

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

Proficiency Testing Program

September 7, 2016

**DIAGNOSTIC IMMUNOLOGY
SUMMARY ANALYSIS**

**Diagnostic Immunology
Proficiency Test Event
September 7, 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 September 7, 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)

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16346 - 90% of participants reported negative.			
All Labs	1	38	3
Bio-Rad Bioplex	-	3	-
BioRad EIA Systems (any)	-	3	-
BioRad/Kallestad IFA Systems (any)	-	6	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	1	-
Immuno Concepts IFA Systems (any)	-	3	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	6	-
Phadia/Pharmacia Immunocap/UniCap (all models)	1	1	1
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	2	2
Wampole/Zeus ANA IFA Hep-2	-	7	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	1	-
SAMPLE 16347 - 79% of participants reported positive. *			
All Labs	33	9	-
Bio-Rad Bioplex	3	-	-
BioRad EIA Systems (any)	2	1	-
BioRad/Kallestad IFA Systems (any)	6	-	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	1	-	-
Immuno Concepts IFA Systems (any)	2	1	-
IMMCO Diagnostics IFA	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	3	3	-
Phadia/Pharmacia Immunocap/UniCap (all models)	3	-	-
RhiGene Fluor ANA IFA Test	1	-	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	4	-	-
Wampole/Zeus ANA IFA Hep-2	6	1	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	1	-	-
SAMPLE 16348 - 88% of participants reported negative.			
All Labs	3	37	2
Bio-Rad Bioplex	-	3	-
BioRad EIA Systems (any)	-	3	-
BioRad/Kallestad IFA Systems (any)	-	6	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	1	-
Immuno Concepts IFA Systems (any)	-	3	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	6	-
Phadia/Pharmacia Immunocap/UniCap (all models)	1	1	1
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	1	1	-
Wampole ANA EIA	1	2	1
Wampole/Zeus ANA IFA Hep-2	-	7	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	1	-

Qualitative Antinuclear Ab (ANA)

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16349 - 100% of participants reported positive.			
All Labs	42	-	-
Bio-Rad Bioplex	3	-	-
BioRad EIA Systems (any)	3	-	-
BioRad/Kallestad IFA Systems (any)	6	-	-
DiaSorin ANA Screen EIA	1	-	-
Diamedix EIA Systems (any)	1	-	-
Immuno Concepts IFA Systems (any)	3	-	-
IMMCO Diagnostics IFA	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	6	-	-
Phadia/Pharmacia Immunocap/UniCap (all models)	3	-	-
RhiGene Fluor ANA IFA Test	1	-	-
Trinity Biotech ANA EIA Test	2	-	-
Wampole ANA EIA	4	-	-
Wampole/Zeus ANA IFA Hep-2	7	-	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	1	-	-
SAMPLE 16350 - 90% of participants reported negative.			
All Labs	2	38	2
Bio-Rad Bioplex	-	3	-
BioRad EIA Systems (any)	-	3	-
BioRad/Kallestad IFA Systems (any)	-	6	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	1	-
Immuno Concepts IFA Systems (any)	-	3	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	6	-
Phadia/Pharmacia Immunocap/UniCap (all models)	-	2	1
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	1	1	-
Wampole ANA EIA	1	2	1
Wampole/Zeus ANA IFA Hep-2	-	7	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	1	-

*** Unable to validate sample #16347. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.**

Antinuclear Ab (ANA) IFA Titers

The number of laboratories that reported titers for positive test samples 16347 and 16349.

Primary Test Kit/Assay	No. Labs	Sample 16347 Titers *							
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280	≥ 1:2560
All Labs	29	6	1	3	6	4	5	3	1
BioRad/Kallestad IFA Systems (any)	8	-	-	-	1	3	3	1	-
Immuno Concepts IFA Systems (any)	3	1	-	-	1	-	1	-	-
IMMCO Diagnostics IFA	2	1	1	-	-	-	-	-	-
INOVA IFA Systems/NOVA Lite Hep-2	8	3	-	2	-	-	1	1	1
RhiGene Fluor ANA IFA Test	1	-	-	-	1	-	-	-	-
Wampole/Zeus ANA IFA Hep-2	7	1	-	1	3	1	-	1	-

Staining Pattern - 23 labs reported a staining pattern, of those 22 labs (96%) reported speckled, and 1 lab (4%) homogenous. The reporting of a staining pattern here is for informational purposes only and is not graded.

* Unable to validate sample #16347. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.

Primary Test Kit/Assay	No. Labs	Sample 16349 Titers							
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280	≥ 1:2560
All Labs	29	-	1	3	12	7	5	1	-
BioRad/Kallestad IFA Systems (any)	8	-	-	1	4	3	-	-	-
Immuno Concepts IFA Systems (any)	3	-	-	-	1	1	1	-	-
IMMCO Diagnostics IFA	2	-	-	-	1	-	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	8	-	1	-	2	3	1	1	-
RhiGene Fluor ANA IFA Test	1	-	-	-	1	-	-	-	-
Wampole/Zeus ANA IFA Hep-2	7	-	-	2	3	-	2	-	-

Staining Pattern - 29 labs reported a staining pattern, of those 27 labs (93%) reported homogenous, and 2 labs (7%) reported speckled. The reporting of a staining pattern here is for informational purposes only and is not graded.

Qualitative Antistreptolysin O

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16316 - 100% of participants reported positive.		
All Labs	28	-
Arlington Scientific ASO Latex Test	3	-
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	1	-
Siemens (Dade Behring) RapiTex Latex Test	6	-
Wampole Color Card ASO Latex Test	1	-
SAMPLE 16317 - 100% of participants reported negative.		
All Labs	-	28
Arlington Scientific ASO Latex Test	-	3
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	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	6
Wampole Color Card ASO Latex Test	-	1
SAMPLE 16318 - 100% of participants reported negative.		
All Labs	-	28
Arlington Scientific ASO Latex Test	-	3
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	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	6
Wampole Color Card ASO Latex Test	-	1
SAMPLE 16319 - 100% of participants reported negative.		
All Labs	-	28
Arlington Scientific ASO Latex Test	-	3
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	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	6
Wampole Color Card ASO Latex Test	-	1
SAMPLE 16320 - 100% of participants reported positive.		
All Labs	28	-
Arlington Scientific ASO Latex Test	3	-
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	1	-
Siemens (Dade Behring) RapiTex Latex Test	6	-
Wampole Color Card ASO Latex Test	1	-

Antistreptolysin O (ASO) Titers

The number of laboratories that reported titers for positive test samples 16316, and 16320.

Primary Test Kit/Assay	No. Labs	Sample 16316 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	-	-	2	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16320 Titers					
		< C.O.	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	7	-	1	6	-	-	-
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	-	-	2	-	-	-

Semi-quantitative Antistreptolysin O (ASO)

The number of laboratories that reported semi-quantitative results for positive test samples 16316, and 16320.

Primary Test Kit/Assay	No. Labs	Sample 16316 Results (IU/ml)					
		< C.O.	200	400	800	1600	≥ 3200
All Labs	18	-	6	10	2	-	-
Arlington Scientific ASO Latex Test	1	-	-	1	-	-	-
BioKit Rheumajet ASO Latex Test	5	-	2	2	1	-	-
Fisher Sure-Vue ASO Latex Test	6	-	1	4	1	-	-
Remel Seratest ASO Latex Test	1	-	1	-	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	5	-	2	3	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16320 Results (IU/ml)					
		< C.O.	200	400	800	1600	≥ 3200
All Labs	18	-	6	11	1	-	-
Arlington Scientific ASO Latex Test	1	-	-	1	-	-	-
BioKit Rheumajet ASO Latex Test	5	-	1	4	-	-	-
Fisher Sure-Vue ASO Latex Test	6	-	2	4	-	-	-
Remel Seratest ASO Latex Test	1	-	-	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	5	-	3	1	1	-	-

Quantitative Antistreptolysin O (ASO) IU/ml

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 16316		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		26	26	220.00	442.37	331.18	37.06
Nephelometry Total		5	5	-	-	350.40	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	221.00	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	388.67	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	365.00	-
Turbidimetry Total		21	21	294.92	442.25	368.58	24.55
	<i>Abbott Architect</i>	1	1	-	-	218.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	3	-	-	231.90	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	10	10	335.79	367.07	351.43	5.21
	<i>Roche Diagnostics Cobas (all systems)</i>	2	2	-	-	395.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	366.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	3	3	-	-	404.20	-
	<i>Siemens Dimension VISTA</i>	1	1	-	-	383.00	-

Sample 16317		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		26	13	0.00	100.00	50.00	16.67
Nephelometry Total		5	1	-	-	21.00	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	3	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	21.00	-
Turbidimetry Total		21	12	13.68	33.68	23.68	3.33
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	1	-	-	31.20	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	10	4	-	-	21.68	-
	<i>Roche Diagnostics Cobas (all systems)</i>	2	2	-	-	23.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	20.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	3	3	-	-	25.50	-
	<i>Siemens Dimension VISTA</i>	1	1	-	-	23.80	-

Sample 16318		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		26	9	0.00	100.00	50.00	16.67
Nephelometry Total		5	1	-	-	22.50	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	3	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	22.50	-
Turbidimetry Total		21	8	-	-	20.90	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	1	-	-	12.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	10	4	-	-	21.68	-
	<i>Roche Diagnostics Cobas (all systems)</i>	2	1	-	-	25.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	3	1	-	-	21.00	-
	<i>Siemens Dimension VISTA</i>	1	1	-	-	22.50	-

Quantitative Antistreptolysin O (ASO) IU/ml

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 16319		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		26	11	0.00	100.00	50.00	16.67
Nephelometry Total		5	2	-	-	23.35	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	25.00	-
	<i>Siemens Dimension VISTA</i>	3	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	21.70	-
Turbidimetry Total		21	9	-	-	22.29	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	1	-	-	11.90	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	10	4	-	-	21.68	-
	<i>Roche Diagnostics Cobas (all systems)</i>	2	1	-	-	25.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	3	2	-	-	27.00	-
	<i>Siemens Dimension VISTA</i>	1	1	-	-	23.00	-

Sample 16320		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		26	26	127.09	504.42	315.75	62.89
Nephelometry Total		5	5	-	-	254.20	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	188.00	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	271.33	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	269.00	-
Turbidimetry Total		21	21	153.66	507.16	330.41	58.92
	<i>Abbott Architect</i>	1	1	-	-	247.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	3	-	-	226.03	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	10	10	348.09	386.45	367.27	6.39
	<i>Roche Diagnostics Cobas (all systems)</i>	2	2	-	-	328.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	276.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	3	3	-	-	376.60	-
	<i>Siemens Dimension VISTA</i>	1	1	-	-	279.00	-

Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16311 - 95% of participants reported negative.			
All Labs	1	19	-
Bio-Rad CMV IgG EIA	-	1	-
Bio-Rad Bioplex Torc IgG	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	6	-
Diamedix CMV EIA Systems (any)	-	1	-
DiaSorin Liaison CMV IgG	-	5	-
Siemens Immulite Systems (all models)	-	2	-
Trinity Biotech CAPTIA CMV IgG EIA	1	-	-
Zeus Scientific CMV IgG EIA	-	1	-
SAMPLE 16312 - 100% of participants reported positive.			
All Labs	20	-	-
Bio-Rad CMV IgG EIA	1	-	-
Bio-Rad Bioplex Torc IgG	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	6	-	-
Diamedix CMV EIA Systems (any)	1	-	-
DiaSorin Liaison CMV IgG	5	-	-
Siemens Immulite Systems (all models)	2	-	-
Trinity Biotech CAPTIA CMV IgG EIA	1	-	-
Zeus Scientific CMV IgG EIA	1	-	-
SAMPLE 16313 - 100% of participants reported negative.			
All Labs	-	20	-
Bio-Rad CMV IgG EIA	-	1	-
Bio-Rad Bioplex Torc IgG	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	6	-
Diamedix CMV EIA Systems (any)	-	1	-
DiaSorin Liaison CMV IgG	-	5	-
Siemens Immulite Systems (all models)	-	2	-
Trinity Biotech CAPTIA CMV IgG EIA	-	1	-
Zeus Scientific CMV IgG EIA	-	1	-

Qualitative Cytomegalovirus Ab (CMV)

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16314 - 95% of participants reported negative.			
All Labs	1	19	-
Bio-Rad CMV IgG EIA	-	1	-
Bio-Rad Bioplex Torc IgG	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	6	-
Diamedix CMV EIA Systems (any)	-	1	-
DiaSorin Liaison CMV IgG	-	5	-
Siemens Immulite Systems (all models)	-	2	-
Trinity Biotech CAPTIA CMV IgG EIA	1	-	-
Zeus Scientific CMV IgG EIA	-	1	-

SAMPLE 16315 - 95% of participants reported negative.			
All Labs	1	19	-
Bio-Rad CMV IgG EIA	-	1	-
Bio-Rad Bioplex Torc IgG	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	6	-
Diamedix CMV EIA Systems (any)	-	1	-
DiaSorin Liaison CMV IgG	-	5	-
Siemens Immulite Systems (all models)	-	2	-
Trinity Biotech CAPTIA CMV IgG EIA	1	-	-
Zeus Scientific CMV IgG EIA	-	1	-

Qualitative Hepatitis B core Ab

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16306 - 98% of participants reported nonreactive.		
All Labs	1	48
Abbott Architect	1	14
Ortho Vitros (all models)	-	11
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	-	19
Siemens Immulite Systems (all models)	-	3
SAMPLE 16307 - 100% of participants reported nonreactive.		
All Labs	-	49
Abbott Architect	-	15
Ortho Vitros (all models)	-	11
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	-	19
Siemens Immulite Systems (all models)	-	3
SAMPLE 16308 - 100% of participants reported nonreactive.		
All Labs	-	49
Abbott Architect	-	15
Ortho Vitros (all models)	-	11
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	-	19
Siemens Immulite Systems (all models)	-	3
SAMPLE 16309 - 100% of participants reported nonreactive.		
All Labs	-	49
Abbott Architect	-	15
Ortho Vitros (all models)	-	11
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	-	19
Siemens Immulite Systems (all models)	-	3
SAMPLE 16310 - 100% of participants reported reactive.		
All Labs	49	-
Abbott Architect	15	-
Ortho Vitros (all models)	11	-
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	1	-
Siemens ADVIA Centaur	19	-
Siemens Immulite Systems (all models)	3	-

Qualitative Hepatitis B surface Ag

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16306 - 100% of participants reported nonreactive.		
All Labs	-	75
Abbott Architect	-	17
DiaSorin ETI MAK-2 Plus	-	1
Ortho Vitros (all models)	-	14
Roche Diagnostics Cobas (all systems)	-	6
Roche Diagnostics Elecsys Systems	-	1
Siemens ADVIA Centaur	-	32
Siemens Immulite Systems (all models)	-	1
SAMPLE 16307 - 100% of participants reported nonreactive.		
All Labs	-	75
Abbott Architect	-	17
DiaSorin ETI MAK-2 Plus	-	1
Ortho Vitros (all models)	-	14
Roche Diagnostics Cobas (all systems)	-	6
Roche Diagnostics Elecsys Systems	-	1
Siemens ADVIA Centaur	-	32
Siemens Immulite Systems (all models)	-	1
SAMPLE 16308 - 100% of participants reported reactive.		
All Labs	75	-
Abbott Architect	17	-
DiaSorin ETI MAK-2 Plus	1	-
Ortho Vitros (all models)	14	-
Roche Diagnostics Cobas (all systems)	6	-
Roche Diagnostics Elecsys Systems	1	-
Siemens ADVIA Centaur	32	-
Siemens Immulite Systems (all models)	1	-
SAMPLE 16309 - 100% of participants reported nonreactive.		
All Labs	-	75
Abbott Architect	-	17
DiaSorin ETI MAK-2 Plus	-	1
Ortho Vitros (all models)	-	14
Roche Diagnostics Cobas (all systems)	-	6
Roche Diagnostics Elecsys Systems	-	1
Siemens ADVIA Centaur	-	32
Siemens Immulite Systems (all models)	-	1
SAMPLE 16310 - 100% of participants reported reactive.		
All Labs	75	-
Abbott Architect	17	-
DiaSorin ETI MAK-2 Plus	1	-
Ortho Vitros (all models)	14	-
Roche Diagnostics Cobas (all systems)	6	-
Roche Diagnostics Elecsys Systems	1	-
Siemens ADVIA Centaur	32	-
Siemens Immulite Systems (all models)	1	-

Qualitative Hepatitis B surface Ag Confirmation

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16306 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	3	33
Abbott Architect	-	-	11
Abbott HBsAg Confirmatory Assay	-	-	1
DiaSorin ETI MAK-2 Plus	-	-	1
Ortho Vitros (all models)	-	-	5
Roche Diagnostics Cobas (all systems)	-	-	2
Siemens ADVIA Centaur	-	3	13
SAMPLE 16307 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	3	33
Abbott Architect	-	-	11
Abbott HBsAg Confirmatory Assay	-	-	1
DiaSorin ETI MAK-2 Plus	-	-	1
Ortho Vitros (all models)	-	-	5
Roche Diagnostics Cobas (all systems)	-	-	2
Siemens ADVIA Centaur	-	3	13
SAMPLE 16308 - 100% of participants reported reactive.			
All Labs	36	-	-
Abbott Architect	11	-	-
Abbott HBsAg Confirmatory Assay	1	-	-
DiaSorin ETI MAK-2 Plus	1	-	-
Ortho Vitros (all models)	5	-	-
Roche Diagnostics Cobas (all systems)	2	-	-
Siemens ADVIA Centaur	16	-	-
SAMPLE 16309 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	3	33
Abbott Architect	-	-	11
Abbott HBsAg Confirmatory Assay	-	-	1
DiaSorin ETI MAK-2 Plus	-	-	1
Ortho Vitros (all models)	-	-	5
Roche Diagnostics Cobas (all systems)	-	-	2
Siemens ADVIA Centaur	-	3	13
SAMPLE 16310 - 100% of participants reported reactive.			
All Labs	36	-	-
Abbott Architect	11	-	-
Abbott HBsAg Confirmatory Assay	1	-	-
DiaSorin ETI MAK-2 Plus	1	-	-
Ortho Vitros (all models)	5	-	-
Roche Diagnostics Cobas (all systems)	2	-	-
Siemens ADVIA Centaur	16	-	-

Qualitative Hepatitis Be Ag

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16366 - 100% of participants reported nonreactive.		
All Labs	-	6
DiaSorin ETI-EBK Plus	-	2
DiaSorin ETI MAK 3000	-	1
Ortho Vitros (all models)	-	2
Siemens ADVIA Centaur	-	1
SAMPLE 16367 - 100% of participants reported nonreactive.		
All Labs	-	6
DiaSorin ETI-EBK Plus	-	2
DiaSorin ETI MAK 3000	-	1
Ortho Vitros (all models)	-	2
Siemens ADVIA Centaur	-	1
SAMPLE 16368 - 100% of participants reported reactive.		
All Labs	6	-
DiaSorin ETI-EBK Plus	2	-
DiaSorin ETI MAK 3000	1	-
Ortho Vitros (all models)	2	-
Siemens ADVIA Centaur	1	-
SAMPLE 16369 - 100% of participants reported nonreactive.		
All Labs	-	6
DiaSorin ETI-EBK Plus	-	2
DiaSorin ETI MAK 3000	-	1
Ortho Vitros (all models)	-	2
Siemens ADVIA Centaur	-	1
SAMPLE 16370 - 100% of participants reported reactive.		
All Labs	6	-
DiaSorin ETI-EBK Plus	2	-
DiaSorin ETI MAK 3000	1	-
Ortho Vitros (all models)	2	-
Siemens ADVIA Centaur	1	-

Qualitative Hepatitis C Virus Ab

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16371 - 98% of participants reported reactive.		
All Labs	62	1
Abbott Architect	17	-
HCV Ortho Version 3.0 ELISA	2	-
Ortho Vitros (all models)	12	-
Roche Diagnostics Elecsys Systems	3	-
Siemens ADVIA Centaur	28	1
SAMPLE 16372 - 100% of participants reported nonreactive.		
All Labs	-	63
Abbott Architect	-	17
HCV Ortho Version 3.0 ELISA	-	2
Ortho Vitros (all models)	-	12
Roche Diagnostics Elecsys Systems	-	3
Siemens ADVIA Centaur	-	29
SAMPLE 16373 - 98% of participants reported nonreactive.		
All Labs	-	63
Abbott Architect	-	17
HCV Ortho Version 3.0 ELISA	-	2
Ortho Vitros (all models)	-	12
Roche Diagnostics Elecsys Systems	-	3
Siemens ADVIA Centaur	-	29
SAMPLE 16374 - 100% of participants reported nonreactive.		
All Labs	-	63
Abbott Architect	-	17
HCV Ortho Version 3.0 ELISA	-	2
Ortho Vitros (all models)	-	12
Roche Diagnostics Elecsys Systems	-	3
Siemens ADVIA Centaur	-	29
SAMPLE 16375 - 98% of participants reported reactive.		
All Labs	62	1
Abbott Architect	17	-
HCV Ortho Version 3.0 ELISA	2	-
Ortho Vitros (all models)	12	-
Roche Diagnostics Elecsys Systems	3	-
Siemens ADVIA Centaur	28	1

Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16331 - 100% of participants reported nonreactive.		
All Labs	-	137
Architect HIV Ag/Ab Combo Assay (Abbott)	-	21
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	6
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	22
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	2
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	5
Chembio HIV 1/2 Stat-Pak (Alere)	-	1
Clearview Complete HIV 1/2 (Alere)	-	4
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	47
Vitros Anti-HIV 1+2 (Ortho)	-	11
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	-	11
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	7

SAMPLE 16332 - 100% of participants reported reactive.		
All Labs	137	-
Architect HIV Ag/Ab Combo Assay (Abbott)	21	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	6	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	22	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	2	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	5	-
Chembio HIV 1/2 Stat-Pak (Alere)	1	-
Clearview Complete HIV 1/2 (Alere)	4	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	47	-
Vitros Anti-HIV 1+2 (Ortho)	11	-
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	11	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	7	-

SAMPLE 16333 - 100% of participants reported nonreactive.		
All Labs	-	137
Architect HIV Ag/Ab Combo Assay (Abbott)	-	21
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	6
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	22
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	2
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	5
Chembio HIV 1/2 Stat-Pak (Alere)	-	1
Clearview Complete HIV 1/2 (Alere)	-	4
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	47
Vitros Anti-HIV 1+2 (Ortho)	-	11
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	-	11
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	7

Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16334 - 100% of participants reported reactive.		
All Labs	137	-
Architect HIV Ag/Ab Combo Assay (Abbott)	21	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	6	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	22	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	2	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	5	-
Chembio HIV 1/2 Stat-Pak (Alere)	1	-
Clearview Complete HIV 1/2 (Alere)	4	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	47	-
Vitros Anti-HIV 1+2 (Ortho)	11	-
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	11	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	7	-
SAMPLE 16335 - 100% of participants reported nonreactive.		
All Labs	-	137
Architect HIV Ag/Ab Combo Assay (Abbott)	-	21
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	6
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	22
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	2
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	5
Chembio HIV 1/2 Stat-Pak (Alere)	-	1
Clearview Complete HIV 1/2 (Alere)	-	4
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	47
Vitros Anti-HIV 1+2 (Ortho)	-	11
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	-	11
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	7

Qualitative HIV-1 Ab - Supplemental/Confirmation Tests

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16331 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	1	19
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	-	-	2
GS HIV-1 Western Blot (Bio-Rad)	-	-	1
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	1	16
SAMPLE 16332 - 100% of participants reported reactive.			
All Labs	20	-	-
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	2	-	-
GS HIV-1 Western Blot (Bio-Rad)	1	-	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	17	-	-
SAMPLE 16333 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	1	19
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	-	-	2
GS HIV-1 Western Blot (Bio-Rad)	-	-	1
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	1	16
SAMPLE 16334 - 100% of participants reported reactive.			
All Labs	20	-	-
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	2	-	-
GS HIV-1 Western Blot (Bio-Rad)	1	-	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	17	-	-
SAMPLE 16335 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	2	18
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	-	-	2
GS HIV-1 Western Blot (Bio-Rad)	-	-	1
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	2	15

Qualitative Infectious Mononucleosis

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16326 - 99% of participants reported positive.			
All Labs	137	-	-
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	4	-	-
Clearview Mono	25	-	-
Fisher Sure-View Color Mono Latex Test Kit	3	-	-
Fisher Sure-View Mono Latex	37	-	-
Fisher Sure-View Signature Mono Test Kit	5	-	-
Inverness BioStar Acceava Mono/Mono II Test	4	-	-
Meridian MonoSpot Latex	2	-	-
Meridian ImmunoCard Mono *	3	-	-
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	-	-
RELY Mono Rapid Test (Stanbio)	1	-	-
Wampole Color Card MONO	8	-	-

* One laboratory reported "Invalid" as a result.

Qualitative Infectious Mononucleosis

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16327 - 100% of participants reported negative.			
All Labs	-	138	-
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	-	4	-
Clearview Mono	-	25	-
Fisher Sure-View Color Mono Latex Test Kit	-	3	-
Fisher Sure-View Mono Latex	-	37	-
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	-
RELY Mono Rapid Test (Stanbio)	-	1	-
Wampole Color Card MONO	-	8	-

Qualitative Infectious Mononucleosis

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16328 - 99% of participants reported positive.			
All Labs	137	1	-
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	4	-	-
Clearview Mono	25	-	-
Fisher Sure-View Color Mono Latex Test Kit	2	1	-
Fisher Sure-View Mono Latex	37	-	-
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	-	-
RELY Mono Rapid Test (Stanbio)	1	-	-
Wampole Color Card MONO	8	-	-

Qualitative Infectious Mononucleosis

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16329 - 100% of participants reported negative.			
All Labs	-	138	-
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	-	4	-
Clearview Mono	-	25	-
Fisher Sure-View Color Mono Latex Test Kit	-	3	-
Fisher Sure-View Mono Latex	-	37	-
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	-
RELY Mono Rapid Test (Stanbio)	-	1	-
Wampole Color Card MONO	-	8	-

Qualitative Infectious Mononucleosis

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
SAMPLE 16330 - 100% of participants reported negative.			
All Labs	-	138	-
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	-	4	-
Clearview Mono	-	25	-
Fisher Sure-View Color Mono Latex Test Kit	-	3	-
Fisher Sure-View Mono Latex	-	37	-
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	-
RELY Mono Rapid Test (Stanbio)	-	1	-
Wampole Color Card MONO	-	8	-

Qualitative Lyme Disease Ab

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16341 - 100% of participants reported positive.		
All Labs	38	-
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)	2	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	16	-
Immunitics C6 B. burgdorferi EIA Test	3	-
Laboratory developed assay	1	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	3	-
SAMPLE 16342 - 100% of participants reported negative.		
All Labs	-	38
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)	-	2
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	16
Immunitics C6 B. burgdorferi EIA Test	-	3
Laboratory developed assay	-	1
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	3
SAMPLE 16343 - 100% of participants reported positive.		
All Labs	38	-
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)	2	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	16	-
Immunitics C6 B. burgdorferi EIA Test	3	-
Laboratory developed assay	1	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	3	-

Qualitative Lyme Disease Ab

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16344 - 100% of participants reported negative.		
All Labs	-	38
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)	-	2
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	16
Immunetics C6 B. burgdorferi EIA Test	-	3
Laboratory developed assay	-	1
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	3
SAMPLE 16345 - 100% of participants reported negative.		
All Labs	-	38
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)	-	2
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	16
Immunetics C6 B. burgdorferi EIA Test	-	3
Laboratory developed assay	-	1
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	3

Qualitative Lyme Western Blot IgG

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16341 - 100% of participants reported positive.			
All Labs	12	-	-
Borrelia B31 ViraStrip IgG (Viramed)	2	-	-
Laboratory developed assay	2	-	-
MarDx Lyme Disease (IgG) Marblot Strip Test	8	-	-
SAMPLE 16342 - 100% of participants reported negative or testing not indicated.			
All Labs	-	10	2
Borrelia B31 ViraStrip IgG (Viramed)	-	2	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	6	2
SAMPLE 16343 - 67% of participants reported positive. *			
All Labs	8	4	-
Borrelia B31 ViraStrip IgG (Viramed)	1	1	-
Laboratory developed assay	1	1	-
MarDx Lyme Disease (IgG) Marblot Strip Test	6	2	-
SAMPLE 16344 - 100% of participants reported negative or testing not indicated.			
All Labs	-	10	2
Borrelia B31 ViraStrip IgG (Viramed)	-	2	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	6	2
SAMPLE 16345 - 100% of participants reported negative or testing not indicated.			
All Labs	-	10	2
Borrelia B31 ViraStrip IgG (Viramed)	-	2	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	6	2

* Unable to validate sample #16343. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.

Qualitative Lyme Western Blot IgM

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16341 - 83% of participants reported negative.			
All Labs	2	10	-
Borrelia B31 ViraStrip IgM (Viramed)	-	2	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	2	6	-
SAMPLE 16342 - 100% of participants reported negative or testing not indicated.			
All Labs	-	10	2
Borrelia B31 ViraStrip IgM (Viramed)	-	2	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	6	2
SAMPLE 16343 - 100% of participants reported positive.			
All Labs	-	12	-
Borrelia B31 ViraStrip IgM (Viramed)	-	2	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	8	-
SAMPLE 16344 - 100% of participants reported negative or testing not indicated.			
All Labs	-	10	2
Borrelia B31 ViraStrip IgM (Viramed)	-	2	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	6	2
SAMPLE 16345 - 100% of participants reported negative or testing not indicated.			
All Labs	-	10	2
Borrelia B31 ViraStrip IgM (Viramed)	-	2	-
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	6	2

Qualitative Rheumatoid Factor

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16326 - 100% of participants reported positive.		
All Labs	48	-
Arlington Scientific RF Latex Test	4	-
Beckman Coulter Immage	1	-
Biokit Rheumajet RF Latex	5	-
Cardinal Health SP RF Latex	2	-
Fisher Sure-Vue RF Latex	23	-
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	1	-
Wampole Colorcard RF	1	-
Wampole Rheumatex RF	1	-
SAMPLE 16327 - 100% of participants reported negative.		
All Labs	-	48
Arlington Scientific RF Latex Test	-	4
Beckman Coulter Immage	-	1
Biokit Rheumajet RF Latex	-	5
Cardinal Health SP RF Latex	-	2
Fisher Sure-Vue RF Latex	-	23
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	-	1
Wampole Colorcard RF	-	1
Wampole Rheumatex RF	-	1
SAMPLE 16328 - 100% of participants reported positive.		
All Labs	48	-
Arlington Scientific RF Latex Test	4	-
Beckman Coulter Immage	1	-
Biokit Rheumajet RF Latex	5	-
Cardinal Health SP RF Latex	2	-
Fisher Sure-Vue RF Latex	23	-
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	1	-
Wampole Colorcard RF	1	-

Wampole Rheumatex RF

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Qualitative Rheumatoid Factor

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16329 - 100% of participants reported negative.		
All Labs	-	48
Arlington Scientific RF Latex Test	-	4
Beckman Coulter Immage	-	1
Biokit Rheumajet RF Latex	-	5
Cardinal Health SP RF Latex	-	2
Fisher Sure-View RF Latex	-	23
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	-	1
Wampole Colorcard RF	-	1
Wampole Rheumatex RF	-	1
SAMPLE 16330 - 100% of participants reported negative.		
All Labs	-	48
Arlington Scientific RF Latex Test	-	4
Beckman Coulter Immage	-	1
Biokit Rheumajet RF Latex	-	5
Cardinal Health SP RF Latex	-	2
Fisher Sure-View RF Latex	-	23
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	-	1
Wampole Colorcard RF	-	1
Wampole Rheumatex RF	-	1

Rheumatoid Factor Titers

The number of laboratories that reported titers is listed for positive test samples 16326 and 16328.

Primary Test Kit/Assay	No. Labs	Sample 16326 Titers					
		< C.O	1:16	1:32	1:64	1:128	≥ 1:256
All Labs	15	-	6	8	1	-	-
Arlington Scientific RF Latex Test	1	-	-	-	1	-	-
Biokit Rheumajet RF Latex	2	-	1	1	-	-	-
Cardinal Health SP RF Latex	1	-	-	1	-	-	-
Fisher Sure-View RF Latex	10	-	5	5	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	1	-	-	1	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16328 Titers					
		< C.O	1:16	1:32	1:64	1:128	≥ 1:256
All Labs	15	-	2	9	4	-	-
Arlington Scientific RF Latex Test	1	-	-	1	-	-	-
Biokit Rheumajet RF Latex	2	-	-	2	-	-	-
Cardinal Health SP RF Latex	1	-	1	-	-	-	-
Fisher Sure-View RF Latex	10	-	1	6	3	-	-
Siemens (Dade Behring) RapiTex Latex Test	1	-	-	-	1	-	-

Semi-Quantitative Rheumatoid Factor

The number of laboratories reporting semi-quantitative results for positive samples 16326 and 16328.

Primary Test Kit/Assay	No. Labs	Sample 16326 Results (IU/ml)					
		< C.O.	80	160	320	640	≥ 1280
All Labs	15	-	2	5	8	-	-
Biokit Rheumajet RF Latex	2	-	-	-	2	-	-
Fisher Sure-View RF Latex	10	-	1	4	5	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	1	1	-	-
Wampole Colorcard RF	1	-	1	-	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16328 Results (IU/ml)					
		< C.O.	80	160	320	640	≥ 1280
All Labs	15	-	1	1	11	2	-
Biokit Rheumajet RF Latex	2	-	-	-	2	-	-
Fisher Sure-View RF Latex	10	-	-	1	8	1	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	-	1	1	-
Wampole Colorcard RF	1	-	1	-	-	-	-

Quantitative Rheumatoid Factor (RF) IU/ml

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 16326		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		49	47	140.83	264.98	202.91	20.69
Chemiluminescence Total		1	1	-	-	238.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	1	1	-	-	238.00	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>IMMCO Diagnostics ImmuLisa Rheumatoid Factor - IgM</i>	1	0	-	-	-	-
Nephelometry Total		20	19	173.80	241.41	207.61	11.27
	<i>Beckman Coulter Immage</i>	2	1	-	-	389.00	-
	<i>Beckman Coulter AU System</i>	1	1	-	-	176.90	-
	<i>Siemens Dimension VISTA</i>	14	14	192.43	228.57	210.50	6.02
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	204.33	-
Turbidimetry Total		27	27	126.06	270.55	198.30	24.08
	<i>Architect (Abbott)</i>	1	1	-	-	185.90	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	409.00	-
	<i>Kamiya Biomedical RF</i>	1	1	-	-	248.30	-
	<i>Beckman Coulter AU System</i>	11	11	158.10	219.96	189.03	10.31
	<i>Ortho Vitros (all models)</i>	1	1	-	-	183.60	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	182.25	-
	<i>Roche Diagnostics RF II</i>	1	1	-	-	189.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	178.50	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	5	5	-	-	236.76	-

Sample 16327		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		49	10	0.00	14.71	5.36	3.12
Chemiluminescence Total		1	0	-	-	-	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	5.40	-
	<i>IMMCO Diagnostics ImmuLisa Rheumatoid Factor - IgM</i>	1	1	-	-	5.40	-
Nephelometry Total		20	1	-	-	3.00	-
	<i>Beckman Coulter Immage</i>	2	0	-	-	-	-
	<i>Beckman Coulter AU System</i>	1	1	-	-	3.00	-
	<i>Siemens Dimension VISTA</i>	14	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	0	-	-	-	-
Turbidimetry Total		27	8	-	-	5.65	-
	<i>Architect (Abbott)</i>	1	0	-	-	-	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Kamiya Biomedical RF</i>	1	0	-	-	-	-
	<i>Beckman Coulter AU System</i>	11	3	-	-	4.33	-
	<i>Ortho Vitros (all models)</i>	1	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	1	-	-	7.00	-
	<i>Roche Diagnostics RF II</i>	1	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	1	-	-	12.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	5	3	-	-	4.40	-

Quantitative Rheumatoid Factor (RF) IU/ml

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 16328		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		49	44	223.29	361.28	292.28	23.00
Chemiluminescence Total		1	1	-	-	319.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	1	1	-	-	319.00	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>IMMCO Diagnostics ImmuLisa Rheumatoid Factor - IgM</i>	1	0	-	-	-	-
Nephelometry Total		20	19	262.77	329.67	296.22	11.15
	<i>Beckman Coulter Immage</i>	2	2	-	-	321.50	-
	<i>Beckman Coulter AU System</i>	1	1	-	-	183.60	-
	<i>Siemens Dimension VISTA</i>	14	13	272.40	326.18	299.29	8.96
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	282.33	-
Turbidimetry Total		27	24	189.42	375.27	282.34	30.97
	<i>Architect (Abbott)</i>	1	1	-	-	245.90	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	254.00	-
	<i>Kamiya Biomedical RF</i>	1	1	-	-	252.00	-
	<i>Beckman Coulter AU System</i>	11	8	-	-	289.36	-
	<i>Ortho Vitros (all models)</i>	1	1	-	-	273.50	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	278.75	-
	<i>Roche Diagnostics RF II</i>	1	1	-	-	287.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	2	2	-	-	257.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	5	5	-	-	321.84	-

Sample 16329		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		49	10	0.00	13.59	6.80	2.27
Chemiluminescence Total		1	0	-	-	-	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	5.40	-
	<i>IMMCO Diagnostics ImmuLisa Rheumatoid Factor - IgM</i>	1	1	-	-	5.40	-
Nephelometry Total		20	2	-	-	160.40	-
	<i>Beckman Coulter Immage</i>	2	0	-	-	-	-
	<i>Beckman Coulter AU System</i>	1	1	-	-	3.80	-
	<i>Siemens Dimension VISTA</i>	14	1	-	-	317.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	0	-	-	-	-
Turbidimetry Total		27	7	-	-	5.73	-
	<i>Architect (Abbott)</i>	1	0	-	-	-	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Kamiya Biomedical RF</i>	1	0	-	-	-	-
	<i>Beckman Coulter AU System</i>	11	3	-	-	4.20	-
	<i>Ortho Vitros (all models)</i>	1	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>	2	1	-	-	9.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	5	2	-	-	5.25	-

Quantitative Rheumatoid Factor (RF) IU/ml

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 16330		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		49	10	0.00	13.52	5.13	2.80
Chemiluminescence Total		1	0	-	-	-	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	1	0	-	-	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	5.00	-
	<i>IMMCO Diagnostics ImmuLISA Rheumatoid Factor - IgM</i>	1	1	-	-	5.00	-
Nephelometry Total		20	1	-	-	3.20	-
	<i>Beckman Coulter Immage</i>	2	0	-	-	-	-
	<i>Beckman Coulter AU System</i>	1	1	-	-	3.20	-
	<i>Siemens Dimension VISTA</i>	14	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	0	-	-	-	-
Turbidimetry Total		27	8	-	-	5.39	-
	<i>Architect (Abbott)</i>	1	0	-	-	-	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Kamiya Biomedical RF</i>	1	0	-	-	-	-
	<i>Beckman Coulter AU System</i>	11	3	-	-	3.87	-
	<i>Ortho Vitros (all models)</i>	1	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>	2	1	-	-	9.00	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	5	3	-	-	4.83	-

Qualitative Rubella Ab

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16311 - 100% of participants reported negative.		
All Labs	-	64
Beckman Coulter UniCel DxI Systems (all models)	-	6
Bio-Rad Bioplex MMRV IgG	-	2
Bio-Rad Rubella IgG EIA	-	1
bioMerieux VIDAS/mini VIDAS Systems	-	6
Clearview Rubella Plus	-	1
Diasorin Liaison Rubella IgG	-	8
Diasorin Rubella IgG ELISA	-	1
Diamedix Rubella EIA Systems IgG	-	1
Fisher Sure-View Rubella	-	5
Ortho Vitros (all models)	-	4
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	4
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	16
Siemens Immulite Systems (all models)	-	1
Trinity Biotech CAPTIA Rubella IgG EIA	-	2
Wampole Rubella IgG ELISA/ELISA II	-	1
Inverness/Wampole Rubella IgG EIA Systems	-	3

SAMPLE 16312 - 100% of participants reported positive.		
All Labs	64	-
Beckman Coulter UniCel DxI Systems (all models)	6	-
Bio-Rad Bioplex MMRV IgG	2	-
Bio-Rad Rubella IgG EIA	1	-
bioMerieux VIDAS/mini VIDAS Systems	6	-
Clearview Rubella Plus	1	-
Diasorin Liaison Rubella IgG	8	-
Diasorin Rubella IgG ELISA	1	-
Diamedix Rubella EIA Systems IgG	1	-
Fisher Sure-View Rubella	5	-
Ortho Vitros (all models)	4	-
Remel Ruba-Test	1	-
Roche Diagnostics Cobas (all systems)	4	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA Centaur	16	-
Siemens Immulite Systems (all models)	1	-
Trinity Biotech CAPTIA Rubella IgG EIA	2	-
Wampole Rubella IgG ELISA/ELISA II	1	-
Inverness/Wampole Rubella IgG EIA Systems	3	-

Qualitative Rubella Ab

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16313 - 98% of participants reported positive.		
All Labs	63	1
Beckman Coulter UniCel Dxl Systems (all models)	6	-
Bio-Rad Bioplex MMRV IgG	2	-
Bio-Rad Rubella IgG EIA	1	-
bioMerieux VIDAS/mini VIDAS Systems	6	-
Clearview Rubella Plus	1	-
Diasorin Liaison Rubella IgG	8	-
Diasorin Rubella IgG ELISA	1	-
Diamedix Rubella EIA Systems IgG	1	-
Fisher Sure-View Rubella	5	-
Ortho Vitros (all models)	4	-
Remel Ruba-Test	1	-
Roche Diagnostics Cobas (all systems)	4	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA Centaur	16	-
Siemens Immulite Systems (all models)	1	-
Trinity Biotech CAPTIA Rubella IgG EIA	1	1
Wampole Rubella IgG ELISA/ELISA II	1	-
Inverness/Wampole Rubella IgG EIA Systems	3	-

SAMPLE 16314 - 97% of participants reported negative.		
All Labs	2	62
Beckman Coulter UniCel Dxl Systems (all models)	-	6
Bio-Rad Bioplex MMRV IgG	-	2
Bio-Rad Rubella IgG EIA	-	1
bioMerieux VIDAS/mini VIDAS Systems	-	6
Clearview Rubella Plus	-	1
Diasorin Liaison Rubella IgG	1	7
Diasorin Rubella IgG ELISA	-	1
Diamedix Rubella EIA Systems IgG	-	1
Fisher Sure-View Rubella	-	5
Ortho Vitros (all models)	-	4
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	4
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	16
Siemens Immulite Systems (all models)	-	1
Trinity Biotech CAPTIA Rubella IgG EIA	-	2
Wampole Rubella IgG ELISA/ELISA II	-	1
Inverness/Wampole Rubella IgG EIA Systems	1	2

Qualitative Rubella Ab

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16315 - 100% of participants reported negative.		
All Labs	-	64
Beckman Coulter UniCel Dxl Systems (all models)	-	6
Bio-Rad Bioplex MMRV IgG	-	2
Bio-Rad Rubella IgG EIA	-	1
bioMerieux VIDAS/mini VIDAS Systems	-	6
Clearview Rubella Plus	-	1
Diasorin Liaison Rubella IgG	-	8
Diasorin Rubella IgG ELISA	-	1
Diamedix Rubella EIA Systems IgG	-	1
Fisher Sure-View Rubella	-	5
Ortho Vitros (all models)	-	4
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	4
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	16
Siemens Immulite Systems (all models)	-	1
Trinity Biotech CAPTIA Rubella IgG EIA	-	2
Wampole Rubella IgG ELISA/ELISA II	-	1
Inverness/Wampole Rubella IgG EIA Systems	-	3

Quantitative Rubella Ab IU/ml

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 16311		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		27	11	0.00	3.40	1.41	0.66
Chemiluminescence Total		24	9	-	-	1.54	-
	<i>Beckman Coulter UniCel Dxl Systems (all models)</i>	3	3	-	-	1.00	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	2	0	-	-	-	-
	<i>Ortho Vitros (all models)</i>	2	2	-	-	2.51	-
	<i>Roche Diagnostics Cobas (all systems)</i>	1	1	-	-	2.04	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-
	<i>Siemens ADVIA Centaur</i>	13	3	-	-	1.27	-
	<i>Siemens Immulite Systems (all models)</i>	2	0	-	-	-	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	2	-	-	0.80	-
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	0.60	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	1	-	-	1.00	-

Sample 16312		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		27	27	0.00	111.34	49.53	20.61
Chemiluminescence Total		24	24	17.01	89.04	53.02	12.00
	<i>Beckman Coulter UniCel Dxl Systems (all models)</i>	3	3	-	-	45.13	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	2	2	-	-	4.08	-
	<i>Ortho Vitros (all models)</i>	2	2	-	-	61.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	1	1	-	-	26.79	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	123.80	-
	<i>Siemens ADVIA Centaur</i>	13	13	37.93	80.17	59.05	7.04
	<i>Siemens Immulite Systems (all models)</i>	2	2	-	-	33.85	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	3	-	-	38.00	-
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	42.00	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	2	-	-	36.00	-

Sample 16313		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		27	12	0.00	501.00	250.50	83.50
Chemiluminescence Total		24	9	-	-	184.86	-
	<i>Beckman Coulter UniCel Dxl Systems (all models)</i>	3	3	-	-	210.43	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	2	2	-	-	18.60	-
	<i>Ortho Vitros (all models)</i>	2	1	-	-	291.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	1	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	406.20	-
	<i>Siemens ADVIA Centaur</i>	13	0	-	-	-	-
	<i>Siemens Immulite Systems (all models)</i>	2	2	-	-	149.00	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	3	-	-	133.80	-
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	174.40	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	2	-	-	113.50	-

Quantitative Rubella Ab IU/ml

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 16314		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		27	13	0.00	3.29	1.29	0.67
Chemiluminescence Total		24	11	0.00	3.45	1.37	0.70
	<i>Beckman Coulter UniCel Dxl Systems (all models)</i>	3	3	-	-	0.90	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	2	0	-	-	-	-
	<i>Ortho Vitros (all models)</i>	2	2	-	-	2.44	-
	<i>Roche Diagnostics Cobas (all systems)</i>	1	1	-	-	1.94	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-
	<i>Siemens ADVIA Centaur</i>	13	5	-	-	1.10	-
	<i>Siemens Immulite Systems (all models)</i>	2	0	-	-	-	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	2	-	-	0.85	-
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	0.70	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	1	-	-	1.00	-

Sample 16315		Total Labs	Labs *	Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay			Low	High		
All Methods		27	14	0.00	3.35	1.26	0.70
Chemiluminescence Total		24	12	0.00	3.52	1.33	0.73
	<i>Beckman Coulter UniCel Dxl Systems (all models)</i>	3	3	-	-	1.03	-
	<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>	2	0	-	-	-	-
	<i>Ortho Vitros (all models)</i>	2	2	-	-	2.42	-
	<i>Roche Diagnostics Cobas (all systems)</i>	1	1	-	-	1.97	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-
	<i>Siemens ADVIA Centaur</i>	13	6	-	-	1.00	-
	<i>Siemens Immulite Systems (all models)</i>	2	0	-	-	-	-
Enzyme Linked Fluorescent Assay (ELFA) Total		3	2	-	-	0.85	-
	<i>Beckman Coulter ACCESS</i>	1	1	-	-	0.70	-
	<i>bioMerieux VIDAS/mini VIDAS Systems</i>	2	1	-	-	1.00	-

Qualitative Rubella IgM Specific

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
SAMPLE 16356 - 100% of participants reported positive.		
All Labs	12	-
DiaSorin Liaison Rubella IgM	4	-
Diamedix Rubella EIA Systems IgM	1	-
Rubella IgM EIA Systems (Roche)	1	-
Siemens ADVIA Centaur	3	-
Siemens Immulite Systems (all models)	3	-
SAMPLE 16357 - 100% of participants reported negative.		
All Labs	-	12
DiaSorin Liaison Rubella IgM	-	4
Diamedix Rubella EIA Systems IgM	-	1
Rubella IgM EIA Systems (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	3
SAMPLE 16358 - 100% of participants reported negative.		
All Labs	-	12
DiaSorin Liaison Rubella IgM	-	4
Diamedix Rubella EIA Systems IgM	-	1
Rubella IgM EIA Systems (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	3
SAMPLE 16359 - 92% of participants reported negative.		
All Labs	-	11
DiaSorin Liaison Rubella IgM	-	4
Diamedix Rubella EIA Systems IgM	-	1
Rubella IgM EIA Systems (Roche)	-	1
Siemens ADVIA Centaur *	-	2
Siemens Immulite Systems (all models)	-	3
* One laboratory reported "Equivocal" as a result.		
SAMPLE 16360 - 100% of participants reported negative.		
All Labs	-	12
DiaSorin Liaison Rubella IgM	-	4
Diamedix Rubella EIA Systems IgM	-	1
Rubella IgM EIA Systems (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	3

Qualitative Syphilis Reagin Ab

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16301 - 100% of participants reported reactive.			
All Labs	105	-	-
Ampcor RPR Card Test	1	-	-
ASI RPR Card Test for Syphilis	19	-	-
Becton Dickenson Macro-vue RPR	41	-	-
Select RPR (BioKit)	1	-	-
Fisher Sure-Vue RPR	23	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-
True Medix Diagnostics Trutest RPR	10	-	-
Wampole IMPACT RPR	9	-	-
SAMPLE 16302 - 100% of participants reported reactive.			
All Labs	105	-	-
Ampcor RPR Card Test	1	-	-
ASI RPR Card Test for Syphilis	19	-	-
Becton Dickenson Macro-vue RPR	41	-	-
Select RPR (BioKit)	1	-	-
Fisher Sure-Vue RPR	23	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-
True Medix Diagnostics Trutest RPR	10	-	-
Wampole IMPACT RPR	9	-	-
SAMPLE 16303 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	102	3
Ampcor RPR Card Test	-	1	-
ASI RPR Card Test for Syphilis	-	19	-
Becton Dickenson Macro-vue RPR	-	39	2
Select RPR (BioKit)	-	1	-
Fisher Sure-Vue RPR	-	23	-
Stanbio Syphilis (RPR) Quicktest	-	1	-
True Medix Diagnostics Trutest RPR	-	10	-
Wampole IMPACT RPR	-	8	1

Qualitative Syphilis Reagin Ab

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
SAMPLE 16304 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	102	3
Ampcor RPR Card Test	-	1	-
ASI RPR Card Test for Syphilis	-	19	-
Becton Dickenson Macro-vue RPR	-	39	2
Select RPR (BioKit)	-	1	-
Fisher Sure-Vue RPR	-	23	-
Stanbio Syphilis (RPR) Quicktest	-	1	-
True Medix Diagnostics Trutest RPR	-	10	-
Wampole IMPACT RPR	-	8	1
SAMPLE 16305 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	102	3
Ampcor RPR Card Test	-	1	-
ASI RPR Card Test for Syphilis	-	19	-
Becton Dickenson Macro-vue RPR	-	39	2
Select RPR (BioKit)	-	1	-
Fisher Sure-Vue RPR	-	23	-
Stanbio Syphilis (RPR) Quicktest	-	1	-
True Medix Diagnostics Trutest RPR	-	10	-
Wampole IMPACT RPR	-	8	1

Syphilis Reagin Ab (RPR) Titers

The number of laboratories that reported titers is listed for reactive test samples 16301 and 16302.

Primary Test Kit/Assay	No. Labs	Sample 16301 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	96	-	1	56	36	3	-	-
Ampcor RPR Card Test	1	-	-	-	1	-	-	-
ASI RPR Card Test for Syphilis	11	-	1	5	5	-	-	-
Becton Dickenson Macro-vue RPR	41	-	-	26	15	-	-	-
Select RPR (BioKit)	1	-	-	1	-	-	-	-
Fisher Sure-Vue RPR	22	-	-	14	6	2	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-	1	-	-	-	-
True Medix Diagnostics Trutest RPR	10	-	-	6	4	-	-	-
Wampole IMPACT RPR	9	-	-	3	5	1	-	-

Primary Test Kit/Assay	No. Labs	Sample 16302 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	96	-	-	-	3	7	35	51
Ampcor RPR Card Test	1	-	-	-	-	-	-	1
ASI RPR Card Test for Syphilis	11	-	-	-	-	2	4	5
Becton Dickenson Macro-vue RPR	41	-	-	-	-	3	11	27
Select RPR (BioKit)	1	-	-	-	-	-	1	-
Fisher Sure-Vue RPR	22	-	-	-	-	1	12	9
Stanbio Syphilis (RPR) Quicktest	1	-	-	-	-	-	1	-
True Medix Diagnostics Trutest RPR	10	-	-	-	2	1	3	4
Wampole IMPACT RPR	9	-	-	-	1	-	3	5

Qualitative Syphilis Treponemal Ab

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Not Indicated
SAMPLE 16301 - 96% of participants reported reactive.			
All Labs	47	1	-
Bio-Rad Bioplex	1	-	-
DiaSorin Liaison Treponemal Assay	11	-	-
Fujirebio Serodia-TP-PA	11	-	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	2	1	-
Siemens ADVIA Centaur SYPH Assay	6	-	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test *	4	-	-
Wampole IMPACT IFA	1	-	-
Zeus Scientific FTA-ABS	5	-	-
Treponema Pallidum IgG ELISA (Zeus Scientific)	2	-	-

* One laboratory reported "Equivocal" as a result.

SAMPLE 16302 - 98% of participants reported reactive.			
All Labs	48	1	-
Bio-Rad Bioplex	1	-	-
DiaSorin Liaison Treponemal Assay	11	-	-
Fujirebio Serodia-TP-PA	11	-	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	2	1	-
Siemens ADVIA Centaur SYPH Assay	6	-	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	5	-	-
Wampole IMPACT IFA	1	-	-
Zeus Scientific FTA-ABS	5	-	-
Treponema Pallidum IgG ELISA (Zeus Scientific)	2	-	-

SAMPLE 16303 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	41	8
Bio-Rad Bioplex	-	1	-
DiaSorin Liaison Treponemal Assay	-	11	-
Fujirebio Serodia-TP-PA	-	7	4
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	3	-
Siemens ADVIA Centaur SYPH Assay	-	5	1
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	4	1
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	3	2
Treponema Pallidum IgG ELISA (Zeus Scientific)	-	2	-

Qualitative Syphilis Treponemal Ab

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Not Indicated
SAMPLE 16304 - 100% of participants reported nonreactive or testing not indicated.			
All Labs	-	41	8
Bio-Rad Bioplex	-	1	-
DiaSorin Liaison Treponemal Assay	-	11	-
Fujirebio Serodia-TP-PA	-	7	4
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	3	-
Siemens ADVIA Centaur SYPH Assay	-	5	1
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	4	1
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	3	2
Treponema Pallidum IgG ELISA (Zeus Scientific)	-	2	-

SAMPLE 16305 - 99% of participants reported nonreactive or testing not indicated.			
All Labs	1	40	8
Bio-Rad Bioplex	-	1	-
DiaSorin Liaison Treponemal Assay	1	10	-
Fujirebio Serodia-TP-PA	-	7	4
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	-	3	-
Siemens ADVIA Centaur SYPH Assay	-	5	1
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	4	1
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	3	2
Treponema Pallidum IgG ELISA (Zeus Scientific)	-	2	-

Quantitative Alpha-1 Antitrypsin (mg/dl)

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 16376		Total Labs	Labs *	Acceptable Range			S.D.
Method	Primary Test Kit/Assay			Low	High	Mean	
All Methods		13	9	0.00	30.00	15.00	5.00
Nephelometry Total		8	8	-	-	11.85	-
	<i>Beckman Coulter Image</i>	1	1	-	-	11.10	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	11.57	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	12.25	-
Turbidimetry Total		5	1	-	-	5.00	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	1	-	-	5.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-

Sample 16377		Total Labs	Labs *	Acceptable Range			S.D.
Method	Primary Test Kit/Assay			Low	High	Mean	
All Methods		13	13	7.54	260.14	133.84	42.10
Nephelometry Total		8	8	-	-	169.00	-
	<i>Beckman Coulter Image</i>	1	1	-	-	64.20	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	179.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	161.50	-
Turbidimetry Total		5	5	-	-	98.54	-
	<i>Abbott Architect</i>	1	1	-	-	94.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	3	-	-	99.90	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	99.00	-

Sample 16378		Total Labs	Labs *	Acceptable Range			S.D.
Method	Primary Test Kit/Assay			Low	High	Mean	
All Methods		13	13	50.50	180.96	115.73	21.74
Nephelometry Total		8	8	-	-	125.85	-
	<i>Beckman Coulter Image</i>	1	1	-	-	75.80	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	141.33	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	126.75	-
Turbidimetry Total		5	5	-	-	99.54	-
	<i>Abbott Architect</i>	1	1	-	-	99.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	3	-	-	99.23	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	101.00	-

Quantitative Alpha-1 Antitrypsin (mg/dl)

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 16379		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		13	13	43.53	125.15	84.34	13.60
Nephelometry Total		8	8	-	-	94.94	-
	<i>Beckman Coulter Image</i>	1	1	-	-	60.80	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	97.20	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	93.25	-
Turbidimetry Total		5	5	-	-	74.20	-
	<i>Abbott Architect</i>	1	1	-	-	72.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	3	-	-	73.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	80.00	-

Sample 16380		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		13	11	26.44	47.40	36.92	3.49
Nephelometry Total		8	8	-	-	38.26	-
	<i>Beckman Coulter Image</i>	1	1	-	-	34.30	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	36.93	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	40.25	-
Turbidimetry Total		5	3	-	-	33.33	-
	<i>Abbott Architect</i>	1	1	-	-	32.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	1	-	-	32.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	36.00	-

Quantitative Complement C3 (mg/dl)

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 16376		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		38	36	14.24	28.50	21.37	2.38
Nephelometry Total		15	14	18.37	22.37	20.37	0.67
	<i>Beckman Coulter Immage</i>	2	2	-	-	17.60	-
	<i>Siemens Dimension VISTA</i>	10	9	-	-	20.29	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	21.00	-
Turbidimetry Total		23	22	14.60	29.82	22.21	2.54
	<i>Abbott Architect</i>	2	2	-	-	22.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	18.30	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	17.20	29.70	23.45	2.08
	<i>Ortho Vitros (all models)</i>	1	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	20.70	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	21.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	19.00	-

Sample 16377		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		38	38	103.77	132.95	118.36	4.86
Nephelometry Total		15	15	105.34	136.80	121.07	5.24
	<i>Beckman Coulter Immage</i>	2	2	-	-	114.00	-
	<i>Siemens Dimension VISTA</i>	10	10	110.30	130.30	120.30	3.33
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	128.33	-
Turbidimetry Total		23	23	105.36	127.84	116.60	3.75
	<i>Abbott Architect</i>	2	2	-	-	119.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	111.40	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	107.20	125.15	116.17	2.99
	<i>Ortho Vitros (all models)</i>	1	1	-	-	118.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	119.57	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	121.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	112.00	-

Quantitative Complement C3 (mg/dl)

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 16378		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		38	38	60.83	92.56	76.70	5.29
Nephelometry Total		15	15	73.43	89.33	81.38	2.65
	<i>Beckman Coulter Immage</i>	2	2	-	-	68.65	-
	<i>Siemens Dimension VISTA</i>	10	10	72.55	89.85	81.20	2.88
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	82.00	-
Turbidimetry Total		23	23	61.56	87.92	74.74	4.39
	<i>Abbott Architect</i>	2	2	-	-	76.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	81.90	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	65.90	78.66	72.28	2.13
	<i>Ortho Vitros (all models)</i>	1	1	-	-	80.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	76.23	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	81.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	73.00	-

Sample 16379		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		38	38	69.18	123.77	96.48	9.10
Nephelometry Total		15	15	87.40	123.88	105.64	6.08
	<i>Beckman Coulter Immage</i>	2	2	-	-	102.05	-
	<i>Siemens Dimension VISTA</i>	10	10	92.15	121.55	106.85	4.90
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	104.00	-
Turbidimetry Total		23	23	76.71	104.29	90.50	4.60
	<i>Abbott Architect</i>	2	2	-	-	96.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	93.95	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	81.86	93.76	87.81	1.98
	<i>Ortho Vitros (all models)</i>	1	1	-	-	103.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	92.03	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	93.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	88.00	-

Quantitative Complement C3 (mg/dl)

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 16380		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		38	38	48.04	66.51	57.27	3.08
Nephelometry Total		15	15	52.04	66.56	59.30	2.42
	<i>Beckman Coulter Immage</i>	2	2	-	-	54.85	-
	<i>Siemens Dimension VISTA</i>	10	10	55.20	64.56	59.88	1.56
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	60.33	-
Turbidimetry Total		23	23	47.69	64.22	55.95	2.76
	<i>Abbott Architect</i>	2	2	-	-	55.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	59.05	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	51.03	57.39	54.21	1.06
	<i>Ortho Vitros (all models)</i>	1	1	-	-	61.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	56.63	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	57.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	54.00	-

Quantitative Complement C4 (mg/dl)

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 16376		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	21	0.92	5.39	3.16	0.75
Nephelometry Total		13	10	2.04	4.84	3.44	0.47
	<i>Beckman Coulter Immage</i>	2	2	-	-	2.90	-
	<i>Siemens Dimension VISTA</i>	8	5	-	-	3.80	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	3.20	-
Turbidimetry Total		24	11	1.16	4.20	2.68	0.51
	<i>Abbott Architect</i>	2	2	-	-	4.05	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	0	-	-	-	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	5	-	-	2.46	-
	<i>Ortho Vitros (all models)</i>	1	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	1	-	-	2.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	3.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	3.00	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	3.00	-

Sample 16377		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	37	22.73	31.73	27.23	1.50
Nephelometry Total		13	13	24.80	30.55	27.68	0.96
	<i>Beckman Coulter Immage</i>	2	2	-	-	26.90	-
	<i>Siemens Dimension VISTA</i>	8	8	-	-	27.56	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	28.50	-
Turbidimetry Total		24	24	20.01	33.98	27.00	2.33
	<i>Abbott Architect</i>	2	2	-	-	26.80	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	24.40	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	23.85	33.09	28.47	1.54
	<i>Ortho Vitros (all models)</i>	1	1	-	-	26.60	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	3	-	-	24.60	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	24.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	23.00	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	28.00	-

Quantitative Complement C4 (mg/dl)

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 16378		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	37	10.96	20.15	15.55	1.53
Nephelometry Total		13	13	13.58	20.08	16.83	1.08
	<i>Beckman Coulter Immage</i>	2	2	-	-	14.85	-
	<i>Siemens Dimension VISTA</i>	8	8	-	-	17.48	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	16.43	-
Turbidimetry Total		24	24	11.02	18.70	14.86	1.28
	<i>Abbott Architect</i>	2	2	-	-	15.65	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	15.40	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	10.73	19.02	14.88	1.38
	<i>Ortho Vitros (all models)</i>	1	1	-	-	15.60	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	3	-	-	13.87	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	14.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	14.00	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	16.00	-

Sample 16379		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	37	10.77	24.50	17.64	2.29
Nephelometry Total		13	13	19.28	21.63	20.45	0.39
	<i>Beckman Coulter Immage</i>	2	2	-	-	19.20	-
	<i>Siemens Dimension VISTA</i>	8	8	-	-	20.54	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	19.47	-
Turbidimetry Total		24	24	11.58	21.04	16.31	1.58
	<i>Abbott Architect</i>	2	2	-	-	17.40	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	17.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	11.21	21.20	16.21	1.66
	<i>Ortho Vitros (all models)</i>	1	1	-	-	17.60	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	3	-	-	14.77	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	15.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	16.00	-
	<i>SPAplus C4 Kit (The Binding Site)</i>	1	1	-	-	19.00	-

Quantitative Complement C4 (mg/dl)

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 16380		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		37	37	7.43	15.48	11.45	1.34
Nephelometry Total		13	13	11.34	14.12	12.73	0.46
	<i>Beckman Coulter Immage</i>	2	2	-	-	12.15	-
	<i>Siemens Dimension VISTA</i>	8	8	-	-	12.95	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	12.53	-
Turbidimetry Total		24	24	7.37	14.16	10.76	1.13
	<i>Abbott Architect</i>	2	2	-	-	11.85	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	10.55	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	7.00	14.65	10.82	1.28
	<i>Ortho Vitros (all models)</i>	1	1	-	-	11.60	-
	<i>Roche Diagnostics Cobas (all models)</i>	3	3	-	-	9.73	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	10.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	10.00	-
	<i>SPApplus C4 Kit (The Binding Site)</i>	1	1	-	-	12.00	-

Quantitative Immunoglobulin A (mg/dl)

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 16381 Method	Primary Test Kit/Assay	Total Labs	Labs *	Acceptable Range			
				Low	High	Mean	S.D.
All Methods		43	38	20.81	42.27	31.54	3.58
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	13	18.34	44.59	31.46	4.38
	<i>Beckman Coulter Immage</i>	4	3	-	-	25.10	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	34.10	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	6	-	-	33.93	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	32.00	-
Turbidimetry Total		26	25	22.29	46.00	34.14	3.95
	<i>Abbott Architect</i>	3	3	-	-	44.73	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	34.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	28.01	37.64	32.83	1.61
	<i>Ortho Vitros (all models)</i>	1	0	-	-	-	-
	<i>Imola (Randox)</i>	1	1	-	-	32.56	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	28.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	26.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	31.50	-

Sample 16382 Method	Primary Test Kit/Assay	Total Labs	Labs *	Acceptable Range			
				Low	High	Mean	S.D.
All Methods		43	42	103.21	218.17	160.69	19.16
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	16	95.18	247.73	171.46	25.43
	<i>Beckman Coulter Immage</i>	4	4	-	-	130.75	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	166.30	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	187.75	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	184.00	-
Turbidimetry Total		26	26	136.93	172.97	154.95	6.01
	<i>Abbott Architect</i>	3	3	-	-	151.53	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	153.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	150.91	160.25	155.58	1.56
	<i>Ortho Vitros (all models)</i>	1	1	-	-	164.08	-
	<i>Imola (Randox)</i>	1	1	-	-	167.80	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	148.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	131.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	144.00	-

Quantitative Immunoglobulin A (mg/dl)

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 16383		Total Labs	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay			Low	High	Mean	S.D.
All Methods		43	42	156.70	243.48	200.09	14.46
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	16	164.35	249.92	207.14	14.26
	<i>Beckman Coulter Immage</i>	4	4	-	-	186.00	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	210.20	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	216.25	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	210.00	-
Turbidimetry Total		26	26	176.53	209.03	192.78	5.42
	<i>Abbott Architect</i>	3	3	-	-	187.07	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	193.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	186.87	201.66	194.26	2.46
	<i>Ortho Vitros (all models)</i>	1	1	-	-	217.98	-
	<i>Imola (Randox)</i>	1	1	-	-	237.39	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	191.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	172.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	189.00	-

Sample 16384		Total Labs	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay			Low	High	Mean	S.D.
All Methods		43	42	101.50	176.63	139.06	12.52
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	16	102.06	188.14	145.10	14.35
	<i>Beckman Coulter Immage</i>	4	4	-	-	123.50	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	140.60	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	154.62	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	150.00	-
Turbidimetry Total		26	26	112.74	158.35	135.54	7.60
	<i>Abbott Architect</i>	3	3	-	-	133.40	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	127.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	130.51	145.28	137.90	2.46
	<i>Ortho Vitros (all models)</i>	1	1	-	-	149.41	-
	<i>Imola (Randox)</i>	1	1	-	-	154.71	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	129.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	110.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	125.00	-

Quantitative Immunoglobulin A (mg/dl)

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 16385		Total Labs	Labs *	Acceptable Range			
Method	Primary Test Kit/Assay			Low	High	Mean	S.D.
All Methods		43	42	86.16	143.33	114.75	9.53
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
Nephelometry Total		16	16	87.30	141.32	114.31	9.00
	<i>Beckman Coulter Immage</i>	4	4	-	-	102.60	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	115.60	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	119.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	117.00	-
Turbidimetry Total		26	26	106.51	128.24	117.38	3.62
	<i>Abbott Architect</i>	3	3	-	-	118.63	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	106.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	13	13	109.16	127.28	118.22	3.02
	<i>Ortho Vitros (all models)</i>	1	1	-	-	119.65	-
	<i>Imola (Randox)</i>	1	1	-	-	128.20	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	108.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	90.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	100.50	-

Quantitative Immunoglobulin E (IU/ml)

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 16381		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		34	34	10.62	22.16	16.39	1.92
Chemiluminescence Total		20	20	10.82	21.60	16.21	1.80
	<i>Beckman Coulter ACCESS</i>	3	3	-	-	18.07	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	2	2	-	-	18.93	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	15.55	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	15.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	59.79	-
	<i>Siemens Immulite Systems (all models)</i>	11	11	11.01	19.88	15.45	1.48
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	54.38	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	54.38	-
Fluoroenzyme Immunoassay (FEIA) Total		8	8	-	-	16.30	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	7	7	-	-	16.83	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	12.60	-
Nephelometry Total		5	5	-	-	24.54	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	25.57	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	20.40	-

Sample 16382		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		34	34	40.21	79.83	60.02	6.60
Chemiluminescence Total		20	20	38.01	78.64	58.33	6.77
	<i>Beckman Coulter ACCESS</i>	3	3	-	-	64.80	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	2	2	-	-	67.89	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	64.95	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	64.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	297.40	-
	<i>Siemens Immulite Systems (all models)</i>	11	11	45.30	60.90	53.10	2.60
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	312.03	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	312.03	-
Fluoroenzyme Immunoassay (FEIA) Total		8	8	-	-	64.04	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	7	7	-	-	64.36	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	61.80	-
Nephelometry Total		5	5	-	-	103.66	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	105.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	98.30	-

Quantitative Immunoglobulin E (IU/ml)

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 16383		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		34	34	64.54	95.02	79.78	5.08
Chemiluminescence Total		20	20	62.83	97.78	80.30	5.83
	<i>Beckman Coulter ACCESS</i>	3	3	-	-	77.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	2	2	-	-	77.60	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	82.15	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	80.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	90.29	-
	<i>Siemens Immulite Systems (all models)</i>	11	11	59.65	101.04	80.35	6.90
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	80.60	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	80.60	-
Fluoroenzyme Immunoassay (FEIA) Total		8	8	-	-	77.92	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	7	7	-	-	77.43	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	81.40	-
Nephelometry Total		5	5	-	-	80.48	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	80.90	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	78.80	-

Sample 16384		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		34	34	8.33	74.21	41.27	10.98
Chemiluminescence Total		20	20	20.49	51.78	36.13	5.22
	<i>Beckman Coulter ACCESS</i>	3	3	-	-	42.87	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	2	2	-	-	43.66	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	37.80	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	37.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	193.09	-
	<i>Siemens Immulite Systems (all models)</i>	11	11	25.02	40.07	32.55	2.51
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	162.01	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	162.01	-
Fluoroenzyme Immunoassay (FEIA) Total		8	8	-	-	39.21	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	7	7	-	-	40.36	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	31.20	-
Nephelometry Total		5	5	-	-	64.08	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	64.03	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	64.30	-

Quantitative Immunoglobulin E (IU/ml)

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 16385		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		34	34	7.79	40.20	23.99	5.40
Chemiluminescence Total		20	20	5.34	42.11	23.72	6.13
	<i>Beckman Coulter ACCESS</i>	3	3	-	-	33.23	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	2	2	-	-	33.33	-
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	22.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	22.00	-
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	290.87	-
	<i>Siemens Immulite Systems (all models)</i>	11	11	17.35	22.87	20.11	0.92
ELISA Enzyme-linked Immunosorbent Assay (EIA)		1	1	-	-	272.08	-
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	272.08	-
Fluoroenzyme Immunoassay (FEIA) Total		8	8	-	-	24.64	-
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	7	7	-	-	25.57	-
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	18.10	-
Nephelometry Total		5	5	-	-	72.36	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	71.70	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	75.00	-

Quantitative Immunoglobulin G (mg/dl)

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 16381		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		40	39	138.51	230.85	184.68	15.39
Nephelometry Total		16	16	148.94	248.23	198.59	16.55
	<i>Beckman Coulter Immage</i>	4	4	-	-	221.25	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	217.20	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	198.50	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	196.67	-
Turbidimetry Total		24	23	130.26	217.10	173.68	14.47
	<i>Abbott Architect</i>	2	2	-	-	193.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	189.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	123.70	206.16	164.93	13.74
	<i>Ortho Vitros (all models)</i>	1	0	-	-	-	-
	<i>Imola (Randox)</i>	1	1	-	-	116.73	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	195.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	125.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	205.00	-

Sample 16382		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		40	40	521.51	869.18	695.35	57.95
Nephelometry Total		16	16	565.31	942.19	753.75	62.81
	<i>Beckman Coulter Immage</i>	4	4	-	-	687.50	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	831.00	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	742.71	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	794.67	-
Turbidimetry Total		24	24	488.90	814.83	651.86	54.32
	<i>Abbott Architect</i>	2	2	-	-	660.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	682.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	485.05	808.42	646.74	53.89
	<i>Ortho Vitros (all models)</i>	1	1	-	-	676.36	-
	<i>Imola (Randox)</i>	1	1	-	-	573.36	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	671.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	607.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	667.50	-

Quantitative Immunoglobulin G (mg/dl)

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 16383		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		40	40	341.90	569.84	455.87	37.99
Nephelometry Total		16	16	362.86	604.77	483.82	40.32
	<i>Beckman Coulter Immage</i>	4	4	-	-	467.75	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	528.10	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	484.62	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	488.33	-
Turbidimetry Total		24	24	324.71	541.18	432.95	36.08
	<i>Abbott Architect</i>	2	2	-	-	443.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	447.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	315.83	526.39	421.11	35.09
	<i>Ortho Vitros (all models)</i>	1	1	-	-	450.43	-
	<i>Imola (Randox)</i>	1	1	-	-	494.14	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	444.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	375.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	447.00	-

Sample 16384		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		40	40	491.95	819.91	655.93	54.66
Nephelometry Total		16	16	517.44	862.40	689.92	57.49
	<i>Beckman Coulter Immage</i>	4	4	-	-	664.25	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	767.70	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	682.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	719.33	-
Turbidimetry Total		24	24	477.06	795.10	636.08	53.01
	<i>Abbott Architect</i>	2	2	-	-	649.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	627.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	472.45	787.41	629.93	52.49
	<i>Ortho Vitros (all models)</i>	1	1	-	-	673.37	-
	<i>Imola (Randox)</i>	1	1	-	-	545.74	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	617.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	584.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	636.00	-

Quantitative Immunoglobulin G (mg/dl)

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Sample 16385		Total		Acceptable Range		Mean	S.D.
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High		
All Methods		40	40	313.01	521.68	417.34	34.78
Nephelometry Total		16	16	329.23	548.72	438.98	36.58
	<i>Beckman Coulter Immage</i>	4	4	-	-	421.50	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	469.60	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	439.88	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	449.67	-
Turbidimetry Total		24	24	301.15	501.92	401.53	33.46
	<i>Abbott Architect</i>	2	2	-	-	421.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	410.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	293.47	489.11	391.29	32.61
	<i>Ortho Vitros (all models)</i>	1	1	-	-	419.86	-
	<i>Imola (Randox)</i>	1	1	-	-	321.35	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	409.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	336.00	-
	<i>SPAplus IgG Kit (The Binding Site)</i>	2	2	-	-	422.00	-

Quantitative Immunoglobulin M (mg/dl)

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 16381		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	29	8.25	26.24	17.24	3.00
Nephelometry Total		15	9	-	-	15.56	-
	<i>Beckman Coulter Immage</i>	4	3	-	-	14.83	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	4	-	-	16.38	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	2	-	-	15.00	-
Turbidimetry Total		24	20	8.22	27.79	18.00	3.26
	<i>Abbott Architect</i>	2	2	-	-	15.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	0	-	-	-	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	10	18.77	23.05	20.91	0.71
	<i>Ortho Vitros (all models)</i>	1	0	-	-	-	-
	<i>Imola (Randox)</i>	1	1	-	-	14.99	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	15.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	14.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	15.50	-

Sample 16382		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	46.88	75.82	61.35	4.82
Nephelometry Total		15	15	53.72	77.75	65.74	4.01
	<i>Beckman Coulter Immage</i>	4	4	-	-	60.55	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	67.59	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	68.33	-
Turbidimetry Total		24	24	51.07	88.58	69.82	6.25
	<i>Abbott Architect</i>	2	2	-	-	58.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	63.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	52.20	65.24	58.72	2.17
	<i>Ortho Vitros (all models)</i>	1	1	-	-	67.11	-
	<i>Imola (Randox)</i>	1	1	-	-	88.58	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	57.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	55.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	57.50	-

Quantitative Immunoglobulin M (mg/dl)

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Sample 16383		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	30.24	45.44	37.84	2.53
Nephelometry Total		15	15	33.03	45.27	39.15	2.04
	<i>Beckman Coulter Immage</i>	4	4	-	-	37.20	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	39.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	40.00	-
Turbidimetry Total		24	24	30.07	74.70	52.38	7.44
	<i>Abbott Architect</i>	2	2	-	-	34.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	38.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	34.21	43.19	38.70	1.50
	<i>Ortho Vitros (all models)</i>	1	1	-	-	40.72	-
	<i>Imola (Randox)</i>	1	1	-	-	74.70	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	35.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	33.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	36.00	-

Sample 16384		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	55.39	108.49	81.94	8.85
Nephelometry Total		15	15	76.06	100.54	88.30	4.08
	<i>Beckman Coulter Immage</i>	4	4	-	-	83.30	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	88.91	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	93.33	-
Turbidimetry Total		24	24	66.38	84.70	75.54	3.05
	<i>Abbott Architect</i>	2	2	-	-	74.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	73.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	66.90	81.91	74.41	2.50
	<i>Ortho Vitros (all models)</i>	1	1	-	-	102.81	-
	<i>Imola (Randox)</i>	1	1	-	-	106.53	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	79.75	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	76.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	76.50	-

Quantitative Immunoglobulin M (mg/dl)

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 16385		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	22.66	40.55	31.61	2.98
Nephelometry Total		15	15	23.72	36.15	29.93	2.07
	<i>Beckman Coulter Immage</i>	4	4	-	-	29.43	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	29.91	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	30.67	-
Turbidimetry Total		24	24	25.31	47.61	36.46	3.72
	<i>Abbott Architect</i>	2	2	-	-	27.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	30.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	31.68	36.04	33.86	0.73
	<i>Ortho Vitros (all models)</i>	1	1	-	-	41.77	-
	<i>Imola (Randox)</i>	1	1	-	-	47.61	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	32.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	30.00	-
	<i>SPAplus IgM Kit (The Binding Site)</i>	2	2	-	-	30.00	-