33.00	-
	Bio-Rad Bioplex Torc IgG	1	1	-	-	33.00	-

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		58	21	0.00	1.78	0.42	0.45
Chemiluminescence Total		54	17	0.00	1.88	0.51	0.46
	<i>Beckman Coulter ACCESS</i>	3	1	-	-	0.30	-
	<i>Beckman Coulter UniCel DxI Systems (all models)</i>	4	3	-	-	0.80	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	4	0	-	-	-	-
	<i>Ortho Vitros (all models)</i>	7	4	-	-	0.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	2	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	0	-	-	-	-
	<i>Siemens ADVIA Centaur</i>	30	9	-	-	0.65	-
	<i>Siemens Immulite Systems (all models)</i>	2	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	0.10	-
	<i>Trinity Biotech CAPTIA Rubella IgG EIA</i>	1	1	-	-	0.10	-
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	-	-	-	-

Qualitative Rubella IgM Specific - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 56 - 100% of participants reported negative.		
All Labs	-	13
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	2
Rubella IgM Immunoassay (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
SAMPLE 57 - 100% of participants reported negative.		
All Labs	-	13
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	2
Rubella IgM Immunoassay (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
SAMPLE 58 - 100% of participants reported negative.		
All Labs	-	13
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	2
Rubella IgM Immunoassay (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
SAMPLE 59 - 100% of participants reported positive.		
All Labs	13	-
DiaSorin Liaison Rubella IgM	3	-
Diamedix Rubella EIA Systems IgM	2	-
Rubella IgM Immunoassay (Roche)	1	-
Siemens ADVIA Centaur	3	-
Siemens Immulite Systems (all models)	4	-
SAMPLE 60 - 100% of participants reported negative.		
All Labs	-	13
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	2
Rubella IgM Immunoassay (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4

Qualitative Syphilis Reagin Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 01 - 93% of participants reported reactive.		
All Labs	180	13
Ampcor RPR Card Test	2	1
ASI RPR Card Test for Syphilis	35	3
Becton Dickenson Macro-vue RPR	83	5
Fisher Sure-Vue RPR	36	2
Stanbio Syphilis (RPR) Quicktest	1	-
True Medix Diagnostics Trutest RPR	8	2
Wampole IMPACT RPR	15	-
SAMPLE 02 - 100% of participants reported nonreactive.		
All Labs	-	193
Ampcor RPR Card Test	-	3
ASI RPR Card Test for Syphilis	-	38
Becton Dickenson Macro-vue RPR	-	88
Fisher Sure-Vue RPR	-	38
Stanbio Syphilis (RPR) Quicktest	-	1
True Medix Diagnostics Trutest RPR	-	10
Wampole IMPACT RPR	-	15
SAMPLE 03 - 99% of participants reported nonreactive.		
All Labs	1	192
Ampcor RPR Card Test	-	3
ASI RPR Card Test for Syphilis	1	37
Becton Dickenson Macro-vue RPR	-	88
Fisher Sure-Vue RPR	-	38
Stanbio Syphilis (RPR) Quicktest	-	1
True Medix Diagnostics Trutest RPR	-	10
Wampole IMPACT RPR	-	15

Qualitative Syphilis Reagin Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 04 - 99% of participants reported nonreactive.		
All Labs	2	191
Ampcor RPR Card Test	-	3
ASI RPR Card Test for Syphilis	-	38
Becton Dickenson Macro-vue RPR	-	88
Fisher Sure-Vue RPR	1	37
Stanbio Syphilis (RPR) Quicktest	-	1
True Medix Diagnostics Trutest RPR	-	10
Wampole IMPACT RPR	1	14
SAMPLE 05 - 100% of participants reported reactive.		
All Labs	193	-
Ampcor RPR Card Test	3	-
ASI RPR Card Test for Syphilis	38	-
Becton Dickenson Macro-vue RPR	88	-
Fisher Sure-Vue RPR	38	-
Stanbio Syphilis (RPR) Quicktest	1	-
True Medix Diagnostics Trutest RPR	10	-
Wampole IMPACT RPR	15	-

Syphilis Reagin Ab (RPR) Titers - Diagnostic Services

The number of laboratories that reported titers is listed for reactive test samples 01 and 05.

Primary Test Kit/Assay	No. Labs	Sample 01 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	182	13	-	-	32	102	34	1
Ampcor RPR Card Test	3	1	-	-	-	1	1	-
ASI RPR Card Test for Syphilis	30	3	-	-	1	16	10	-
Becton Dickinson Macro-vue RPR	88	5	-	-	17	50	16	-
Fisher Sure-Vue RPR	36	2	-	-	5	22	7	-
Stanbio Syphilis (RPR) Quicktest	1	-	-	-	-	1	-	-
True Medix Diagnostics Trutest RPR	10	2	-	-	2	5	-	1
Wampole IMPACT RPR	14	-	-	-	7	7	-	-

Primary Test Kit/Assay	No. Labs	Sample 05 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	182	1	1	74	96	7	3	-
Ampcor RPR Card Test	3	-	-	2	1	-	-	-
ASI RPR Card Test for Syphilis	30	-	-	10	17	3	-	-
Becton Dickinson Macro-vue RPR	88	1	1	29	53	2	2	-
Fisher Sure-Vue RPR	36	-	-	14	20	2	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-	-	1	-	-	-
True Medix Diagnostics Trutest RPR	10	-	-	6	3	-	1	-
Wampole IMPACT RPR	14	-	-	13	1	-	-	-

Qualitative Syphilis Reagin Ab - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 21 - 100% of participants reported nonreactive.		
All Labs	-	17
ASI RPR Card Test for Syphilis	-	9
Becton Dickenson Macro-vue RPR	-	8
SAMPLE 22 - 100% of participants reported nonreactive.		
All Labs	-	17
ASI RPR Card Test for Syphilis	-	9
Becton Dickenson Macro-vue RPR	-	8
SAMPLE 23 - 100% of participants reported nonreactive.		
All Labs	-	17
ASI RPR Card Test for Syphilis	-	9
Becton Dickenson Macro-vue RPR	-	8
SAMPLE 24 - 88% of participants reported reactive.		
All Labs	15	2
ASI RPR Card Test for Syphilis	8	1
Becton Dickenson Macro-vue RPR	7	1
SAMPLE 25 - 100% of participants reported reactive.		
All Labs	17	-
ASI RPR Card Test for Syphilis	9	-
Becton Dickenson Macro-vue RPR	8	-

Qualitative Syphilis Treponemal Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Equivocal
SAMPLE 01 - 88% of participants reported nonreactive.			
All Labs	7	83	4
Bio-Rad Bioplex	2	7	-
Bio-Rad Evolis	-	1	-
DiaSorin Liaison Treponemal Assay	-	20	-
Fujirebio Serodia-TP-PA	1	17	1
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	8	-
Scimedx FTA-ABS Test System	1	-	-
Siemens ADVIA Centaur SYPH Assay	-	8	-
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	10	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	3	6	3
Other	-	1	-
SAMPLE 02 - 100% of participants reported nonreactive.			
All Labs	-	94	-
Bio-Rad Bioplex	-	9	-
Bio-Rad Evolis	-	1	-
DiaSorin Liaison Treponemal Assay	-	20	-
Fujirebio Serodia-TP-PA	-	19	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	8	-
Scimedx FTA-ABS Test System	-	1	-
Siemens ADVIA Centaur SYPH Assay	-	8	-
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	10	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	12	-
Other	-	1	-
SAMPLE 03 - 100% of participants reported nonreactive.			
All Labs	-	94	-
Bio-Rad Bioplex	-	9	-
Bio-Rad Evolis	-	1	-
DiaSorin Liaison Treponemal Assay	-	20	-
Fujirebio Serodia-TP-PA	-	19	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	8	-
Scimedx FTA-ABS Test System	-	1	-
Siemens ADVIA Centaur SYPH Assay	-	8	-
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	10	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	12	-
Other	-	1	-

Qualitative Syphilis Treponemal Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Equivocal
SAMPLE 04 - 100% of participants reported nonreactive.			
All Labs	-	94	-
Bio-Rad Bioplex	-	9	-
Bio-Rad Evolis	-	1	-
DiaSorin Liaison Treponemal Assay	-	20	-
Fujirebio Serodia-TP-PA	-	19	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	8	-
Scimedx FTA-ABS Test System	-	1	-
Siemens ADVIA Centaur SYPH Assay	-	8	-
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	10	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	12	-
Other	-	1	-
SAMPLE 05 - 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	19	-	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	8	-	-
Scimedx FTA-ABS Test System	1	-	-
Siemens ADVIA Centaur SYPH Assay	8	-	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	10	-	-
Wampole IMPACT IFA	1	-	-
Zeus Scientific FTA-ABS	12	-	-
Other	1	-	-

Qualitative Syphilis Treponemal Ab - Donor Services

Primary Test Kit/Assay	Participant Results	
	Reactive	Nonreactive
SAMPLE 21 - 100% of participants reported nonreactive.		
All Labs	-	21
DiaSorin Liaison Treponemal Assay	-	1
Fujirebio Serodia-TP-PA	-	2
Immucor Capture S	-	1
Beckman Coulter (formerly Olympus) PK-TP System	-	10
Scimedx FTA-ABS Test System	-	3
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	4
SAMPLE 22 - 100% of participants reported nonreactive.		
All Labs	-	21
DiaSorin Liaison Treponemal Assay	-	1
Fujirebio Serodia-TP-PA	-	2
Immucor Capture S	-	1
Beckman Coulter (formerly Olympus) PK-TP System	-	10
Scimedx FTA-ABS Test System	-	3
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	4
SAMPLE 23 - 100% of participants reported nonreactive.		
All Labs	-	21
DiaSorin Liaison Treponemal Assay	-	1
Fujirebio Serodia-TP-PA	-	2
Immucor Capture S	-	1
Beckman Coulter (formerly Olympus) PK-TP System	-	10
Scimedx FTA-ABS Test System	-	3
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	4
SAMPLE 24 - 90% of participants reported nonreactive.		
All Labs	2	19
DiaSorin Liaison Treponemal Assay	-	1
Fujirebio Serodia-TP-PA	-	2
Immucor Capture S	-	1
Beckman Coulter (formerly Olympus) PK-TP System	-	10
Scimedx FTA-ABS Test System	2	1
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	4
SAMPLE 25 - 100% of participants reported reactive.		
All Labs	21	-
DiaSorin Liaison Treponemal Assay	1	-
Fujirebio Serodia-TP-PA	2	-
Immucor Capture S	1	-
Beckman Coulter (formerly Olympus) PK-TP System	10	-
Scimedx FTA-ABS Test System	3	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	4	-

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		36	36	72.19	165.93	119.06	15.62
Nephelometry Total		22	22	88.08	167.43	127.75	13.22
	Beckman Coulter Immage	4	4	-	-	88.95	-
	Siemens Dimension VISTA	4	4	-	-	136.00	-
	Siemens Nephelometer Systems (all models)	14	14	110.40	149.74	130.07	6.56
Turbidimetry Total		14	14	96.28	127.36	111.82	5.18
	Abbott Architect	1	1	-	-	110.00	-
	Beckman Coulter (formerly Olympus) AU System	3	3	-	-	117.00	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	112.50	-
	Roche/Hitachi Modular Systems (all models)	6	6	-	-	109.08	-

Sample 77		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		36	36	69.27	121.85	95.56	8.76
Nephelometry Total		22	22	55.67	133.81	94.74	13.02
	Beckman Coulter Immage	4	4	-	-	74.90	-
	Siemens Dimension VISTA	4	4	-	-	98.65	-
	Siemens Nephelometer Systems (all models)	14	14	78.69	119.88	99.29	6.87
Turbidimetry Total		14	14	83.15	105.66	94.41	3.75
	Abbott Architect	1	1	-	-	94.00	-
	Beckman Coulter (formerly Olympus) AU System	3	3	-	-	100.00	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	94.00	-
	Roche/Hitachi Modular Systems (all models)	6	6	-	-	91.95	-

Sample 78		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		36	36	58.08	138.50	98.29	13.40
Nephelometry Total		22	22	87.46	127.66	107.56	6.70
	Beckman Coulter Immage	4	4	-	-	71.08	-
	Siemens Dimension VISTA	4	4	-	-	106.53	-
	Siemens Nephelometer Systems (all models)	14	14	95.19	120.52	107.86	4.22
Turbidimetry Total		14	14	81.38	109.87	95.62	4.75
	Abbott Architect	1	1	-	-	95.00	-
	Beckman Coulter (formerly Olympus) AU System	3	3	-	-	102.00	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	89.00	-
	Roche/Hitachi Modular Systems (all models)	6	6	-	-	93.52	-

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		36	36	30.56	64.94	47.75	5.73
Nephelometry Total		22	22	34.38	66.08	50.23	5.28
	Beckman Coulter Image	4	4	-	-	41.42	-
	Siemens Dimension VISTA	4	4	-	-	53.50	-
	Siemens Nephelometer Systems (all models)	14	14	42.92	60.71	51.81	2.96
Turbidimetry Total		14	14	31.68	56.02	43.85	4.06
	Abbott Architect	1	1	-	-	46.00	-
	Beckman Coulter (formerly Olympus) AU System	3	3	-	-	49.67	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	44.00	-
	Roche/Hitachi Modular Systems (all models)	6	6	-	-	40.48	-

Sample 80		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		36	36	30.56	64.94	47.75	5.73
Nephelometry Total		22	22	34.38	66.08	50.23	5.28
	Beckman Coulter Image	4	4	-	-	41.42	-
	Siemens Dimension VISTA	4	4	-	-	53.50	-
	Siemens Nephelometer Systems (all models)	14	14	42.92	60.71	51.81	2.96
Turbidimetry Total		14	14	31.68	56.02	43.85	4.06
	Abbott Architect	1	1	-	-	46.00	-
	Beckman Coulter (formerly Olympus) AU System	3	3	-	-	49.67	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	44.00	-
	Roche/Hitachi Modular Systems (all models)	6	6	-	-	40.48	-

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		98	97	94.10	117.26	105.68	3.86
Nephelometry Total		31	31	91.06	122.91	106.99	5.31
	Beckman Coulter Immage	6	6	-	-	100.43	-
	Beckman Coulter (formerly Olympus) AU System	1	1	-	-	104.00	-
	Siemens Dimension VISTA	13	13	100.17	119.99	110.08	3.30
	Siemens Nephelometer Systems (all models)	11	11	96.26	115.54	105.90	3.21
Turbidimetry Total		67	66	95.41	115.14	105.27	3.29
	Abbott Architect	5	5	-	-	108.20	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	101.90	-
	Kamiya Biomedical Complement Assay	1	1	-	-	81.00	-
	Beckman Coulter (formerly Olympus) AU System	20	20	97.33	111.87	104.60	2.42
	Ortho Vitros (all models)	5	5	-	-	107.20	-
	Roche Diagnostics Cobas (all systems)	16	16	95.77	118.23	107.00	3.74
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	104.84	-
	Siemens ADVIA 1200/1650/1800/2400	8	7	-	-	100.94	-
		1	1	-	-	107.00	-

Sample 77		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		98	97	55.07	71.05	63.06	2.66
Nephelometry Total		31	31	54.94	73.10	64.02	3.03
	Beckman Coulter Immage	6	6	-	-	56.27	-
	Beckman Coulter (formerly Olympus) AU System	1	1	-	-	63.00	-
	Siemens Dimension VISTA	13	13	59.43	70.57	65.00	1.86
	Siemens Nephelometer Systems (all models)	11	11	56.85	72.55	64.70	2.62
Turbidimetry Total		67	66	56.43	68.38	62.40	1.99
	Abbott Architect	5	5	-	-	63.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	60.70	-
	Kamiya Biomedical Complement Assay	1	1	-	-	54.00	-
	Beckman Coulter (formerly Olympus) AU System	20	20	57.87	68.37	63.12	1.75
	Ortho Vitros (all models)	5	5	-	-	63.80	-
	Roche Diagnostics Cobas (all systems)	16	16	56.54	67.96	62.25	1.90
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	62.67	-
	Siemens ADVIA 1200/1650/1800/2400	8	7	-	-	58.97	-
		1	1	-	-	62.00	-

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		98	97	68.66	88.63	78.65	3.33
Nephelometry Total		31	31	63.18	92.86	78.02	4.95
	Beckman Coulter Immage	6	6	-	-	70.68	-
	Beckman Coulter (formerly Olympus) AU System	1	1	-	-	78.00	-
	Siemens Dimension VISTA	13	13	75.33	86.39	80.86	1.84
	Siemens Nephelometer Systems (all models)	11	11	67.81	91.32	79.56	3.92
Turbidimetry Total		67	66	71.00	85.65	78.33	2.44
	Abbott Architect	5	5	-	-	78.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	76.70	-
	Kamiya Biomedical Complement Assay	1	1	-	-	68.00	-
	Beckman Coulter (formerly Olympus) AU System	20	20	74.37	84.55	79.46	1.70
	Ortho Vitros (all models)	5	5	-	-	79.40	-
	Roche Diagnostics Cobas (all systems)	16	16	68.56	91.20	79.88	3.77
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	78.31	-
	Siemens ADVIA 1200/1650/1800/2400	8	7	-	-	74.21	-
		1	1	-	-	62.00	-

Sample 79		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		98	92	33.39	49.33	41.36	2.66
Nephelometry Total		31	31	32.13	50.70	41.42	3.10
	Beckman Coulter Immage	6	6	-	-	36.78	-
	Beckman Coulter (formerly Olympus) AU System	1	1	-	-	40.00	-
	Siemens Dimension VISTA	13	13	38.12	48.49	43.31	1.73
	Siemens Nephelometer Systems (all models)	11	11	39.76	43.34	41.55	0.60
Turbidimetry Total		67	61	34.03	48.63	41.33	2.43
	Abbott Architect	5	5	-	-	44.40	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	40.50	-
	Kamiya Biomedical Complement Assay	1	1	-	-	34.00	-
	Beckman Coulter (formerly Olympus) AU System	20	20	37.08	45.71	41.40	1.44
	Ortho Vitros (all models)	5	0	-	-	-	-
	Roche Diagnostics Cobas (all systems)	16	16	35.29	44.15	39.72	1.48
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	41.94	-
	Siemens ADVIA 1200/1650/1800/2400	8	7	-	-	40.60	-
		1	1	-	-	44.00	-

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		98	97	76.56	99.55	88.05	3.83
Nephelometry Total		31	31	72.43	105.13	88.78	5.45
	<i>Beckman Coulter Immage</i>	6	6	-	-	80.52	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	1	1	-	-	87.00	-
	<i>Siemens Dimension VISTA</i>	13	13	83.03	98.46	90.75	2.57
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	76.77	105.46	91.12	4.78
Turbidimetry Total		67	66	78.95	95.72	87.33	2.80
	<i>Abbott Architect</i>	5	5	-	-	87.80	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	84.70	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	72.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	20	20	80.96	95.04	88.00	2.35
	<i>Ortho Vitros (all models)</i>	5	5	-	-	88.40	-
	<i>Roche Diagnostics Cobas (all systems)</i>	16	16	77.38	101.24	89.31	3.98
	<i>Roche/Hitachi Modular Systems (all models)</i>	9	9	-	-	86.33	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	8	7	-	-	83.76	-
		1	1	-	-	84.00	-

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		97	96	21.13	33.91	27.52	2.13
Nephelometry Total		28	28	24.79	31.02	27.91	1.04
	<i>Beckman Coulter Immage</i>	7	7	-	-	28.27	-
	<i>Siemens Dimension VISTA</i>	11	11	25.14	30.42	27.78	0.88
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	24.34	31.34	27.84	1.17
Turbidimetry Total		69	68	20.06	34.66	27.36	2.43
	<i>Abbott Architect</i>	5	5	-	-	27.48	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	24.90	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	24.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	21	27.45	33.48	30.46	1.00
	<i>Ortho Vitros (all models)</i>	5	5	-	-	28.48	-
	<i>Roche Diagnostics Cobas (all models)</i>	16	16	24.13	27.51	25.82	0.56
	<i>Roche/Hitachi Modular Systems (all models)</i>	9	9	-	-	26.32	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	8	7	-	-	24.36	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	27.00	-

Sample 77		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		97	96	8.37	13.74	11.06	0.90
Nephelometry Total		28	28	10.18	13.60	11.89	0.57
	<i>Beckman Coulter Immage</i>	6	6	-	-	12.15	-
	<i>Siemens Dimension VISTA</i>	11	11	10.97	13.42	12.19	0.41
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	10.26	12.54	11.40	0.38
Turbidimetry Total		69	68	8.48	13.02	10.75	0.76
	<i>Abbott Architect</i>	5	5	-	-	10.96	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	10.45	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	10.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	21	9.26	13.21	11.23	0.66
	<i>Ortho Vitros (all models)</i>	5	5	-	-	11.30	-
	<i>Roche Diagnostics Cobas (all models)</i>	16	16	8.81	11.84	10.32	0.51
	<i>Roche/Hitachi Modular Systems (all models)</i>	9	9	-	-	10.92	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	8	7	-	-	9.67	-
		1	1	-	-	11.00	-

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		97	96	11.49	18.49	14.99	1.17
Nephelometry Total		28	28	13.34	17.73	15.54	0.73
	<i>Beckman Coulter Image</i>	6	6	-	-	15.95	-
	<i>Siemens Dimension VISTA</i>	11	11	14.32	17.40	15.86	0.51
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	13.00	17.31	15.15	0.72
Turbidimetry Total		69	68	11.05	18.48	14.76	1.24
	<i>Abbott Architect</i>	5	5	-	-	14.80	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	12.95	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	14.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	21	16.00	16.00	16.00	0.00
	<i>Ortho Vitros (all models)</i>	5	5	-	-	15.62	-
	<i>Roche Diagnostics Cobas (all models)</i>	16	16	14.00	14.00	14.00	0.00
	<i>Roche/Hitachi Modular Systems (all models)</i>	9	9	-	-	14.70	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	8	7	-	-	13.34	-
		1	1	-	-	15.00	-

Sample 79		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		97	76	4.78	8.88	6.83	0.68
Nephelometry Total		28	28	5.80	8.97	7.39	0.53
	<i>Beckman Coulter Image</i>	6	6	-	-	7.07	-
	<i>Siemens Dimension VISTA</i>	11	11	6.49	9.13	7.81	0.44
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	6.65	7.57	7.11	0.15
Turbidimetry Total		69	48	4.90	8.09	6.50	0.53
	<i>Abbott Architect</i>	5	5	-	-	7.10	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	6.60	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	6.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	9	-	-	6.35	-
	<i>Ortho Vitros (all models)</i>	5	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all models)</i>	16	14	6.00	6.00	6.00	0.00
	<i>Roche/Hitachi Modular Systems (all models)</i>	9	9	-	-	7.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	8	6	-	-	6.08	-
		1	1	-	-	7.00	-

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		97	96	14.74	23.22	18.98	1.41
Nephelometry Total		28	28	17.25	21.74	19.49	0.75
	<i>Beckman Coulter Immage</i>	6	6	-	-	19.85	-
	<i>Siemens Dimension VISTA</i>	11	11	17.67	21.48	19.57	0.63
	<i>Siemens Nephelometer Systems (all models)</i>	11	11	17.05	21.39	19.22	0.72
Turbidimetry Total		69	68	14.06	23.46	18.76	1.57
	<i>Abbott Architect</i>	5	5	-	-	18.88	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	15.90	-
	<i>Kamiya Biomedical Complement Assay</i>	1	1	-	-	18.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	21	21	18.18	22.87	20.52	0.78
	<i>Ortho Vitros (all models)</i>	5	5	-	-	19.74	-
	<i>Roche Diagnostics Cobas (all models)</i>	16	16	16.43	19.81	18.12	0.56
	<i>Roche/Hitachi Modular Systems (all models)</i>	9	9	-	-	18.26	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	8	7	-	-	16.97	-
		1	1	-	-	19.00	-

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 81		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		103	101	81.45	134.47	107.96	8.84
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
Nephelometry Total		37	37	78.22	141.04	109.63	10.47
	Beckman Coulter Immage	9	9	-	-	97.51	-
	The Binding Site MININEPH	2	2	-	-	95.35	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	102.55	129.16	115.86	4.44
	Siemens Nephelometer Systems (all models)	12	12	90.11	137.55	113.83	7.91
Turbidimetry Total		65	64	84.01	129.99	107.00	7.66
	Abbott Architect	5	5	-	-	112.52	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	97.00	-
	Beckman Coulter (formerly Olympus) AU System	19	19	102.65	123.40	113.03	3.46
	Ortho Vitros (all models)	4	4	-	-	107.29	-
	Roche Diagnostics Cobas (all systems)	14	14	93.88	102.59	98.23	1.45
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	98.22	-
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	112.62	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	115.00	-
	SPAPLUS IgA Kit (The Binding Site)	2	2	-	-	104.50	-

Sample 82		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		103	101	40.44	76.92	58.68	6.08
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
Nephelometry Total		37	37	40.74	79.87	60.31	6.52
	Beckman Coulter Immage	9	9	-	-	51.42	-
	The Binding Site MININEPH	2	2	-	-	53.05	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	56.72	67.65	62.19	1.82
	Siemens Nephelometer Systems (all models)	12	12	54.34	77.62	65.98	3.88
Turbidimetry Total		65	64	40.79	74.68	57.74	5.65
	Abbott Architect	5	5	-	-	67.48	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	52.00	-
	Beckman Coulter (formerly Olympus) AU System	19	19	52.24	66.65	59.45	2.40
	Ortho Vitros (all models)	4	4	-	-	51.74	-
	Roche Diagnostics Cobas (all systems)	14	14	40.18	65.86	53.02	4.28
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	53.78	-
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	60.88	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	60.00	-
	SPAPLUS IgA Kit (The Binding Site)	2	2	-	-	62.00	-

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 83		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		103	101	77.58	124.77	101.18	7.87
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
Nephelometry Total		37	37	74.63	128.96	101.79	9.05
	Beckman Coulter Immage	9	9	-	-	90.21	-
	The Binding Site MININEPH	2	2	-	-	89.30	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	95.63	119.37	107.50	3.96
	Siemens Nephelometer Systems (all models)	12	12	86.10	125.70	105.90	6.60
Turbidimetry Total		65	64	79.40	122.25	100.82	7.14
	Abbott Architect	5	5	-	-	105.96	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	90.00	-
	Beckman Coulter (formerly Olympus) AU System	19	19	102.54	113.20	107.87	1.78
	Ortho Vitros (all models)	4	4	-	-	100.25	-
	Roche Diagnostics Cobas (all systems)	14	14	86.99	99.46	93.22	2.08
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	92.78	-
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	105.25	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	106.00	-
	SPAPLUS IgA Kit (The Binding Site)	2	2	-	-	99.50	-

Sample 84		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		103	100	50.02	83.99	67.00	5.66
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
Nephelometry Total		37	36	48.32	86.63	67.48	6.38
	Beckman Coulter Immage	9	9	-	-	59.64	-
	The Binding Site MININEPH	2	2	-	-	60.20	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	65.81	75.27	70.54	1.58
	Siemens Nephelometer Systems (all models)	12	11	61.47	84.93	73.20	3.91
Turbidimetry Total		65	64	51.00	82.47	66.73	5.25
	Abbott Architect	5	5	-	-	75.72	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	60.50	-
	Beckman Coulter (formerly Olympus) AU System	19	19	66.34	73.31	69.82	1.16
	Ortho Vitros (all models)	4	4	-	-	62.16	-
	Roche Diagnostics Cobas (all systems)	14	14	55.28	72.12	63.70	2.81
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	61.56	-
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	69.38	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	69.00	-
	SPAPLUS IgA Kit (The Binding Site)	2	2	-	-	67.50	-

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 85		Total	Labs *	Acceptable Range			S.D.
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	
All Methods		103	101	119.30	185.78	152.54	11.08
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		37	37	116.40	194.20	155.30	12.97
	<i>Beckman Coulter Immage</i>	9	9	-	-	138.78	-
	<i>The Binding Site MININEPH</i>	2	2	-	-	137.60	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	14	14	150.35	178.36	164.36	4.67
	<i>Siemens Nephelometer Systems (all models)</i>	12	12	132.07	188.09	160.08	9.34
Turbidimetry Total		65	64	122.22	179.67	150.94	9.58
	<i>Abbott Architect</i>	5	5	-	-	153.36	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	138.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	19	143.63	172.52	158.07	4.81
	<i>Ortho Vitros (all models)</i>	4	4	-	-	160.85	-
	<i>Roche Diagnostics Cobas (all systems)</i>	14	14	134.98	146.99	140.98	2.00
	<i>Roche/Hitachi Modular Systems (all models)</i>	9	9	-	-	139.44	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	9	8	-	-	158.88	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	156.00	-
	<i>SPAPlus IgA Kit (The Binding Site)</i>	2	2	-	-	148.00	-

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 81		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		77	77	188.08	290.69	239.38	17.10
Chemiluminescence Total		43	43	184.28	302.97	243.62	19.78
	Beckman Coulter ACCESS	5	5	-	-	231.33	-
	Beckman Coulter Synchron LX/Unicel Systems	5	5	-	-	227.72	-
	Roche Diagnostics Cobas (all models)	5	5	-	-	241.52	-
	Roche/Hitachi Modular Systems (all models)	5	5	-	-	235.34	-
	Siemens ADVIA Centaur	9	9	-	-	239.23	-
	Siemens Immulite Systems (all models)	17	17	174.26	357.11	265.69	30.48
ELISA Enzyme-linked Immunosorbent Assay (EIA)		2	2	-	-	240.85	-
	Hy-Tec Total IgE EIA (Hycor Biomedical)	2	2	-	-	222.90	-
Fluoroenzyme Immunoassay (FEIA) Total		23	23	182.03	281.96	232.00	16.65
	ImmunoCAP Total IgE FEIA (Phadia/Fisher)	22	22	196.83	272.36	234.60	12.59
	ST AIA-Pack IgE II (Tosoh Bioscience)	1	1	-	-	246.40	-
Nephelometry Total		6	6	211.24	265.09	238.17	8.98
	Siemens Dimension/Vista/Xpand (all models)	4	4	-	-	238.00	-
	Siemens Nephelometer Systems (all models)	2	2	-	-	238.50	-

Sample 82		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		77	77	72.95	117.99	95.47	7.51
Chemiluminescence Total		43	43	69.84	127.02	98.43	9.53
	Beckman Coulter ACCESS	4	4	-	-	90.34	-
	Beckman Coulter Synchron LX/Unicel Systems	4	4	-	-	96.49	-
	Roche Diagnostics Cobas (all models)	5	5	-	-	93.04	-
	Roche/Hitachi Modular Systems (all models)	5	5	-	-	91.25	-
	Siemens ADVIA Centaur	9	9	-	-	91.98	-
	Siemens Immulite Systems (all models)	16	16	91.99	122.54	107.27	5.09
ELISA Enzyme-linked Immunosorbent Assay (EIA)		2	2	-	-	93.00	-
	Hy-Tec Total IgE EIA (Hycor Biomedical)	2	2	-	-	85.19	-
Fluoroenzyme Immunoassay (FEIA) Total		23	23	79.89	106.86	93.37	4.49
	ImmunoCAP Total IgE FEIA (Phadia/Fisher)	22	22	79.23	107.14	93.19	4.65
	ST AIA-Pack IgE II (Tosoh Bioscience)	1	1	-	-	96.60	-
Nephelometry Total		6	6	-	-	96.65	-
	Siemens Dimension/Vista/Xpand (all models)	4	4	-	-	97.10	-
	Siemens Nephelometer Systems (all models)	2	2	-	-	95.75	-

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		77	77	111.69	172.60	142.15	10.15
Chemiluminescence Total		43	43	106.66	190.88	148.77	14.04
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	136.72	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	4	4	-	-	138.92	-
	<i>Roche Diagnostics Cobas (all models)</i>	5	5	-	-	144.10	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	5	5	-	-	141.96	-
	<i>Siemens ADVIA Centaur</i>	9	9	-	-	140.91	-
	<i>Siemens Immulite Systems (all models)</i>	16	16	124.68	199.82	162.25	12.52
ELISA Enzyme-linked Immunosorbent Assay (EIA)		2	2	-	-	130.93	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	2	2	-	-	124.10	-
Fluoroenzyme Immunoassay (FEIA) Total		23	23	110.46	163.35	136.91	8.81
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	22	22	110.58	161.14	135.86	8.43
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	146.90	-
Nephelometry Total		6	6	-	-	143.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	144.25	-
	<i>Siemens Nephelometer Systems (all models)</i>	2	2	-	-	140.50	-

Sample 84		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		77	77	251.43	378.44	314.94	21.17
Chemiluminescence Total		46	46	253.73	380.07	316.90	21.06
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	248.69	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	4	4	-	-	314.22	-
	<i>Roche Diagnostics Cobas (all models)</i>	5	5	-	-	312.52	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	5	5	-	-	310.62	-
	<i>Siemens ADVIA Centaur</i>	9	9	-	-	320.31	-
	<i>Siemens Immulite Systems (all models)</i>	16	16	223.22	445.91	334.56	37.11
ELISA Enzyme-linked Immunosorbent Assay (EIA)		2	2	-	-	295.18	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	2	2	-	-	250.21	-
Fluoroenzyme Immunoassay (FEIA) Total		23	23	249.73	370.36	310.04	20.11
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	22	22	248.03	368.53	308.28	20.08
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	327.90	-
Nephelometry Total		6	6	-	-	320.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	318.75	-
	<i>Siemens Nephelometer Systems (all models)</i>	2	2	-	-	324.00	-

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		77	77	36.28	68.93	52.60	5.44
Chemiluminescence Total		46	46	32.41	76.86	54.64	7.41
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	49.40	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	4	4	-	-	53.42	-
	<i>Roche Diagnostics Cobas (all models)</i>	5	5	-	-	52.84	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	5	5	-	-	52.22	-
	<i>Siemens ADVIA Centaur</i>	9	9	-	-	46.26	-
	<i>Siemens Immulite Systems (all models)</i>	16	16	45.16	79.40	62.28	5.71
ELISA Enzyme-linked Immunosorbent Assay (EIA)		2	2	-	-	53.59	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	2	2	-	-	54.27	-
Fluoroenzyme Immunoassay (FEIA) Total		23	23	43.99	57.38	50.68	2.23
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	22	22	43.85	57.65	50.75	2.30
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	48.80	-
Nephelometry Total		6	6	-	-	53.60	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	56.08	-
	<i>Siemens Nephelometer Systems (all models)</i>	2	2	-	-	48.65	-

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		101	100	344.54	574.24	459.39	38.28
Nephelometry Total		35	35	351.27	585.45	468.36	39.03
	Beckman Coulter Immage	8	8	-	-	475.00	-
	The Binding Site MININEPH	1	1	-	-	431.20	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	348.27	580.45	464.36	38.70
	Siemens Nephelometer Systems (all models)	12	12	354.00	590.00	472.00	39.33
Turbidimetry Total		66	65	343.00	571.67	457.34	38.11
	Abbott Architect	4	4	-	-	464.00	-
	Beckman Coulter Synchron LX/Unicel Systems	2	2	-	-	469.00	-
	Laboratory developed assay	1	1	-	-	482.62	-
	Beckman Coulter (formerly Olympus) AU System	19	19	341.99	569.99	455.99	38.00
	Ortho Vitros (all models)	4	4	-	-	477.34	-
	Roche Diagnostics Cobas (all systems)	14	14	342.56	570.94	456.75	38.06
	Roche/Hitachi Modular Systems (all models)	10	10	327.15	545.25	436.20	36.35
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	449.38	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	474.00	-
	SPAplus IgG Kit (The Binding Site)	2	2	-	-	481.00	-

Sample 82		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		101	94	206.22	343.70	274.96	22.91
Nephelometry Total		35	35	213.91	356.52	285.21	23.77
	Beckman Coulter Immage	8	8	-	-	282.00	-
	The Binding Site MININEPH	1	1	-	-	229.00	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	214.39	357.32	285.86	23.82
	Siemens Nephelometer Systems (all models)	12	12	218.12	363.54	290.83	24.24
Turbidimetry Total		66	59	200.52	334.20	267.36	22.28
	Abbott Architect	4	4	-	-	275.75	-
	Beckman Coulter Synchron LX/Unicel Systems	2	2	-	-	276.00	-
	Laboratory developed assay	1	1	-	-	288.00	-
	Beckman Coulter (formerly Olympus) AU System	19	19	196.38	327.30	261.84	21.82
	Ortho Vitros (all models)	4	2	-	-	292.53	-
	Roche Diagnostics Cobas (all systems)	14	13	203.31	338.85	271.08	22.59
	Roche/Hitachi Modular Systems (all models)	10	8	195.19	325.31	260.25	21.69
	Siemens ADVIA 1200/1650/1800/2400	9	7	-	-	265.14	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	278.00	-
	SPAplus IgG Kit (The Binding Site)	2	2	-	-	318.00	-

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 83		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		101	100	273.73	456.21	364.97	30.41
Nephelometry Total		35	35	281.54	469.23	375.38	31.28
	Beckman Coulter Immage	8	8	-	-	377.38	-
	The Binding Site MININEPH	1	1	-	-	340.40	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	279.05	465.09	372.07	31.01
	Siemens Nephelometer Systems (all models)	12	12	285.62	476.04	380.83	31.74
Turbidimetry Total		66	65	270.27	450.46	360.36	30.03
	Abbott Architect	4	4	-	-	367.00	-
	Beckman Coulter Synchron LX/Unicel Systems	2	2	-	-	368.00	-
	Laboratory developed assay	1	1	-	-	373.66	-
	Beckman Coulter (formerly Olympus) AU System	19	19	269.13	448.55	358.84	29.90
	Ortho Vitros (all models)	4	4	-	-	374.28	-
	Roche Diagnostics Cobas (all systems)	14	14	274.34	457.23	365.79	30.48
	Roche/Hitachi Modular Systems (all models)	10	10	253.05	421.75	337.40	28.12
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	357.12	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	377.00	-
	SPAplus IgG Kit (The Binding Site)	2	2	-	-	401.00	-

Sample 84		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		101	99	295.21	492.01	393.61	32.80
Nephelometry Total		35	34	300.15	500.25	400.20	33.35
	Beckman Coulter Immage	8	8	-	-	402.75	-
	The Binding Site MININEPH	1	1	-	-	391.60	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	299.25	498.75	399.00	33.25
	Siemens Nephelometer Systems (all models)	12	11	304.77	507.95	406.36	33.86
Turbidimetry Total		66	65	292.66	487.77	390.21	32.52
	Abbott Architect	4	4	-	-	399.50	-
	Beckman Coulter Synchron LX/Unicel Systems	2	2	-	-	407.50	-
	Laboratory developed assay	1	1	-	-	425.14	-
	Beckman Coulter (formerly Olympus) AU System	19	19	291.31	485.51	388.41	32.37
	Ortho Vitros (all models)	4	4	-	-	400.45	-
	Roche Diagnostics Cobas (all systems)	14	14	296.08	493.46	394.77	32.90
	Roche/Hitachi Modular Systems (all models)	10	10	276.52	460.88	368.70	30.72
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	379.00	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	406.00	-
	SPAplus IgG Kit (The Binding Site)	2	2	-	-	429.50	-

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 85		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		101	100	439.51	732.52	586.02	48.83
Nephelometry Total		35	35	446.52	744.19	595.35	49.61
	<i>Beckman Coulter Immage</i>	8	8	-	-	597.62	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	565.40	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	14	14	438.27	730.45	584.36	48.70
	<i>Siemens Nephelometer Systems (all models)</i>	12	12	456.88	761.46	609.17	50.76
Turbidimetry Total		66	65	436.66	727.76	582.21	48.52
	<i>Abbott Architect</i>	4	4	-	-	584.75	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	2	2	-	-	574.50	-
	<i>Laboratory developed assay</i>	1	1	-	-	646.77	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	19	438.53	730.88	584.71	48.73
	<i>Ortho Vitros (all models)</i>	4	4	-	-	658.14	-
	<i>Roche Diagnostics Cobas (all systems)</i>	14	14	435.00	725.00	580.00	48.33
	<i>Roche/Hitachi Modular Systems (all models)</i>	10	10	420.38	700.62	560.50	46.71
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	9	8	-	-	565.86	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	580.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	615.50	-

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		99	98	46.45	69.61	58.03	3.86
Nephelometry Total		34	34	54.01	66.80	60.41	2.13
	Beckman Coulter Image	8	8	-	-	59.05	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	56.47	66.05	61.26	1.60
	Siemens Nephelometer Systems (all models)	12	12	53.08	67.68	60.38	2.43
Turbidimetry Total		65	64	47.71	66.31	57.01	3.10
	Abbott Architect	4	4	-	-	56.75	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	58.00	-
	Laboratory developed assay	1	1	-	-	53.10	-
	Beckman Coulter (formerly Olympus) AU System	19	19	51.76	58.00	54.88	1.04
	Ortho Vitros (all models)	4	4	-	-	59.22	-
	Roche Diagnostics Cobas (all systems)	14	14	51.57	65.38	58.47	2.30
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	52.58	-
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	60.50	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	66.00	-
	SPAPLUS IgM Kit (The Binding Site)	2	2	-	-	53.50	-

Sample 82		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		99	98	24.43	51.14	37.79	4.45
Nephelometry Total		34	34	31.57	51.79	41.68	3.37
	Beckman Coulter Image	8	8	-	-	35.74	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	36.28	51.02	43.65	2.46
	Siemens Nephelometer Systems (all models)	12	12	36.32	46.26	41.29	1.66
Turbidimetry Total		65	64	27.13	45.61	36.37	3.08
	Abbott Architect	4	4	-	-	34.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	39.50	-
	Laboratory developed assay	1	1	-	-	30.40	-
	Beckman Coulter (formerly Olympus) AU System	19	19	33.42	39.84	36.63	1.07
	Ortho Vitros (all models)	4	4	-	-	36.69	-
	Roche Diagnostics Cobas (all systems)	14	14	29.09	39.91	34.50	1.80
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	30.24	-
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	41.00	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	44.00	-
	SPAPLUS IgM Kit (The Binding Site)	2	2	-	-	35.00	-

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 83		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		99	98	34.15	48.46	41.30	2.38
Nephelometry Total		34	34	33.50	49.55	41.52	2.68
	Beckman Coulter Image	8	8	-	-	38.99	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	38.53	47.07	42.80	1.42
	Siemens Nephelometer Systems (all models)	12	12	35.01	48.44	41.73	2.24
Turbidimetry Total		65	64	35.43	46.90	41.17	1.91
	Abbott Architect	4	4	-	-	39.75	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	40.50	-
	Laboratory developed assay	1	1	-	-	48.20	-
	Beckman Coulter (formerly Olympus) AU System	19	19	37.79	43.85	40.82	1.01
	Ortho Vitros (all models)	4	4	-	-	42.95	-
	Roche Diagnostics Cobas (all systems)	14	14	34.85	48.95	41.90	2.35
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	37.46	-
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	42.12	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	44.00	-
	SPAPlus IgM Kit (The Binding Site)	2	2	-	-	36.50	-

Sample 84		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		99	97	54.35	87.17	70.76	5.47
Nephelometry Total		34	33	63.05	87.05	75.05	4.00
	Beckman Coulter Image	8	8	-	-	70.29	-
	Siemens Dimension/Vista/Xpand (all models)	14	14	70.06	86.04	78.05	2.66
	Siemens Nephelometer Systems (all models)	12	11	68.55	80.84	74.69	2.05
Turbidimetry Total		65	64	54.21	82.88	68.54	4.78
	Abbott Architect	4	4	-	-	67.50	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	70.50	-
	Laboratory developed assay	1	1	-	-	71.40	-
	Beckman Coulter (formerly Olympus) AU System	19	19	60.15	69.80	64.97	1.61
	Ortho Vitros (all models)	4	4	-	-	71.39	-
	Roche Diagnostics Cobas (all systems)	14	14	64.58	76.77	70.67	2.03
	Roche/Hitachi Modular Systems (all models)	9	9	-	-	64.55	-
	Siemens ADVIA 1200/1650/1800/2400	9	8	-	-	75.25	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	80.00	-
	SPAPlus IgM Kit (The Binding Site)	2	2	-	-	66.00	-

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		99	97	21.81	37.51	29.66	2.62
Nephelometry Total		34	33	22.25	36.38	29.32	2.35
	<i>Beckman Coulter Image</i>	8	8	-	-	27.19	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	14	13	24.60	36.62	30.61	2.00
	<i>Siemens Nephelometer Systems (all models)</i>	12	12	23.43	35.24	29.33	1.97
Turbidimetry Total		65	64	21.61	38.08	29.84	2.74
	<i>Abbott Architect</i>	4	4	-	-	27.75	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	32.50	-
	<i>Laboratory developed assay</i>	1	1	-	-	36.50	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	19	19	28.09	34.91	31.50	1.14
	<i>Ortho Vitros (all models)</i>	4	4	-	-	32.47	-
	<i>Roche Diagnostics Cobas (all systems)</i>	14	14	20.58	36.52	28.55	2.66
	<i>Roche/Hitachi Modular Systems (all models)</i>	9	9	-	-	27.14	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	9	8	-	-	30.75	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	30.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	25.00	-