

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

# **Proficiency Testing Program**

**April 26, 2016**

**DIAGNOSTIC IMMUNOLOGY  
SUMMARY ANALYSIS**



**Diagnostic Immunology  
Proficiency Test Event  
April 26, 2016**

**Summary Analysis**

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

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The data summarized in this report were tabulated from proficiency test results and accompanying information submitted by laboratories that participated in the April 26, 2016 Diagnostic Immunology Proficiency Test event. Participants are encouraged to review the data and to compare results and test kit performances.

Laboratories were evaluated on the basis of their responses for each analyte and on overall performance for all the analytes tested in the permit category. Appropriate responses were determined by participant consensus requiring 80% agreement in each test.

Qualitative/quantitative results were graded in relation to results given by participants for specific test kits. When the number of participants that used a specific test kit was less than 10, results were graded considering results given for the method used. Target values and acceptable ranges were determined as indicated in Page 4.

#### **Grading Criteria:**

- \* For each separate analyte where results were reported, qualitative or quantitative, twenty points were deducted for each incorrect answer. Titering of positive Syphilis-Reagin samples is mandatory for all Diagnostic Services laboratories who perform this test, unless given an exemption. Failure to titer the positive samples to the endpoint will result in failure for the Syphilis-Reagin analyte.
- \* Failure to attain an overall testing score of at least 80% is unsatisfactory performance
- \* Laboratories failing two out of three consecutive proficiency test events for an analyte or for the permit category will fail the proficiency testing program for the analyte or for the permit category and may be required to cease patient testing for that analyte/category.

#### **Summary Tables**

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

For qualitative tests, results are summarized as the number of laboratories that reported a test sample as reactive to the number that reported it as non-reactive. In addition, where test results depend on a quantitative value (e.g. titer, IU/ml) the values reported are given in separate tables. They are expressed, where applicable, as the Mean  $\pm$  S.D. when ten or more laboratories reported data. Titers are given as endpoint titers.

#### **Disclaimer**

The use of brand and/or trade names in this report does not constitute an endorsement of the products on the part of the Wadsworth Center or the New York State Department of Health.

## Determination of Acceptable Responses

Analyte or Test	Criteria
Alpha-1 Antitrypsin	Target value $\pm$ 3 S.D.
Antinuclear Antibody	Positive or negative
Antinuclear Antibody Quantitative (IFA titers only)	Target value $\pm$ 2 dilutions
Antistreptolysin O	Positive or negative
Antistreptolysin O Quantitative, Semi-Quant, and Titer	Target value $\pm$ 2 dilutions or Target value $\pm$ 3 S.D.
Complement C'3, C'4	Target value $\pm$ 3 S.D.
Cytomegalovirus Antibody	Positive or negative
Hepatitis (HbsAg, anti-HBc, HBeAg, and HCAb)	Reactive or nonreactive
HIV 1 Ab	Reactive or nonreactive
Lyme Disease Ab, WB IgG, and WB IgM	Positive or negative
Immunoglobulin A, E, M	Target value $\pm$ 3 S.D.
Immunoglobulin G	Target value $\pm$ 25 %
Infectious Mononucleosis	Positive or negative
Rheumatoid Factor	Positive or negative
Rheumatoid Factor Quantitative, Semi-Quant. and Titer	Target value $\pm$ 2 dilutions or Target value $\pm$ 3 S.D.
Rubella Ab, IgM	Positive or negative or Immune or nonimmune
Rubella Ab Quantitative	Target value $\pm$ 3 S.D.
Syphilis Reagin Antibody	Reactive or nonreactive Target value $\pm$ 1 dilution
Syphilis Treponemal Antibody	Reactive or nonreactive

## Qualitative Antinuclear Ab (ANA) - Diagnostic Services

### Participant Results

Primary Test Kit/Assay	Positive	Negative	Equivocal
<b>SAMPLE 16246 - 96% of participants reported negative.</b>			
All Labs	2	44	-
Bio-Rad Bioplex	-	3	-
BioRad EIA Systems (any)	-	3	-
BioRad/Kallestad IFA Systems (any)	-	8	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	1	-
Immuno Concepts IFA Systems (any)	-	2	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	6	-
INOVA Novalite/Quanta Lite	-	1	-
Phadia/Pharmacia Immunocap/UniCap (all models)	2	1	-
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	5	-
Wampole/Zeus ANA IFA Hep-2	-	8	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	1	-

### **SAMPLE 16247 - 89% of participants reported positive.**

All Labs	41	3	2
Bio-Rad Bioplex	1	2	-
BioRad EIA Systems (any)	3	-	-
BioRad/Kallestad IFA Systems (any)	8	-	-
DiaSorin ANA Screen EIA	1	-	-
Diamedix EIA Systems (any)	-	-	1
Immuno Concepts IFA Systems (any)	2	-	-
IMMCO Diagnostics IFA	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	6	-	-
INOVA Novalite/Quanta Lite	1	-	-
Phadia/Pharmacia Immunocap/UniCap (all models)	2	-	1
RhiGene Fluor ANA IFA Test	1	-	-
Trinity Biotech ANA EIA Test	1	1	-
Wampole ANA EIA	5	-	-
Wampole/Zeus ANA IFA Hep-2	8	-	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	1	-	-

## Qualitative Antinuclear Ab (ANA) - Diagnostic Services

### Participant Results

Primary Test Kit/Assay	Positive	Negative	Equivocal
<b>SAMPLE 16248 - 100% of participants reported positive.</b>			
All Labs	46	-	-
Bio-Rad Bioplex	3	-	-
BioRad EIA Systems (any)	3	-	-
BioRad/Kallestad IFA Systems (any)	8	-	-
DiaSorin ANA Screen EIA	1	-	-
Diamedix EIA Systems (any)	1	-	-
Immuno Concepts IFA Systems (any)	2	-	-
IMMCO Diagnostics IFA	1	-	-
INOVA IFA Systems/NOVA Lite Hep-2	6	-	-
INOVA Novalite/Quanta Lite	1	-	-
Phadia/Pharmacia Immunocap/UniCap (all models)	3	-	-
RhiGene Fluor ANA IFA Test	1	-	-
Trinity Biotech ANA EIA Test	2	-	-
Wampole ANA EIA	5	-	-
Wampole/Zeus ANA IFA Hep-2	8	-	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	1	-	-

**SAMPLE 16249 - 96% of participants reported negative.**

All Labs	1	44	1
Bio-Rad Bioplex	-	3	-
BioRad EIA Systems (any)	-	3	-
BioRad/Kallestad IFA Systems (any)	-	8	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	1	-
Immuno Concepts IFA Systems (any)	-	2	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	6	-
INOVA Novalite/Quanta Lite	-	1	-
Phadia/Pharmacia Immunocap/UniCap (all models)	1	1	1
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	5	-
Wampole/Zeus ANA IFA Hep-2	-	8	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	1	-

## Qualitative Antinuclear Ab (ANA) - Diagnostic Services

### Participant Results

Primary Test Kit/Assay	Positive	Negative	Equivocal
<b>SAMPLE 16250 - 98% of participants reported negative.</b>			
All Labs	1	45	-
Bio-Rad Bioplex	-	3	-
BioRad EIA Systems (any)	-	3	-
BioRad/Kallestad IFA Systems (any)	-	8	-
DiaSorin ANA Screen EIA	-	1	-
Diamedix EIA Systems (any)	-	1	-
Immuno Concepts IFA Systems (any)	-	2	-
IMMCO Diagnostics IFA	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	-	6	-
INOVA Novalite/Quanta Lite	-	1	-
Phadia/Pharmacia Immunocap/UniCap (all models)	1	2	-
RhiGene Fluor ANA IFA Test	-	1	-
Trinity Biotech ANA EIA Test	-	2	-
Wampole ANA EIA	-	5	-
Wampole/Zeus ANA IFA Hep-2	-	8	-
Zeus Scientific AtheNA Multi-Lyte ANA Test	-	1	-

### Antinuclear Ab (ANA) IFA Titers - Diagnostic Services

The number of laboratories that reported titers for positive test samples 16247 and 16248.

Primary Test Kit/Assay	No. Labs	Sample 16247 Titers						
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280
All Labs	31	-	-	1	-	3	8	8
BioRad/Kallestad IFA Systems (any)	10	-	-	-	-	1	2	3
Immuno Concepts IFA Systems (any)	2	-	-	-	-	-	-	2
IMMCO Diagnostics IFA	2	-	-	-	-	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	8	-	-	1	-	-	2	3
RhiGene Fluor ANA IFA Test	1	-	-	-	-	-	-	1
Wampole/Zeus ANA IFA Hep-2	8	-	-	-	-	2	3	2

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

Primary Test Kit/Assay	No. Labs	Sample 16248 Titers						
		< C.O.	1:40	1:80	1:160	1:320	1:640	1:1280
All Labs	31	-	1	3	7	9	9	2
BioRad/Kallestad IFA Systems (any)	10	-	-	2	4	2	2	-
Immuno Concepts IFA Systems (any)	2	-	-	-	1	-	1	-
IMMCO Diagnostics IFA	2	-	-	-	1	-	1	-
INOVA IFA Systems/NOVA Lite Hep-2	8	-	1	-	-	4	2	1
RhiGene Fluor ANA IFA Test	1	-	-	-	-	1	-	-
Wampole/Zeus ANA IFA Hep-2	8	-	-	1	1	2	3	1

Staining Pattern - 31 labs reported a staining pattern, of those 29 labs (97%) reported homogenous, and 1 lab (3%) reported speckled. The reporting of a staining pattern here is for informational purposes only and is not graded.

## Qualitative Antistreptolysin O - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16216 - 100% of participants reported negative.</b>		
All Labs	-	29
Arlington Scientific ASO Latex Test	-	2
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	2
BioKit Rheumajet ASO Latex Test	-	5
Fisher Sure-Vue ASO Latex Test	-	10
Remel Seratest ASO Latex Test	-	2
Siemens (Dade Behring) RapiTex Latex Test	-	6
True Medix Trutest Latex Test	-	1
Wampole Color Card ASO Latex Test	-	1

**SAMPLE 16217 - 100% of participants reported positive.**

All Labs	29	-
Arlington Scientific ASO Latex Test	2	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	2	-
BioKit Rheumajet ASO Latex Test	5	-
Fisher Sure-Vue ASO Latex Test	10	-
Remel Seratest ASO Latex Test	2	-
Siemens (Dade Behring) RapiTex Latex Test	6	-
True Medix Trutest Latex Test	1	-
Wampole Color Card ASO Latex Test	1	-

**SAMPLE 16218 - 100% of participants reported negative.**

All Labs	-	29
Arlington Scientific ASO Latex Test	-	2
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	2
BioKit Rheumajet ASO Latex Test	-	5
Fisher Sure-Vue ASO Latex Test	-	10
Remel Seratest ASO Latex Test	-	2
Siemens (Dade Behring) RapiTex Latex Test	-	6
True Medix Trutest Latex Test	-	1
Wampole Color Card ASO Latex Test	-	1

## Qualitative Antistreptolysin O - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16219 - 100% of participants reported positive.</b>		
All Labs	29	-
Arlington Scientific ASO Latex Test	2	-
Beckman Coulter Synchron LX/Unicel Systems (all models)	2	-
BioKit Rheumajet ASO Latex Test	5	-
Fisher Sure-Vue ASO Latex Test	10	-
Remel Seratest ASO Latex Test	2	-
Siemens (Dade Behring) RapiTex Latex Test	6	-
True Medix Trutest Latex Test	1	-
Wampole Color Card ASO Latex Test	1	-

**SAMPLE 16220 - 100% of participants reported negative.**

All Labs	-	29
Arlington Scientific ASO Latex Test	-	2
Beckman Coulter Synchron LX/Unicel Systems (all models)	-	2
BioKit Rheumajet ASO Latex Test	-	5
Fisher Sure-Vue ASO Latex Test	-	10
Remel Seratest ASO Latex Test	-	2
Siemens (Dade Behring) RapiTex Latex Test	-	6
True Medix Trutest Latex Test	-	1
Wampole Color Card ASO Latex Test	-	1

## Antistreptolysin O (ASO) Titers - Diagnostic Services

The number of laboratories that reported titers for positive test samples 16217, and 16219.

Primary Test Kit/Assay	No. Labs	Sample 16217 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	-	-	3	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	2	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16219 Titers					
		< C.O.	1:1	1:2	1:4	1:8	≥ 1:16
All Labs	7	-	3	3	1	-	-
Arlington Scientific ASO Latex Test	1	-	-	1	-	-	-
BioKit Rheumajet ASO Latex Test	1	-	1	-	-	-	-
Fisher Sure-Vue ASO Latex Test	3	-	2	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	1	1	-	-

## Semi-quantitative Antistreptolysin O (ASO) - Diagnostic Services

The number of laboratories that reported semi-quantitative results for positive test samples 16217, and 16219.

Primary Test Kit/Assay	No. Labs	Sample 16217 Results (IU/ml)					
		< C.O.	200	400	800	1600	≥ 3200
All Labs	19	-	9	10	-	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	5	-	4	1	-	-	-
Fisher Sure-Vue ASO Latex Test	6	-	1	5	-	-	-
Remel Seratest ASO Latex Test	2	-	1	1	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	5	-	2	3	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16219 Results (IU/ml)					
		< C.O.	200	400	800	1600	≥ 3200
All Labs	19	-	11	7	1	-	-
Arlington Scientific ASO Latex Test	1	-	1	-	-	-	-
BioKit Rheumajet ASO Latex Test	5	-	3	2	-	-	-
Fisher Sure-Vue ASO Latex Test	6	-	5	1	-	-	-
Remel Seratest ASO Latex Test	2	-	-	2	-	-	-
Siemens (Dade Behring) RapiTex Latex Test	5	-	2	2	1	-	-

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

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

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			
				<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>26</b>	-	<b>0.00</b>	<b>50.00</b>	<b>25.00</b>	<b>8.33</b>
<b>Nephelometry Total</b>		<b>5</b>	<b>1</b>	-	-	<b>19.00</b>	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	3	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	19.00	-
<b>Turbidimetry Total</b>		<b>21</b>	<b>6</b>	-	-	<b>21.05</b>	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	1	-	-	14.30	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	4	-	-	21.75	-
	<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>	2	0	-	-	-	-

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			
				<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>26</b>	<b>26</b>	<b>273.07</b>	<b>449.09</b>	<b>361.08</b>	<b>29.34</b>
<b>Nephelometry Total</b>		<b>5</b>	<b>5</b>	-	-	<b>335.00</b>	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	223.00	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	363.33	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	362.00	-
<b>Turbidimetry Total</b>		<b>21</b>	<b>21</b>	<b>168.17</b>	<b>507.22</b>	<b>337.70</b>	<b>56.51</b>
	<i>Abbott Architect</i>	1	1	-	-	257.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	3	-	-	234.63	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	324.80	373.82	349.31	8.17
	<i>Roche Diagnostics Cobas (all systems)</i>	2	2	-	-	406.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	371.90	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	2	2	-	-	407.20	-

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			
				<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>26</b>	-	<b>0.00</b>	<b>50.00</b>	<b>25.00</b>	<b>8.33</b>
<b>Nephelometry Total</b>		<b>5</b>	<b>1</b>	-	-	<b>19.00</b>	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	3	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	19.00	-
<b>Turbidimetry Total</b>		<b>21</b>	<b>6</b>	-	-	<b>19.22</b>	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	1	-	-	9.30	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	4	-	-	20.75	-
	<i>Roche Diagnostics Cobas (all systems)</i>	2	1	-	-	23.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	2	0	-	-	-	-

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

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

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total</b>	<b>Labs *</b>	<b>Acceptable Range</b>			<b>S.D.</b>
		<b>Labs</b>		<b>Low</b>	<b>High</b>	<b>Mean</b>	
<b>All Methods</b>		<b>26</b>	<b>26</b>	<b>132.57</b>	<b>507.34</b>	<b>319.95</b>	<b>62.46</b>
<b>Nephelometry Total</b>		<b>5</b>	<b>5</b>	-	-	<b>254.60</b>	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	197.00	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	270.00	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	266.00	-
<b>Turbidimetry Total</b>		<b>21</b>	<b>21</b>	<b>162.66</b>	<b>508.37</b>	<b>335.51</b>	<b>57.62</b>
	<i>Abbott Architect</i>	1	1	-	-	267.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	3	-	-	236.83	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	12	339.82	399.78	369.80	9.99
	<i>Roche Diagnostics Cobas (all systems)</i>	2	2	-	-	340.50	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	275.60	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	2	2	-	-	387.95	-

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total</b>	<b>Labs *</b>	<b>Acceptable Range</b>			<b>S.D.</b>
		<b>Labs</b>		<b>Low</b>	<b>High</b>	<b>Mean</b>	
<b>All Methods</b>		<b>26</b>	<b>-</b>	<b>0.00</b>	<b>50.00</b>	<b>25.00</b>	<b>8.33</b>
<b>Nephelometry Total</b>		<b>5</b>	<b>1</b>	-	-	<b>18.00</b>	-
	<i>Beckman Coulter Immage</i>	1	0	-	-	-	-
	<i>Siemens Dimension VISTA</i>	3	0	-	-	-	-
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	18.00	-
<b>Turbidimetry Total</b>		<b>21</b>	<b>6</b>	-	-	<b>21.45</b>	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	3	1	-	-	18.70	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	12	4	-	-	22.25	-
	<i>Roche Diagnostics Cobas (all systems)</i>	2	1	-	-	21.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-
	<i>Siemens ADVIA 1200/1650/1800/2400</i>	2	0	-	-	-	-

## Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

### Participant Results

Primary Test Kit/Assay	Positive	Negative	Equivocal
<b>SAMPLE 16211 - 100% of participants reported positive.</b>			
All Labs	23	-	-
Bio-Rad CMV IgG EIA	1	-	-
Bio-Rad Bioplex Torc IgG	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	7	-	-
Diamedix CMV EIA Systems (any)	1	-	-
DiaSorin Liaison CMV IgG	6	-	-
Siemens Immulite Systems (all models)	2	-	-
Trinity Biotech CAPTIA CMV IgG EIA	1	-	-
Wampole Zeus Scientific CMV IgG ELISA	1	-	-
Zeus Scientific CMV IgG EIA	3	-	-

### **SAMPLE 16212 - 96% of participants reported negative.**

All Labs	-	22	1
Bio-Rad CMV IgG EIA	-	1	-
Bio-Rad Bioplex Torc IgG	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	7	-
Diamedix CMV EIA Systems (any)	-	-	1
DiaSorin Liaison CMV IgG	-	6	-
Siemens Immulite Systems (all models)	-	2	-
Trinity Biotech CAPTIA CMV IgG EIA	-	1	-
Wampole Zeus Scientific CMV IgG ELISA	-	1	-
Zeus Scientific CMV IgG EIA	-	3	-

### **SAMPLE 16213 - 96% of participants reported negative.**

All Labs	-	22	1
Bio-Rad CMV IgG EIA	-	1	-
Bio-Rad Bioplex Torc IgG	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	7	-
Diamedix CMV EIA Systems (any)	-	-	1
DiaSorin Liaison CMV IgG	-	6	-
Siemens Immulite Systems (all models)	-	2	-
Trinity Biotech CAPTIA CMV IgG EIA	-	1	-
Wampole Zeus Scientific CMV IgG ELISA	-	1	-
Zeus Scientific CMV IgG EIA	-	3	-

## Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
<b>SAMPLE 16214 - 100% of participants reported positive.</b>			
All Labs	23	-	-
Bio-Rad CMV IgG EIA	1	-	-
Bio-Rad Bioplex Torc IgG	1	-	-
bioMerieux VIDAS/mini VIDAS Systems	7	-	-
Diamedix CMV EIA Systems (any)	1	-	-
DiaSorin Liaison CMV IgG	6	-	-
Siemens Immulite Systems (all models)	2	-	-
Trinity Biotech CAPTIA CMV IgG EIA	1	-	-
Wampole Zeus Scientific CMV IgG ELISA	1	-	-
Zeus Scientific CMV IgG EIA	3	-	-

**SAMPLE 16215 - 96% of participants reported negative.**

All Labs	-	22	1
Bio-Rad CMV IgG EIA	-	1	-
Bio-Rad Bioplex Torc IgG	-	1	-
bioMerieux VIDAS/mini VIDAS Systems	-	7	-
Diamedix CMV EIA Systems (any)	-	-	1
DiaSorin Liaison CMV IgG	-	6	-
Siemens Immulite Systems (all models)	-	2	-
Trinity Biotech CAPTIA CMV IgG EIA	-	1	-
Wampole Zeus Scientific CMV IgG ELISA	-	1	-
Zeus Scientific CMV IgG EIA	-	3	-

## Qualitative Hepatitis B core Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16206 - 100% of participants reported nonreactive.</b>		
All Labs	-	53
Abbott Architect	-	15
BioRad MONOLISA HBC	-	1
Ortho Vitros (all models)	-	12
Cobas Anti-HBC Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	-	21
Siemens Immulite Systems (all models)	-	3

**SAMPLE 16207 - 100% of participants reported nonreactive.**

All Labs	-	53
Abbott Architect	-	15
BioRad MONOLISA HBC	-	1
Ortho Vitros (all models)	-	12
Cobas Anti-HBC Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	-	21
Siemens Immulite Systems (all models)	-	3

**SAMPLE 16208 - 100% of participants reported nonreactive.**

All Labs	-	53
Abbott Architect	-	15
BioRad MONOLISA HBC	-	1
Ortho Vitros (all models)	-	12
Cobas Anti-HBC Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	-	21
Siemens Immulite Systems (all models)	-	3

## Qualitative Hepatitis B core Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16209 - 100% of participants reported reactive.</b>		
All Labs	53	-
Abbott Architect	15	-
BioRad MONOLISA HBc	1	-
Ortho Vitros (all models)	12	-
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	1	-
Siemens ADVIA Centaur	21	-
Siemens Immulite Systems (all models)	3	-

**SAMPLE 16210 - 100% of participants reported nonreactive.**

All Labs	-	53
Abbott Architect	-	15
BioRad MONOLISA HBc	-	1
Ortho Vitros (all models)	-	12
Cobas Anti-HBc Immunoassay (Roche Diagnostics)	-	1
Siemens ADVIA Centaur	-	21
Siemens Immulite Systems (all models)	-	3

## Qualitative Hepatitis B surface Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16206 - 99% of participants reported nonreactive.</b>		
All Labs	1	77
Abbott Architect	-	17
Bio-Rad GS HBsAg EIA	-	1
DiaSorin ETI MAK-2 Plus	-	1
Ortho Vitros (all models)	-	15
Roche Diagnostics Cobas (all systems)	-	6
Roche Diagnostics Elecsys Systems	-	1
Siemens ADVIA Centaur	1	32
Siemens Immulite Systems (all models)	-	4
 <b>SAMPLE 16207 - 100% of participants reported reactive.</b>		
All Labs	78	-
Abbott Architect	17	-
Bio-Rad GS HBsAg EIA	1	-
DiaSorin ETI MAK-2 Plus	1	-
Ortho Vitros (all models)	15	-
Roche Diagnostics Cobas (all systems)	6	-
Roche Diagnostics Elecsys Systems	1	-
Siemens ADVIA Centaur	33	-
Siemens Immulite Systems (all models)	4	-
 <b>SAMPLE 16208 - 96% of participants reported nonreactive.</b>		
All Labs	3	75
Abbott Architect	1	16
Bio-Rad GS HBsAg EIA	-	1
DiaSorin ETI MAK-2 Plus	-	1
Ortho Vitros (all models)	-	15
Roche Diagnostics Cobas (all systems)	-	6
Roche Diagnostics Elecsys Systems	-	1
Siemens ADVIA Centaur	2	31
Siemens Immulite Systems (all models)	-	4

## Qualitative Hepatitis B surface Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16209 - 100% of participants reported reactive.</b>		
All Labs	78	-
Abbott Architect	17	-
Bio-Rad GS HBsAg EIA	1	-
DiaSorin ETI MAK-2 Plus	1	-
Ortho Vitros (all models)	15	-
Roche Diagnostics Cobas (all systems)	6	-
Roche Diagnostics Elecsys Systems	1	-
Siemens ADVIA Centaur	33	-
Siemens Immulite Systems (all models)	4	-

**SAMPLE 16210 - 97% of participants reported nonreactive.**

All Labs	2	76
Abbott Architect	1	16
Bio-Rad GS HBsAg EIA	-	1
DiaSorin ETI MAK-2 Plus	-	1
Ortho Vitros (all models)	-	15
Roche Diagnostics Cobas (all systems)	-	6
Roche Diagnostics Elecsys Systems	-	1
Siemens ADVIA Centaur	1	32
Siemens Immulite Systems (all models)	-	4

### Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

#### Participant Results

Primary Test Kit/Assay	Positive	Negative	Not Indicated
<b>SAMPLE 16206 - 100% of participants reported nonreactive or testing not indicated.</b>			
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 16207 - 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 16208 - 94% of participants reported nonreactive or testing not indicated.**

All Labs	2	3	31
Abbott Architect	1	-	10
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	1	3	12

### Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

#### Participant Results

##### Primary Test Kit/Assay

Primary Test Kit/Assay	Positive	Negative	Not Indicated
<b>SAMPLE 16209 - 100% of participants reported reactive or testing not indicated.</b>			
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 16210 - 97% of participants reported nonreactive or testing not indicated.**

Primary Test Kit/Assay	Positive	Negative	Not Indicated
<b>SAMPLE 16210 - 97% of participants reported nonreactive or testing not indicated.</b>			
All Labs	1	5	30
Abbott Architect	1	-	10
Abbott HBsAg Confirmatory Assay	-	-	1
DiaSorin ETI MAK-2 Plus	-	-	1
Ortho Vitros (all models)	-	1	4
Roche Diagnostics Cobas (all systems)	-	-	2
Siemens ADVIA Centaur	-	4	12

## Qualitative Hepatitis Be Ag - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16266 - 100% of participants reported reactive.</b>		
All Labs	6	-
DiaSorin ETI-EBK Plus	2	-
DiaSorin ETI MAK 3000	1	-
Ortho Vitros (all models)	2	-
Siemens ADVIA Centaur	1	-

**SAMPLE 16267 - 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 16268 - 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 16269 - 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 16270 - 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

## Qualitative Hepatitis C Virus Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16271 - 100% of participants reported nonreactive.</b>		
All Labs	-	66
Abbott Architect	-	17
HCV Ortho Version 3.0 ELISA	-	3
Ortho Vitros (all models)	-	13
Roche Diagnostics Elecsys Systems	-	3
Siemens ADVIA Centaur	-	30
<b>SAMPLE 16272 - 100% of participants reported nonreactive.</b>		
All Labs	-	66
Abbott Architect	-	17
HCV Ortho Version 3.0 ELISA	-	3
Ortho Vitros (all models)	-	13
Roche Diagnostics Elecsys Systems	-	3
Siemens ADVIA Centaur	-	30
<b>SAMPLE 16273 - 98% of participants reported reactive.</b>		
All Labs	65	1
Abbott Architect	17	-
HCV Ortho Version 3.0 ELISA	3	-
Ortho Vitros (all models)	13	-
Roche Diagnostics Elecsys Systems	3	-
Siemens ADVIA Centaur	29	1
<b>SAMPLE 16274 - 100% of participants reported reactive.</b>		
All Labs	66	-
Abbott Architect	17	-
HCV Ortho Version 3.0 ELISA	3	-
Ortho Vitros (all models)	13	-
Roche Diagnostics Elecsys Systems	3	-
Siemens ADVIA Centaur	30	-
<b>SAMPLE 16275 - 100% of participants reported nonreactive.</b>		
All Labs	-	66
Abbott Architect	-	17
HCV Ortho Version 3.0 ELISA	-	3
Ortho Vitros (all models)	-	13
Roche Diagnostics Elecsys Systems	-	3
Siemens ADVIA Centaur	-	30

## Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16231 - 100% of participants reported nonreactive.</b>		
All Labs	-	139
Architect HIV Ag/Ab Combo Assay (Abbott)	-	21
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	7
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	20
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	3
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	5
Clearview Complete HIV 1/2 (Alere)	-	4
Clearview HIV 1/2 Stat-Pak (Alere)	-	1
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	48
Vitros Anti-HIV 1+2 (Ortho)	-	11
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	-	11
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	7
Other	-	1
<b>SAMPLE 16232 - 99% of participants reported reactive.</b>		
All Labs	138	1
Architect HIV Ag/Ab Combo Assay (Abbott)	21	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	7	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	20	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	3	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	5	-
Clearview Complete HIV 1/2 (Alere)	4	-
Clearview HIV 1/2 Stat-Pak (Alere)	1	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	47	1
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	-
Other	1	-
<b>SAMPLE 16233 - 100% of participants reported nonreactive.</b>		
All Labs	-	139
Architect HIV Ag/Ab Combo Assay (Abbott)	-	21
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	7
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	20
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	3
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	5
Clearview Complete HIV 1/2 (Alere)	-	4
Clearview HIV 1/2 Stat-Pak (Alere)	-	1
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	48
Vitros Anti-HIV 1+2 (Ortho)	-	11
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	-	11
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	7
Other	-	1

## Qualitative HIV Ab - Screening Tests

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16234 - 99% of participants reported nonreactive.</b>		
All Labs	1	138
Architect HIV Ag/Ab Combo Assay (Abbott)	-	21
Advia Centaur HIV 1/O/2 EHIV (Siemens)	-	7
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	-	20
GS HIV-1/HIV-2 Plus O (Bio-Rad)	-	3
GS HIV Ag/Ab Combo EIA (Bio-Rad)	-	5
Clearview Complete HIV 1/2 (Alere)	-	4
Clearview HIV 1/2 Stat-Pak (Alere)	-	1
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	-	48
Vitros Anti-HIV 1+2 (Ortho)	-	11
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	-	11
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	-	7
Other	1	-

**SAMPLE 16235 - 99% of participants reported reactive.**

All Labs	138	1
Architect HIV Ag/Ab Combo Assay (Abbott)	21	-
Advia Centaur HIV 1/O/2 EHIV (Siemens)	7	-
Determine HIV-1/2 Ag/Ab Combo Test (Alere)	20	-
GS HIV-1/HIV-2 Plus O (Bio-Rad)	3	-
GS HIV Ag/Ab Combo EIA (Bio-Rad)	4	1
Clearview Complete HIV 1/2 (Alere)	4	-
Clearview HIV 1/2 Stat-Pak (Alere)	1	-
OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)	48	-
Vitros Anti-HIV 1+2 (Ortho)	11	-
Advia Centaur HIV Ag/Ab Combo CHIV (Siemens)	11	-
Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)	7	-
Other	1	-

## Qualitative HIV-1 Ab - Supplemental/Confirmation Tests

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
<b>SAMPLE 16231 - 100% of participants reported nonreactive or testing not indicated.</b>			
All Labs	-	-	22
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	-	-	1
GS HIV-1 Western Blot (Bio-Rad)	-	-	2
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	-	19
<b>SAMPLE 16232 - 100% of participants reported reactive.</b>			
All Labs	22	-	-
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	1	-	-
GS HIV-1 Western Blot (Bio-Rad)	2	-	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	19	-	-
<b>SAMPLE 16233 - 100% of participants reported nonreactive or testing not indicated.</b>			
All Labs	-	-	22
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	-	-	1
GS HIV-1 Western Blot (Bio-Rad)	-	-	2
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	-	19
<b>SAMPLE 16234 - 100% of participants reported nonreactive or testing not indicated.</b>			
All Labs	-	-	22
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	-	-	1
GS HIV-1 Western Blot (Bio-Rad)	-	-	2
Multispot HIV-1/2 Rapid Test (Bio-Rad)	-	-	19
<b>SAMPLE 16235 - 95% of participants reported reactive.</b>			
All Labs	21	-	1
Geenius HIV 1/2 Supplemental Assay (Bio-Rad)	-	-	1
GS HIV-1 Western Blot (Bio-Rad)	2	-	-
Multispot HIV-1/2 Rapid Test (Bio-Rad)	19	-	-

## Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
<b>SAMPLE 16226 - 88% of participants reported negative.</b>			
All Labs	16	125	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	2	24	-
Fisher Sure-Vue Color Mono Latex Test Kit	-	4	-
Fisher Sure-Vue Mono Latex	-	37	-
Fisher Sure-Vue Signature Mono Test Kit	-	5	-
Inverness BioStar Acceava Mono/Mono II Test	-	4	-
Meridian MonoSpot Latex	-	2	-
Meridian ImmunoCard Mono	-	4	-
Nova Scientific Infectious Mono Latex Assay	-	1	-
OSOM Mono Test	-	3	-
Polymedco PolyStat Mono	-	1	-
Rapid Response BTNX	-	2	-
Remel Color Slide II Mononucleosis	6	3	-
Remel Mono-Lex Test	-	3	-
Remel SeraTest MONO	-	2	-
Serodyn Color Slide II Mononucleosis	2	-	-
RELY Mono Rapid Test (Stanbio)	-	1	-
Wampole Color Card MONO	6	3	1

## Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
<b>SAMPLE 16227 - 100% of participants reported negative.</b>			
All Labs	-	142	-
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	-	26	-
Fisher Sure-Vue Color Mono Latex Test Kit	-	4	-
Fisher Sure-Vue Mono Latex	-	37	-
Fisher Sure-Vue 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	-
Serodyn Color Slide II Mononucleosis	-	2	-
RELY Mono Rapid Test (Stanbio)	-	1	-
Wampole Color Card MONO	-	10	-

## Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
<b>SAMPLE 16228 - 100% of participants reported negative.</b>			
All Labs	-	142	-
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	-	26	-
Fisher Sure-Vue Color Mono Latex Test Kit	-	4	-
Fisher Sure-Vue Mono Latex	-	37	-
Fisher Sure-Vue 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	-
Serodyn Color Slide II Mononucleosis	-	2	-
RELY Mono Rapid Test (Stanbio)	-	1	-
Wampole Color Card MONO	-	10	-

## Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
<b>SAMPLE 16229 - 99% of participants reported positive.</b>			
All Labs	141	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	26	-	-
Fisher Sure-Vue Color Mono Latex Test Kit	4	-	-
Fisher Sure-Vue Mono Latex	37	-	-
Fisher Sure-Vue 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	2	1	-
Remel SeraTest MONO	2	-	-
Serodyn Color Slide II Mononucleosis	2	-	-
RELY Mono Rapid Test (Stanbio)	1	-	-
Wampole Color Card MONO	10	-	-

## Qualitative Infectious Mononucleosis - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Equivocal
<b>SAMPLE 16230 - 100% of participants reported negative.</b>			
All Labs	-	142	-
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	-	26	-
Fisher Sure-Vue Color Mono Latex Test Kit	-	4	-
Fisher Sure-Vue Mono Latex	-	37	-
Fisher Sure-Vue 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	-
Serodyn Color Slide II Mononucleosis	-	2	-
RELY Mono Rapid Test (Stanbio)	-	1	-
Wampole Color Card MONO	-	10	-

## Qualitative Lyme Disease Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16241 - 100% of participants reported negative.</b>		
All Labs	-	39
Bio-Rad Evolis	-	1
Bio-Rad Platelia Lyme IgG/IgM	-	2
bioMerieux VIDAS/mini VIDAS Systems	-	10
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	4
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	15
Immunetics C6 B. burgdorferi EIA Test	-	3
Laboratory developed assay	-	1
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	3

**SAMPLE 16242 - 100% of participants reported positive.**

All Labs	39	-
Bio-Rad Evolis	1	-
Bio-Rad Platelia Lyme IgG/IgM	2	-
bioMerieux VIDAS/mini VIDAS Systems	10	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	4	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	15	-
Immunetics C6 B. burgdorferi EIA Test	3	-
Laboratory developed assay	1	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	3	-

**SAMPLE 16243 - 100% of participants reported negative.**

All Labs	-	39
Bio-Rad Evolis	-	1
Bio-Rad Platelia Lyme IgG/IgM	-	2
bioMerieux VIDAS/mini VIDAS Systems	-	10
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	4
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	15
Immunetics C6 B. burgdorferi EIA Test	-	3
Laboratory developed assay	-	1
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	3

## Qualitative Lyme Disease Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16244 - 100% of participants reported positive.</b>		
All Labs	39	-
Bio-Rad Evolis	1	-
Bio-Rad Platelia Lyme IgG/IgM	2	-
bioMerieux VIDAS/mini VIDAS Systems	10	-
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	4	-
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	15	-
Immunetics C6 B. burgdorferi EIA Test	3	-
Laboratory developed assay	1	-
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	3	-

**SAMPLE 16245 - 100% of participants reported negative.**

All Labs	-	39
Bio-Rad Evolis	-	1
Bio-Rad Platelia Lyme IgG/IgM	-	2
bioMerieux VIDAS/mini VIDAS Systems	-	10
Borrelia VlsE1/pepC10 IgG/IgM ELISA Test (Zeus)	-	4
DiaSorin Liaison B. burgdorferi Chemiluminescent Assay	-	15
Immunetics C6 B. burgdorferi EIA Test	-	3
Laboratory developed assay	-	1
Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)	-	3

## Qualitative Lyme Western Blot IgG - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
<b>SAMPLE 16241 - 100% of participants reported negative or testing not indicated.</b>			
All Labs	-	8	4
Borrelia B31 ViraStrip IgG (Viramed)	-	1	1
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	5	3
<b>SAMPLE 16242 - 92% of participants reported positive.</b>			
All Labs	11	1	-
Borrelia B31 ViraStrip IgG (Viramed)	2	-	-
Laboratory developed assay	1	1	-
MarDx Lyme Disease (IgG) Marblot Strip Test	8	-	-
<b>SAMPLE 16243 - 100% of participants reported negative or testing not indicated.</b>			
All Labs	-	8	4
Borrelia B31 ViraStrip IgG (Viramed)	-	1	1
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	5	3
<b>SAMPLE 16244 - 100% of participants reported positive.</b>			
All Labs	12	-	-
Borrelia B31 ViraStrip IgG (Viramed)	2	-	-
Laboratory developed assay	2	-	-
MarDx Lyme Disease (IgG) Marblot Strip Test	8	-	-
<b>SAMPLE 16245 - 100% of participants reported negative or testing not indicated.</b>			
All Labs	-	8	4
Borrelia B31 ViraStrip IgG (Viramed)	-	1	1
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgG) Marblot Strip Test	-	5	3

## Qualitative Lyme Western Blot IgM - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
<b>SAMPLE 16241 - 100% of participants reported negative or testing not indicated.</b>			
All Labs	-	8	4
Borrelia B31 ViraStrip IgM (Viramed)	-	1	1
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	5	3
<b>SAMPLE 16242 - 100% of participants reported positive.</b>			
All Labs	12	-	-
Borrelia B31 ViraStrip IgM (Viramed)	2	-	-
Laboratory developed assay	2	-	-
MarDx Lyme Disease (IgM) Marblot Strip Test	8	-	-
<b>SAMPLE 16243 - 100% of participants reported negative or testing not indicated.</b>			
All Labs	-	8	4
Borrelia B31 ViraStrip IgM (Viramed)	-	1	1
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	5	3
<b>SAMPLE 16244 - 58% of participants reported positive.*</b>			
All Labs	7	5	-
Borrelia B31 ViraStrip IgM (Viramed)	1	1	-
Laboratory developed assay	2	-	-
MarDx Lyme Disease (IgM) Marblot Strip Test	4	4	-
<b>SAMPLE 16245 - 100% of participants reported negative or testing not indicated.</b>			
All Labs	-	8	4
Borrelia B31 ViraStrip IgM (Viramed)	-	1	1
Laboratory developed assay	-	2	-
MarDx Lyme Disease (IgM) Marblot Strip Test	-	5	3

\* Unable to validate sample #16244. 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 Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16226 - 100% of participants reported positive.</b>		
All Labs	50	-
Arlington Scientific RF Latex Test	3	-
Beckman Coulter Immage	1	-
Biokit Rheumajet RF Latex	5	-
Cardinal Health SP RF Latex	2	-
Fisher Sure-Vue RF Latex	24	-
Beckman Coulter (formerly Olympus) AU System	1	-
Ortho Vitros (all models)	1	-
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	2	-
Siemens ADVIA 1200/1650/1800/2400	1	-
Siemens Dimension VISTA	2	-
Siemens Nephelometer Systems (all models)	1	-
Siemens (Dade Behring) RapiTex Latex Test	3	-
True Medix Diagnostics Trutest RF	2	-
Wampole Colorcard RF	1	-
Wampole Rheumatex RF	1	-

### **SAMPLE 16227 - 98% of participants reported negative.**

All Labs	1	49
Arlington Scientific RF Latex Test	-	3
Beckman Coulter Immage	-	1
Biokit Rheumajet RF Latex	-	5
Cardinal Health SP RF Latex	1	1
Fisher Sure-Vue RF Latex	-	24
Beckman Coulter (formerly Olympus) AU System	-	1
Ortho Vitros (all models)	-	1
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2
Siemens ADVIA 1200/1650/1800/2400	-	1
Siemens Dimension VISTA	-	2
Siemens Nephelometer Systems (all models)	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	3
True Medix Diagnostics Trutest RF	-	2
Wampole Colorcard RF	-	1
Wampole Rheumatex RF	-	1

## Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16228 - 98% of participants reported negative.</b>		
All Labs	1	49
Arlington Scientific RF Latex Test	-	3
Beckman Coulter Immage	-	1
Biokit Rheumajet RF Latex	-	5
Cardinal Health SP RF Latex	1	1
Fisher Sure-Vue RF Latex	-	24
Beckman Coulter (formerly Olympus) AU System	-	1
Ortho Vitros (all models)	-	1
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2
Siemens ADVIA 1200/1650/1800/2400	-	1
Siemens Dimension VISTA	-	2
Siemens Nephelometer Systems (all models)	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	3
True Medix Diagnostics Trutest RF	-	2
Wampole Colorcard RF	-	1
Wampole Rheumatex RF	-	1

**SAMPLE 16229 - 98% of participants reported negative.**

All Labs	1	49
Arlington Scientific RF Latex Test	-	3
Beckman Coulter Immage	-	1
Biokit Rheumajet RF Latex	-	5
Cardinal Health SP RF Latex	-	2
Fisher Sure-Vue RF Latex	-	24
Beckman Coulter (formerly Olympus) AU System	-	1
Ortho Vitros (all models)	-	1
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2
Siemens ADVIA 1200/1650/1800/2400	-	1
Siemens Dimension VISTA	-	2
Siemens Nephelometer Systems (all models)	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	3
True Medix Diagnostics Trutest RF	-	2
Wampole Colorcard RF	1	-
Wampole Rheumatex RF	-	1

## Qualitative Rheumatoid Factor - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16230 - 98% of participants reported negative.</b>		
All Labs	1	49
Arlington Scientific RF Latex Test	-	3
Beckman Coulter Immage	-	1
Biokit Rheumajet RF Latex	-	5
Cardinal Health SP RF Latex	1	1
Fisher Sure-Vue RF Latex	-	24
Beckman Coulter (formerly Olympus) AU System	-	1
Ortho Vitros (all models)	-	1
QUANTA Lite RF IgM ELISA (INOVA Diagnostics)	-	2
Siemens ADVIA 1200/1650/1800/2400	-	1
Siemens Dimension VISTA	-	2
Siemens Nephelometer Systems (all models)	-	1
Siemens (Dade Behring) RapiTex Latex Test	-	3
True Medix Diagnostics Trutest RF	-	2
Wampole Colorcard RF	-	1
Wampole Rheumatex RF	-	1

## Rheumatoid Factor Titers - Diagnostic Services

The number of laboratories that reported titers is listed for positive test sample 16226.

Primary Test Kit/Assay	No. Labs	Sample 16226 Titers					
		< C.O.	1:16	1:32	1:64	1:128	≥ 1:256
All Labs	14	-	-	1	3	5	5
Arlington Scientific RF Latex Test	1	-	-	1	-	-	-
Biokit Rheumajet RF Latex	1	-	-	-	-	1	-
Cardinal Health SP RF Latex	1	-	-	-	-	-	1
Fisher Sure-Vue RF Latex	10	-	-	-	2	4	4
Siemens (Dade Behring) RapiTex Latex Test	1	-	-	-	1	-	-

## Semi-Quantitative Rheumatoid Factor - Diagnostic Services

The number of laboratories reporting semi-quantitative results for positive sample 16226.

Primary Test Kit/Assay	No. Labs	Sample 16226 Results (IU/ml)					
		< C.O.	80	160	320	640	≥ 1280
All Labs	15	-	-	1	5	1	8
Biokit Rheumajet RF Latex	2	-	-	-	-	-	2
Fisher Sure-Vue RF Latex	10	-	-	-	5	1	4
Siemens (Dade Behring) RapiTex Latex Test	2	-	-	-	-	-	2
Wampole Colorcard RF	1	-	-	1	-	-	-

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

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

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			
				<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
All Methods		51	38	585.32	1330.96	958.14	124.27
<b>Chemiluminescence Total</b>		1	1	-	-	920.00	-
<i>Siemens ADVIA 1200/1650/1800/2400</i>		1	1	-	-	920.00	-
<b>ELISA Enzyme-linked Immunosorbent Assay Total</b>		1	0	-	-	-	-
<i>IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM</i>		1	0	-	-	-	-
<b>Nephelometry Total</b>		20	17	747.41	1318.71	1033.06	95.22
<i>Beckman Coulter Immage</i>		2	1	-	-	2770.00	-
<i>Beckman Coulter AU System</i>		1	1	-	-	825.00	-
<i>Siemens Dimension VISTA</i>		14	12	807.99	1301.51	1054.75	82.25
<i>Siemens Nephelometer Systems (all models)</i>		3	3	-	-	1015.67	-
<b>Turbidimetry Total</b>		29	20	685.85	1161.25	923.55	79.23
<i>Architect (Abbott)</i>		1	1	-	-	844.10	-
<i>Beckman Coulter Immage</i>		1	1	-	-	2430.00	-
<i>Kamiya Biomedical RF</i>		2	2	-	-	778.85	-
<i>Beckman Coulter AU System</i>		12	8	-	-	851.86	-
<i>Ortho Vitros (all models)</i>		2	1	-	-	921.00	-
<i>Roche Diagnostics Cobas (all systems)</i>		4	2	-	-	935.00	-
<i>Roche Diagnostics RF II</i>		1	0	-	-	-	-
<i>Roche/Hitachi Modular Systems (all models)</i>		2	2	-	-	912.80	-
<i>Siemens ADVIA 1200/1650/1800/2400</i>		4	3	-	-	1034.83	-

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			
				<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
All Methods		51	16	0.00	16.44	7.20	3.08
<b>Chemiluminescence Total</b>		1	1	-	-	8.00	-
<i>Siemens ADVIA 1200/1650/1800/2400</i>		1	1	-	-	8.00	-
<b>ELISA Enzyme-linked Immunosorbent Assay Total</b>		1	1	-	-	3.30	-
<i>IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM</i>		1	1	-	-	3.30	-
<b>Nephelometry Total</b>		20	2	-	-	32.30	-
<i>Beckman Coulter Immage</i>		2	0	-	-	-	-
<i>Beckman Coulter AU System</i>		1	1	-	-	2.60	-
<i>Siemens Dimension VISTA</i>		14	1	-	-	62.00	-
<i>Siemens Nephelometer Systems (all models)</i>		3	0	-	-	-	-
<b>Turbidimetry Total</b>		29	12	0.00	16.47	7.84	2.88
<i>Architect (Abbott)</i>		1	0	-	-	-	-
<i>Beckman Coulter Immage</i>		1	0	-	-	-	-
<i>Kamiya Biomedical RF</i>		2	2	-	-	6.35	-
<i>Beckman Coulter AU System</i>		12	3	-	-	5.57	-
<i>Ortho Vitros (all models)</i>		2	1	-	-	9.40	-
<i>Roche Diagnostics Cobas (all systems)</i>		4	1	-	-	9.00	-
<i>Roche Diagnostics RF II</i>		1	1	-	-	10.00	-
<i>Roche/Hitachi Modular Systems (all models)</i>		2	0	-	-	-	-
<i>Siemens ADVIA 1200/1650/1800/2400</i>		4	4	-	-	9.07	-

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

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

<b>Sample 16228</b> <b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			<b>Mean</b>	<b>S.D.</b>
				<b>Low</b>	<b>High</b>			
All Methods		51	18	0.00	17.61	8.67	2.98	
<b>Chemiluminescence Total</b>		1	1	-	-	11.00		
	Siemens ADVIA 1200/1650/1800/2400	1	1	-	-	11.00		
<b>ELISA Enzyme-linked Immunosorbent Assay Total</b>		1	1	-	-	3.60		
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	1	-	-	3.60		
<b>Nephelometry Total</b>		20	1	-	-	5.00		
	Beckman Coulter Immage	2	0	-	-	-		
	Beckman Coulter AU System	1	1	-	-	5.00		
	Siemens Dimension VISTA	14	0	-	-	-		
	Siemens Nephelometer Systems (all models)	3	0	-	-	-		
<b>Turbidimetry Total</b>		29	15	4.03	15.22	9.62	1.86	
	Architect (Abbott)	1	0	-	-	-		
	Beckman Coulter Immage	1	0	-	-	-		
	Kamiya Biomedical RF	2	2	-	-	3.85		
	Beckman Coulter AU System	12	3	-	-	8.77		
	Ortho Vitros (all models)	2	0	-	-	-		
	Roche Diagnostics Cobas (all systems)	4	3	-	-	10.00		
	Roche Diagnostics RF II	1	1	-	-	11.00		
	Roche/Hitachi Modular Systems (all models)	2	2	-	-	10.95		
	Siemens ADVIA 1200/1650/1800/2400	4	4	-	-	9.88		

<b>Sample 16229</b> <b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			<b>Mean</b>	<b>S.D.</b>
				<b>Low</b>	<b>High</b>			
All Methods		51	-	0.00	10.00	5.00	1.67	
<b>Chemiluminescence Total</b>		1	0	-	-	-		
	Siemens ADVIA 1200/1650/1800/2400	1	0	-	-	-		
<b>ELISA Enzyme-linked Immunosorbent Assay Total</b>		1	1	-	-	3.30		
	IMMCO Diagnostics Immulisa Rheumatoid Factor - IgM	1	1	-	-	3.30		
<b>Nephelometry Total</b>		20	1	-	-	0.00		
	Beckman Coulter Immage	2	0	-	-	-		
	Beckman Coulter AU System	1	1	-	-	0.00		
	Siemens Dimension VISTA	14	0	-	-	-		
	Siemens Nephelometer Systems (all models)	3	0	-	-	-		
<b>Turbidimetry Total</b>		29	4	-	-	5.33		
	Architect (Abbott)	1	0	-	-	-		
	Beckman Coulter Immage	1	0	-	-	-		
	Kamiya Biomedical RF	2	1	-	-	4.60		
	Beckman Coulter AU System	12	1	-	-	8.10		
	Ortho Vitros (all models)	2	0	-	-	-		
	Roche Diagnostics Cobas (all systems)	4	1	-	-	7.00		
	Roche Diagnostics RF II	1	0	-	-	-		
	Roche/Hitachi Modular Systems (all models)	2	0	-	-	-		
	Siemens ADVIA 1200/1650/1800/2400	4	1	-	-	1.60		

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

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

<b>Sample 16230</b> <b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			<b>Mean</b>	<b>S.D.</b>
				<b>Low</b>	<b>High</b>			
All Methods		51	19	0.00	18.37	9.06	3.10	-
Chemiluminescence Total		1	1	-	-	10.00	-	-
	Siemens ADVIA 1200/1650/1800/2400	1	1	-	-	10.00	-	-
ELISA Enzyme-linked Immunosorbent Assay Total		1	1	-	-	3.10	-	-
	IMMCO Diagnostics ImmuLisa Rheumatoid Factor - IgM	1	1	-	-	3.10	-	-
Nephelometry Total		20	1	-	-	5.70	-	-
	Beckman Coulter Immage	2	0	-	-	-	-	-
	Beckman Coulter AU System	1	1	-	-	5.70	-	-
	Siemens Dimension VISTA	14	0	-	-	-	-	-
	Siemens Nephelometer Systems (all models)	3	0	-	-	-	-	-
Turbidimetry Total		29	16	8.43	13.06	10.75	0.77	-
	Architect (Abbott)	1	0	-	-	-	-	-
	Beckman Coulter Immage	1	0	-	-	-	-	-
	Kamiya Biomedical RF	2	1	-	-	1.00	-	-
	Beckman Coulter AU System	12	4	-	-	8.68	-	-
	Ortho Vitros (all models)	2	0	-	-	-	-	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	10.50	-	-
	Roche Diagnostics RF II	1	1	-	-	12.00	-	-
	Roche/Hitachi Modular Systems (all models)	2	2	-	-	10.90	-	-
	Siemens ADVIA 1200/1650/1800/2400	4	4	-	-	10.45	-	-

## Qualitative Rubella Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16211 - 100% of participants reported positive.</b>		
All Labs	65	-
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-Vue Rubella	5	-
Ortho Vitros (all models)	5	-
Remel Ruba-Test	1	-
Roche Diagnostics Cobas (all systems)	4	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA Centaur	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 16212 - 100% of participants reported negative.**

All Labs	-	65
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-Vue Rubella	-	5
Ortho Vitros (all models)	-	5
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	4
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	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 - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16213 - 100% of participants reported negative.</b>		
All Labs	-	65
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-Vue Rubella	-	5
Ortho Vitros (all models)	-	5
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	4
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	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 16214 - 98% of participants reported positive.**

All Labs	64	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-Vue Rubella	4	1
Ortho Vitros (all models)	5	-
Remel Ruba-Test	1	-
Roche Diagnostics Cobas (all systems)	4	-
Roche/Hitachi Modular Systems (all models)	1	-
Siemens ADVIA Centaur	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 - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16215 - 98% of participants reported negative.</b>		
All Labs	1	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-Vue Rubella	1	4
Ortho Vitros (all models)	-	5
Remel Ruba-Test	-	1
Roche Diagnostics Cobas (all systems)	-	4
Roche/Hitachi Modular Systems (all models)	-	1
Siemens ADVIA Centaur	-	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 - Diagnostic Services

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

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			<b>S.D.</b>
				<b>Low</b>	<b>High</b>	<b>Mean</b>	
<b>All Methods</b>		<b>30</b>	<b>30</b>	<b>0.00</b>	<b>92.53</b>	<b>45.84</b>	<b>15.56</b>
<b>Chemiluminescence Total</b>		<b>27</b>	<b>27</b>	<b>21.02</b>	<b>80.06</b>	<b>50.54</b>	<b>9.84</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	40.50	-
<i>Beckman Coulter UniCel Dxl Systems (all models)</i>		3	3	-	-	39.60	-
<i>DiASorin Liaison Rubella IgG Chemiluminescent Assay</i>		2	2	-	-	3.33	-
<i>Ortho Vitros (all models)</i>		3	3	-	-	60.20	-
<i>Roche Diagnostics Cobas (all systems)</i>		1	1	-	-	136.20	-
<i>Roche/Hitachi Modular Systems (all models)</i>		1	1	-	-	133.10	-
<i>Siemens ADVIA Centaur</i>		14	14	32.83	74.19	53.51	6.89
<i>Siemens Immulite Systems (all models)</i>		2	2	-	-	36.70	-
<b>Enzyme Linked Fluorescent Assay (ELFA) Total</b>		<b>3</b>	<b>3</b>	<b>-</b>	<b>-</b>	<b>38.13</b>	<b>-</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	46.40	-
<i>bioMerieux VIDAS/mini VIDAS Systems</i>		2	2	-	-	34.00	-

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			<b>S.D.</b>
				<b>Low</b>	<b>High</b>	<b>Mean</b>	
<b>All Methods</b>		<b>30</b>	<b>15</b>	<b>0.00</b>	<b>2.20</b>	<b>0.66</b>	<b>0.51</b>
<b>Chemiluminescence Total</b>		<b>27</b>	<b>13</b>	<b>0.00</b>	<b>1.70</b>	<b>0.55</b>	<b>0.38</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	0.40	-
<i>Beckman Coulter UniCel Dxl Systems (all models)</i>		3	3	-	-	1.07	-
<i>DiASorin Liaison Rubella IgG Chemiluminescent Assay</i>		2	1	-	-	0.20	-
<i>Ortho Vitros (all models)</i>		3	3	-	-	0.26	-
<i>Roche Diagnostics Cobas (all systems)</i>		1	0	-	-	-	-
<i>Roche/Hitachi Modular Systems (all models)</i>		1	0	-	-	-	-
<i>Siemens ADVIA Centaur</i>		14	5	-	-	0.52	-
<i>Siemens Immulite Systems (all models)</i>		2	0	-	-	-	-
<b>Enzyme Linked Fluorescent Assay (ELFA) Total</b>		<b>3</b>	<b>2</b>	<b>-</b>	<b>-</b>	<b>1.35</b>	<b>-</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	0.70	-
<i>bioMerieux VIDAS/mini VIDAS Systems</i>		2	1	-	-	2.00	-

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			<b>S.D.</b>
				<b>Low</b>	<b>High</b>	<b>Mean</b>	
<b>All Methods</b>		<b>30</b>	<b>15</b>	<b>0.00</b>	<b>2.17</b>	<b>0.72</b>	<b>0.48</b>
<b>Chemiluminescence Total</b>		<b>27</b>	<b>12</b>	<b>0.00</b>	<b>2.24</b>	<b>0.69</b>	<b>0.52</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	0.60	-
<i>Beckman Coulter UniCel Dxl Systems (all models)</i>		3	3	-	-	1.30	-
<i>DiASorin Liaison Rubella IgG Chemiluminescent Assay</i>		2	1	-	-	0.20	-
<i>Ortho Vitros (all models)</i>		3	3	-	-	0.33	-
<i>Roche Diagnostics Cobas (all systems)</i>		1	0	-	-	-	-
<i>Roche/Hitachi Modular Systems (all models)</i>		1	0	-	-	-	-
<i>Siemens ADVIA Centaur</i>		14	4	-	-	0.65	-
<i>Siemens Immulite Systems (all models)</i>		2	0	-	-	-	-
<b>Enzyme Linked Fluorescent Assay (ELFA) Total</b>		<b>3</b>	<b>3</b>	<b>-</b>	<b>-</b>	<b>2.60</b>	<b>-</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	0.80	-
<i>bioMerieux VIDAS/mini VIDAS Systems</i>		2	2	-	-	3.50	-

## Quantitative Rubella Ab IU/ml - Diagnostic Services

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

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Acceptable Range</b>				<b>S.D.</b>
			<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	
<b>All Methods</b>		<b>30</b>	<b>29</b>	<b>0.00</b>	<b>140.97</b>	<b>58.17</b>	<b>27.60</b>
<b>CHEMILUMINESCENCE Total</b>		<b>27</b>	<b>26</b>	<b>0.00</b>	<b>144.97</b>	<b>60.68</b>	<b>28.10</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	36.70	-
<i>Beckman Coulter UniCel Dxl Systems (all models)</i>		3	3	-	-	42.90	-
<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>		2	2	-	-	3.42	-
<i>Ortho Vitros (all models)</i>		3	3	-	-	57.90	-
<i>Roche Diagnostics Cobas (all systems)</i>		1	1	-	-	125.80	-
<i>Roche/Hitachi Modular Systems (all models)</i>		1	1	-	-	125.80	-
<i>Siemens ADVIA Centaur</i>		14	13	46.46	92.94	69.70	7.75
<i>Siemens Immulite Systems (all models)</i>		2	2	-	-	37.00	-
<b>ENZYME LINKED FLUORESCENT ASSAY (ELFA) Total</b>		<b>3</b>	<b>3</b>	<b>-</b>	<b>-</b>	<b>36.47</b>	<b>-</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	39.40	-
<i>bioMerieux VIDAS/mini VIDAS Systems</i>		2	2	-	-	35.00	-

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total Labs</b>	<b>Acceptable Range</b>				<b>S.D.</b>
			<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	
<b>All Methods</b>		<b>30</b>	<b>17</b>	<b>0.00</b>	<b>1.93</b>	<b>0.68</b>	<b>0.42</b>
<b>CHEMILUMINESCENCE Total</b>		<b>27</b>	<b>14</b>	<b>0.00</b>	<b>1.96</b>	<b>0.65</b>	<b>0.44</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	0.60	-
<i>Beckman Coulter UniCel Dxl Systems (all models)</i>		3	3	-	-	1.30	-
<i>DiaSorin Liaison Rubella IgG Chemiluminescent Assay</i>		2	1	-	-	0.20	-
<i>Ortho Vitros (all models)</i>		3	3	-	-	0.34	-
<i>Roche Diagnostics Cobas (all systems)</i>		1	0	-	-	-	-
<i>Roche/Hitachi Modular Systems (all models)</i>		1	0	-	-	-	-
<i>Siemens ADVIA Centaur</i>		14	6	-	-	0.54	-
<i>Siemens Immulite Systems (all models)</i>		2	0	-	-	-	-
<b>ENZYME LINKED FLUORESCENT ASSAY (ELFA) Total</b>		<b>3</b>	<b>3</b>	<b>-</b>	<b>-</b>	<b>3.60</b>	<b>-</b>
<i>Beckman Coulter ACCESS</i>		1	1	-	-	0.80	-
<i>bioMerieux VIDAS/mini VIDAS Systems</i>		2	2	-	-	5.00	-

## Qualitative Rubella IgM Specific - Diagnostic Services

Primary Test Kit/Assay	Participant Results	
	Positive	Negative
<b>SAMPLE 16256 - 100% of participants reported negative.</b>		
All Labs	-	12
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	1
Rubella IgM EIA Systems (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
<b>SAMPLE 16257 - 100% of participants reported negative.</b>		
All Labs	-	12
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	1
Rubella IgM EIA Systems (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
<b>SAMPLE 16258 - 100% of participants reported positive.</b>		
All Labs	12	-
DiaSorin Liaison Rubella IgM	3	-
Diamedix Rubella EIA Systems IgM	1	-
Rubella IgM EIA Systems (Roche)	1	-
Siemens ADVIA Centaur	3	-
Siemens Immulite Systems (all models)	4	-
<b>SAMPLE 16259 - 100% of participants reported negative.</b>		
All Labs	-	12
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	1
Rubella IgM EIA Systems (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4
<b>SAMPLE 16260 - 100% of participants reported negative.</b>		
All Labs	-	12
DiaSorin Liaison Rubella IgM	-	3
Diamedix Rubella EIA Systems IgM	-	1
Rubella IgM EIA Systems (Roche)	-	1
Siemens ADVIA Centaur	-	3
Siemens Immulite Systems (all models)	-	4

## Qualitative Syphilis Reagin Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
<b>SAMPLE 16201 - 100% of participants reported nonreactive or testing not indicated.</b>			
All Labs	-	107	3
Ampcor RPR Card Test	-	1	-
ASI RPR Card Test for Syphilis	-	18	-
Becton Dickenson Macro-vue RPR	-	41	3
Fisher Sure-Vue RPR	-	26	-
Stanbio Syphilis (RPR) Quicktest	-	1	-
True Medix Diagnostics Trutest RPR	-	10	-
Wampole IMPACT RPR	-	9	-
Other	-	1	-
<b>SAMPLE 16202 - 100% of participants reported nonreactive or testing not indicated.</b>			
All Labs	-	107	3
Ampcor RPR Card Test	-	1	-
ASI RPR Card Test for Syphilis	-	18	-
Becton Dickenson Macro-vue RPR	-	41	3
Fisher Sure-Vue RPR	-	26	-
Stanbio Syphilis (RPR) Quicktest	-	1	-
True Medix Diagnostics Trutest RPR	-	10	-
Wampole IMPACT RPR	-	9	-
Other	-	1	-
<b>SAMPLE 16203 - 100% of participants reported nonreactive or testing not indicated.</b>			
All Labs	-	107	3
Ampcor RPR Card Test	-	1	-
ASI RPR Card Test for Syphilis	-	18	-
Becton Dickenson Macro-vue RPR	-	41	3
Fisher Sure-Vue RPR	-	26	-
Stanbio Syphilis (RPR) Quicktest	-	1	-
True Medix Diagnostics Trutest RPR	-	10	-
Wampole IMPACT RPR	-	9	-
Other	-	1	-

## Qualitative Syphilis Reagin Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Positive	Negative	Not Indicated
<b>SAMPLE 16204 - 100% of participants reported reactive.</b>			
All Labs	110	-	-
Ampcor RPR Card Test	1	-	-
ASI RPR Card Test for Syphilis	18	-	-
Becton Dickenson Macro-vue RPR	44	-	-
Fisher Sure-Vue RPR	26	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-
True Medix Diagnostics Trutest RPR	10	-	-
Wampole IMPACT RPR	9	-	-
Other	1	-	-
<b>SAMPLE 16205 - 100% of participants reported reactive.</b>			
All Labs	110	-	-
Ampcor RPR Card Test	1	-	-
ASI RPR Card Test for Syphilis	18	-	-
Becton Dickenson Macro-vue RPR	44	-	-
Fisher Sure-Vue RPR	26	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-
True Medix Diagnostics Trutest RPR	10	-	-
Wampole IMPACT RPR	9	-	-
Other	1	-	-

## Syphilis Reagin Ab (RPR) Titers - Diagnostic Services

The number of laboratories that reported titers is listed for reactive test samples 16204 and 16205.

Primary Test Kit/Assay	No. Labs	Sample 16204 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	101	-	-	14	72	15	-	-
Ampcor RPR Card Test	1	-	-	-	-	1	-	-
ASI RPR Card Test for Syphilis	10	-	-	2	7	1	-	-
Becton Dickenson Macro-vue RPR	44	-	-	4	32	8	-	-
Fisher Sure-Vue RPR	25	-	-	5	17	3	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-	-	1	-	-	-
True Medix Diagnostics Trutest RPR	10	-	-	1	7	2	-	-
Wampole IMPACT RPR	9	-	-	2	7	-	-	-
Other	1	-	-	-	1	-	-	-

Primary Test Kit/Assay	No. Labs	Sample 16205 Titers						
		< 1:1	1:1	1:2	1:4	1:8	1:16	≥ 1:32
All Labs	101	-	2	53	41	5	-	-
Ampcor RPR Card Test	1	-	-	-	1	-	-	-
ASI RPR Card Test for Syphilis	10	-	1	5	4	-	-	-
Becton Dickenson Macro-vue RPR	44	-	1	19	20	4	-	-
Fisher Sure-Vue RPR	25	-	-	19	6	-	-	-
Stanbio Syphilis (RPR) Quicktest	1	-	-	1	-	-	-	-
True Medix Diagnostics Trutest RPR	10	-	-	4	6	-	-	-
Wampole IMPACT RPR	9	-	-	4	4	1	-	-
Other	1	-	-	1	-	-	-	-

## Qualitative Syphilis Treponemal Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Not Indicated
<b>SAMPLE 16201 - 96% of participants reported nonreactive or testing not indicated.</b>			
All Labs	2	40	8
Bio-Rad Bioplex	-	1	-
DiaSorin Liaison Treponemal Assay	-	11	-
Fujirebio Serodia-TP-PA	-	7	4
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	2	1	-
Siemens ADVIA Centaur SYPH Assay	-	4	1
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	6	1
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	3	2
Treponema Pallidum IgG ELISA (Zeus Scientific)	-	1	-
Other	-	1	-
<b>SAMPLE 16202 - 96% of participants reported nonreactive or testing not indicated.</b>			
All Labs	2	40	8
Bio-Rad Bioplex	-	1	-
DiaSorin Liaison Treponemal Assay	-	11	-
Fujirebio Serodia-TP-PA	-	7	4
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	2	1	-
Siemens ADVIA Centaur SYPH Assay	-	4	1
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	6	1
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	3	2
Treponema Pallidum IgG ELISA (Zeus Scientific)	-	1	-
Other	-	1	-
<b>SAMPLE 16203 - 96% of participants reported nonreactive or testing not indicated.</b>			
All Labs	2	40	8
Bio-Rad Bioplex	-	1	-
DiaSorin Liaison Treponemal Assay	-	11	-
Fujirebio Serodia-TP-PA	-	7	4
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	2	1	-
Siemens ADVIA Centaur SYPH Assay	-	4	1
Siemens Immulite Systems (all models)	-	4	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	-	6	1
Wampole IMPACT IFA	-	1	-
Zeus Scientific FTA-ABS	-	3	2
Treponema Pallidum IgG ELISA (Zeus Scientific)	-	1	-
Other	-	1	-

## Qualitative Syphilis Treponemal Ab - Diagnostic Services

Primary Test Kit/Assay	Participant Results		
	Reactive	Nonreactive	Not Indicated
<b>SAMPLE 16204 - 100% of participants reported reactive.</b>			
All Labs	50	-	-
Bio-Rad Bioplex	1	-	-
DiaSorin Liaison Treponemal Assay	11	-	-
Fujirebio Serodia-TP-PA	11	-	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	3	-	-
Siemens ADVIA Centaur SYPH Assay	5	-	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	7	-	-
Wampole IMPACT IFA	1	-	-
Zeus Scientific FTA-ABS	5	-	-
Treponema Pallidum IgG ELISA (Zeus Scientific)	1	-	-
Other	1	-	-
<b>SAMPLE 16205 - 100% of participants reported reactive.</b>			
All Labs	50	-	-
Bio-Rad Bioplex	1	-	-
DiaSorin Liaison Treponemal Assay	11	-	-
Fujirebio Serodia-TP-PA	11	-	-
Phoenix Bio-Tech Trep-Sure Anti-Treponema EIA	3	-	-
Siemens ADVIA Centaur SYPH Assay	5	-	-
Siemens Immulite Systems (all models)	4	-	-
Trinity Biotech CAPTIA Syphilis-G ELISA Test	7	-	-
Wampole IMPACT IFA	1	-	-
Zeus Scientific FTA-ABS	5	-	-
Treponema Pallidum IgG ELISA (Zeus Scientific)	1	-	-
Other	1	-	-

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

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

<b>Sample 16276</b>		<b>Total</b>	<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>13</b>	<b>13</b>	<b>38.55</b>	<b>201.39</b>	<b>119.97</b>	<b>27.14</b>
<b>Nephelometry Total</b>		<b>8</b>	<b>8</b>	-	-	<b>140.57</b>	-
	Beckman Coulter Immage	1	1	-	-	66.00	-
	Siemens Dimension VISTA	3	3	-	-	151.67	-
	Siemens Nephelometer Systems (all models)	4	4	-	-	132.25	-
<b>Turbidimetry Total</b>		<b>5</b>	<b>5</b>	-	-	<b>101.92</b>	-
	Abbott Architect	1	1	-	-	102.00	-
	Beckman Coulter (formerly Olympus) AU System	3	3	-	-	102.87	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	99.00	-

<b>Sample 16277</b>		<b>Total</b>	<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>13</b>	-	<b>13.35</b>	<b>32.18</b>	<b>22.76</b>	<b>3.14</b>
<b>Nephelometry Total</b>		<b>8</b>	<b>6</b>	-	-	<b>22.77</b>	-
	Beckman Coulter Immage	1	1	-	-	17.00	-
	Siemens Dimension VISTA	3	1	-	-	12.30	-
	Siemens Nephelometer Systems (all models)	4	4	-	-	23.75	-
<b>Turbidimetry Total</b>		<b>5</b>	<b>0</b>	-	-	-	-
	Abbott Architect	1	0	-	-	-	-
	Beckman Coulter (formerly Olympus) AU System	3	0	-	-	-	-
	Roche/Hitachi Modular Systems (all models)	1	0	-	-	-	-

<b>Sample 16278</b>		<b>Total</b>	<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>13</b>	<b>13</b>	<b>34.61</b>	<b>148.07</b>	<b>91.34</b>	<b>18.91</b>
<b>Nephelometry Total</b>		<b>8</b>	<b>8</b>	-	-	<b>106.71</b>	-
	Beckman Coulter Immage	1	1	-	-	58.00	-
	Siemens Dimension VISTA	3	3	-	-	113.33	-
	Siemens Nephelometer Systems (all models)	4	4	-	-	101.75	-
<b>Turbidimetry Total</b>		<b>5</b>	<b>5</b>	-	-	<b>76.48</b>	-
	Abbott Architect	1	1	-	-	74.00	-
	Beckman Coulter (formerly Olympus) AU System	3	3	-	-	77.27	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	76.60	-

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

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

<b>Sample 16279</b>		<b>Total</b>	<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>13</b>	-	<b>19.79</b>	<b>27.36</b>	<b>23.58</b>	<b>1.26</b>
<b>Nephelometry Total</b>		<b>8</b>	<b>8</b>	-	-	<b>23.57</b>	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	26.00	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	23.53	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	23.00	-
<b>Turbidimetry Total</b>		<b>5</b>	<b>0</b>	-	-	-	-
	<i>Abbott Architect</i>	1	0	-	-	-	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	0	-	-	-	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	0	-	-	-	-

<b>Sample 16280</b>		<b>Total</b>	<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>13</b>	<b>13</b>	<b>17.92</b>	<b>242.08</b>	<b>130.00</b>	<b>37.36</b>
<b>Nephelometry Total</b>		<b>8</b>	<b>8</b>	-	-	<b>157.00</b>	-
	<i>Beckman Coulter Immage</i>	1	1	-	-	70.00	-
	<i>Siemens Dimension VISTA</i>	3	3	-	-	168.67	-
	<i>Siemens Nephelometer Systems (all models)</i>	4	4	-	-	156.25	-
<b>Turbidimetry Total</b>		<b>5</b>	<b>5</b>	-	-	<b>97.80</b>	-
	<i>Abbott Architect</i>	1	1	-	-	94.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	3	3	-	-	98.67	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	99.00	-

## Quantitative Complement C3 (mg/dl) - Diagnostic Services

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

<b>Sample 16276</b>		<b>Total</b>		<b>Acceptable Range</b>			
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>40</b>	<b>40</b>	<b>49.35</b>	<b>95.75</b>	<b>72.55</b>	<b>7.73</b>
<b>Nephelometry Total</b>		<b>14</b>	<b>14</b>	<b>58.59</b>	<b>96.21</b>	<b>77.40</b>	<b>6.27</b>
	<i>Beckman Coulter Immage</i>	2	2	-	-	66.65	-
	<i>Siemens Dimension VISTA</i>	9	9	-	-	80.92	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	74.00	-
<b>Turbidimetry Total</b>		<b>26</b>	<b>26</b>	<b>48.18</b>	<b>91.70</b>	<b>69.94</b>	<b>7.25</b>
	<i>Abbott Architect</i>	2	2	-	-	84.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	78.05	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	61.23	68.66	64.95	1.24
	<i>Ortho Vitros (all models)</i>	2	2	-	-	79.50	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	70.53	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	80.50	-
	<i>Dimension (Siemens)</i>	1	1	-	-	68.00	-

<b>Sample 16277</b>		<b>Total</b>		<b>Acceptable Range</b>			
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>40</b>	<b>38</b>	<b>19.74</b>	<b>31.29</b>	<b>25.51</b>	<b>1.93</b>
<b>Nephelometry Total</b>		<b>14</b>	<b>14</b>	<b>21.38</b>	<b>27.08</b>	<b>24.23</b>	<b>0.95</b>
	<i>Beckman Coulter Immage</i>	2	2	-	-	22.55	-
	<i>Siemens Dimension VISTA</i>	9	9	-	-	24.68	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	24.00	-
<b>Turbidimetry Total</b>		<b>26</b>	<b>24</b>	<b>20.37</b>	<b>32.16</b>	<b>26.26</b>	<b>1.97</b>
	<i>Abbott Architect</i>	2	2	-	-	27.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	22.20	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	23.56	30.74	27.15	1.20
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	25.30	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	24.80	-
	<i>Dimension (Siemens)</i>	1	1	-	-	23.00	-

## Quantitative Complement C3 (mg/dl) - Diagnostic Services

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

<b>Sample 16278</b>		<b>Total</b>		<b>Acceptable Range</b>			
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>40</b>	<b>40</b>	<b>80.35</b>	<b>118.35</b>	<b>99.35</b>	<b>6.33</b>
<b>Nephelometry Total</b>		<b>14</b>	<b>14</b>	<b>93.10</b>	<b>119.47</b>	<b>106.28</b>	<b>4.40</b>
	<i>Beckman Coulter Immage</i>	2	2	-	-	101.85	-
	<i>Siemens Dimension VISTA</i>	9	9	-	-	107.62	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	105.67	-
<b>Turbidimetry Total</b>		<b>26</b>	<b>26</b>	<b>84.58</b>	<b>107.18</b>	<b>95.88</b>	<b>3.77</b>
	<i>Abbott Architect</i>	2	2	-	-	100.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	100.05	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	88.11	98.38	93.25	1.71
	<i>Ortho Vitros (all models)</i>	2	2	-	-	102.00	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	98.03	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	98.00	-
	<i>Dimension (Siemens)</i>	1	1	-	-	98.00	-

<b>Sample 16279</b>		<b>Total</b>		<b>Acceptable Range</b>			
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>40</b>	<b>38</b>	<b>27.11</b>	<b>36.66</b>	<b>31.88</b>	<b>1.59</b>
<b>Nephelometry Total</b>		<b>14</b>	<b>14</b>	<b>28.36</b>	<b>37.29</b>	<b>32.82</b>	<b>1.49</b>
	<i>Beckman Coulter Immage</i>	2	2	-	-	33.35	-
	<i>Siemens Dimension VISTA</i>	9	9	-	-	33.09	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	31.67	-
<b>Turbidimetry Total</b>		<b>26</b>	<b>24</b>	<b>27.13</b>	<b>35.49</b>	<b>31.31</b>	<b>1.39</b>
	<i>Abbott Architect</i>	2	2	-	-	36.50	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	2	2	-	-	30.45	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	28.10	34.49	31.29	1.06
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	3	3	-	-	31.00	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	31.90	-
	<i>Dimension (Siemens)</i>	1	1	-	-	30.00	-

## Quantitative Complement C3 (mg/dl) - Diagnostic Services

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

Method	Primary Test Kit/Assay	Total		Acceptable Range			
		Labs	Labs *	Low	High	Mean	S.D.
All Methods		40	40	96.19	119.28	107.74	3.85
Nephelometry Total		14	14	97.06	123.65	110.36	4.43
	Beckman Coulter Immage	2	2	-	-	109.50	-
	Siemens Dimension VISTA	9	9	-	-	111.56	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	107.33	-
Turbidimetry Total		26	26	98.40	114.26	106.33	2.64
	Abbott Architect	2	2	-	-	109.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	103.95	-
	Beckman Coulter (formerly Olympus) AU System	15	15	97.74	113.58	105.66	2.64
	Ortho Vitros (all models)	2	2	-	-	109.50	-
	Roche Diagnostics Cobas (all systems)	3	3	-	-	107.97	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	106.80	-
	Dimension (Siemens)	1	1	-	-	104.00	-

## Quantitative Complement C4 (mg/dl) - Diagnostic Services

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

Sample 16276		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	7.50	19.89	13.69	2.07
Nephelometry Total		12	12	11.77	19.86	15.82	1.35
	Beckman Coulter Immage	2	2	-	-	13.70	-
	Siemens Dimension VISTA	7	7	-	-	16.79	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	14.97	-
Turbidimetry Total		27	27	8.04	17.47	12.75	1.57
	Abbott Architect	2	2	-	-	14.30	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	16.00	-
	Beckman Coulter (formerly Olympus) AU System	15	15	10.05	13.38	11.71	0.55
	Ortho Vitros (all models)	2	2	-	-	14.55	-
	Roche Diagnostics Cobas (all models)	3	3	-	-	12.20	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	14.30	-
	Dimension (Siemens)	1	1	-	-	13.00	-
	SPAplus C4 Kit (The Binding Site)	1	1	-	-	15.00	-

Sample 16277		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	22	2.40	5.35	3.87	0.49
Nephelometry Total		12	10	3.49	4.90	4.19	0.24
	Beckman Coulter Immage	2	2	-	-	4.33	-
	Siemens Dimension VISTA	7	5	-	-	4.28	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	3.97	-
Turbidimetry Total		27	12	2.12	5.10	3.61	0.50
	Abbott Architect	2	2	-	-	4.10	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	0	-	-	-	-
	Beckman Coulter (formerly Olympus) AU System	15	5	-	-	3.30	-
	Ortho Vitros (all models)	2	0	-	-	-	-
	Roche Diagnostics Cobas (all models)	3	2	-	-	3.75	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	4.10	-
	Dimension (Siemens)	1	1	-	-	3.00	-
	SPAplus C4 Kit (The Binding Site)	1	1	-	-	4.00	-

## Quantitative Complement C4 (mg/dl) - Diagnostic Services

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

Sample 16278		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	14.88	23.30	19.09	1.40
Nephelometry Total		12	12	18.18	22.95	20.57	0.80
	Beckman Coulter Immage	2	2	-	-	20.55	-
	Siemens Dimension VISTA	7	7	-	-	20.83	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	19.97	-
Turbidimetry Total		27	27	15.21	21.65	18.43	1.07
	Abbott Architect	2	2	-	-	17.30	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	17.90	-
	Beckman Coulter (formerly Olympus) AU System	15	15	16.44	20.59	18.51	0.69
	Ortho Vitros (all models)	2	2	-	-	21.20	-
	Roche Diagnostics Cobas (all models)	3	3	-	-	17.47	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	17.70	-
	Dimension (Siemens)	1	1	-	-	18.00	-
	SPplus C4 Kit (The Binding Site)	1	1	-	-	19.00	-

Sample 16279		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	25	1.95	7.90	4.92	0.99
Nephelometry Total		12	11	5.80	6.28	6.04	0.08
	Beckman Coulter Immage	2	2	-	-	4.15	-
	Siemens Dimension VISTA	7	6	-	-	6.13	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	5.93	-
Turbidimetry Total		27	14	2.44	6.16	4.30	0.62
	Abbott Architect	2	2	-	-	4.65	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	1	-	-	5.10	-
	Beckman Coulter (formerly Olympus) AU System	15	5	-	-	3.74	-
	Ortho Vitros (all models)	2	0	-	-	-	-
	Roche Diagnostics Cobas (all models)	3	3	-	-	4.07	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	4.90	-
	Dimension (Siemens)	1	1	-	-	5.00	-
	SPplus C4 Kit (The Binding Site)	1	1	-	-	5.00	-

## Quantitative Complement C4 (mg/dl) - Diagnostic Services

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

Method	Primary Test Kit/Assay	Total		Acceptable Range			
		Labs	Labs *	Low	High	Mean	S.D.
All Methods		39	39	19.96	29.11	24.53	1.53
Nephelometry Total		12	12	22.52	27.23	24.87	0.78
	Beckman Coulter Immage	2	2	-	-	25.15	-
	Siemens Dimension VISTA	7	7	-	-	24.98	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	24.47	-
Turbidimetry Total		27	27	19.19	29.59	24.39	1.73
	Abbott Architect	2	2	-	-	22.20	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	2	2	-	-	22.70	-
	Beckman Coulter (formerly Olympus) AU System	15	15	23.47	26.80	25.14	0.56
	Ortho Vitros (all models)	2	2	-	-	27.15	-
	Roche Diagnostics Cobas (all models)	3	3	-	-	22.17	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	22.10	-
	Dimension (Siemens)	1	1	-	-	22.00	-
	SPApplus C4 Kit (The Binding Site)	1	1	-	-	25.00	-

## Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

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

<b>Sample 16281</b>		<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			
<b>Method</b>	<b>Primary Test Kit/Assay</b>			<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>46</b>	<b>45</b>	<b>209.29</b>	<b>356.75</b>	<b>283.02</b>	<b>24.58</b>
<b>ELISA Enzyme-linked Immunosorbent Assay Total</b>		<b>1</b>	<b>0</b>	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
<b>Nephelometry Total</b>		<b>16</b>	<b>16</b>	<b>243.40</b>	<b>370.95</b>	<b>307.18</b>	<b>21.26</b>
	<i>Beckman Coulter Immage</i>	4	4	-	-	278.25	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	288.80	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	319.57	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	326.00	-
<b>Turbidimetry Total</b>		<b>29</b>	<b>29</b>	<b>235.63</b>	<b>300.49</b>	<b>268.06</b>	<b>10.81</b>
	<i>Abbott Architect</i>	3	3	-	-	252.33	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	265.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	246.61	298.23	272.42	8.60
	<i>Ortho Vitros (all models)</i>	2	2	-	-	303.96	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	261.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	264.80	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	273.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	261.00	-

<b>Sample 16282</b>		<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			
<b>Method</b>	<b>Primary Test Kit/Assay</b>			<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>46</b>	<b>40</b>	<b>22.12</b>	<b>41.60</b>	<b>31.86</b>	<b>3.25</b>
<b>ELISA Enzyme-linked Immunosorbent Assay Total</b>		<b>1</b>	<b>0</b>	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
<b>Nephelometry Total</b>		<b>16</b>	<b>14</b>	<b>20.82</b>	<b>41.71</b>	<b>31.26</b>	<b>3.48</b>
	<i>Beckman Coulter Immage</i>	4	3	-	-	26.90	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	25.80	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	7	-	-	33.31	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	32.67	-
<b>Turbidimetry Total</b>		<b>29</b>	<b>26</b>	<b>22.77</b>	<b>41.59</b>	<b>32.18</b>	<b>3.14</b>
	<i>Abbott Architect</i>	3	3	-	-	37.43	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	29.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	27.28	38.12	32.70	1.81
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	3	-	-	28.67	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	30.90	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	25.00	-
	<i>SPAplus IgA Kit (The Binding Site)</i>	2	2	-	-	31.50	-

## Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

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

<b>Sample 16283</b>		<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			
<b>Method</b>	<b>Primary Test Kit/Assay</b>			<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>46</b>	<b>45</b>	<b>92.13</b>	<b>173.80</b>	<b>132.97</b>	<b>13.61</b>
<b>ELISA Enzyme-linked Immunosorbent Assay Total</b>		<b>1</b>	<b>0</b>	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
<b>Nephelometry Total</b>		<b>16</b>	<b>16</b>	<b>82.46</b>	<b>196.87</b>	<b>139.66</b>	<b>19.07</b>
	<i>Beckman Coulter Immage</i>	4	4	-	-	114.00	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	133.60	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	148.25	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	153.00	-
<b>Turbidimetry Total</b>		<b>29</b>	<b>29</b>	<b>116.50</b>	<b>140.31</b>	<b>128.41</b>	<b>3.97</b>
	<i>Abbott Architect</i>	3	3	-	-	125.53	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	125.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	122.47	139.23	130.85	2.79
	<i>Ortho Vitros (all models)</i>	2	2	-	-	139.77	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	123.25	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	121.90	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	120.00	-
	<i>SPplus IgA Kit (The Binding Site)</i>	2	2	-	-	138.50	-

<b>Sample 16284</b>		<b>Total Labs</b>	<b>Labs *</b>	<b>Acceptable Range</b>			
<b>Method</b>	<b>Primary Test Kit/Assay</b>			<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>46</b>	<b>38</b>	<b>14.73</b>	<b>42.55</b>	<b>28.64</b>	<b>4.64</b>
<b>ELISA Enzyme-linked Immunosorbent Assay Total</b>		<b>1</b>	<b>0</b>	-	-	-	-
	<i>Laboratory developed assay</i>	1	0	-	-	-	-
<b>Nephelometry Total</b>		<b>16</b>	<b>12</b>	<b>7.81</b>	<b>51.31</b>	<b>29.56</b>	<b>7.25</b>
	<i>Beckman Coulter Immage</i>	4	3	-	-	19.33	-
	<i>The Binding Site MININEPH</i>	1	1	-	-	43.10	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	5	-	-	30.92	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	33.00	-
<b>Turbidimetry Total</b>		<b>29</b>	<b>26</b>	<b>17.16</b>	<b>50.00</b>	<b>33.58</b>	<b>5.47</b>
	<i>Abbott Architect</i>	3	3	-	-	48.13	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	46.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	15	15	21.48	36.08	28.78	2.43
	<i>Ortho Vitros (all models)</i>	2	0	-	-	-	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	3	-	-	29.67	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	28.60	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	19.00	-
	<i>SPplus IgA Kit (The Binding Site)</i>	2	2	-	-	27.00	-

## Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

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

Method	Primary Test Kit/Assay	Total Labs	Labs *	Acceptable Range			
				Low	High	Mean	S.D.
All Methods		46	45	103.03	220.41	161.72	19.56
ELISA Enzyme-linked Immunosorbent Assay Total		1	0	-	-	-	-
	Laboratory developed assay	1	0	-	-	-	-
Nephelometry Total		16	16	100.71	253.76	177.24	25.51
	Beckman Coulter Immage	4	4	-	-	137.75	-
	The Binding Site MININEPH	1	1	-	-	163.80	-
	Siemens Dimension/Vista/Xpand (all models)	8	8	-	-	193.38	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	191.33	-
Turbidimetry Total		29	29	138.34	169.34	153.84	5.17
	Abbott Architect	3	3	-	-	149.53	2.50
	Beckman Coulter Synchron LX/Unicel Systems (all models)	1	1	-	-	153.00	0.00
	Beckman Coulter (formerly Olympus) AU System	15	15	141.59	166.46	154.03	4.15
	Ortho Vitros (all models)	2	2	-	-	163.53	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	146.50	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	153.50	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	164.00	-
	SPAplus IgA Kit (The Binding Site)	2	2	-	-	149.50	-

## Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

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

<b>Sample 16281</b>		<b>Total</b>		<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>	
<b>All Methods</b>		<b>35</b>	<b>23</b>	<b>0.43</b>	<b>2.52</b>	<b>1.47</b>	<b>0.35</b>	
<b>CHEMILUMINESCENCE Total</b>		<b>21</b>	<b>20</b>	<b>0.68</b>	<b>2.06</b>	<b>1.37</b>	<b>0.23</b>	
	Beckman Coulter ACCESS	4	4	-	-	1.45	-	
	Beckman Coulter Synchron LX/Unicel Systems	2	2	-	-	1.25	-	
	Roche Diagnostics Cobas (all models)	2	2	-	-	1.50	-	
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	1.47	-	
	Siemens ADVIA Centaur	1	1	-	-	1.00	-	
	Siemens Immulite Systems (all models)	11	10	0.57	2.16	1.37	0.26	
<b>ELISA Enzyme-linked Immunosorbent Assay (EIA)</b>		<b>1</b>	<b>0</b>	-	-	-	-	
	Hy-Tec Total IgE EIA (Hycor Biomedical)	1	0	-	-	-	-	
<b>FLUORENZYME Immunoassay (FEIA) Total</b>		<b>8</b>	<b>3</b>	-	-	<b>2.15</b>	-	
	ImmunoCAP Total IgE FEIA (Phadia/Fisher)	7	3	-	-	2.15	-	
	ST AIA-Pack IgE II (Tosoh Bioscience)	1	0	-	-	-	-	
<b>NEPHELOMETRY Total</b>		<b>5</b>	<b>0</b>	-	-	-	-	
	Siemens Dimension/Vista/Xpand (all models)	4	0	-	-	-	-	
	Siemens Nephelometer Systems (all models)	1	0	-	-	-	-	

<b>Sample 16282</b>		<b>Total</b>		<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>	
<b>All Methods</b>		<b>35</b>	<b>33</b>	<b>17.19</b>	<b>40.71</b>	<b>28.95</b>	<b>3.92</b>	
<b>CHEMILUMINESCENCE Total</b>		<b>21</b>	<b>21</b>	<b>16.85</b>	<b>42.72</b>	<b>29.78</b>	<b>4.31</b>	
	Beckman Coulter ACCESS	4	4	-	-	27.80	-	
	Beckman Coulter Synchron LX/Unicel Systems	2	2	-	-	28.08	-	
	Roche Diagnostics Cobas (all models)	2	2	-	-	26.90	-	
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	27.73	-	
	Siemens ADVIA Centaur	1	1	-	-	29.00	-	
	Siemens Immulite Systems (all models)	11	11	16.38	46.82	31.60	5.07	
<b>ELISA Enzyme-linked Immunosorbent Assay (EIA)</b>		<b>1</b>	<b>1</b>	-	-	<b>21.48</b>	-	
	Hy-Tec Total IgE EIA (Hycor Biomedical)	1	1	-	-	21.48	-	
<b>FLUORENZYME Immunoassay (FEIA) Total</b>		<b>8</b>	<b>8</b>	-	-	<b>27.84</b>	-	
	ImmunoCAP Total IgE FEIA (Phadia/Fisher)	7	7	-	-	27.81	-	
	ST AIA-Pack IgE II (Tosoh Bioscience)	1	1	-	-	28.00	-	
<b>NEPHELOMETRY Total</b>		<b>5</b>	<b>3</b>	-	-	<b>28.53</b>	-	
	Siemens Dimension/Vista/Xpand (all models)	4	2	-	-	28.35	-	
	Siemens Nephelometer Systems (all models)	1	1	-	-	28.90	-	

## Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

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

<b>Sample 16283</b>		<b>Total</b>		<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>	
<b>All Methods</b>		<b>35</b>	<b>34</b>	<b>1.58</b>	<b>11.45</b>	<b>6.51</b>	<b>1.65</b>	
<b>Chemiluminescence Total</b>		<b>21</b>	<b>21</b>	<b>2.00</b>	<b>9.27</b>	<b>5.64</b>	<b>1.21</b>	
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	5.80	-	
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	2	2	-	-	5.85	-	
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	6.60	-	
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	6.67	-	
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	3.90	-	
	<i>Siemens Immulite Systems (all models)</i>	11	11	1.00	9.85	5.43	1.48	
<b>ELISA Enzyme-linked Immunosorbent Assay (EIA)</b>		<b>1</b>	<b>1</b>	-	-	<b>20.45</b>	-	
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	20.45	-	
<b>Fluroenzyme Immunoassay (FEIA) Total</b>		<b>8</b>	<b>7</b>	-	-	<b>7.78</b>	-	
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	7	7	-	-	7.78	-	
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	0	-	-	-	-	
<b>Nephelometry Total</b>		<b>5</b>	<b>5</b>	-	-	<b>8.42</b>	-	
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	8.72	-	
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	7.20	-	

<b>Sample 16284</b>		<b>Total</b>		<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>	
<b>All Methods</b>		<b>35</b>	<b>35</b>	<b>8.81</b>	<b>31.15</b>	<b>19.98</b>	<b>3.72</b>	
<b>Chemiluminescence Total</b>		<b>21</b>	<b>21</b>	<b>9.03</b>	<b>32.19</b>	<b>20.61</b>	<b>3.86</b>	
	<i>Beckman Coulter ACCESS</i>	4	4	-	-	22.50	-	
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	2	2	-	-	22.19	-	
	<i>Roche Diagnostics Cobas (all models)</i>	2	2	-	-	15.70	-	
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	16.15	-	
	<i>Siemens ADVIA Centaur</i>	1	1	-	-	17.00	-	
	<i>Siemens Immulite Systems (all models)</i>	11	11	15.93	25.94	20.93	1.67	
<b>ELISA Enzyme-linked Immunosorbent Assay (EIA)</b>		<b>1</b>	<b>1</b>	-	-	<b>97.51</b>	-	
	<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>	1	1	-	-	97.51	-	
<b>Fluroenzyme Immunoassay (FEIA) Total</b>		<b>8</b>	<b>8</b>	-	-	<b>18.32</b>	-	
	<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>	7	7	-	-	19.13	-	
	<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>	1	1	-	-	12.70	-	
<b>Nephelometry Total</b>		<b>5</b>	<b>5</b>	-	-	<b>37.56</b>	-	
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	4	4	-	-	38.67	-	
	<i>Siemens Nephelometer Systems (all models)</i>	1	1	-	-	33.10	-	

## Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

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

<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Total</b>		<b>Acceptable Range</b>			
		<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>
<b>All Methods</b>		<b>35</b>	<b>35</b>	<b>14.50</b>	<b>32.16</b>	<b>23.33</b>	<b>2.94</b>
<b>Chemiluminescence Total</b>		<b>21</b>	<b>21</b>	<b>13.66</b>	<b>32.45</b>	<b>23.06</b>	<b>3.13</b>
<i>Beckman Coulter ACCESS</i>		4	4	-	-	23.32	-
<i>Beckman Coulter Synchron LX/Unicel Systems</i>		2	2	-	-	23.83	-
<i>Roche Diagnostics Cobas (all models)</i>		2	2	-	-	22.55	-
<i>Roche/Hitachi Modular Systems (all models)</i>		1	1	-	-	22.63	-
<i>Siemens ADVIA Centaur</i>		1	1	-	-	16.10	-
<i>Siemens Immulite Systems (all models)</i>		11	11	13.55	33.61	23.58	3.34
<b>ELISA Enzyme-linked Immunosorbent Assay (EIA)</b>		<b>1</b>	<b>1</b>	-	-	<b>103.34</b>	-
<i>Hy-Tec Total IgE EIA (Hycor Biomedical)</i>		1	1	-	-	103.34	-
<b>Fluroenzyme Immunoassay (FEIA) Total</b>		<b>8</b>	<b>8</b>	-	-	<b>24.05</b>	-
<i>ImmunoCAP Total IgE FEIA (Phadia/Fisher)</i>		7	7	-	-	24.34	-
<i>ST AIA-Pack IgE II (Tosoh Bioscience)</i>		1	1	-	-	22.00	-
<b>Nephelometry Total</b>		<b>5</b>	<b>5</b>	-	-	<b>38.16</b>	-
<i>Siemens Dimension/Vista/Xpand (all models)</i>		4	4	-	-	38.48	-
<i>Siemens Nephelometer Systems (all models)</i>		1	1	-	-	36.90	-

## Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

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

Sample 16281		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		43	43	350.08	583.46	466.77	38.90
Nephelometry Total		16	16	380.75	634.58	507.66	42.31
	Beckman Coulter Immage	4	4	-	-	456.50	-
	The Binding Site MININEPH	1	1	-	-	551.60	-
	Siemens Dimension/Vista/Xpand (all models)	8	8	-	-	522.33	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	520.00	-
Turbidimetry Total		27	27	329.35	548.91	439.13	36.59
	Abbott Architect	2	2	-	-	442.00	-
	Beckman Coulter Synchron LX/Unicel Systems	1	1	-	-	458.00	-
	Beckman Coulter (formerly Olympus) AU System	14	14	320.49	534.14	427.31	35.61
	Ortho Vitros (all models)	2	2	-	-	479.00	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	450.00	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	422.00	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	531.00	-
	SPApplus IgG Kit (The Binding Site)	2	2	-	-	456.50	-

Sample 16282		Total	Acceptable Range				
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		43	39	123.68	206.13	164.91	13.74
Nephelometry Total		16	15	132.25	220.41	176.33	14.69
	Beckman Coulter Immage	4	3	-	-	194.00	-
	The Binding Site MININEPH	1	1	-	-	190.60	-
	Siemens Dimension/Vista/Xpand (all models)	8	8	-	-	174.38	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	171.00	-
Turbidimetry Total		27	24	114.68	191.13	152.90	12.74
	Abbott Architect	2	2	-	-	166.00	-
	Beckman Coulter Synchron LX/Unicel Systems	1	1	-	-	168.00	-
	Beckman Coulter (formerly Olympus) AU System	14	14	106.93	178.21	142.57	11.88
	Ortho Vitros (all models)	2	0	-	-	-	-
	Roche Diagnostics Cobas (all systems)	4	3	-	-	171.33	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	139.80	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	234.00	-
	SPApplus IgG Kit (The Binding Site)	2	2	-	-	183.50	-

## Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

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

<b>Sample 16283</b>		<b>Total</b>		<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>	
<b>All Methods</b>		<b>43</b>	<b>43</b>	<b>496.11</b>	<b>826.85</b>	<b>661.48</b>	<b>55.12</b>	
<b>Nephelometry Total</b>		<b>16</b>	<b>16</b>	<b>524.44</b>	<b>874.06</b>	<b>699.25</b>	<b>58.27</b>	
	<i>Beckman Coulter Immage</i>	4	4	-	-	661.00	-	
	<i>The Binding Site MININEPH</i>	1	1	-	-	771.00	-	
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	727.43	-	
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	715.33	-	
<b>Turbidimetry Total</b>		<b>27</b>	<b>27</b>	<b>479.33</b>	<b>798.88</b>	<b>639.10</b>	<b>53.26</b>	
	<i>Abbott Architect</i>	2	2	-	-	637.00	-	
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	675.00	-	
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	469.37	782.29	625.83	52.15	
	<i>Ortho Vitros (all models)</i>	2	2	-	-	691.03	-	
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	642.25	-	
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	620.10	-	
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	684.00	-	
	<i>SPApplus IgG Kit (The Binding Site)</i>	2	2	-	-	645.00	-	

<b>Sample 16284</b>		<b>Total</b>		<b>Acceptable Range</b>				
<b>Method</b>	<b>Primary Test Kit/Assay</b>	<b>Labs</b>	<b>Labs *</b>	<b>Low</b>	<b>High</b>	<b>Mean</b>	<b>S.D.</b>	
<b>All Methods</b>		<b>43</b>	<b>42</b>	<b>202.27</b>	<b>337.12</b>	<b>269.70</b>	<b>22.47</b>	
<b>Nephelometry Total</b>		<b>16</b>	<b>16</b>	<b>221.77</b>	<b>369.62</b>	<b>295.70</b>	<b>24.64</b>	
	<i>Beckman Coulter Immage</i>	4	4	-	-	247.50	-	
	<i>The Binding Site MININEPH</i>	1	1	-	-	327.10	-	
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	298.38	-	
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	285.33	-	
<b>Turbidimetry Total</b>		<b>27</b>	<b>26</b>	<b>195.21</b>	<b>325.35</b>	<b>260.28</b>	<b>21.69</b>	
	<i>Abbott Architect</i>	2	2	-	-	286.50	-	
	<i>Beckman Coulter Synchron LX/Unicel Systems</i>	1	1	-	-	273.00	-	
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	179.56	299.26	239.41	19.95	
	<i>Ortho Vitros (all models)</i>	2	2	-	-	290.31	-	
	<i>Roche Diagnostics Cobas (all systems)</i>	4	3	-	-	296.67	-	
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	217.90	-	
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	327.00	-	
	<i>SPApplus IgG Kit (The Binding Site)</i>	2	2	-	-	277.00	-	

## Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

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

Sample 16285		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		43	43	417.66	696.10	556.88	46.41
Nephelometry Total		16	16	451.30	752.16	601.73	50.14
	Beckman Coulter Immage	4	4	-	-	546.50	-
	The Binding Site MININEPH	1	1	-	-	647.70	-
	Siemens Dimension/Vista/Xpand (all models)	8	8	-	-	620.25	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	610.67	-
Turbidimetry Total		27	27	395.08	658.46	526.77	43.90
	Abbott Architect	2	2	-	-	530.00	-
	Beckman Coulter Synchron LX/Unicel Systems	1	1	-	-	571.00	-
	Beckman Coulter (formerly Olympus) AU System	14	14	387.28	645.46	516.37	43.03
	Ortho Vitros (all models)	2	2	-	-	569.49	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	523.50	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	513.80	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	622.00	-
	SPAplus IgG Kit (The Binding Site)	2	2	-	-	544.50	-

## Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

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

Sample 16281		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		42	41	21.65	36.54	29.09	2.48
Nephelometry Total		15	14	19.49	37.89	28.69	3.07
	Beckman Coulter Immage	4	3	-	-	26.07	-
	Siemens Dimension/Vista/Xpand (all models)	8	8	-	-	28.06	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	33.00	-
Turbidimetry Total		27	27	22.89	35.72	29.30	2.14
	Abbott Architect	2	2	-	-	25.50	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	1	1	-	-	30.00	-
	Beckman Coulter (formerly Olympus) AU System	14	14	25.08	34.25	29.66	1.53
	Ortho Vitros (all models)	2	2	-	-	29.81	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	28.25	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	20.50	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	32.00	-
	SPplus IgM Kit (The Binding Site)	2	2	-	-	30.50	-

Sample 16282		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		42	22	6.11	26.93	16.52	3.47
Nephelometry Total		15	10	4.12	30.48	17.30	4.39
	Beckman Coulter Immage	4	3	-	-	14.37	-
	Siemens Dimension/Vista/Xpand (all models)	8	4	-	-	20.23	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	16.33	-
Turbidimetry Total		27	12	8.41	23.34	15.88	2.49
	Abbott Architect	2	2	-	-	15.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	1	0	-	-	-	-
	Beckman Coulter (formerly Olympus) AU System	14	3	-	-	18.33	-
	Ortho Vitros (all models)	2	0	-	-	-	-
	Roche Diagnostics Cobas (all systems)	4	3	-	-	15.33	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	12.50	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	20.00	-
	SPplus IgM Kit (The Binding Site)	2	2	-	-	13.50	-

## Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

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

Sample 16283		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		42	41	40.31	100.61	70.46	10.05
Nephelometry Total		15	14	52.22	104.04	78.13	8.64
	Beckman Coulter Immage	4	4	-	-	71.05	-
	Siemens Dimension/Vista/Xpand (all models)	8	7	-	-	81.23	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	80.33	-
Turbidimetry Total		27	27	51.41	77.80	64.60	4.40
	Abbott Architect	2	2	-	-	68.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	1	1	-	-	73.00	-
	Beckman Coulter (formerly Olympus) AU System	14	14	55.60	67.44	61.52	1.97
	Ortho Vitros (all models)	2	2	-	-	72.10	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	68.00	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	63.60	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	81.00	-
	SPplus IgM Kit (The Binding Site)	2	2	-	-	82.00	-

Sample 16284		Total		Acceptable Range			
Method	Primary Test Kit/Assay	Labs	Labs *	Low	High	Mean	S.D.
All Methods		42	41	21.85	42.26	32.06	3.40
Nephelometry Total		15	14	22.21	40.01	31.11	2.97
	Beckman Coulter Immage	4	3	-	-	27.47	-
	Siemens Dimension/Vista/Xpand (all models)	8	8	-	-	32.26	-
	Siemens Nephelometer Systems (all models)	3	3	-	-	31.67	-
Turbidimetry Total		27	27	23.01	41.37	32.19	3.06
	Abbott Architect	2	2	-	-	27.00	-
	Beckman Coulter Synchron LX/Unicel Systems (all models)	1	1	-	-	29.00	-
	Beckman Coulter (formerly Olympus) AU System	14	14	28.06	37.74	32.90	1.61
	Ortho Vitros (all models)	2	2	-	-	36.22	-
	Roche Diagnostics Cobas (all systems)	4	4	-	-	33.50	-
	Roche/Hitachi Modular Systems (all models)	1	1	-	-	26.70	-
	Siemens Dimension/Vista/Xpand (all models)	1	1	-	-	42.00	-
	SPplus IgM Kit (The Binding Site)	2	2	-	-	41.00	-

## Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

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

Method	Primary Test Kit/Assay	Total		Acceptable Range			
		Labs	Labs *	Low	High	Mean	S.D.
<b>All Methods</b>		<b>42</b>	<b>42</b>	<b>45.90</b>	<b>80.36</b>	<b>63.13</b>	<b>5.74</b>
<b>Nephelometry Total</b>		<b>15</b>	<b>15</b>	<b>54.93</b>	<b>81.93</b>	<b>68.43</b>	<b>4.50</b>
	<i>Beckman Coulter Immage</i>	4	4	-	-	63.77	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	8	8	-	-	71.54	-
	<i>Siemens Nephelometer Systems (all models)</i>	3	3	-	-	66.33	-
<b>Turbidimetry Total</b>		<b>27</b>	<b>27</b>	<b>50.31</b>	<b>69.08</b>	<b>59.70</b>	<b>3.13</b>
	<i>Abbott Architect</i>	2	2	-	-	64.00	-
	<i>Beckman Coulter Synchron LX/Unicel Systems (all models)</i>	1	1	-	-	66.00	-
	<i>Beckman Coulter (formerly Olympus) AU System</i>	14	14	53.50	63.11	58.31	1.60
	<i>Ortho Vitros (all models)</i>	2	2	-	-	64.08	-
	<i>Roche Diagnostics Cobas (all systems)</i>	4	4	-	-	60.75	-
	<i>Roche/Hitachi Modular Systems (all models)</i>	1	1	-	-	54.70	-
	<i>Siemens Dimension/Vista/Xpand (all models)</i>	1	1	-	-	73.00	-
	<i>SPPlus IgM Kit (The Binding Site)</i>	2	2	-	-	58.00	-