

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

Proficiency Testing Program

January 11, 2016

**DIAGNOSTIC IMMUNOLOGY
SUMMARY ANALYSIS**

**Diagnostic Immunology
Proficiency Test Event
January 11, 2016**

Summary Analysis

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The data summarized in this report were tabulated from proficiency test results and accompanying information submitted by laboratories that participated in the January 11, 2016 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.
- * Failure to attain an overall testing score of at least 80% 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	Reactive or nonreactive
Lyme Disease Ab, WB IgG, and WB 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 16146 - 100% of participants reported negative.			
All Labs	-	47	-
Bio-Rad Bioplex	-	3	-
BioRad EIA Systems (any)	-	3	-
BioRad/Kallestad IFA Systems (any)	-	8	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	3	-
Hycor Autostat II EIA	-	1	-
Immuno Concepts IFA Systems (any)	-	2	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	5	-
INOVA Novalite/Quanta Lite	-	2	-
Phadia/Pharmacia Immunocap/UniCap (all models)	-	2	-
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	4	-
Wampole/Zeus ANA IFA Hep-2	-	8	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	1	-

SAMPLE 16147 - 100% of participants reported negative.			
All Labs	-	47	-
Bio-Rad Bioplex	-	3	-
BioRad EIA Systems (any)	-	3	-
BioRad/Kallestad IFA Systems (any)	-	8	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	3	-
Hycor Autostat II EIA	-	1	-
Immuno Concepts IFA Systems (any)	-	2	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	5	-
INOVA Novalite/Quanta Lite	-	2	-
Phadia/Pharmacia Immunocap/UniCap (all models)	-	2	-
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	4	-
Wampole/Zeus ANA IFA Hep-2	-	8	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	1	-

Qualitative Antinuclear Ab (ANA) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16148 - 100% of participants reported negative.			
All Labs	-	47	-
Bio-Rad Bioplex	-	3	-
BioRad EIA Systems (any)	-	3	-
BioRad/Kallestad IFA Systems (any)	-	8	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	3	-
Hycor Autostat II EIA	-	1	-
Immuno Concepts IFA Systems (any)	-	2	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	5	-
INOVA Novalite/Quanta Lite	-	2	-
Phadia/Pharmacia Immunocap/UniCap (all models)	-	2	-
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	4	-
Wampole/Zeus ANA IFA Hep-2	-	8	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	1	-
SAMPLE 16149 - 100% of participants reported positive.			
All Labs	47	-	-
Bio-Rad Bioplex	3	-	-
BioRad EIA Systems (any)	3	-	-
BioRad/Kallestad IFA Systems (any)	8	-	-
DiaSorin ANA Screen EIA	1	-	-
Diamedix EIA Systems (any)	3	-	-
Hycor Autostat II EIA	1	-	-
Immuno Concepts IFA Systems (any)	2	-	-
IMMCO Diagnostics IFA	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	5	-	-
INOVA Novalite/Quanta Lite	2	-	-
Phadia/Pharmacia Immunocap/UniCap (all models)	2	-	-
RhiGene Fluor ANA IFA Test	1	-	-
Trinity Biotech ANA EIA Test	2	-	-
Wampole ANA EIA	4	-	-
Wampole/Zeus ANA IFA Hep-2	8	-	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	1	-	-

Qualitative Antinuclear Ab (ANA) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16150 - 91% of participants reported positive.			
All Labs	43	4	-
Bio-Rad Bioplex	3	-	-
BioRad EIA Systems (any)	3	-	-
BioRad/Kallestad IFA Systems (any)	8	-	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	3	-	-
Hycor Autostat II EIA	1	-	-
Immuno Concepts IFA Systems (any)	1	1	-
IMMCO Diagnostics IFA	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	4	1	-
INOVA Novalite/Quanta Lite	2	-	-
Phadia/Pharmacia Immunocap/UniCap (all models)	2	-	-
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	2	-	-
Wampole ANA EIA	4	-	-
Wampole/Zeus ANA IFA Hep-2	8	-	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	1	-	-

Antinuclear Ab (ANA) IFA Titers - Diagnostic Services

The number of laboratories that reported titers for positive test samples 16149 and 16150.

Primary Test Kit/Assay	No. Labs	Sample 16149 Titers							
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280	≥ 1:2560
All Labs	32	-	-	5	6	11	6	3	1
BioRad/Kallestad IFA Systems (any)	10	-	-	2	4	3	1	-	-
Immuno Concepts IFA Systems (any)	2	-	-	-	-	2	-	-	-
IMMCO Diagnostics IFA	2	-	-	-	-	1	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	8	-	-	-	1	2	2	3	-
RhiGene Fluor ANA IFA Test	1	-	-	-	1	-	-	-	-
Wampole/Zeus ANA IFA Hep-2	9	-	-	3	-	3	2	-	1

Staining Pattern - 31 labs reported a staining pattern, of those 30 labs (97%) reported homogenous, and 1 lab (3%) speckled. The reporting of a staining pattern here is for informational purposes only and is not graded.

Primary Test Kit/Assay	No. Labs	Sample 16150 Titers							
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280	≥ 1:2560
All Labs	32	3	1	3	8	5	7	2	3
BioRad/Kallestad IFA Systems (any)	10	-	-	-	4	2	4	-	-
Immuno Concepts IFA Systems (any)	2	1	-	-	-	-	1	-	-
IMMCO Diagnostics IFA	2	-	1	1	-	-	-	-	-
INOVA IFA Systems/NOVA Lite Hep-2	8	1	-	-	1	1	1	2	2
RhiGene Fluor ANA IFA Test	1	1	-	-	-	-	-	-	-
Wampole/Zeus ANA IFA Hep-2	9	-	-	2	3	2	1	-	1

Staining Pattern - 28 labs reported a staining pattern, of those 24 labs (86%) reported speckled, 1 lab (3%) reported nucleolar, and 3 labs (11%) reported homogenous. 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	Equivocal
SAMPLE 16116 - 97% of participants reported positive.			
All Labs	28	1	-
Arlington Scientific ASO Latex Test	2	-	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	2	-	-
BioKit Rheumajet ASO Latex Test	5	-	-
Fisher Sure-Vue ASO Latex Test	10	-	-
Remel Seratest ASO Latex Test	2	-	-
Siemens (Dade Behring) RapiTex Latex Test	6	-	-
True Medix Trutest Latex Test	1	-	-
Wampole Color Card ASO Latex Test	-	1	-
SAMPLE 16117 - 100% of participants reported negative.			
All Labs	-	29	-
Arlington Scientific ASO Latex Test	-	2	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	2	-
BioKit Rheumajet ASO Latex Test	-	5	-
Fisher Sure-Vue ASO Latex Test	-	10	-
Remel Seratest ASO Latex Test	-	2	-
Siemens (Dade Behring) RapiTex Latex Test	-	6	-
True Medix Trutest Latex Test	-	1	-
Wampole Color Card ASO Latex Test	-	1	-
SAMPLE 16118 - 100% of participants reported positive.			
All Labs	29	-	-
Arlington Scientific ASO Latex Test	2	-	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	2	-	-
BioKit Rheumajet ASO Latex Test	5	-	-
Fisher Sure-Vue ASO Latex Test	10	-	-
Remel Seratest ASO Latex Test	2	-	-
Siemens (Dade Behring) RapiTex Latex Test	6	-	-
True Medix Trutest Latex Test	1	-	-
Wampole Color Card ASO Latex Test	1	-	-

Qualitative Antistreptolysin O - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16119 - 100% of participants reported negative.			
All Labs	-	29	-
Arlington Scientific ASO Latex Test	-	2	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	2	-
BioKit Rheumajet ASO Latex Test	-	5	-
Fisher Sure-View ASO Latex Test	-	10	-
Remel Seratest ASO Latex Test	-	2	-
Siemens (Dade Behring) RapiTex Latex Test	-	6	-
True Medix Trutest Latex Test	-	1	-
Wampole Color Card ASO Latex Test	-	1	-
SAMPLE 16120 - 100% of participants reported positive.			
All Labs	29	-	-
Arlington Scientific ASO Latex Test	2	-	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	2	-	-
BioKit Rheumajet ASO Latex Test	5	-	-
Fisher Sure-View ASO Latex Test	10	-	-
Remel Seratest ASO Latex Test	2	-	-
Siemens (Dade Behring) RapiTex Latex Test	6	-	-
True Medix Trutest Latex Test	1	-	-
Wampole Color Card ASO Latex Test	1	-	-

Antistreptolysin O (ASO) Titers - Diagnostic Services

The number of laboratories that reported titers for positive test samples 16116, 16118 and 16120.

Primary Test Kit/Assay	No. Labs	Sample 16116 Titers					
		< C.O.	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	7	-	1	5	1	-	-
Arlington Scientific ASO Latex Test	1	-	-	1	-	-	-
BioKit Rheumajet ASO Latex Test	1	-	-	1	-	-	-
Fisher Sure-Vue ASO Latex Test	3	-	1	2	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	1	1	-	-

Primary Test Kit/Assay	No. Labs	Sample 16118 Titers					
		< C.O.	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	7	-	1	4	2	-	-
Arlington Scientific ASO Latex Test	1	-	-	-	1	-	-
BioKit Rheumajet ASO Latex Test	1	-	-	1	-	-	-
Fisher Sure-Vue ASO Latex Test	3	-	1	2	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	1	1	-	-

Primary Test Kit/Assay	No. Labs	Sample 16120 Titers					
		< C.O.	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	7	-	2	4	1	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	1	-	-	1	-	-	-
Fisher Sure-Vue ASO Latex Test	3	-	1	2	-	-	-
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 16116, 16118 and 16120.

Primary Test Kit/Assay	No. Labs	Sample 16116 Results (IU/ml)					
		< C.O.	200	400	800	1600	≥ 3200
All Labs	19	-	8	9	2	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	5	-	2	3	-	-	-
Fisher Sure-Vue ASO Latex Test	6	-	3	3	-	-	-
Remel Seratest ASO Latex Test	2	-	1	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	5	-	1	2	2	-	-

Primary Test Kit/Assay	No. Labs	Sample 16118 Results (IU/ml)					
		< C.O.	200	400	800	1600	≥ 3200
All Labs	19	-	10	8	1	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	5	-	4	1	-	-	-
Fisher Sure-Vue ASO Latex Test	6	-	2	4	-	-	-
Remel Seratest ASO Latex Test	2	-	1	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	5	-	2	2	1	-	-

Primary Test Kit/Assay	No. Labs	Sample 16120 Results (IU/ml)					
		< C.O.	200	400	800	1600	≥ 3200
All Labs	19	-	12	6	1	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	5	-	4	1	-	-	-
Fisher Sure-Vue ASO Latex Test	6	-	4	2	-	-	-
Remel Seratest ASO Latex Test	2	-	1	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	5	-	2	2	1	-	-

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

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16116		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		25	25	120.14	525.31	322.72	67.53
Nephelometry Total		5	5	-	-	260.20	-
	Beckman Coulter Immage	1	1	-	-	187.00	-
	Siemens Dimension VISTA	3	3	-	-	285.00	-
	Siemens Nephelometer Systems (all models)	1	1	-	-	259.00	-
Turbidimetry Total		20	20	148.14	528.57	338.36	63.41
	Abbott Architect	1	1	-	-	261.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	3	-	-	226.63	-
	Beckman Coulter (formerly Olympus) AU System	11	11	340.75	417.41	379.08	12.78
	Roche Diagnostics Cobas (all systems)	2	2	-	-	345.00	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	301.00	-
	Siemens ADVIA 1200/1650/1800/2400	2	2	-	-	389.70	-

Sample 16117		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		25	14	13.90	86.50	50.20	12.10
Nephelometry Total		5	4	-	-	58.60	-
	Beckman Coulter Immage	1	1	-	-	42.00	-
	Siemens Dimension VISTA	3	2	-	-	68.50	-
	Siemens Nephelometer Systems (all models)	1	1	-	-	55.40	-
Turbidimetry Total		20	10	15.76	77.92	46.84	10.36
	Abbott Architect	1	0	-	-	-	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	1	-	-	31.00	-
	Beckman Coulter (formerly Olympus) AU System	11	4	-	-	39.48	-
	Roche Diagnostics Cobas (all systems)	2	2	-	-	59.50	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	53.00	-
	Siemens ADVIA 1200/1650/1800/2400	2	2	-	-	53.75	-

Sample 16118		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		25	25	141.94	556.99	349.46	69.17
Nephelometry Total		5	5	-	-	378.20	-
	Beckman Coulter Immage	1	1	-	-	225.00	-
	Siemens Dimension VISTA	3	3	-	-	423.67	-
	Siemens Nephelometer Systems (all models)	1	1	-	-	395.00	-
Turbidimetry Total		20	20	151.64	532.92	342.28	63.55
	Abbott Architect	1	1	-	-	247.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	3	-	-	236.50	-
	Beckman Coulter (formerly Olympus) AU System	11	11	315.63	385.99	350.81	11.73
	Roche Diagnostics Cobas (all systems)	2	2	-	-	423.00	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	404.00	-
	Siemens ADVIA 1200/1650/1800/2400	2	2	-	-	420.50	-

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

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16119		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		25	14	13.98	86.45	50.21	12.08
Nephelometry Total		5	4	-	-	58.02	-
	Beckman Coulter Immage	1	1	-	-	45.00	-
	Siemens Dimension VISTA	3	2	-	-	65.00	-
	Siemens Nephelometer Systems (all models)	1	1	-	-	57.10	-
Turbidimetry Total		20	10	11.46	82.72	47.09	11.88
	Abbott Architect	1	0	-	-	-	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	1	-	-	27.00	-
	Beckman Coulter (formerly Olympus) AU System	11	4	-	-	39.17	-
	Roche Diagnostics Cobas (all systems)	2	2	-	-	60.00	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	56.00	-
	Siemens ADVIA 1200/1650/1800/2400	2	2	-	-	55.60	-

Sample 16120		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		25	25	150.66	524.28	337.47	62.27
Nephelometry Total		5	5	-	-	324.60	-
	Beckman Coulter Immage	1	1	-	-	197.00	-
	Siemens Dimension VISTA	3	3	-	-	364.00	-
	Siemens Nephelometer Systems (all models)	1	1	-	-	334.00	-
Turbidimetry Total		20	20	160.75	520.62	340.69	59.98
	Abbott Architect	1	1	-	-	250.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	3	3	-	-	231.17	-
	Beckman Coulter (formerly Olympus) AU System	11	11	277.56	435.73	356.65	26.36
	Roche Diagnostics Cobas (all systems)	2	2	-	-	385.50	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	361.00	-
	Siemens ADVIA 1200/1650/1800/2400	2	2	-	-	407.55	-

Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16111 - 100% of participants reported positive.			
All Labs	23	-	-
Bio-Rad CMV IgG EIA	1	-	-
Bio-Rad Bioplex Torc IgG	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	7	-	-
Diamedix CMV EIA Systems (any)	1	-	-
DiaSorin Liaison CMV IgG	5	-	-
Siemens Immulite Systems (all models)	3	-	-
Trinity Biotech CAPTIA CMV IgG EIA	1	-	-
Wampole Zeus Scientific CMV IgG ELISA	1	-	-
Zeus Scientific CMV IgG EIA	3	-	-

SAMPLE 16112 - 100% of participants reported negative.			
All Labs	-	23	-
Bio-Rad CMV IgG EIA	-	1	-
Bio-Rad Bioplex Torc IgG	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	7	-
Diamedix CMV EIA Systems (any)	-	1	-
DiaSorin Liaison CMV IgG	-	5	-
Siemens Immulite Systems (all models)	-	3	-
Trinity Biotech CAPTIA CMV IgG EIA	-	1	-
Wampole Zeus Scientific CMV IgG ELISA	-	1	-
Zeus Scientific CMV IgG EIA	-	3	-

SAMPLE 16113 - 100% of participants reported positive.			
All Labs	23	-	-
Bio-Rad CMV IgG EIA	1	-	-
Bio-Rad Bioplex Torc IgG	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	7	-	-
Diamedix CMV EIA Systems (any)	1	-	-
DiaSorin Liaison CMV IgG	5	-	-
Siemens Immulite Systems (all models)	3	-	-
Trinity Biotech CAPTIA CMV IgG EIA	1	-	-
Wampole Zeus Scientific CMV IgG ELISA	1	-	-
Zeus Scientific CMV IgG EIA	3	-	-

Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16114 - 100% of participants reported negative.			
All Labs	-	23	-
Bio-Rad CMV IgG EIA	-	1	-
Bio-Rad Bioplex Torc IgG	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	7	-
Diamedix CMV EIA Systems (any)	-	1	-
DiaSorin Liaison CMV IgG	-	5	-
Siemens Immulite Systems (all models)	-	3	-
Trinity Biotech CAPTIA CMV IgG EIA	-	1	-
Wampole Zeus Scientific CMV IgG ELISA	-	1	-
Zeus Scientific CMV IgG EIA	-	3	-

SAMPLE 16115 - 100% of participants reported positive.			
All Labs	23	-	-
Bio-Rad CMV IgG EIA	1	-	-
Bio-Rad Bioplex Torc IgG	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	7	-	-
Diamedix CMV EIA Systems (any)	1	-	-
DiaSorin Liaison CMV IgG	5	-	-
Siemens Immulite Systems (all models)	3	-	-
Trinity Biotech CAPTIA CMV IgG EIA	1	-	-
Wampole Zeus Scientific CMV IgG ELISA	1	-	-
Zeus Scientific CMV IgG EIA	3	-	-

Qualitative Hepatitis B core Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16106 - 100% of participants reported reactive.			
All Labs	54	-	-
Abbott Architect	13	-	-
BioRad MONOLISA HBc	1	-	-
Ortho HBc ELISA	1	-	-
Ortho Vitros (all models)	12	-	-
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	1	-	-
Siemens ADVIA Centaur	23	-	-
Siemens Immulite Systems (all models)	3	-	-
SAMPLE 16107 - 100% of participants reported nonreactive.			
All Labs	-	54	-
Abbott Architect	-	13	-
BioRad MONOLISA HBc	-	1	-
Ortho HBc ELISA	-	1	-
Ortho Vitros (all models)	-	12	-
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1	-
Siemens ADVIA Centaur	-	23	-
Siemens Immulite Systems (all models)	-	3	-
SAMPLE 16108 - 98% of participants reported reactive.			
All Labs	53	1	-
Abbott Architect	12	1	-
BioRad MONOLISA HBc	1	-	-
Ortho HBc ELISA	1	-	-
Ortho Vitros (all models)	12	-	-
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	1	-	-
Siemens ADVIA Centaur	23	-	-
Siemens Immulite Systems (all models)	3	-	-

Qualitative Hepatitis B core Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16109 - 100% of participants reported nonreactive.			
All Labs	-	54	-
Abbott Architect	-	13	-
BioRad MONOLISA HBc	-	1	-
Ortho HBc ELISA	-	1	-
Ortho Vitros (all models)	-	12	-
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1	-
Siemens ADVIA Centaur	-	23	-
Siemens Immulite Systems (all models)	-	3	-

SAMPLE 16110 - 98% of participants reported nonreactive.			
All Labs	-	53	1
Abbott Architect	-	13	-
BioRad MONOLISA HBc	-	1	-
Ortho HBc ELISA	-	1	-
Ortho Vitros (all models)	-	11	1
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1	-
Siemens ADVIA Centaur	-	23	-
Siemens Immulite Systems (all models)	-	3	-

Qualitative Hepatitis B surface Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16106 - 100% of participants reported nonreactive.			
All Labs	-	80	-
Abbott Architect	-	14	-
Bio-Rad GS HBsAg EIA	-	2	-
DiaSorin ETI MAK-2 Plus	-	1	-
Ortho Vitros (all models)	-	15	-
Roche Diagnostics Cobas (all systems)	-	6	-
Roche Diagnostics Elecsys Systems	-	1	-
Siemens ADVIA Centaur	-	38	-
Siemens Immulite Systems (all models)	-	3	-
SAMPLE 16107 - 100% of participants reported nonreactive.			
All Labs	-	80	-
Abbott Architect	-	14	-
Bio-Rad GS HBsAg EIA	-	2	-
DiaSorin ETI MAK-2 Plus	-	1	-
Ortho Vitros (all models)	-	15	-
Roche Diagnostics Cobas (all systems)	-	6	-
Roche Diagnostics Elecsys Systems	-	1	-
Siemens ADVIA Centaur	-	38	-
Siemens Immulite Systems (all models)	-	3	-
SAMPLE 16108 - 100% of participants reported reactive.			
All Labs	80	-	-
Abbott Architect	14	-	-
Bio-Rad GS HBsAg EIA	2	-	-
DiaSorin ETI MAK-2 Plus	1	-	-
Ortho Vitros (all models)	15	-	-
Roche Diagnostics Cobas (all systems)	6	-	-
Roche Diagnostics Elecsys Systems	1	-	-
Siemens ADVIA Centaur	38	-	-
Siemens Immulite Systems (all models)	3	-	-

Qualitative Hepatitis B surface Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16109 - 99% of participants reported nonreactive.			
All Labs	1	79	-
Abbott Architect	-	14	-
Bio-Rad GS HBsAg EIA	-	2	-
DiaSorin ETI MAK-2 Plus	-	1	-
Ortho Vitros (all models)	-	15	-
Roche Diagnostics Cobas (all systems)	-	6	-
Roche Diagnostics Elecsys Systems	-	1	-
Siemens ADVIA Centaur	1	37	-
Siemens Immulite Systems (all models)	-	3	-
SAMPLE 16110 - 100% of participants reported reactive.			
All Labs	80	-	-
Abbott Architect	14	-	-
Bio-Rad GS HBsAg EIA	2	-	-
DiaSorin ETI MAK-2 Plus	1	-	-
Ortho Vitros (all models)	15	-	-
Roche Diagnostics Cobas (all systems)	6	-	-
Roche Diagnostics Elecsys Systems	1	-	-
Siemens ADVIA Centaur	38	-	-
Siemens Immulite Systems (all models)	3	-	-

Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16106 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	1	36
Abbott Architect	-	-	9
Abbott HBsAg Confirmatory Assay	-	-	1
Bio-Rad GS HBsAg Confirmatory Assay	-	-	1
DiaSorin ETI MAK-2 Plus	-	-	1
Ortho Vitros (all models)	-	-	5
Roche Diagnostics Cobas (all systems)	-	-	2
Siemens ADVIA Centaur	-	1	17
SAMPLE 16107 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	1	36
Abbott Architect	-	-	9
Abbott HBsAg Confirmatory Assay	-	-	1
Bio-Rad GS HBsAg Confirmatory Assay	-	-	1
DiaSorin ETI MAK-2 Plus	-	-	1
Ortho Vitros (all models)	-	-	5
Roche Diagnostics Cobas (all systems)	-	-	2
Siemens ADVIA Centaur	-	1	17
SAMPLE 16108 - 100% of participants reported reactive or testing not indicated.			
All Labs	29	-	8
Abbott Architect	9	-	-
Abbott HBsAg Confirmatory Assay	1	-	-
Bio-Rad GS HBsAg Confirmatory Assay	1	-	-
DiaSorin ETI MAK-2 Plus	1	-	-
Ortho Vitros (all models)	2	-	3
Roche Diagnostics Cobas (all systems)	2	-	-
Siemens ADVIA Centaur	13	-	5

Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16109 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	1	36
Abbott Architect	-	-	9
Abbott HBsAg Confirmatory Assay	-	-	1
Bio-Rad GS HBsAg Confirmatory Assay	-	-	1
DiaSorin ETI MAK-2 Plus	-	-	1
Ortho Vitros (all models)	-	-	5
Roche Diagnostics Cobas (all systems)	-	-	2
Siemens ADVIA Centaur	-	1	17

SAMPLE 16110 - 100% of participants reported reactive or testing not indicated.			
All Labs	29	-	8
Abbott Architect	9	-	-
Abbott HBsAg Confirmatory Assay	1	-	-
Bio-Rad GS HBsAg Confirmatory Assay	1	-	-
DiaSorin ETI MAK-2 Plus	1	-	-
Ortho Vitros (all models)	2	-	3
Roche Diagnostics Cobas (all systems)	2	-	-
Siemens ADVIA Centaur	13	-	5

Qualitative Hepatitis Be Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16166 - 100% of participants reported nonreactive.			
All Labs	-	7	-
DiaSorin ETI-EBK Plus	-	2	-
DiaSorin ETI MAK 3000	-	1	-
Ortho Vitros (all models)	-	2	-
Siemens ADVIA Centaur	-	2	-
SAMPLE 16167 - 100% of participants reported reactive.			
All Labs	7	-	-
DiaSorin ETI-EBK Plus	2	-	-
DiaSorin ETI MAK 3000	1	-	-
Ortho Vitros (all models)	2	-	-
Siemens ADVIA Centaur	2	-	-
SAMPLE 16168 - 100% of participants reported reactive.			
All Labs	7	-	-
DiaSorin ETI-EBK Plus	2	-	-
DiaSorin ETI MAK 3000	1	-	-
Ortho Vitros (all models)	2	-	-
Siemens ADVIA Centaur	2	-	-
SAMPLE 16169 - 100% of participants reported nonreactive.			
All Labs	-	7	-
DiaSorin ETI-EBK Plus	-	2	-
DiaSorin ETI MAK 3000	-	1	-
Ortho Vitros (all models)	-	2	-
Siemens ADVIA Centaur	-	2	-
SAMPLE 16170 - 100% of participants reported reactive.			
All Labs	7	-	-
DiaSorin ETI-EBK Plus	2	-	-
DiaSorin ETI MAK 3000	1	-	-
Ortho Vitros (all models)	2	-	-
Siemens ADVIA Centaur	2	-	-

Qualitative Hepatitis C Virus Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16171 - 100% of participants reported reactive.			
All Labs	68	-	-
Abbott Architect	16	-	-
HCV Ortho Version 3.0 ELISA	3	-	-
Ortho Vitros (all models)	13	-	-
Roche Diagnostics Elecsys Systems	3	-	-
Siemens ADVIA Centaur	33	-	-
SAMPLE 16172 - 100% of participants reported reactive.			
All Labs	68	-	-
Abbott Architect	16	-	-
HCV Ortho Version 3.0 ELISA	3	-	-
Ortho Vitros (all models)	13	-	-
Roche Diagnostics Elecsys Systems	3	-	-
Siemens ADVIA Centaur	33	-	-
SAMPLE 16173 - 100% of participants reported nonreactive.			
All Labs	-	68	-
Abbott Architect	-	16	-
HCV Ortho Version 3.0 ELISA	-	3	-
Ortho Vitros (all models)	-	13	-
Roche Diagnostics Elecsys Systems	-	3	-
Siemens ADVIA Centaur	-	33	-
SAMPLE 16174 - 100% of participants reported nonreactive.			
All Labs	-	68	-
Abbott Architect	-	16	-
HCV Ortho Version 3.0 ELISA	-	3	-
Ortho Vitros (all models)	-	13	-
Roche Diagnostics Elecsys Systems	-	3	-
Siemens ADVIA Centaur	-	33	-
SAMPLE 16175 - 100% of participants reported nonreactive.			
All Labs	-	68	-
Abbott Architect	-	16	-
HCV Ortho Version 3.0 ELISA	-	3	-
Ortho Vitros (all models)	-	13	-
Roche Diagnostics Elecsys Systems	-	3	-
Siemens ADVIA Centaur	-	33	-

Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Invalid
SAMPLE 16131 - 100% of participants reported reactive.			
All Labs	141	-	-
Architect HIV Ag/Ab Combo Assay (Abbott)	21	-	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	10	-	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	20	-	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	3	-	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	4	-	-
Clearview Complete HIV 1/2 (Alere)	5	-	-
Clearview HIV 1/2 Stat-Pak (Alere)	1	-	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	48	-	-
Vitros Anti-HIV 1+2 (Ortho)	11	-	-
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	10	-	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	7	-	-
Other	1	-	-
SAMPLE 16132 - 97% of participants reported nonreactive.			
All Labs	-	137	4
Architect HIV Ag/Ab Combo Assay (Abbott)	-	21	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	10	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	20	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	3	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	4	-
Clearview Complete HIV 1/2 (Alere)	-	5	-
Clearview HIV 1/2 Stat-Pak (Alere)	-	1	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	48	-
Vitros Anti-HIV 1+2 (Ortho)	-	11	-
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	-	10	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	3	4
Other	-	1	-
SAMPLE 16133 - 100% of participants reported reactive.			
All Labs	141	-	-
Architect HIV Ag/Ab Combo Assay (Abbott)	21	-	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	10	-	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	20	-	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	3	-	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	4	-	-
Clearview Complete HIV 1/2 (Alere)	5	-	-
Clearview HIV 1/2 Stat-Pak (Alere)	1	-	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	48	-	-
Vitros Anti-HIV 1+2 (Ortho)	11	-	-
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	10	-	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	7	-	-
Other	1	-	-

Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Invalid
SAMPLE 16134 - 100% of participants reported reactive.			
All Labs	141	-	-
Architect HIV Ag/Ab Combo Assay (Abbott)	21	-	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	10	-	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	20	-	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	3	-	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	4	-	-
Clearview Complete HIV 1/2 (Alere)	5	-	-
Clearview HIV 1/2 Stat-Pak (Alere)	1	-	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	48	-	-
Vitros Anti-HIV 1+2 (Ortho)	11	-	-
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	10	-	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	7	-	-
Other	1	-	-

SAMPLE 16135 - 97% of participants reported nonreactive.			
All Labs	-	137	4
Architect HIV Ag/Ab Combo Assay (Abbott)	-	21	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	10	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	20	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	3	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	4	-
Clearview Complete HIV 1/2 (Alere)	-	5	-
Clearview HIV 1/2 Stat-Pak (Alere)	-	1	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	48	-
Vitros Anti-HIV 1+2 (Ortho)	-	11	-
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	-	10	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	3	4
Other	-	1	-

Qualitative HIV-1 Ab - Supplemental/Confirmation Tests

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16131 - 100% of participants reported reactive.			
All Labs	20	-	-
GS HIV-1 Western Blot (Bio-Rad)	1	-	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	19	-	-
SAMPLE 16132 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	4	16
GS HIV-1 Western Blot (Bio-Rad)	-	-	1
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	4	15
SAMPLE 16133 - 100% of participants reported reactive.			
All Labs	20	-	-
GS HIV-1 Western Blot (Bio-Rad)	1	-	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	19	-	-
SAMPLE 16134 - 100% of participants reported reactive.			
All Labs	20	-	-
GS HIV-1 Western Blot (Bio-Rad)	1	-	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	19	-	-
SAMPLE 16135 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	4	16
GS HIV-1 Western Blot (Bio-Rad)	-	-	1
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	4	15

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16126 - 100% of participants reported negative.			
All Labs	-	143	-
Alere Acceava Mono Cassette (Inverness)	-	5	-
Arlington Scientific Mono Tests	-	2	-
Beckman Coulter ICON Mono	-	5	-
Biokit Monogen Latex	-	6	-
Cardinal Health Color Mono Latex	-	4	-
Cardinal Health SP Brand Rapid Mono Test	-	3	-
Clearview Mono	-	26	-
Fisher Sure-View Color Mono Latex Test Kit	-	4	-
Fisher Sure-View Mono Latex	-	39	-
Fisher Sure-View Signature Mono Test Kit	-	5	-
Inverness BioStar Acceava Mono/Mono II Test	-	4	-
Meridian MonoSpot Latex	-	2	-
Meridian ImmunoCard Mono	-	4	-
Nova Scientific Infectious Mono Latex Assay	-	1	-
OSOM Mono Test	-	3	-
Polymedco PolyStat Mono	-	1	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	-	9	-
Remel Mono-Lex Test	-	3	-
Remel SeraTest MONO	-	2	-
Seradyn Color Slide II Mononucleosis	-	2	-
Wampole Color Card MONO	-	10	-
Other	-	1	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16127 - 99% of participants reported positive.			
All Labs	141	2	-
Alere Acceava Mono Cassette (Inverness)	5	-	-
Arlington Scientific Mono Tests	2	-	-
Beckman Coulter ICON Mono	5	-	-
Biokit Monogen Latex	6	-	-
Cardinal Health Color Mono Latex	4	-	-
Cardinal Health SP Brand Rapid Mono Test	3	-	-
Clearview Mono	26	-	-
Fisher Sure-View Color Mono Latex Test Kit	4	-	-
Fisher Sure-View Mono Latex	38	1	-
Fisher Sure-View Signature Mono Test Kit	5	-	-
Inverness BioStar Acceava Mono/Mono II Test	4	-	-
Meridian MonoSpot Latex	2	-	-
Meridian ImmunoCard Mono	4	-	-
Nova Scientific Infectious Mono Latex Assay	1	-	-
OSOM Mono Test	3	-	-
Polymedco PolyStat Mono	1	-	-
Rapid Response BTNX	2	-	-
Remel Color Slide II Mononucleosis	9	-	-
Remel Mono-Lex Test	3	-	-
Remel SeraTest MONO	2	-	-
Seradyn Color Slide II Mononucleosis	2	-	-
Wampole Color Card MONO	9	1	-
Other	1	-	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16128 - 93% of participants reported negative.			
All Labs	10	133	-
Alere Acceava Mono Cassette (Inverness)	-	5	-
Arlington Scientific Mono Tests	-	2	-
Beckman Coulter ICON Mono	-	5	-
Biokit Monogen Latex	-	6	-
Cardinal Health Color Mono Latex	-	4	-
Cardinal Health SP Brand Rapid Mono Test	-	3	-
Clearview Mono	-	26	-
Fisher Sure-View Color Mono Latex Test Kit	-	4	-
Fisher Sure-View Mono Latex	-	39	-
Fisher Sure-View Signature Mono Test Kit	-	5	-
Inverness BioStar Acceava Mono/Mono II Test	-	4	-
Meridian MonoSpot Latex	-	2	-
Meridian ImmunoCard Mono	-	4	-
Nova Scientific Infectious Mono Latex Assay	-	1	-
OSOM Mono Test	-	3	-
Polymedco PolyStat Mono	-	1	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	6	3	-
Remel Mono-Lex Test	-	3	-
Remel SeraTest MONO	-	2	-
Seradyn Color Slide II Mononucleosis	2	-	-
Wampole Color Card MONO	2	8	-
Other	-	1	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16129 - 100% of participants reported negative.			
All Labs	-	143	-
Alere Acceava Mono Cassette (Inverness)	-	5	-
Arlington Scientific Mono Tests	-	2	-
Beckman Coulter ICON Mono	-	5	-
Biokit Monogen Latex	-	6	-
Cardinal Health Color Mono Latex	-	4	-
Cardinal Health SP Brand Rapid Mono Test	-	3	-
Clearview Mono	-	26	-
Fisher Sure-View Color Mono Latex Test Kit	-	4	-
Fisher Sure-View Mono Latex	-	39	-
Fisher Sure-View Signature Mono Test Kit	-	5	-
Inverness BioStar Acceava Mono/Mono II Test	-	4	-
Meridian MonoSpot Latex	-	2	-
Meridian ImmunoCard Mono	-	4	-
Nova Scientific Infectious Mono Latex Assay	-	1	-
OSOM Mono Test	-	3	-
Polymedco PolyStat Mono	-	1	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	-	9	-
Remel Mono-Lex Test	-	3	-
Remel SeraTest MONO	-	2	-
Seradyn Color Slide II Mononucleosis	-	2	-
Wampole Color Card MONO	-	10	-
Other	-	1	-

Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16130 - 100% of participants reported positive.			
All Labs	143	-	-
Alere Acceava Mono Cassette (Inverness)	5	-	-
Arlington Scientific Mono Tests	2	-	-
Beckman Coulter ICON Mono	5	-	-
Biokit Monogen Latex	6	-	-
Cardinal Health Color Mono Latex	4	-	-
Cardinal Health SP Brand Rapid Mono Test	3	-	-
Clearview Mono	26	-	-
Fisher Sure-View Color Mono Latex Test Kit	4	-	-
Fisher Sure-View Mono Latex	39	-	-
Fisher Sure-View Signature Mono Test Kit	5	-	-
Inverness BioStar Acceava Mono/Mono II Test	4	-	-
Meridian MonoSpot Latex	2	-	-
Meridian ImmunoCard Mono	4	-	-
Nova Scientific Infectious Mono Latex Assay	1	-	-
OSOM Mono Test	3	-	-
Polymedco PolyStat Mono	1	-	-
Rapid Response BTNX	2	-	-
Remel Color Slide II Mononucleosis	9	-	-
Remel Mono-Lex Test	3	-	-
Remel SeraTest MONO	2	-	-
Seradyn Color Slide II Mononucleosis	2	-	-
Wampole Color Card MONO	10	-	-
Other	1	-	-

Qualitative Lyme Disease Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16141 - 100% of participants reported positive.			
All Labs	40	-	-
Bio-Rad Evolis	1	-	-
Bio-Rad Platelia Lyme IgG/IgM	2	-	-
bioMerieux VIDAS/mini VIDAS Systems	10	-	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	4	-	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	15	-	-
Immunetics C6 B. burgdorferi EIA Test	3	-	-
Laboratory developed assay	1	-	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	4	-	-

SAMPLE 16142 - 100% of participants reported negative.			
All Labs	-	40	-
Bio-Rad Evolis	-	1	-
Bio-Rad Platelia Lyme IgG/IgM	-	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	10	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	4	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	15	-
Immunetics C6 B. burgdorferi EIA Test	-	3	-
Laboratory developed assay	-	1	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	4	-

SAMPLE 16143 - 100% of participants reported negative.			
All Labs	-	40	-
Bio-Rad Evolis	-	1	-
Bio-Rad Platelia Lyme IgG/IgM	-	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	10	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	4	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	15	-
Immunetics C6 B. burgdorferi EIA Test	-	3	-
Laboratory developed assay	-	1	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	4	-

Qualitative Lyme Disease Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16144 - 100% of participants reported negative.			
All Labs	-	40	-
Bio-Rad Evolis	-	1	-
Bio-Rad Platelia Lyme IgG/IgM	-	2	-
bioMerieux VIDAS/mini VIDAS Systems	-	10	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	4	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	15	-
Immunetics C6 B. burgdorferi EIA Test	-	3	-
Laboratory developed assay	-	1	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	4	-

SAMPLE 16145 - 100% of participants reported positive.			
All Labs	40	-	-
Bio-Rad Evolis	1	-	-
Bio-Rad Platelia Lyme IgG/IgM	2	-	-
bioMerieux VIDAS/mini VIDAS Systems	10	-	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	4	-	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	15	-	-
Immunetics C6 B. burgdorferi EIA Test	3	-	-
Laboratory developed assay	1	-	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	4	-	-

Qualitative Lyme Western Blot IgG - Diagnostic Services

Primary Test Kit/Assay	Participant Results			
	Positive	Negative	Not Indicated	Equivocal
SAMPLE 16141 - 85% of participants reported positive.				
All Labs	11	2	-	-
Borrelia B31 ViraStrip IgG (Viramed)	-	2	-	-
Laboratory developed assay	2	-	-	-
MarDx Lyme Disease (IgG) Marblot Strip Test	9	-	-	-
SAMPLE 16142 - 100% of participants reported negative or testing not indicated.				
All Labs	-	10	3	-
Borrelia B31 ViraStrip IgG (Viramed)	-	2	-	-
Laboratory developed assay	-	2	-	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	6	3	-
SAMPLE 16143 - 100% of participants reported negative or testing not indicated.				
All Labs	-	10	3	-
Borrelia B31 ViraStrip IgG (Viramed)	-	2	-	-
Laboratory developed assay	-	2	-	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	6	3	-
SAMPLE 16144 - 100% of participants reported negative or testing not indicated.				
All Labs	-	10	3	-
Borrelia B31 ViraStrip IgG (Viramed)	-	2	-	-
Laboratory developed assay	-	2	-	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	6	3	-
SAMPLE 16145 - 100% of participants reported positive.				
All Labs	13	-	-	-
Borrelia B31 ViraStrip IgG (Viramed)	2	-	-	-
Laboratory developed assay	2	-	-	-
MarDx Lyme Disease (IgG) Marblot Strip Test	9	-	-	-

Qualitative Lyme Western Blot IgM - Diagnostic Services

Primary Test Kit/Assay	Participant Results			
	Positive	Negative	Not Indicated	Equivocal
SAMPLE 41 - 92% of participants reported positive.				
All Labs	12	1	-	-
Borrelia B31 ViraStrip IgM (Viramed)	2	-	-	-
Laboratory developed assay	2	-	-	-
MarDx Lyme Disease (IgM) Marblot Strip Test	8	1	-	-
SAMPLE 42 - 100% of participants reported negative.				
All Labs	-	10	3	-
Borrelia B31 ViraStrip IgM (Viramed)	-	2	-	-
Laboratory developed assay	-	2	-	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	6	3	-
SAMPLE 43 - 100% of participants reported negative.				
All Labs	-	10	3	-
Borrelia B31 ViraStrip IgM (Viramed)	-	2	-	-
Laboratory developed assay	-	2	-	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	6	3	-
SAMPLE 44 - 100% of participants reported negative.				
All Labs	-	10	3	-
Borrelia B31 ViraStrip IgM (Viramed)	-	2	-	-
Laboratory developed assay	-	2	-	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	6	3	-
SAMPLE 45 - 92% of participants reported negative.				
All Labs	1	12	-	-
Borrelia B31 ViraStrip IgM (Viramed)	-	2	-	-
Laboratory developed assay	1	1	-	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	9	-	-

Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16126 - 100% of participants reported negative.			
All Labs	-	50	-
Arlington Scientific RF Latex Test	-	3	-
Beckman Coulter Immage	-	1	-
Biokit Rheumajet RF Latex	-	4	-
Cardinal Health SP RF Latex	-	2	-
Fisher Sure-View RF Latex	-	25	-
Beckman Coulter (formerly Olympus) AU System	-	1	-
Ortho Vitros (all models)	-	1	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2	-
Siemens ADVIA 1200/1650/1800/2400	-	1	-
Siemens Dimension VISTA	-	2	-
Siemens Nephelometer Systems (all models)	-	1	-
Siemens (Dade Behring) RapiTex Latex Test	-	3	-
True Medix Diagnostics Trutest RF	-	2	-
Wampole Colorcard RF	-	1	-
Wampole Rheumatex RF	-	1	-

SAMPLE 16127 - 100% of participants reported positive.			
All Labs	50	-	-
Arlington Scientific RF Latex Test	3	-	-
Beckman Coulter Immage	1	-	-
Biokit Rheumajet RF Latex	4	-	-
Cardinal Health SP RF Latex	2	-	-
Fisher Sure-View RF Latex	25	-	-
Beckman Coulter (formerly Olympus) AU System	1	-	-
Ortho Vitros (all models)	1	-	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	2	-	-
Siemens ADVIA 1200/1650/1800/2400	1	-	-
Siemens Dimension VISTA	2	-	-
Siemens Nephelometer Systems (all models)	1	-	-
Siemens (Dade Behring) RapiTex Latex Test	3	-	-
True Medix Diagnostics Trutest RF	2	-	-
Wampole Colorcard RF	1	-	-
Wampole Rheumatex RF	1	-	-

Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16128 - 100% of participants reported positive.			
All Labs	50	-	-
Arlington Scientific RF Latex Test	3	-	-
Beckman Coulter Immage	1	-	-
Biokit Rheumajet RF Latex	4	-	-
Cardinal Health SP RF Latex	2	-	-
Fisher Sure-Vue RF Latex	25	-	-
Beckman Coulter (formerly Olympus) AU System	1	-	-
Ortho Vitros (all models)	1	-	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	2	-	-
Siemens ADVIA 1200/1650/1800/2400	1	-	-
Siemens Dimension VISTA	2	-	-
Siemens Nephelometer Systems (all models)	1	-	-
Siemens (Dade Behring) RapiTex Latex Test	3	-	-
True Medix Diagnostics Trutest RF	2	-	-
Wampole Colorcard RF	1	-	-
Wampole Rheumatex RF	1	-	-

SAMPLE 16129 - 100% of participants reported negative.			
All Labs	-	50	-
Arlington Scientific RF Latex Test	-	3	-
Beckman Coulter Immage	-	1	-
Biokit Rheumajet RF Latex	-	4	-
Cardinal Health SP RF Latex	-	2	-
Fisher Sure-Vue RF Latex	-	25	-
Beckman Coulter (formerly Olympus) AU System	-	1	-
Ortho Vitros (all models)	-	1	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2	-
Siemens ADVIA 1200/1650/1800/2400	-	1	-
Siemens Dimension VISTA	-	2	-
Siemens Nephelometer Systems (all models)	-	1	-
Siemens (Dade Behring) RapiTex Latex Test	-	3	-
True Medix Diagnostics Trutest RF	-	2	-
Wampole Colorcard RF	-	1	-
Wampole Rheumatex RF	-	1	-

Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16130 - 98% of participants reported negative.			
All Labs	1	49	-
Arlington Scientific RF Latex Test	-	3	-
Beckman Coulter Immage	-	1	-
Biokit Rheumajet RF Latex	-	4	-
Cardinal Health SP RF Latex	1	1	-
Fisher Sure-View RF Latex	-	25	-
Beckman Coulter (formerly Olympus) AU System	-	1	-
Ortho Vitros (all models)	-	1	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2	-
Siemens ADVIA 1200/1650/1800/2400	-	1	-
Siemens Dimension VISTA	-	2	-
Siemens Nephelometer Systems (all models)	-	1	-
Siemens (Dade Behring) RapiTex Latex Test	-	3	-
True Medix Diagnostics Trutest RF	-	2	-
Wampole Colorcard RF	-	1	-
Wampole Rheumatex RF	-	1	-

Rheumatoid Factor Titers - Diagnostic Services

The number of laboratories that reported titers is listed for positive test samples 16127 and 16128.

Primary Test Kit/Assay	No. Labs	Sample 16127 Titers					
		< C.O.	1:16	1:32	1:64	1:128	≥ 1:256
All Labs	15	-	4	9	1	1	-
Arlington Scientific RF Latex Test	1	-	-	1	-	-	-
Biokit Rheumajet RF Latex	2	-	-	2	-	-	-
Cardinal Health SP RF Latex	1	-	-	-	1	-	-
Fisher Sure-Vue RF Latex	10	-	3	6	-	1	-
Siemens (Dade Behring) RapiTex Latex Test	1	-	1	-	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16128 Titers					
		< C.O.	1:16	1:32	1:64	1:128	≥ 1:256
All Labs	15	-	-	1	3	6	5
Arlington Scientific RF Latex Test	1	-	-	-	1	-	-
Biokit Rheumajet RF Latex	2	-	-	1	-	1	-
Cardinal Health SP RF Latex	1	-	-	-	-	-	1
Fisher Sure-Vue RF Latex	10	-	-	-	1	5	4
Siemens (Dade Behring) RapiTex Latex Test	1	-	-	-	1	-	-

Semi-Quantitative Rheumatoid Factor - Diagnostic Services

The number of laboratories reporting semi-quantitative results for positive samples 16127 and 16128.

Primary Test Kit/Assay	No. Labs	Sample 16127 Results (IU/ml)					
		< C.O.	80	160	320	640	≥ 1280
All Labs	15	-	1	7	6	1	-
Biokit Rheumajet RF Latex	1	-	-	1	-	-	-
Fisher Sure-Vue RF Latex	11	-	-	5	6	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	1	-	1	-
Wampole Colorcard RF	1	-	1	-	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16128 Results (IU/ml)					
		< C.O.	80	160	320	640	≥ 1280
All Labs	15	-	-	1	4	1	9
Biokit Rheumajet RF Latex	1	-	-	-	-	-	1
Fisher Sure-Vue RF Latex	11	-	-	-	4	1	6
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. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16126		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		52	7	0.00	10.00	5.00	1.67
Chemiluminescence Total		1	0	-	-	-	-
	Siemens ADVIA 1200/1650/1800/2400	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		2	2	-	-	3.50	-
	Diamedix RF EIA Systems	1	1	-	-	2.70	-
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	1	-	-	4.30	-
Nephelometry Total		20	1	-	-	0.00	-
	Beckman Coulter Immage	2	0	-	-	-	-
	Beckman Coulter AU System	1	1	-	-	0.00	-
	Siemens Dimension VISTA	14	0	-	-	-	-
	Siemens Nephelometer Systems (all models)	3	0	-	-	-	-
Turbidimetry Total		29	4	-	-	4.88	-
	Beckman Coulter Immage	1	0	-	-	-	-
	Kamiya Biomedical RF	2	1	-	-	8.10	-
	Beckman Coulter AU System	12	1	-	-	6.40	-
	Ortho Vitros (all models)	2	0	-	-	-	-
	Roche Diagnostics Cobas (all systems)	4	2	-	-	2.50	-
	Roche Diagnostics RF II	1	0	-	-	-	-
	Roche/Hitachi Modular Systems (all models)	3	0	-	-	-	-
	Siemens ADVIA 1200/1650/1800/2400	4	0	-	-	-	-

Sample 16127		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		52	49	169.28	200.59	184.94	5.22
Chemiluminescence Total		1	1	-	-	216.00	-
	Siemens ADVIA 1200/1650/1800/2400	1	1	-	-	216.00	-
ELISA Enzyme-linked Immunosorbent Assay Total		2	1	-	-	278.00	-
	Diamedix RF EIA Systems	1	1	-	-	278.00	-
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	0	-	-	-	-
Nephelometry Total		20	20	150.85	215.59	183.22	10.79
	Beckman Coulter Immage	2	2	-	-	348.00	-
	Beckman Coulter AU System	1	1	-	-	159.00	-
	Siemens Dimension VISTA	14	14	166.71	201.71	184.21	5.83
	Siemens Nephelometer Systems (all models)	3	3	-	-	186.67	-
Turbidimetry Total		29	27	171.09	198.99	185.04	4.65
	Beckman Coulter Immage	1	1	-	-	343.00	-
	Kamiya Biomedical RF	2	2	-	-	180.60	-
	Beckman Coulter AU System	12	12	177.84	196.20	187.02	3.06
	Ortho Vitros (all models)	2	2	-	-	187.25	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	184.00	-
	Roche Diagnostics RF II	1	0	-	-	-	-
	Roche/Hitachi Modular Systems (all models)	3	2	-	-	179.45	-
	Siemens ADVIA 1200/1650/1800/2400	4	4	-	-	224.82	-

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

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16128		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		52	40	430.54	1442.48	936.51	168.66
Chemiluminescence Total		1	1	-	-	964.00	-
	Siemens ADVIA 1200/1650/1800/2400	1	1	-	-	964.00	-
ELISA Enzyme-linked Immunosorbent Assay Total		2	1	-	-	1142.00	-
	Diamedix RF EIA Systems	1	1	-	-	1142.00	-
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	0	-	-	-	-
Nephelometry Total		20	18	834.41	1282.45	1058.43	74.67
	Beckman Coulter Immage	2	2	-	-	2325.00	-
	Beckman Coulter AU System	1	1	-	-	334.00	-
	Siemens Dimension VISTA	14	12	846.80	1234.54	1040.67	64.62
	Siemens Nephelometer Systems (all models)	3	3	-	-	966.33	-
Turbidimetry Total		29	20	574.73	1208.00	891.36	105.55
	Beckman Coulter Immage	1	1	-	-	2180.00	-
	Kamiya Biomedical RF	2	1	-	-	662.50	-
	Beckman Coulter AU System	12	9	-	-	782.89	-
	Ortho Vitros (all models)	2	2	-	-	919.10	-
	Roche Diagnostics Cobas (all systems)	4	2	-	-	915.00	-
	Roche Diagnostics RF II	1	0	-	-	-	-
	Roche/Hitachi Modular Systems (all models)	3	2	-	-	865.50	-
	Siemens ADVIA 1200/1650/1800/2400	4	3	-	-	1037.87	-

Sample 16129		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		52	11	0.00	49.12	10.54	12.86
Chemiluminescence Total		1	0	-	-	-	-
	Siemens ADVIA 1200/1650/1800/2400	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		2	2	-	-	3.45	-
	Diamedix RF EIA Systems	1	1	-	-	4.20	-
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	1	-	-	2.70	-
Nephelometry Total		20	3	-	-	121.00	-
	Beckman Coulter Immage	2	0	-	-	-	-
	Beckman Coulter AU System	1	1	-	-	0.00	-
	Siemens Dimension VISTA	14	2	-	-	181.50	-
	Siemens Nephelometer Systems (all models)	3	0	-	-	-	-
Turbidimetry Total		29	6	-	-	10.08	-
	Beckman Coulter Immage	1	0	-	-	-	-
	Kamiya Biomedical RF	2	1	-	-	2.20	-
	Beckman Coulter AU System	12	1	-	-	6.30	-
	Ortho Vitros (all models)	2	0	-	-	-	-
	Roche Diagnostics Cobas (all systems)	4	2	-	-	3.50	-
	Roche Diagnostics RF II	1	0	-	-	-	-
	Roche/Hitachi Modular Systems (all models)	3	2	-	-	22.50	-
	Siemens ADVIA 1200/1650/1800/2400	4	0	-	-	-	-

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

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16130		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		52	10	0.00	12.46	4.78	2.56
Chemiluminescence Total		1	1	-	-	3.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	1	1	-	-	3.00	-
ELISA Enzyme-linked Immunosorbent Assay Total		2	2	-	-	3.25	-
	<i>Diamedix RF EIA Systems</i>	1	1	-	-	2.90	-
	<i>IMMCO Diagnostics ImmuLisa Rheumatoid Factor - IgM</i>	1	1	-	-	3.60	-
Nephelometry Total		20	1	-	-	1.50	-
	<i>Beckman Coulter Immage</i>	2	0	-	-	-	-
	<i>Beckman Coulter AU System</i>	1	1	-	-	1.50	-
	<i>Siemens Dimension VISTA</i>	14	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	0	-	-	-	-
Turbidimetry Total		29	6	-	-	6.13	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Kamiya Biomedical RF</i>	2	1	-	-	5.50	-
	<i>Beckman Coulter AU System</i>	12	2	-	-	4.65	-
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	1	-	-	8.00	-
	<i>Roche Diagnostics RF II</i>	1	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	3	1	-	-	8.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	4	1	-	-	6.00	-

Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16111 - 100% of participants reported positive.			
All Labs	66	-	-
Beckman Coulter ACCESS	2	-	-
Beckman Coulter UniCel DxI Systems (all models)	3	-	-
Bio-Rad Bioplex MMRV IgG	2	-	-
Bio-Rad Rubella IgG EIA	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	5	-	-
Clearview Rubella Plus	1	-	-
Diasorin Liaison Rubella IgG	8	-	-
Diasorin Rubella IgG ELISA	1	-	-
Diamedix Rubella EIA Systems IgG	2	-	-
Fisher Sure-View Rubella	5	-	-
Ortho Vitros (all models)	5	-	-
Remel Ruba-Test	1	-	-
Roche Diagnostics Cobas (all systems)	4	-	-
Roche/Hitachi Modular Systems (all models)	1	-	-
Siemens ADVIA Centaur	17	-	-
Siemens Immulite Systems (all models)	1	-	-
Trinity Biotech CAPTIA Rubella IgG EIA	3	-	-
Wampole Rubella IgG ELISA/ELISA II	1	-	-
Inverness/Wampole Rubella IgG EIA Systems	3	-	-

SAMPLE 16112 - 98% of participants reported positive.			
All Labs	65	1	-
Beckman Coulter ACCESS	2	-	-
Beckman Coulter UniCel DxI Systems (all models)	3	-	-
Bio-Rad Bioplex MMRV IgG	2	-	-
Bio-Rad Rubella IgG EIA	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	5	-	-
Clearview Rubella Plus	1	-	-
Diasorin Liaison Rubella IgG	8	-	-
Diasorin Rubella IgG ELISA	-	1	-
Diamedix Rubella EIA Systems IgG	2	-	-
Fisher Sure-View Rubella	5	-	-
Ortho Vitros (all models)	5	-	-
Remel Ruba-Test	1	-	-
Roche Diagnostics Cobas (all systems)	4	-	-
Roche/Hitachi Modular Systems (all models)	1	-	-
Siemens ADVIA Centaur	17	-	-
Siemens Immulite Systems (all models)	1	-	-
Trinity Biotech CAPTIA Rubella IgG EIA	3	-	-
Wampole Rubella IgG ELISA/ELISA II	1	-	-
Inverness/Wampole Rubella IgG EIA Systems	3	-	-

Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16113 - 100% of participants reported negative.			
All Labs	-	66	-
Beckman Coulter ACCESS	-	2	-
Beckman Coulter UniCel DxI Systems (all models)	-	3	-
Bio-Rad Bioplex MMRV IgG	-	2	-
Bio-Rad Rubella IgG EIA	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	5	-
Clearview Rubella Plus	-	1	-
Diasorin Liaison Rubella IgG	-	8	-
Diasorin Rubella IgG ELISA	-	1	-
Diamedix Rubella EIA Systems IgG	-	2	-
Fisher Sure-View Rubella	-	5	-
Ortho Vitros (all models)	-	5	-
Remel Ruba-Test	-	1	-
Roche Diagnostics Cobas (all systems)	-	4	-
Roche/Hitachi Modular Systems (all models)	-	1	-
Siemens ADVIA Centaur	-	17	-
Siemens Immulite Systems (all models)	-	1	-
Trinity Biotech CAPTIA Rubella IgG EIA	-	3	-
Wampole Rubella IgG ELISA/ELISA II	-	1	-
Inverness/Wampole Rubella IgG EIA Systems	-	3	-

SAMPLE 16114 - 98% of participants reported positive.			
All Labs	65	1	-
Beckman Coulter ACCESS	2	-	-
Beckman Coulter UniCel DxI Systems (all models)	3	-	-
Bio-Rad Bioplex MMRV IgG	2	-	-
Bio-Rad Rubella IgG EIA	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	5	-	-
Clearview Rubella Plus	1	-	-
Diasorin Liaison Rubella IgG	8	-	-
Diasorin Rubella IgG ELISA	1	-	-
Diamedix Rubella EIA Systems IgG	2	-	-
Fisher Sure-View Rubella	5	-	-
Ortho Vitros (all models)	4	1	-
Remel Ruba-Test	1	-	-
Roche Diagnostics Cobas (all systems)	4	-	-
Roche/Hitachi Modular Systems (all models)	1	-	-
Siemens ADVIA Centaur	17	-	-
Siemens Immulite Systems (all models)	1	-	-
Trinity Biotech CAPTIA Rubella IgG EIA	3	-	-
Wampole Rubella IgG ELISA/ELISA II	1	-	-
Inverness/Wampole Rubella IgG EIA Systems	3	-	-

Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16115 - 100% of participants reported positive.			
All Labs	66	-	-
Beckman Coulter ACCESS	2	-	-
Beckman Coulter UniCel DxI Systems (all models)	3	-	-
Bio-Rad Bioplex MMRV IgG	2	-	-
Bio-Rad Rubella IgG EIA	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	5	-	-
Clearview Rubella Plus	1	-	-
Diasorin Liaison Rubella IgG	8	-	-
Diasorin Rubella IgG ELISA	1	-	-
Diamedix Rubella EIA Systems IgG	2	-	-
Fisher Sure-View Rubella	5	-	-
Ortho Vitros (all models)	5	-	-
Remel Ruba-Test	1	-	-
Roche Diagnostics Cobas (all systems)	4	-	-
Roche/Hitachi Modular Systems (all models)	1	-	-
Siemens ADVIA Centaur	17	-	-
Siemens Immulite Systems (all models)	1	-	-
Trinity Biotech CAPTIA Rubella IgG EIA	3	-	-
Wampole Rubella IgG ELISA/ELISA II	1	-	-
Inverness/Wampole Rubella IgG EIA Systems	3	-	-

Quantitative Rubella Ab IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16111		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		34	34	0.00	149.36	60.95	29.47
Chemiluminescence Total		31	31	0.00	119.50	56.65	20.95
	Beckman Coulter ACCESS	1	1	-	-	30.60	-
	Beckman Coulter UniCel DxI Systems (all models)	3	3	-	-	44.67	-
	DiaSorin Liaison Rubella IgG Chemiluminescent Assay	2	2	-	-	2.85	-
	Ortho Vitros (all models)	3	3	-	-	59.23	-
	Roche Diagnostics Cobas (all systems)	2	2	-	-	128.55	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	130.00	-
	Siemens ADVIA Centaur	17	17	42.15	95.37	68.76	8.87
	Siemens Immulite Systems (all models)	2	2	-	-	34.60	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	3	-	-	33.07	-
	Beckman Coulter ACCESS	1	1	-	-	38.20	-
	bioMerieux VIDAS/mini VIDAS Systems	2	2	-	-	30.50	-

Sample 16112		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		34	18	0.00	498.55	143.50	118.35
Chemiluminescence Total		31	15	0.00	531.58	158.60	124.33
	Beckman Coulter ACCESS	1	1	-	-	95.70	-
	Beckman Coulter UniCel DxI Systems (all models)	3	3	-	-	113.67	-
	DiaSorin Liaison Rubella IgG Chemiluminescent Assay	2	2	-	-	8.63	-
	Ortho Vitros (all models)	3	3	-	-	159.00	-
	Roche Diagnostics Cobas (all systems)	2	2	-	-	274.85	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	272.00	-
	Siemens ADVIA Centaur	17	1	-	-	476.10	-
	Siemens Immulite Systems (all models)	2	2	-	-	75.15	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	3	-	-	67.97	-
	Beckman Coulter ACCESS	1	1	-	-	95.90	-
	bioMerieux VIDAS/mini VIDAS Systems	2	2	-	-	54.00	-

Sample 16113		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		34	21	0.00	2.35	0.66	0.56
Chemiluminescence Total		31	19	0.00	2.40	0.69	0.57
	Beckman Coulter ACCESS	1	1	-	-	0.90	-
	Beckman Coulter UniCel DxI Systems (all models)	3	3	-	-	1.33	-
	DiaSorin Liaison Rubella IgG Chemiluminescent Assay	2	0	-	-	-	-
	Ortho Vitros (all models)	3	3	-	-	0.00	-
	Roche Diagnostics Cobas (all systems)	2	2	-	-	0.39	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	0.30	-
	Siemens ADVIA Centaur	17	9	-	-	0.78	-
	Siemens Immulite Systems (all models)	2	0	-	-	-	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	2	-	-	0.40	-
	Beckman Coulter ACCESS	1	1	-	-	0.80	-
	bioMerieux VIDAS/mini VIDAS Systems	2	1	-	-	0.00	-

Quantitative Rubella Ab IU/ml - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16114		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		34	4	0.00	1023.97	360.50	221.16
Chemiluminescence Total		31	4	-	-	360.50	-
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	501.00	-
	<i>Beckman Coulter UniCel DxI Systems (all models)</i>	3	0	-	-	-	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	2	1	-	-	30.50	-
	<i>Ortho Vitros (all models)</i>	3	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	2	1	-	-	463.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	447.00	-
	<i>Siemens ADVIA Centaur</i>	17	0	-	-	-	-
	<i>Siemens Immulite Systems (all models)</i>	2	0	-	-	-	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	0	-	-	-	-
	<i>Beckman Coulter ACCESS</i>	1	0	-	-	-	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	0	-	-	-	-

Sample 16115		Total	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs		Low	High		
All Methods		34	34	0.00	94.07	46.61	15.82
Chemiluminescence Total		31	31	20.99	81.95	51.47	10.16
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	34.20	-
	<i>Beckman Coulter UniCel DxI Systems (all models)</i>	3	3	-	-	44.13	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	2	2	-	-	3.03	-
	<i>Ortho Vitros (all models)</i>	3	3	-	-	63.30	-
	<i>Roche Diagnostics Cobas (all systems)</i>	2	2	-	-	142.95	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	143.00	-
	<i>Siemens ADVIA Centaur</i>	17	17	32.04	75.05	53.55	7.17
	<i>Siemens Immulite Systems (all models)</i>	2	2	-	-	35.70	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	3	-	-	33.60	-
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	33.80	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	2	-	-	33.50	-

Qualitative Rubella IgM Specific - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16156 - 100% of participants reported negative.			
All Labs	-	12	-
DiaSorin Liaison Rubella IgM	-	3	-
Diamedix Rubella EIA Systems IgM	-	1	-
Rubella IgM EIA Systems (Roche)	-	1	-
Siemens ADVIA Centaur	-	3	-
Siemens Immulite Systems (all models)	-	4	-
SAMPLE 16157 - 83% of participants reported positive.			
All Labs	10	-	2
DiaSorin Liaison Rubella IgM	3	-	-
Diamedix Rubella EIA Systems IgM	1	-	-
Rubella IgM EIA Systems (Roche)	1	-	-
Siemens ADVIA Centaur	3	-	-
Siemens Immulite Systems (all models)	2	-	2
SAMPLE 16158 - 100% of participants reported negative.			
All Labs	-	12	-
DiaSorin Liaison Rubella IgM	-	3	-
Diamedix Rubella EIA Systems IgM	-	1	-
Rubella IgM EIA Systems (Roche)	-	1	-
Siemens ADVIA Centaur	-	3	-
Siemens Immulite Systems (all models)	-	4	-
SAMPLE 16159 - 100% of participants reported negative.			
All Labs	-	12	-
DiaSorin Liaison Rubella IgM	-	3	-
Diamedix Rubella EIA Systems IgM	-	1	-
Rubella IgM EIA Systems (Roche)	-	1	-
Siemens ADVIA Centaur	-	3	-
Siemens Immulite Systems (all models)	-	4	-
SAMPLE 16160 - 100% of participants reported negative.			
All Labs	-	12	-
DiaSorin Liaison Rubella IgM	-	3	-
Diamedix Rubella EIA Systems IgM	-	1	-
Rubella IgM EIA Systems (Roche)	-	1	-
Siemens ADVIA Centaur	-	3	-
Siemens Immulite Systems (all models)	-	4	-

Qualitative Syphilis Reagin Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16101 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	106	5
Ampcor RPR Card Test	-	1	-
ASI RPR Card Test for Syphilis	-	17	-
Becton Dickenson Macro-vue RPR	-	41	4
Fisher Sure-Vue RPR	-	26	-
Stanbio Syphilis (RPR) Quicktest	-	1	-
True Medix Diagnostics Trutest RPR	-	9	1
Wampole IMPACT RPR	-	10	-
Other	-	1	-
SAMPLE 16102 - 100% of participants reported reactive.			
All Labs	111	-	-
Ampcor RPR Card Test	1	-	-
ASI RPR Card Test for Syphilis	17	-	-
Becton Dickenson Macro-vue RPR	45	-	-
Fisher Sure-Vue RPR	26	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-
True Medix Diagnostics Trutest RPR	10	-	-
Wampole IMPACT RPR	10	-	-
Other	1	-	-
SAMPLE 16103 - 100% of participants reported reactive.			
All Labs	111	-	-
Ampcor RPR Card Test	1	-	-
ASI RPR Card Test for Syphilis	17	-	-
Becton Dickenson Macro-vue RPR	45	-	-
Fisher Sure-Vue RPR	26	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-
True Medix Diagnostics Trutest RPR	10	-	-
Wampole IMPACT RPR	10	-	-
Other	1	-	-

Qualitative Syphilis Reagin Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16104 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	107	4
Ampcor RPR Card Test	-	1	-
ASI RPR Card Test for Syphilis	-	17	-
Becton Dickenson Macro-vue RPR	-	41	4
Fisher Sure-Vue RPR	-	26	-
Stanbio Syphilis (RPR) Quicktest	-	1	-
True Medix Diagnostics Trutest RPR	-	10	-
Wampole IMPACT RPR	-	10	-
Other	-	1	-
SAMPLE 16105 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	107	4
Ampcor RPR Card Test	-	1	-
ASI RPR Card Test for Syphilis	-	17	-
Becton Dickenson Macro-vue RPR	-	41	4
Fisher Sure-Vue RPR	-	26	-
Stanbio Syphilis (RPR) Quicktest	-	1	-
True Medix Diagnostics Trutest RPR	-	10	-
Wampole IMPACT RPR	-	10	-
Other	-	1	-

Syphilis Reagin Ab (RPR) Titers - Diagnostic Services

The number of laboratories that reported titers is listed for reactive test samples 16102 and 16103.

Primary Test Kit/Assay	No. Labs	Sample 16102 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	103	-	3	40	57	3	-	-
Ampcor RPR Card Test	1	-	-	-	1	-	-	-
ASI RPR Card Test for Syphilis	9	-	1	2	5	1	-	-
Becton Dickinson Macro-vue RPR	45	-	-	21	22	2	-	-
Fisher Sure-Vue RPR	26	-	1	9	16	-	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-	1	-	-	-	-
True Medix Diagnostics Trutest RPR	10	-	1	4	5	-	-	-
Wampole IMPACT RPR	10	-	-	2	8	-	-	-
Other	1	-	-	2	8	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16103 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	103	-	-	8	69	24	2	-
Ampcor RPR Card Test	1	-	-	-	-	1	-	-
ASI RPR Card Test for Syphilis	9	-	-	1	4	3	1	-
Becton Dickinson Macro-vue RPR	45	-	-	2	32	10	1	-
Fisher Sure-Vue RPR	26	-	-	1	17	8	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-	1	-	-	-	-
True Medix Diagnostics Trutest RPR	10	-	-	2	6	2	-	-
Wampole IMPACT RPR	10	-	-	1	9	-	-	-
Other	1	-	-	-	1	-	-	-

Qualitative Syphilis Treponemal Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Not Indicated
SAMPLE 16101 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	45	5
Bio-Rad Bioplex	-	1	-
DiaSorin Liaison Treponemal Assay	-	11	-
Fujirebio Serodia-TP-PA	-	8	3
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	3	-
Siemens ADVIA Centaur SYPH Assay	-	5	-
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	7	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	3	2
Other	-	2	-

SAMPLE 16102 - 100% of participants reported reactive.

All Labs	50	-	-
Bio-Rad Bioplex	1	-	-
DiaSorin Liaison Treponemal Assay	11	-	-
Fujirebio Serodia-TP-PA	11	-	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	3	-	-
Siemens ADVIA Centaur SYPH Assay	5	-	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	7	-	-
Wampole IMPACT IFA	1	-	-
Zeus Scientific FTA-ABS	5	-	-
Other	2	-	-

SAMPLE 16103 - 100% of participants reported reactive.

All Labs	50	-	-
Bio-Rad Bioplex	1	-	-
DiaSorin Liaison Treponemal Assay	11	-	-
Fujirebio Serodia-TP-PA	11	-	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	3	-	-
Siemens ADVIA Centaur SYPH Assay	5	-	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	7	-	-
Wampole IMPACT IFA	1	-	-
Zeus Scientific FTA-ABS	5	-	-
Other	2	-	-

Qualitative Syphilis Treponemal Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Not Indicated
SAMPLE 16104 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	45	5
Bio-Rad Bioplex	-	1	-
DiaSorin Liaison Treponemal Assay	-	11	-
Fujirebio Serodia-TP-PA	-	8	3
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	3	-
Siemens ADVIA Centaur SYPH Assay	-	5	-
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	7	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	3	2
Other	-	2	-

SAMPLE 16105 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	45	5
Bio-Rad Bioplex	-	1	-
DiaSorin Liaison Treponemal Assay	-	11	-
Fujirebio Serodia-TP-PA	-	8	3
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	3	-
Siemens ADVIA Centaur SYPH Assay	-	5	-
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	7	-
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	3	2
Other	-	2	-

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

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16176		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		13	13	85.17	129.66	107.42	7.42
Nephelometry Total		8	8	106.90	120.25	113.57	2.23
	<i>Beckman Coulter Image</i>	1	1	-	-	95.10	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	113.33	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	113.75	-
Turbidimetry Total		5	5	-	-	101.26	-
	<i>Abbott Architect</i>	1	1	-	-	101.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	3	-	-	102.43	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	98.00	-

Sample 16177		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		13	0	0.00	10.00	5.00	1.67
Nephelometry Total		8	0	-	-	-	-
	<i>Beckman Coulter Image</i>	1	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	3	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	0	-	-	-	-
Turbidimetry Total		5	0	-	-	-	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-

Sample 16178		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		13	13	9.52	292.22	150.87	47.12
Nephelometry Total		8	8	158.12	224.16	191.14	11.01
	<i>Beckman Coulter Image</i>	1	1	-	-	73.20	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	187.33	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	194.00	-
Turbidimetry Total		5	5	-	-	110.02	-
	<i>Abbott Architect</i>	1	1	-	-	104.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	3	-	-	114.37	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	103.00	-

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

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16179		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		13	12	79.15	117.73	98.44	6.43
Nephelometry Total		8	8	77.44	122.14	99.79	7.45
	<i>Beckman Coulter Immage</i>	1	1	-	-	92.60	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	94.23	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	105.75	-
Turbidimetry Total		5	4	-	-	95.75	-
	<i>Abbott Architect</i>	1	1	-	-	94.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	3	-	-	96.33	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-

Sample 16180		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		13	13	51.45	135.93	93.69	14.08
Nephelometry Total		8	8	76.51	129.39	102.95	8.81
	<i>Beckman Coulter Immage</i>	1	1	-	-	85.60	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	105.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	105.75	-
Turbidimetry Total		5	5	-	-	78.88	-
	<i>Abbott Architect</i>	1	1	-	-	74.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	3	-	-	80.13	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	80.00	-

Quantitative Complement C3 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16176		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		40	40	70.00	88.69	79.34	3.12
Nephelometry Total		14	14	70.88	91.82	81.35	3.49
	<i>Beckman Coulter Immage</i>	2	2	-	-	70.55	-
	<i>Siemens Dimension VISTA</i>	9	9	-	-	82.50	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	78.67	-
Turbidimetry Total		26	26	71.13	85.56	78.34	2.40
	<i>Abbott Architect</i>	1	1	-	-	74.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	79.30	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	71.31	85.31	78.31	2.33
	<i>Ortho Vitros (all models)</i>	2	2	-	-	79.50	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	78.57	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	80.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	75.00	-

Sample 16177		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		40	23	5.68	19.78	12.73	2.35
Nephelometry Total		14	10	7.85	14.45	11.15	1.10
	<i>Beckman Coulter Immage</i>	2	2	-	-	10.15	-
	<i>Siemens Dimension VISTA</i>	9	5	-	-	11.44	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	11.33	-
Turbidimetry Total		26	13	6.89	21.01	13.95	2.35
	<i>Abbott Architect</i>	1	1	-	-	17.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	0	-	-	-	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	7	-	-	14.90	-
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	2	-	-	11.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	13.50	-
	<i>Dimension (Siemens)</i>	1	1	-	-	11.00	-

Quantitative Complement C3 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16178		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		40	40	112.04	141.86	126.95	4.97
Nephelometry Total		14	14	118.22	144.49	131.36	4.38
	<i>Beckman Coulter Immage</i>	2	2	-	-	130.50	-
	<i>Siemens Dimension VISTA</i>	9	9	-	-	131.11	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	132.67	-
Turbidimetry Total		26	26	114.25	134.90	124.58	3.44
	<i>Abbott Architect</i>	1	1	-	-	124.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	120.50	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	113.12	135.24	124.18	3.69
	<i>Ortho Vitros (all models)</i>	2	2	-	-	126.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	127.43	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	126.50	-
	<i>Dimension (Siemens)</i>	1	1	-	-	124.00	-

Sample 16179		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		40	40	84.37	140.25	112.31	9.31
Nephelometry Total		14	14	109.53	134.90	122.21	4.23
	<i>Beckman Coulter Immage</i>	2	2	-	-	124.00	-
	<i>Siemens Dimension VISTA</i>	9	9	-	-	121.11	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	124.33	-
Turbidimetry Total		26	26	87.65	126.29	106.97	6.44
	<i>Abbott Architect</i>	1	1	-	-	110.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	110.20	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	94.41	113.07	103.74	3.11
	<i>Ortho Vitros (all models)</i>	2	2	-	-	121.50	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	107.27	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	109.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	112.00	-

Quantitative Complement C3 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16180		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		40	40	62.57	92.01	77.29	4.91
Nephelometry Total		14	14	75.66	90.41	83.04	2.46
	Beckman Coulter Immage	2	2	-	-	80.30	-
	Siemens Dimension VISTA	9	9	-	-	83.61	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	81.33	-
Turbidimetry Total		26	26	66.86	81.53	74.20	2.44
	Abbott Architect	1	1	-	-	73.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	73.15	-
	Beckman Coulter (formerly Olympus) AU System	15	15	66.88	81.31	74.09	2.40
	Ortho Vitros (all models)	2	2	-	-	78.00	-
	Roche Diagnostics Cobas (all systems)	3	3	-	-	73.80	-
	Roche/Hitachi Modular Systems (all models)	2	2	-	-	74.50	-
	Dimension (Siemens)	1	1	-	-	72.00	-

Quantitative Complement C4 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16176		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	14.25	20.06	17.16	0.97
Nephelometry Total		12	12	15.60	19.47	17.53	0.64
	<i>Beckman Coulter Immage</i>	2	2	-	-	17.90	-
	<i>Siemens Dimension VISTA</i>	7	7	-	-	17.66	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	17.00	-
Turbidimetry Total		27	27	13.84	20.14	16.99	1.05
	<i>Abbott Architect</i>	1	1	-	-	17.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	16.60	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	14.85	19.78	17.31	0.82
	<i>Ortho Vitros (all models)</i>	2	2	-	-	18.00	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	3	-	-	15.47	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	16.50	-
	<i>Dimension (Siemens)</i>	1	1	-	-	15.00	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	18.00	-

Sample 16177		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	7	1.00	8.00	4.50	1.17
Nephelometry Total		12	0	-	-	-	-
	<i>Beckman Coulter Immage</i>	2	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	7	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	0	-	-	-	-
Turbidimetry Total		27	7	-	-	1.00	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	0	-	-	-	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	5	-	-	0.96	-
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	0	-	-	-	-
	<i>Dimension (Siemens)</i>	1	1	-	-	1.00	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	7.00	-

Quantitative Complement C4 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16178		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	23.50	34.76	29.13	1.88
Nephelometry Total		12	12	25.72	33.81	29.77	1.35
	<i>Beckman Coulter Immage</i>	2	2	-	-	31.55	-
	<i>Siemens Dimension VISTA</i>	7	7	-	-	29.13	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	30.07	-
Turbidimetry Total		27	27	22.77	34.93	28.85	2.03
	<i>Abbott Architect</i>	1	1	-	-	27.80	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	26.60	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	26.19	34.00	30.09	1.30
	<i>Ortho Vitros (all models)</i>	2	2	-	-	30.25	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	3	-	-	26.03	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	26.50	-
	<i>Dimension (Siemens)</i>	1	1	-	-	26.00	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	29.00	-

Sample 16179		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	13.88	26.91	20.40	2.17
Nephelometry Total		12	12	20.37	25.71	23.04	0.89
	<i>Beckman Coulter Immage</i>	2	2	-	-	22.70	-
	<i>Siemens Dimension VISTA</i>	7	7	-	-	22.80	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	23.73	-
Turbidimetry Total		27	27	14.81	23.83	19.32	1.50
	<i>Abbott Architect</i>	1	1	-	-	22.30	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	20.45	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	16.08	21.96	19.02	0.98
	<i>Ortho Vitros (all models)</i>	2	2	-	-	22.40	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	3	-	-	17.47	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	18.50	-
	<i>Dimension (Siemens)</i>	1	1	-	-	20.00	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	19.00	-

Quantitative Complement C4 (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16180		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	10.10	17.42	13.76	1.22
Nephelometry Total		12	12	12.79	17.35	15.07	0.76
	<i>Beckman Coulter Immage</i>	2	2	-	-	15.45	-
	<i>Siemens Dimension VISTA</i>	7	7	-	-	15.09	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	14.77	-
Turbidimetry Total		27	27	10.51	15.84	13.18	0.89
	<i>Abbott Architect</i>	1	1	-	-	14.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	12.95	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	11.51	15.34	13.43	0.64
	<i>Ortho Vitros (all models)</i>	2	2	-	-	14.20	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	3	-	-	11.70	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	12.50	-
	<i>Dimension (Siemens)</i>	1	1	-	-	12.00	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	14.00	-

Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16181		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		46	45	103.61	224.38	164.00	20.13
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	16	97.83	257.11	177.47	26.55
	<i>Beckman Coulter Immage</i>	4	4	-	-	136.00	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	163.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	194.12	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	193.00	-
Turbidimetry Total		29	29	134.93	178.06	156.49	7.19
	<i>Abbott Architect</i>	2	2	-	-	153.25	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	157.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	140.98	176.90	158.94	5.99
	<i>Ortho Vitros (all models)</i>	2	2	-	-	162.88	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	146.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	142.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	184.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	157.00	-

Sample 16182		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		46	45	100.35	201.72	151.03	16.90
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	16	84.72	227.83	156.28	23.85
	<i>Beckman Coulter Immage</i>	4	4	-	-	119.25	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	150.40	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	167.57	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	169.67	-
Turbidimetry Total		29	29	115.36	180.93	148.14	10.93
	<i>Abbott Architect</i>	2	2	-	-	142.15	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	140.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	134.75	171.39	153.07	6.11
	<i>Ortho Vitros (all models)</i>	2	2	-	-	159.42	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	133.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	132.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	151.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	154.00	-

Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16183		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		46	45	101.85	163.39	132.62	10.26
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	16	97.88	175.70	136.79	12.97
	<i>Beckman Coulter Immage</i>	4	4	-	-	119.75	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	132.60	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	141.38	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	148.67	-
Turbidimetry Total		29	29	107.12	153.52	130.32	7.73
	<i>Abbott Architect</i>	2	2	-	-	124.40	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	119.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	119.56	148.98	134.27	4.90
	<i>Ortho Vitros (all models)</i>	2	2	-	-	131.24	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	123.75	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	117.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	134.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	135.50	-

Sample 16184		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		46	45	76.67	127.68	102.18	8.50
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	16	70.45	134.16	102.31	10.62
	<i>Beckman Coulter Immage</i>	4	4	-	-	86.22	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	101.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	107.33	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	109.00	-
Turbidimetry Total		29	29	80.23	123.97	102.10	7.29
	<i>Abbott Architect</i>	2	2	-	-	100.55	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	96.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	94.20	116.33	105.27	3.69
	<i>Ortho Vitros (all models)</i>	2	2	-	-	99.44	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	94.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	91.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	111.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	107.50	-

Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16185		Total	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay	Labs		Low	High	Mean	S.D.
All Methods		46	41	27.80	44.40	36.10	2.77
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	15	24.21	46.00	35.11	3.63
	<i>Beckman Coulter Immage</i>	4	3	-	-	29.50	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	39.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	35.35	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	38.67	-
Turbidimetry Total		29	26	27.68	45.88	36.78	3.03
	<i>Abbott Architect</i>	2	2	-	-	43.35	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	35.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	30.41	43.01	36.71	2.10
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	3	-	-	33.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	33.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	45.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	36.50	-

Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16181		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		36	36	53.75	145.47	99.61	15.29
Chemiluminescence Total		22	22	65.41	118.32	91.87	8.82
	<i>Beckman Coulter ACCESS</i>	5	5	-	-	97.65	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	3	3	-	-	99.49	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	90.85	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	95.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	66.00	-
	<i>Siemens Immulite Systems (all models)</i>	10	10	71.44	106.02	88.73	5.76
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	340.25	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	340.25	-
Fluoroenzyme Immunoassay (FEIA) Total		9	9	-	-	104.41	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	7	7	-	-	102.15	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	91.80	-
Nephelometry Total		5	5	-	-	126.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	126.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	126.00	-

Sample 16182		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		36	36	11.66	69.79	40.73	9.69
Chemiluminescence Total		22	22	11.40	69.01	40.20	9.60
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	52.80	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	3	3	-	-	53.52	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	35.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	37.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	25.00	-
	<i>Siemens Immulite Systems (all models)</i>	10	10	26.83	41.15	33.99	2.39
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	368.22	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	368.22	-
Fluoroenzyme Immunoassay (FEIA) Total		8	8	-	-	38.94	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	6	6	-	-	40.62	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	28.90	-
Nephelometry Total		5	5	-	-	90.88	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	90.75	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	91.40	-

Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

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Sample 16183		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		36	36	53.74	99.55	76.64	7.64
Chemiluminescence Total		22	22	55.01	103.59	79.30	8.10
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	71.38	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	3	3	-	-	76.05	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	73.05	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	77.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	69.00	-
	<i>Siemens Immulite Systems (all models)</i>	10	10	69.33	103.63	86.48	5.72
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	68.80	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	68.80	-
Fluoroenzyme Immunoassay (FEIA) Total		8	8	-	-	72.29	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	6	6	-	-	73.03	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	67.80	-
Nephelometry Total		5	5	-	-	72.60	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	72.55	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	72.80	-

Sample 16184		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		36	36	130.34	232.59	181.46	17.04
Chemiluminescence Total		22	22	135.71	237.59	186.65	16.98
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	179.61	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	3	3	-	-	181.85	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	174.65	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	182.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	170.00	-
	<i>Siemens Immulite Systems (all models)</i>	10	10	140.73	254.67	197.70	18.99
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	149.51	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	149.51	-
Fluoroenzyme Immunoassay (FEIA) Total		8	8	-	-	178.24	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	6	6	-	-	174.17	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	173.40	-
Nephelometry Total		5	5	-	-	170.20	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	170.25	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	170.00	-

Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

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Sample 16185		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		36	36	4.98	13.30	9.14	1.39
Chemiluminescence Total		22	22	6.36	10.74	8.55	0.73
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	7.94	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	3	3	-	-	8.31	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	7.75	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	8.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	9.00	-
	<i>Siemens Immulite Systems (all models)</i>	10	10	7.16	10.87	9.02	0.62
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	24.07	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	24.07	-
Fluoroenzyme Immunoassay (FEIA) Total		8	8	-	-	9.84	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	6	6	-	-	10.17	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	7.20	-
Nephelometry Total		5	5	-	-	10.64	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	10.47	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	11.30	-

Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

Acceptable ranges are given where 10 or more laboratories reported quantitative results. If less than 10 labs for a specific assay can be used in statistics the method total and/or all method range is used. * Outlier values and values with qualifiers are omitted from statistics.

Sample 16181		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		43	43	582.48	970.80	776.64	64.72
Nephelometry Total		16	16	608.06	1013.44	810.75	67.56
	<i>Beckman Coulter Immage</i>	4	4	-	-	780.25	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	817.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	821.62	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	820.33	-
Turbidimetry Total		27	27	566.74	944.56	755.65	62.97
	<i>Abbott Architect</i>	1	1	-	-	756.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	773.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	559.95	933.25	746.60	62.22
	<i>Ortho Vitros (all models)</i>	2	2	-	-	806.78	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	755.75	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	727.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	937.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	787.50	-

Sample 16182		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		43	43	571.85	953.09	762.47	63.54
Nephelometry Total		16	16	561.56	935.94	748.75	62.40
	<i>Beckman Coulter Immage</i>	4	4	-	-	763.75	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	727.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	739.12	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	761.67	-
Turbidimetry Total		27	27	577.95	963.25	770.60	64.22
	<i>Abbott Architect</i>	1	1	-	-	807.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	762.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	574.19	956.98	765.59	63.80
	<i>Ortho Vitros (all models)</i>	2	2	-	-	853.50	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	743.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	735.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	746.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	812.00	-

Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

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Sample 16183		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		43	43	409.47	682.46	545.96	45.50
Nephelometry Total		16	16	411.71	686.18	548.94	45.75
	<i>Beckman Coulter Immage</i>	4	4	-	-	546.75	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	522.10	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	565.38	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	544.67	-
Turbidimetry Total		27	27	408.23	680.39	544.31	45.36
	<i>Abbott Architect</i>	1	1	-	-	561.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	545.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	403.00	671.66	537.33	44.78
	<i>Ortho Vitros (all models)</i>	2	2	-	-	583.41	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	548.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	506.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	561.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	567.50	-

Sample 16184		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		43	43	319.52	532.53	426.03	35.50
Nephelometry Total		16	16	321.81	536.35	429.08	35.76
	<i>Beckman Coulter Immage</i>	4	4	-	-	429.75	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	342.30	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	443.75	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	429.33	-
Turbidimetry Total		27	27	316.72	527.87	422.30	35.19
	<i>Abbott Architect</i>	1	1	-	-	445.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	427.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	310.40	517.33	413.86	34.49
	<i>Ortho Vitros (all models)</i>	2	2	-	-	443.98	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	424.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	388.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	472.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	450.50	-

Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

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Sample 16185		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		43	38	124.67	207.79	166.23	13.85
Nephelometry Total		16	15	131.65	219.41	175.53	14.63
	<i>Beckman Coulter Immage</i>	4	3	-	-	190.67	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	170.90	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	174.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	166.00	-
Turbidimetry Total		27	23	122.27	203.79	163.03	13.59
	<i>Abbott Architect</i>	1	1	-	-	177.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	164.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	113.56	189.26	151.41	12.62
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	2	-	-	173.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	156.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	232.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	198.50	-

Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

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Sample 16181		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		42	42	41.96	78.29	60.13	6.05
Nephelometry Total		15	15	47.43	81.69	64.56	5.71
	<i>Beckman Coulter Image</i>	4	4	-	-	58.03	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	68.04	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	64.00	-
Turbidimetry Total		27	27	48.44	65.40	56.92	2.83
	<i>Abbott Architect</i>	1	1	-	-	57.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	62.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	50.51	63.05	56.78	2.09
	<i>Ortho Vitros (all models)</i>	2	2	-	-	61.03	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	55.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	55.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	77.00	-
	<i>SPAPLUS IgM Kit (The Binding Site)</i>	2	2	-	-	55.50	-

Sample 16182		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		42	42	82.74	121.67	102.20	6.49
Nephelometry Total		15	15	91.33	124.01	107.67	5.45
	<i>Beckman Coulter Image</i>	4	4	-	-	107.75	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	108.25	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	106.00	-
Turbidimetry Total		27	27	85.09	112.75	98.92	4.61
	<i>Abbott Architect</i>	1	1	-	-	102.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	91.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	89.50	103.80	96.65	2.38
	<i>Ortho Vitros (all models)</i>	2	2	-	-	130.01	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	102.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	104.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	109.00	-
	<i>SPAPLUS IgM Kit (The Binding Site)</i>	2	2	-	-	100.00	-

Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

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Sample 16183		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		42	42	50.57	84.31	67.44	5.62
Nephelometry Total		15	15	62.47	83.57	73.02	3.52
	<i>Beckman Coulter Immage</i>	4	4	-	-	70.72	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	74.80	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	71.33	-
Turbidimetry Total		27	27	56.17	70.33	63.25	2.36
	<i>Abbott Architect</i>	1	1	-	-	65.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	62.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	56.42	68.29	62.36	1.98
	<i>Ortho Vitros (all models)</i>	2	2	-	-	71.53	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	64.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	65.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	76.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	65.50	-

Sample 16184		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		42	42	37.48	60.71	49.09	3.87
Nephelometry Total		15	15	43.58	59.81	51.69	2.71
	<i>Beckman Coulter Immage</i>	4	4	-	-	50.23	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	53.06	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	50.00	-
Turbidimetry Total		27	27	39.98	54.22	47.10	2.37
	<i>Abbott Architect</i>	1	1	-	-	45.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	52.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	43.05	51.62	47.34	1.43
	<i>Ortho Vitros (all models)</i>	2	2	-	-	48.92	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	45.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	46.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	62.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	46.00	-

Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

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Sample 16185		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		42	20	6.62	16.04	11.33	1.57
Nephelometry Total		15	9	-	-	11.03	-
	<i>Beckman Coulter Immage</i>	4	3	-	-	9.12	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	4	-	-	12.72	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	2	-	-	10.50	-
Turbidimetry Total		27	11	7.55	15.65	11.60	1.35
	<i>Abbott Architect</i>	1	1	-	-	10.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	0	-	-	-	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	5	-	-	12.80	-
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	2	-	-	10.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	10.50	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	34.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	0	-	-	-	-