Proficiency Test Event
September 5, 2012
Diagnostic Immunology
Summary Report

Steven Bush M.S., Susan Wong Ph.D., and Mary Marchewka
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<td>Page 63 - 65</td>
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## Quantitative Test Analytes

<table>
<thead>
<tr>
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<tr>
<td>Alpha-1 Antitrypsin</td>
<td>Page 66 - 67</td>
</tr>
<tr>
<td>Complement C'3</td>
<td>Page 68 - 70</td>
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<tr>
<td>Complement C'4</td>
<td>Page 71 - 73</td>
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<td>Immunoglobulin A</td>
<td>Page 74 - 76</td>
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<tr>
<td>Immunoglobulin E</td>
<td>Page 77 - 81</td>
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<tr>
<td>Immunoglobulin G</td>
<td>Page 82 - 84</td>
</tr>
<tr>
<td>Immunoglobulin M</td>
<td>Page 85 - 87</td>
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</table>
The data summarized in this report were tabulated from test results and accompanying information submitted by laboratories that participated in the September 5, 2012 Diagnostic Immunology Proficiency Test event. Participants are encouraged to review the data and to compare results and test kit performances.

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

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

**Grading Criteria:**

* For each separate analyte where results were reported, qualitative or quantitative, twenty points were deducted for each incorrect answer. Titering of positive Syphilis-Reagin samples is mandatory for all Diagnostic Services laboratories who perform this test, unless given an exemption. Failure to titer the positive samples to the endpoint will result in failure for the Syphilis-Reagin analyte.
* For **Diagnostic Services** failure to attain an overall testing score of at least 80% is unsatisfactory performance.
* For **Donor Services** failure to attain an overall testing score of 100% is unsatisfactory performance.
* For **HIV** failure to attain an overall testing score of 100% is unsatisfactory performance.
* Laboratories failing two out of three consecutive proficiency test events for an analyte or for the permit category will fail the proficiency testing program for the analyte or for the permit category and may be required to cease patient testing for that analyte/category.

**Summary Tables**

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

For qualitative tests, results are summarized as the number of laboratories that reported a test sample as reactive to the number that reported it as non-reactive. In addition, where test results depend on a quantitative value (e.g. titer, IU/ml) the values reported are given in separate tables. They are expressed, where applicable, as the Mean ± 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

<table>
<thead>
<tr>
<th>Analyte or Test</th>
<th>Criteria</th>
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<tr>
<td>Alpha-1 Antitrypsin</td>
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</tr>
<tr>
<td>Antinuclear Antibody</td>
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<tr>
<td>Antinuclear Antibody Quantitative (IFA titers only)</td>
<td>Target value ± 2 dilutions</td>
</tr>
<tr>
<td>Antistreptolysin O</td>
<td>Positive or negative</td>
</tr>
<tr>
<td>Antistreptolysin O Quantitative, Semi-Quant, and Titer</td>
<td>Target value ± 2 dilutions or Target value ± 3 S.D.</td>
</tr>
<tr>
<td>Complement C’3, C’4</td>
<td>Target value ± 3 S.D.</td>
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<tr>
<td>Cytomegalovirus Antibody</td>
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</tr>
<tr>
<td>Hepatitis (HbsAg, anti-HBc, HBeAg, and HCAb)</td>
<td>Reactive or nonreactive</td>
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<tr>
<td>HIV 1 Ab, Ag</td>
<td>Reactive or nonreactive</td>
</tr>
<tr>
<td>HTLV 1 Ab</td>
<td>Positive or negative</td>
</tr>
<tr>
<td>Lyme Disease Ab, WB IgG, IgM</td>
<td>Positive or negative</td>
</tr>
<tr>
<td>Immunoglobulin A, E, M</td>
<td>Target value ± 3 S.D.</td>
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<tr>
<td>Immunoglobulin G</td>
<td>Target value ± 25 %</td>
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<tr>
<td>Infectious Mononucleosis</td>
<td>Positive or negative</td>
</tr>
<tr>
<td>Rheumatoid Factor</td>
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<td>Rheumatoid Factor Quantitative, Semi-Quant. and Titer</td>
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## Qualitative Antinuclear Ab (ANA) - Diagnostic Services

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<th>Negative</th>
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<tr>
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<td>-</td>
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<tr>
<td>Hycor Autostat II EIA</td>
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<tr>
<td>IMMCO Diagnostics IFA</td>
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<tr>
<td>INOVA IFA Systems/NOVA Lite Hep-2</td>
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<tr>
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<tr>
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**SAMPLE 46 - 100% of participants reported positive.**

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<tr>
<td>INOVA IFA Systems/NOVA Lite Hep-2</td>
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<td>INOVA Novalite/Quanta Lite</td>
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**SAMPLE 47 - 99% of participants reported positive.**

<table>
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<th>Positive</th>
<th>Negative</th>
</tr>
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<tr>
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<td>BioRad EIA Systems (any)</td>
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<tr>
<td>INOVA Novalite/Quanta Lite</td>
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## Qualitative Antinuclear Ab (ANA) - Diagnostic Services

### SAMPLE 48 - 97% of participants reported negative.

<table>
<thead>
<tr>
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<th>Positive</th>
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<td>INOVA IFA Systems/NOVA Lite Hep-2</td>
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* One laboratory reported an equivocal result

### SAMPLE 49 - 98% of participants reported negative.

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<td>BioRad EIA Systems (any)</td>
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<tr>
<td>BioRad/Kallestad IFA Systems (any)</td>
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<td>IMMCO Diagnostics IFA</td>
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<td>Wampole/Zeus ANA IFA Hep-2</td>
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<tr>
<td>Zeus Scientific AtheNA Multi-Lyte ANA Test</td>
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**Qualitative Antinuclear Ab (ANA) - Diagnostic Services**

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<th>Participant Results</th>
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<td>Alpha Scientific Medical Inc ANA Latex Test</td>
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<td>Bio-Rad Bioplex</td>
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<tr>
<td>BioRad/Kallestad IFA Systems (any)</td>
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<td>DiaSorin ANA IFA Systems</td>
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<tr>
<td>DiaSorin ANA Screen EIA</td>
<td>-</td>
</tr>
<tr>
<td>Hemagen Virgo ANA Test</td>
<td>-</td>
</tr>
<tr>
<td>Hycor Autostat II EIA</td>
<td>-</td>
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<tr>
<td>IMMCO Diagnostics IFA</td>
<td>-</td>
</tr>
<tr>
<td>Immuno Concepts EIA Systems (any)</td>
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<tr>
<td>Immuno Concepts IFA Systems (any)</td>
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<tr>
<td>INOVA IFA Systems/NOVA Lite Hep-2</td>
<td>-</td>
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<tr>
<td>INOVA Novalite/Quanta Lite</td>
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<tr>
<td>RhiGene Fluor ANA IFA Test</td>
<td>-</td>
</tr>
<tr>
<td>Sanofi/Kallestad Quantifluor IFA Kit</td>
<td>-</td>
</tr>
<tr>
<td>Trinity Biotech ANA EIA</td>
<td>-</td>
</tr>
<tr>
<td>Wampole ANA EIA</td>
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<tr>
<td>Wampole/Zeus ANA IFA Hep-2</td>
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<tr>
<td>Zeus Scientific AtheNA Multi-Lyte ANA Test</td>
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</table>
## Antinuclear Ab (ANA) IFA Titers - Diagnostic Services

The number of laboratories that reported titers is listed for positive test samples 46 and 47.

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>No. Labs</th>
<th>Sample 46 Titers</th>
<th>Sample 47 Titers</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Labs</td>
<td>88</td>
<td>2</td>
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<tr>
<td>Antibodies Inc. ANA IFA</td>
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<td>-</td>
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<td>BioRad/Kallestad IFA Systems (any)</td>
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<tr>
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<td>-</td>
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<tr>
<td>Hemagen Virgo ANA Test</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>IMMCO Diagnostics IFA</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Immuno Concepts IFA Systems (any)</td>
<td>11</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>INOVA IFA Systems/NOVA Lite Hep-2</td>
<td>15</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>RhiGene Fluor ANA IFA Test</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sanofi/Kallestad Quantifluor IFA Kit</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Wampole/Zeus ANA IFA Hep-2</td>
<td>24</td>
<td>1</td>
<td>2</td>
</tr>
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</table>

Staining Pattern - 85 labs (97%) reported homogenous, and 3 labs (3%) reported peripheral. The reporting of a staining pattern here is for informational purposes only and is not graded.

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>No. Labs</th>
<th>Sample 46 Titers</th>
<th>Sample 47 Titers</th>
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<tbody>
<tr>
<td>All Labs</td>
<td>87</td>
<td>7</td>
<td>7</td>
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<tr>
<td>Antibodies Inc. ANA IFA</td>
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<td>-</td>
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<tr>
<td>BioRad/Kallestad IFA Systems (any)</td>
<td>28</td>
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<td>2</td>
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<tr>
<td>DiaSorin ANA IFA Systems</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hemagen Virgo ANA Test</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>IMMCO Diagnostics IFA</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Immuno Concepts IFA Systems (any)</td>
<td>11</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>INOVA IFA Systems/NOVA Lite Hep-2</td>
<td>15</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>RhiGene Fluor ANA IFA Test</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sanofi/Kallestad Quantifluor IFA Kit</td>
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<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Wampole/Zeus ANA IFA Hep-2</td>
<td>24</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Staining Pattern - 51 labs (59%) reported speckled, 35 labs (40%) reported homogenous, and 1 lab (1%) reported nucleolar. The reporting of a staining pattern here is for informational purposes only and is not graded.
### Qualitative Antistreptolysin O - Diagnostic Services

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Sample Results</th>
<th>Participant Results</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td><strong>SAMPLE 16 - 100% of participants reported negative.</strong></td>
<td></td>
<td>55</td>
</tr>
<tr>
<td>All Labs</td>
<td>-</td>
<td>55</td>
</tr>
<tr>
<td>Arlington Scientific ASO Latex Test</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Beckman Coulter Synchron LX/Unicel Systems (all models)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>BioKit Rheumajet ASO Latex Test</td>
<td>-</td>
<td>10</td>
</tr>
<tr>
<td>Fisher Sure-Vue ASO Latex Test</td>
<td>-</td>
<td>18</td>
</tr>
<tr>
<td>Remel Seratest ASO Latex Test</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>Roche Diagnostics Cobas (all systems)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Siemens (Dade Behring) RapiTex Latex Test</td>
<td>-</td>
<td>12</td>
</tr>
<tr>
<td>True Medix Trutest Latex Test</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td>Wampole Color Card ASO Latex Test</td>
<td>-</td>
<td>1</td>
</tr>
</tbody>
</table>

| **SAMPLE 17 - 96% of participants reported negative.**      |                | 53       |          |
| All Labs                                                     | 2              | 53       |          |
| Arlington Scientific ASO Latex Test                         | -              | 3        |          |
| Beckman Coulter Synchron LX/Unicel Systems (all models)      | -              | 1        |          |
| BioKit Rheumajet ASO Latex Test                             | 1              | 9        |          |
| Fisher Sure-Vue ASO Latex Test                              | 1              | 17       |          |
| Remel Seratest ASO Latex Test                               | -              | 5        |          |
| Roche Diagnostics Cobas (all systems)                       | -              | 1        |          |
| Siemens (Dade Behring) RapiTex Latex Test                   | -              | 12       |          |
| True Medix Trutest Latex Test                               | -              | 4        |          |
| Wampole Color Card ASO Latex Test                           | -              | 1        |          |

| **SAMPLE 18 - 98% of participants reported negative.**      |                | 54       |          |
| All Labs                                                     | 1              | 54       |          |
| Arlington Scientific ASO Latex Test                         | -              | 3        |          |
| Beckman Coulter Synchron LX/Unicel Systems (all models)      | -              | 1        |          |
| BioKit Rheumajet ASO Latex Test                             | -              | 10       |          |
| Fisher Sure-Vue ASO Latex Test                              | -              | 18       |          |
| Remel Seratest ASO Latex Test                               | -              | 5        |          |
| Roche Diagnostics Cobas (all systems)                       | -              | 1        |          |
| Siemens (Dade Behring) RapiTex Latex Test                   | 1              | 11       |          |
| True Medix Trutest Latex Test                               | -              | 4        |          |
| Wampole Color Card ASO Latex Test                           | -              | 1        |          |
## Qualitative Antistreptolysin O - Diagnostic Services

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SAMPLE 19 - 98% of participants reported positive.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
<td>54</td>
<td>1</td>
</tr>
<tr>
<td>Arlington Scientific ASO Latex Test</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Beckman Coulter Synchron LX/Unicel Systems (all models)</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>BioKit Rheumajet ASO Latex Test</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Fisher Sure-Vue ASO Latex Test</td>
<td>18</td>
<td>-</td>
</tr>
<tr>
<td>Remel Seratest ASO Latex Test</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>Roche Diagnostics Cobas (all systems)</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Siemens (Dade Behring) RapiTex Latex Test</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>True Medix Trutest Latex Test</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>Wampole Color Card ASO Latex Test</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td><strong>SAMPLE 20 - 100% of participants reported positive.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
<td>55</td>
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</tr>
<tr>
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<td>-</td>
</tr>
<tr>
<td>Beckman Coulter Synchron LX/Unicel Systems (all models)</td>
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<td>-</td>
</tr>
<tr>
<td>BioKit Rheumajet ASO Latex Test</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>Fisher Sure-Vue ASO Latex Test</td>
<td>18</td>
<td>-</td>
</tr>
<tr>
<td>Remel Seratest ASO Latex Test</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>Roche Diagnostics Cobas (all systems)</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Siemens (Dade Behring) RapiTex Latex Test</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>True Medix Trutest Latex Test</td>
<td>4</td>
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</tr>
<tr>
<td>Wampole Color Card ASO Latex Test</td>
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### Antistreptolysin O (ASO) Titer Results - Diagnostic Services

#### Sample 19 Titers

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>No. Labs</th>
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<th>1:2</th>
<th>1:4</th>
<th>1:8</th>
<th>1:16</th>
<th>&gt; 1:16</th>
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<tbody>
<tr>
<td>All Labs</td>
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<td>4</td>
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<td>Arlington Scientific ASO Latex Test</td>
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<td>-</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>-</td>
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<tr>
<td>BioKit Rheumajet ASO Latex Test</td>
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<tr>
<td>Fisher Sure-Vue ASO Latex Test</td>
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<td>1</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Siemens (Dade Behring) RapiTex Latex Test</td>
<td>2</td>
<td>1</td>
<td>1</td>
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#### Sample 20 Titers

<table>
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<tr>
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<th>No. Labs</th>
<th>1:1</th>
<th>1:2</th>
<th>1:4</th>
<th>1:8</th>
<th>1:16</th>
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<tbody>
<tr>
<td>All Labs</td>
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<td>-</td>
<td>-</td>
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<td>1</td>
<td>-</td>
<td>-</td>
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<td>BioKit Rheumajet ASO Latex Test</td>
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<td>-</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fisher Sure-Vue ASO Latex Test</td>
<td>3</td>
<td>-</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Siemens (Dade Behring) RapiTex Latex Test</td>
<td>2</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>-</td>
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#### Semi-quantitative Antistreptolysin O (ASO) - Diagnostic Services

The number of laboratories that reported semi-quantitative titers for positive test samples 19 and 20.

<table>
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<tr>
<th>Primary Test Kit/Assay</th>
<th>No. Labs</th>
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<th>400</th>
<th>800</th>
<th>1600</th>
<th>3200</th>
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<tr>
<td>All Labs</td>
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<td>30</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>-</td>
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<td>BioKit Rheumajet ASO Latex Test</td>
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<td>1</td>
<td>6</td>
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<td>1</td>
<td>-</td>
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</tr>
<tr>
<td>Fisher Sure-Vue ASO Latex Test</td>
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<td>-</td>
<td>10</td>
<td>1</td>
<td>1</td>
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<tr>
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<td>-</td>
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<tr>
<td>Siemens (Dade Behring) RapiTex Latex Test</td>
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<td>-</td>
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<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
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<tbody>
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<td>1</td>
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<tr>
<td>Siemens (Dade Behring) RapiTex Latex Test</td>
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<td>4</td>
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</table>
Quantitative Antistreptolysin O (ASO) IU/ml - Diagnostic Services

Results are summarized for positive test samples 19 and 20. Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

<table>
<thead>
<tr>
<th>Sample 19 Method</th>
<th>Primary Test Kit/Assay</th>
<th>Total</th>
<th>Acceptable Range</th>
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<tbody>
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<td></td>
<td></td>
<td>Labs</td>
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</tr>
<tr>
<td>All Methods</td>
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<tr>
<td>Nephelometry Total</td>
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<td>Beckman Coulter Immage</td>
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<tr>
<td></td>
<td>Beckman Coulter (formerly Olympus) AU System</td>
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<tr>
<td></td>
<td>Siemens Dimension VISTA</td>
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</tr>
<tr>
<td></td>
<td>Siemens Nephelometer Systems (all models)</td>
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<tr>
<td>Turbidimetry Total</td>
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<tr>
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<td>Beckman Coulter Synchron LX/Unicel Systems (all models)</td>
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</tr>
<tr>
<td></td>
<td>Beckman Coulter (formerly Olympus) AU System</td>
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<td>11</td>
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<tr>
<td></td>
<td>Siemens Dimension VISTA</td>
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<table>
<thead>
<tr>
<th>Sample 20 Method</th>
<th>Primary Test Kit/Assay</th>
<th>Total</th>
<th>Acceptable Range</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Labs</td>
<td>Labs *</td>
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<tr>
<td>All Methods</td>
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<td>Nephelometry Total</td>
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<td>Beckman Coulter (formerly Olympus) AU System</td>
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<td>Siemens Dimension VISTA</td>
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<td>Siemens Nephelometer Systems (all models)</td>
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<tr>
<td>Turbidimetry Total</td>
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<td>Abbott Architect</td>
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<tr>
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<td>Aeroset-Muligent Quantia ASO</td>
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</tr>
<tr>
<td></td>
<td>Beckman Coulter Synchron LX/Unicel Systems (all models)</td>
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<td>5</td>
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<tr>
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# Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td><strong>SAMPLE 11 - 85% of participants reported negative.</strong></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
<td>7</td>
</tr>
<tr>
<td>Abbott AxSYM</td>
<td>-</td>
</tr>
<tr>
<td>bioMerieux VIDAS/mini VIDAS Systems</td>
<td>-</td>
</tr>
<tr>
<td>Bio-Rad Bioplex Torc IgG</td>
<td>-</td>
</tr>
<tr>
<td>Bio-Rad CMV IgG EIA</td>
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</tr>
<tr>
<td>Diamedix CMV EIA Systems (any)</td>
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<tr>
<td>DiaSorin Liaison CMV IgG</td>
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</tr>
<tr>
<td>Immucor Capture CMV</td>
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<tr>
<td>Siemens Immulite Systems (all models)</td>
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</tr>
<tr>
<td>Trinity Biotech CAPTIA CMV IgG EIA</td>
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</tr>
<tr>
<td>Wampole Zeus Scientific CMV IgG ELISA</td>
<td>-</td>
</tr>
<tr>
<td>Zeus Scientific CMV IgG EIA</td>
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<td><strong>SAMPLE 12 - 100% of participants reported positive.</strong></td>
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<td>Zeus Scientific CMV IgG EIA</td>
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<tr>
<td><strong>SAMPLE 13 - 80% of participants reported negative.</strong></td>
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<td>Bio-Rad Bioplex Torc IgG</td>
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<td>Bio-Rad CMV IgG EIA</td>
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<tr>
<td>Diamedix CMV EIA Systems (any)</td>
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<td>DiaSorin Liaison CMV IgG</td>
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<tr>
<td>Immucor Capture CMV</td>
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<tr>
<td>Siemens Immulite Systems (all models)</td>
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<tr>
<td>Trinity Biotech CAPTIA CMV IgG EIA</td>
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<td>Zeus Scientific CMV IgG EIA</td>
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## Qualitative Cytomegalovirus Ab (CMV) - Diagnostic Services

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<tr>
<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Positive</td>
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<tr>
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<tr>
<td>Bio-Rad Bioplex Torc IgG</td>
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<tr>
<td>Bio-Rad CMV IgG EIA</td>
<td>-</td>
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<tr>
<td>Diamedix CMV EIA Systems (any)</td>
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<tr>
<td>DiaSorin Liaison CMV IgG</td>
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<tr>
<td>Immucor Capture CMV</td>
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<tr>
<td>Siemens Immulite Systems (all models)</td>
<td>-</td>
</tr>
<tr>
<td>Trinity Biotech CAPTIA CMV IgG EIA</td>
<td>-</td>
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<tr>
<td>Wampole Zeus Scientific CMV IgG ELISA</td>
<td>-</td>
</tr>
<tr>
<td>Zeus Scientific CMV IgG EIA</td>
<td>-</td>
</tr>
</tbody>
</table>

| **SAMPLE 15 - 100% of participants reported positive.** |          |          |           |
| All Labs                                      | 65       | -        | -         |
| Abbott AxSYM                                  | 2        | -        | -         |
| bioMerieux VIDAS/mini VIDAS Systems           | 17       | -        | -         |
| Bio-Rad Bioplex Torc IgG                     | 1        | -        | -         |
| Bio-Rad CMV IgG EIA                          | 5        | -        | -         |
| Diamedix CMV EIA Systems (any)                | 6        | -        | -         |
| DiaSorin Liaison CMV IgG                     | 5        | -        | -         |
| Immucor Capture CMV                          | 1        | -        | -         |
| Siemens Immulite Systems (all models)         | 7        | -        | -         |
| Trinity Biotech CAPTIA CMV IgG EIA            | 6        | -        | -         |
| Wampole Zeus Scientific CMV IgG ELISA         | 3        | -        | -         |
| Zeus Scientific CMV IgG EIA                  | 12       | -        | -         |
## Qualitative Cytomegalovirus Ab (CMV) - Donor Services

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
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</tr>
</thead>
<tbody>
<tr>
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<tr>
<td><strong>SAMPLE 61 - 100% of participants reported positive.</strong></td>
<td></td>
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<tr>
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<tr>
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<tr>
<td>Immucor Capture CMV</td>
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</tr>
<tr>
<td>Siemens Immulite Systems (all models)</td>
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<tr>
<td>**SAMPLE 62 - 24% of participants reported negative. *</td>
<td></td>
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<tr>
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<tr>
<td>bioMerieux VIDAS/mini VIDAS Systems</td>
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<td>Immucor Capture CMV</td>
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<td>Siemens Immulite Systems (all models)</td>
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<tr>
<td>**SAMPLE 63 - 24% of participants reported negative. *</td>
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<tr>
<td>All Labs</td>
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<tr>
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<td>Beckman Coulter (formerly Olympus) PK System</td>
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<tr>
<td>bioMerieux VIDAS/mini VIDAS Systems</td>
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<tr>
<td>Immucor Capture CMV</td>
<td>7</td>
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<tr>
<td>Siemens Immulite Systems (all models)</td>
<td>-</td>
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<tr>
<td><strong>SAMPLE 64 - 100% of participants reported positive.</strong></td>
<td></td>
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<td>Beckman Coulter (formerly Olympus) PK System</td>
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<td>Immucor Capture CMV</td>
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<tr>
<td>**SAMPLE 65 - 20% of participants reported negative. *</td>
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<tr>
<td>All Labs</td>
<td>20</td>
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</tr>
<tr>
<td>bioMerieux VIDAS/mini VIDAS Systems</td>
<td>-</td>
</tr>
<tr>
<td>Immucor Capture CMV</td>
<td>8</td>
</tr>
<tr>
<td>Siemens Immulite Systems (all models)</td>
<td>-</td>
</tr>
</tbody>
</table>

* Unable to validate sample #62, #63 and #65 the expected result is negative. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.
## Qualitative Hepatitis B core Ab - Diagnostic Services

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reactive</td>
</tr>
<tr>
<td><strong>SAMPLE 06 - 100% of participants reported nonreactive.</strong></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
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</tr>
<tr>
<td>Abbott Architect</td>
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</tr>
<tr>
<td>Abbott AxSYM</td>
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</tr>
<tr>
<td>BioRad MONOLISA HBc</td>
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<tr>
<td>DiaSorin ETI-AB Corek Plus</td>
<td></td>
</tr>
<tr>
<td>Ortho HBC ELISA</td>
<td></td>
</tr>
<tr>
<td>Ortho Vitros (all models)</td>
<td></td>
</tr>
<tr>
<td>Siemens ADVIA Centaur</td>
<td></td>
</tr>
<tr>
<td>Siemens Immulite Systems (all models)</td>
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</tr>
<tr>
<td><strong>SAMPLE 07 - 100% of participants reported reactive.</strong></td>
<td>132</td>
</tr>
<tr>
<td>All Labs</td>
<td></td>
</tr>
<tr>
<td>Abbott Architect</td>
<td>11</td>
</tr>
<tr>
<td>Abbott AxSYM</td>
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<tr>
<td>BioRad MONOLISA HBc</td>
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<td>Ortho HBC ELISA</td>
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<tr>
<td>Ortho Vitros (all models)</td>
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<td>Siemens ADVIA Centaur</td>
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<tr>
<td><strong>SAMPLE 08 - 100% of participants reported nonreactive.</strong></td>
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<tr>
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<tr>
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<td>DiaSorin ETI-AB Corek Plus</td>
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<tr>
<td>Ortho HBC ELISA</td>
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<tr>
<td>Ortho Vitros (all models)</td>
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<tr>
<td>Siemens ADVIA Centaur</td>
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</tr>
<tr>
<td>Siemens Immulite Systems (all models)</td>
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</tbody>
</table>
# Qualitative Hepatitis B core Ab - Diagnostic Services

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
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</thead>
<tbody>
<tr>
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<tr>
<td><strong>SAMPLE 09 - 100% of participants reported reactive.</strong></td>
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<tr>
<td>BioRad MONOLISA HBc</td>
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<tr>
<td>Ortho HBc ELISA</td>
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<tr>
<td>Ortho Vitros (all models)</td>
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<tr>
<td>Siemens ADVIA Centaur</td>
<td>59</td>
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<tr>
<td>Siemens Immulite Systems (all models)</td>
<td>10</td>
</tr>
</tbody>
</table>

| **SAMPLE 10 - 100% of participants reported nonreactive.** |          |            |
| All Labs               | -        | 132        |
| Abbott Architect       | -        | 11         |
| Abbott AxSYM           | -        | 9          |
| BioRad MONOLISA HBc    | -        | 1          |
| DiaSorin ETI-AB Corek Plus | -   | 2          |
| Ortho HBc ELISA        | -        | 2          |
| Ortho Vitros (all models) | -   | 38         |
| Siemens ADVIA Centaur  | -        | 59         |
| Siemens Immulite Systems (all models) | - | 10        |
### Qualitative Hepatitis B Core Ab - Donor Services

<table>
<thead>
<tr>
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<th>Nonreactive</th>
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<tbody>
<tr>
<td><strong>SAMPLE 51 - 100% of participants reported nonreactive.</strong></td>
<td></td>
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</tr>
<tr>
<td>All Labs</td>
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<td>Abbott PRISM</td>
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<td>BioRad MONOLISA HBc</td>
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<tr>
<td>Ortho HBc ELISA</td>
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<tr>
<td>Siemens ADVIA Centaur</td>
<td>-</td>
<td>1</td>
</tr>
</tbody>
</table>

| **SAMPLE 52 - 100% of participants reported reactive.** |          |             |
| All Labs                                               | 25       | -           |
| Abbott AxSYM                                           | 1        | -           |
| Abbott PRISM                                           | 11       | -           |
| BioRad MONOLISA HBc                                    | 1        | -           |
| Ortho HBc ELISA                                        | 11       | -           |
| Siemens ADVIA Centaur                                  | 1        | -           |

| **SAMPLE 53 - 100% of participants reported reactive.** |          |             |
| All Labs                                               | 25       | -           |
| Abbott AxSYM                                           | 1        | -           |
| Abbott PRISM                                           | 11       | -           |
| BioRad MONOLISA HBc                                    | 1        | -           |
| Ortho HBc ELISA                                        | 11       | -           |
| Siemens ADVIA Centaur                                  | 1        | -           |

| **SAMPLE 54 - 100% of participants reported nonreactive.** |          |             |
| All Labs                                               | -        | 25          |
| Abbott AxSYM                                           | -        | 1           |
| Abbott PRISM                                           | -        | 11          |
| BioRad MONOLISA HBc                                    | -        | 1           |
| Ortho HBc ELISA                                        | -        | 11          |
| Siemens ADVIA Centaur                                  | -        | 1           |

| **SAMPLE 55 - 100% of participants reported nonreactive.** |          |             |
| All Labs                                               | -        | 25          |
| Abbott AxSYM                                           | -        | 1           |
| Abbott PRISM                                           | -        | 11          |
| BioRad MONOLISA HBc                                    | -        | 1           |
| Ortho HBc ELISA                                        | -        | 11          |
| Siemens ADVIA Centaur                                  | -        | 1           |
## Qualitative Hepatitis B surface Ag - Diagnostic Services

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
</tr>
</thead>
<tbody>
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<td>Reactive</td>
</tr>
<tr>
<td><strong>SAMPLE 06 - 100% of participants reported nonreactive.</strong></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
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<tr>
<td>Abbott Architect</td>
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</tr>
<tr>
<td>Abbott AxSYM</td>
<td>-</td>
</tr>
<tr>
<td>Bio-Rad GS HBsAg EIA</td>
<td>-</td>
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<tr>
<td>DiaSorin ETI MAK-2 Plus</td>
<td>-</td>
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<tr>
<td>Ortho Vitros (all models)</td>
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<tr>
<td>Roche Diagnostics Cobas (all systems)</td>
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<tr>
<td>Roche Diagnostics Elecsys Systems</td>
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<tr>
<td>Siemens ADVIA Centaur</td>
<td>-</td>
</tr>
<tr>
<td>Siemens Immulite Systems (all models)</td>
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</table>

* Two labs reported an equivocal result.

### SAMPLE 07 - 98% of participants reported reactive.

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<th>Participant Results</th>
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</thead>
<tbody>
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<tr>
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<tr>
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<tr>
<td>Bio-Rad GS HBsAg EIA</td>
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<tr>
<td>DiaSorin ETI MAK-2 Plus</td>
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<tr>
<td>Siemens ADVIA Centaur</td>
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<td>Siemens Immulite Systems (all models)</td>
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### SAMPLE 08 - 100% of participants reported nonreactive.

<table>
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<tr>
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<th>Participant Results</th>
</tr>
</thead>
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<tr>
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</tr>
<tr>
<td>Abbott Architect</td>
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<tr>
<td>Abbott AxSYM</td>
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<tr>
<td>Bio-Rad GS HBsAg EIA</td>
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<tr>
<td>DiaSorin ETI MAK-2 Plus</td>
<td>-</td>
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<tr>
<td>Ortho Vitros (all models)</td>
<td>-</td>
</tr>
<tr>
<td>Roche Diagnostics Cobas (all systems)</td>
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<tr>
<td>Roche Diagnostics Elecsys Systems</td>
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<td>Siemens ADVIA Centaur</td>
<td>-</td>
</tr>
<tr>
<td>Siemens Immulite Systems (all models)</td>
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### Qualitative Hepatitis B surface Ag - Diagnostic Services

#### Participant Results

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<th>Primary Test Kit/Assay</th>
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<th>Nonreactive</th>
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<tbody>
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<td>DiaSorin ETI MAK-2 Plus</td>
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<td>Siemens Immulite Systems (all models)</td>
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<tr>
<td>* One lab reported an equivocal result.</td>
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| All Labs                                       | 1        | 179         |
| Abbott Architect                               | -        | 15          |
| Abbott AxSYM                                   | -        | 8           |
| Bio-Rad GS HBsAg EIA                           | -        | 3           |
| DiaSorin ETI MAK-2 Plus                        | -        | 3           |
| Ortho Vitros (all models)                      | 1        | 50          |
| Roche Diagnostics Cobas (all systems)          | -        | 4           |
| Roche Diagnostics Elecsys Systems              | -        | 7           |
| Siemens ADVIA Centaur                          | -        | 80          |
| Siemens Immulite Systems (all models)          | -        | 9           |

**SAMPLE 10 - 99% of participants reported nonreactive.**
### Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

<table>
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<th>Nonreactive</th>
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<tr>
<td>DiaSorin ETI MAK-2 Plus</td>
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<tr>
<td>Ortho Vitros (all models) *</td>
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<tr>
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<td>Roche Diagnostics Elecsys Systems</td>
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<tr>
<td>Siemens ADVIA Centaur</td>
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<tr>
<td>Siemens Immulite Systems (all models) *</td>
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<tr>
<td>* One laboratory reported an &quot;invalid&quot; result.</td>
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</tbody>
</table>

| **SAMPLE 07 - 99% of participants reported reactive.**      |          |             |
| All Labs                                                    | 116      | 1           |
| Abbott Architect                                           | 7        | -           |
| Abbott AxSYM                                               | 5        | -           |
| Abbott HBsAg Confirmatory Assay                            | 4        | -           |
| Bio-Rad GS HBsAg Confirmatory Assay                        | 2        | -           |
| DiaSorin ETI MAK-2 Plus                                    | 3        | -           |
| Ortho Vitros (all models) *                                 | 31       | -           |
| Roche Diagnostics Cobas (all systems)                      | 2        | -           |
| Roche Diagnostics Elecsys Systems                           | 3        | -           |
| Siemens ADVIA Centaur                                      | 56       | -           |
| Siemens Immulite Systems (all models) *                    | 3        | 1           |
| * One laboratory reported an "invalid" result.              |          |             |

| **SAMPLE 08 - 99% of participants reported nonreactive.**   |          |             |
| All Labs                                                    | -        | 117         |
| Abbott Architect                                           | -        | 7           |
| Abbott AxSYM                                               | -        | 5           |
| Abbott HBsAg Confirmatory Assay                            | -        | 4           |
| Bio-Rad GS HBsAg Confirmatory Assay                        | -        | 2           |
| DiaSorin ETI MAK-2 Plus                                    | -        | 3           |
| Ortho Vitros (all models) *                                 | -        | 31          |
| Roche Diagnostics Cobas (all systems)                      | -        | 2           |
| Roche Diagnostics Elecsys Systems                           | -        | 3           |
| Siemens ADVIA Centaur                                      | -        | 56          |
| Siemens Immulite Systems (all models) *                    | -        | 4           |
| * One laboratory reported an "invalid" result.              |          |             |
## Qualitative Hepatitis B surface Ag Confirmation - Diagnostic Services

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<tr>
<td>Bio-Rad GS HBsAg Confirmatory Assay</td>
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<tr>
<td>DiaSorin ETI MAK-2 Plus</td>
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<td>Ortho Vitros (all models) *</td>
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<td>Roche Diagnostics Cobas (all systems)</td>
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<td>Roche Diagnostics Elecsys Systems</td>
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<td>Siemens Immulite Systems (all models)</td>
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<td><strong>One laboratory reported an &quot;invalid&quot; result.</strong></td>
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## Qualitative Hepatitis B Surface Antigen - Donor Services

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<td><strong>SAMPLE 52 - 100% of participants reported reactive.</strong></td>
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<td>Abbott PRISM</td>
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<td>Ortho Antibody to HBsAg ELISA Test System</td>
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### Qualitative Hepatitis B Surface Ag Confirmation - Donor Services

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</table>

| **SAMPLE 52** - 100% of participants reported reactive. | | |
| All Labs | 19 | - |
| Abbott Architect | 1 | - |
| Abbott AxSYM | 1 | - |
| Abbott PRISM | 6 | - |
| Genetic Systems HBsAg EIA 3.0 | 10 | - |
| Ortho Antibody to HBsAg ELISA Test System | 1 | - |

| **SAMPLE 53** - 100% of participants reported reactive. | | |
| All Labs | 19 | - |
| Abbott Architect | 1 | - |
| Abbott AxSYM | 1 | - |
| Abbott PRISM | 6 | - |
| Genetic Systems HBsAg EIA 3.0 | 10 | - |
| Ortho Antibody to HBsAg ELISA Test System | 1 | - |

| **SAMPLE 54** - 100% of participants reported nonreactive. | | |
| All Labs | - | 19 |
| Abbott Architect | - | 1 |
| Abbott AxSYM | - | 1 |
| Abbott PRISM | - | 6 |
| Genetic Systems HBsAg EIA 3.0 | - | 10 |
| Ortho Antibody to HBsAg ELISA Test System | - | 1 |

| **SAMPLE 55** - 100% of participants reported nonreactive. | | |
| All Labs | - | 19 |
| Abbott Architect | - | 1 |
| Abbott AxSYM | - | 1 |
| Abbott PRISM | - | 6 |
| Genetic Systems HBsAg EIA 3.0 | - | 10 |
| Ortho Antibody to HBsAg ELISA Test System | - | 1 |
## Qualitative Hepatitis Be Ag - Diagnostic Services

<table>
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<td>DiaSorin ETI MAK 3000</td>
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<td><strong>SAMPLE 67 - 100% of participants reported reactive.</strong></td>
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<td>Ortho Vitros (all models)</td>
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<td><strong>SAMPLE 68 - 100% of participants reported nonreactive.</strong></td>
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<td>Laboratory developed assay</td>
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## Qualitative Hepatitis C Virus Ab - Diagnostic Services

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<td>Siemens ADVIA Centaur</td>
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</tbody>
</table>

| **SAMPLE 72 - 100% of participants reported nonreactive.**  |          |             |
| All Labs                                                    | -        | 161         |
| Abbott Architect                                            | -        | 16          |
| Abbott AxSYM                                                | -        | 10          |
| Bio-Rad Evolis                                              | -        | 1           |
| DiaSorin ETI-MAK                                            | -        | 1           |
| HCV Ortho Version 3.0 ELISA                                 | -        | 8           |
| Ortho Vitros (all models)                                   | -        | 47          |
| Roche Diagnostics Elecsys Systems                            | -        | 2           |
| Siemens ADVIA Centaur                                       | -        | 76          |

| **SAMPLE 73 - 100% of participants reported reactive.**     |          |             |
| All Labs                                                    | 161      | -           |
| Abbott Architect                                            | 16       | -           |
| Abbott AxSYM                                                | 10       | -           |
| Bio-Rad Evolis                                              | 1        | -           |
| DiaSorin ETI-MAK                                            | 1        | -           |
| HCV Ortho Version 3.0 ELISA                                 | 8        | -           |
| Ortho Vitros (all models)                                   | 47       | -           |
| Roche Diagnostics Elecsys Systems                            | 2        | -           |
| Siemens ADVIA Centaur                                       | 76       | -           |

| **SAMPLE 74 - 100% of participants reported nonreactive.**  |          |             |
| All Labs                                                    | -        | 161         |
| Abbott Architect                                            | -        | 16          |
| Abbott AxSYM                                                | -        | 10          |
| Bio-Rad Evolis                                              | -        | 1           |
| DiaSorin ETI-MAK                                            | -        | 1           |
| HCV Ortho Version 3.0 ELISA                                 | -        | 8           |
| Ortho Vitros (all models)                                   | -        | 47          |
| Roche Diagnostics Elecsys Systems                            | -        | 2           |
| Siemens ADVIA Centaur                                       | -        | 76          |
## Qualitative Hepatitis C Virus Ab - Diagnostic Services

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## Qualitative Hepatitis C Virus Ab Confirmation - Diagnostic Services

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</thead>
<tbody>
<tr>
<td><strong>SAMPLE 71</strong> - 100% of participants reported reactive.</td>
<td></td>
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</tr>
<tr>
<td>All Labs</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Chiron RIBA HCV 3.0 SIA</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Innogenetics Line Immuno Assay</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Roche Diagnostics Elecsys Systems</td>
<td>1</td>
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</tr>
<tr>
<td>Siemens ADVIA Centaur</td>
<td>1</td>
<td>-</td>
</tr>
</tbody>
</table>

| **SAMPLE 72** - 100% of participants reported nonreactive. | | |
| All Labs | - | 6 |
| Chiron RIBA HCV 3.0 SIA | - | 3 |
| Innogenetics Line Immuno Assay | - | 1 |
| Roche Diagnostics Elecsys Systems | - | 1 |
| Siemens ADVIA Centaur | - | 1 |

| **SAMPLE 73** - 100% of participants reported reactive. | | |
| All Labs | 6 | - |
| Chiron RIBA HCV 3.0 SIA | 3 | - |
| Innogenetics Line Immuno Assay | 1 | - |
| Roche Diagnostics Elecsys Systems | 1 | - |
| Siemens ADVIA Centaur | 1 | - |

| **SAMPLE 74** - 100% of participants reported nonreactive. | | |
| All Labs | - | 6 |
| Chiron RIBA HCV 3.0 SIA | - | 3 |
| Innogenetics Line Immuno Assay | - | 1 |
| Roche Diagnostics Elecsys Systems | - | 1 |
| Siemens ADVIA Centaur | - | 1 |

<p>| <strong>SAMPLE 75</strong> - 100% of participants reported nonreactive. | | |
| All Labs | - | 6 |
| Chiron RIBA HCV 3.0 SIA | - | 3 |
| Innogenetics Line Immuno Assay | - | 1 |
| Roche Diagnostics Elecsys Systems | - | 1 |
| Siemens ADVIA Centaur | - | 1 |</p>
<table>
<thead>
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<tr>
<td>All Labs</td>
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<tr>
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<tr>
<td>Abbott PRISM</td>
<td>-</td>
<td>11</td>
</tr>
<tr>
<td>Ortho HCV Version 3.0 ELISA</td>
<td>-</td>
<td>14</td>
</tr>
<tr>
<td>Siemens ADVIA Centaur</td>
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<table>
<thead>
<tr>
<th>SAMPLE 92 - 100% of participants reported nonreactive.</th>
<th>Reactive</th>
<th>Nonreactive</th>
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<td>All Labs</td>
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<tr>
<th>SAMPLE 93 - 100% of participants reported reactive.</th>
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<tr>
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<tr>
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<tr>
<td>Ortho HCV Version 3.0 ELISA</td>
<td>14</td>
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</tr>
<tr>
<td>Siemens ADVIA Centaur</td>
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<table>
<thead>
<tr>
<th>SAMPLE 94 - 100% of participants reported nonreactive.</th>
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<th>Nonreactive</th>
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<tr>
<td>All Labs</td>
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<td>27</td>
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<tr>
<td>Abbott AxSYM</td>
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<tr>
<td>Abbott PRISM</td>
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<td>11</td>
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<tr>
<td>Ortho HCV Version 3.0 ELISA</td>
<td>-</td>
<td>14</td>
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<tr>
<td>Siemens ADVIA Centaur</td>
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<table>
<thead>
<tr>
<th>SAMPLE 95 - 100% of participants reported reactive.</th>
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<th>Nonreactive</th>
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<td>11</td>
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</tr>
<tr>
<td>Ortho HCV Version 3.0 ELISA</td>
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</tr>
<tr>
<td>Siemens ADVIA Centaur</td>
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## Qualitative Hepatitis C Antibody Confirmation - Donor Services

<table>
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<tr>
<th>Primary Test Kit/Assay</th>
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<th>Nonreactive</th>
</tr>
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<tbody>
<tr>
<td><strong>SAMPLE 91</strong> - 100% of participants reported nonreactive.</td>
<td></td>
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</tr>
<tr>
<td>All Labs</td>
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<td>6</td>
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<tr>
<td>Chiron RIBA HCV 3.0 SIA</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td><strong>SAMPLE 92</strong> - 100% of participants reported nonreactive.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
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<td>6</td>
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<tr>
<td>Chiron RIBA HCV 3.0 SIA</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td><strong>SAMPLE 93</strong> - 100% of participants reported reactive.</td>
<td></td>
<td></td>
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<tr>
<td>All Labs</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
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<td>6</td>
<td>-</td>
</tr>
<tr>
<td><strong>SAMPLE 94</strong> - 100% of participants reported nonreactive.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
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<td>6</td>
</tr>
<tr>
<td>Chiron RIBA HCV 3.0 SIA</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td><strong>SAMPLE 95</strong> - 100% of participants reported reactive.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Chiron RIBA HCV 3.0 SIA</td>
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</tr>
</tbody>
</table>
# Qualitative HIV Ab - Screening Tests

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Reactive</th>
<th>Nonreactive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SAMPLE 31 - 100% of participants reported nonreactive.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
<td>264</td>
<td>-</td>
</tr>
<tr>
<td>Architect HIV Ag/Ab Combo Assay (Abbott)</td>
<td>22</td>
<td>-</td>
</tr>
<tr>
<td>Advia Centaur HIV 1/O/2 EHV (Siemens)</td>
<td>44</td>
<td>-</td>
</tr>
<tr>
<td>Avioq HIV-1 Microelisa System (Avioq)</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>GS HIV-1/HIV-2 Plus O (Bio-Rad)</td>
<td>19</td>
<td>-</td>
</tr>
<tr>
<td>GS HIV Ag/Ab Combo EIA (Bio-Rad)</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Multispot HIV-1/2 Rapid Test (Bio-Rad)</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Clearview HIV 1/2 Stat-Pak (Alere)</td>
<td>31</td>
<td>-</td>
</tr>
<tr>
<td>Reveal Rapid HIV-1 Antibody Test (MedMira)</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)</td>
<td>91</td>
<td>-</td>
</tr>
<tr>
<td>Ortho Vitros Anti-HIV 1+2 (all models)</td>
<td>29</td>
<td>-</td>
</tr>
<tr>
<td>Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)</td>
<td>18</td>
<td>-</td>
</tr>
</tbody>
</table>

| **SAMPLE 32 - 100% of participants reported reactive.** |          |             |
| All Labs | 264 | - |
| Architect HIV Ag/Ab Combo Assay (Abbott) | 22 | - |
| Advia Centaur HIV 1/O/2 EHV (Siemens) | 44 | - |
| Avioq HIV-1 Microelisa System (Avioq) | 1 | - |
| GS HIV-1/HIV-2 Plus O (Bio-Rad) | 19 | - |
| GS HIV Ag/Ab Combo EIA (Bio-Rad) | 1 | - |
| Multispot HIV-1/2 Rapid Test (Bio-Rad) | 2 | - |
| Clearview HIV 1/2 Stat-Pak (Alere) | 31 | - |
| Reveal Rapid HIV-1 Antibody Test (MedMira) | 6 | - |
| OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure) | 91 | - |
| Ortho Vitros Anti-HIV 1+2 (all models) | 29 | - |
| Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech) | 18 | - |

| **SAMPLE 33 - 100% of participants reported reactive.** |          |             |
| All Labs | 264 | - |
| Architect HIV Ag/Ab Combo Assay (Abbott) | 22 | - |
| Advia Centaur HIV 1/O/2 EHV (Siemens) | 44 | - |
| Avioq HIV-1 Microelisa System (Avioq) | 1 | - |
| GS HIV-1/HIV-2 Plus O (Bio-Rad) | 19 | - |
| GS HIV Ag/Ab Combo EIA (Bio-Rad) | 1 | - |
| Multispot HIV-1/2 Rapid Test (Bio-Rad) | 2 | - |
| Clearview HIV 1/2 Stat-Pak (Alere) | 31 | - |
| Reveal Rapid HIV-1 Antibody Test (MedMira) | 6 | - |
| OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure) | 91 | - |
| Ortho Vitros Anti-HIV 1+2 (all models) | 29 | - |
| Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech) | 18 | - |
### Qualitative HIV Ab - Screening Tests

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Reactive</th>
<th>Nonreactive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SAMPLE 34 - 100% of participants reported nonreactive.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
<td>-</td>
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</tr>
<tr>
<td>Architect HIV Ag/Ab Combo Assay (Abbott)</td>
<td>-</td>
<td>22</td>
</tr>
<tr>
<td>Advia Centaur HIV 1/O/2 EHV (Siemens)</td>
<td>-</td>
<td>44</td>
</tr>
<tr>
<td>Avioq HIV-1 Microelisa System (Avioq)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>GS HIV-1/HIV-2 Plus O (Bio-Rad)</td>
<td>-</td>
<td>19</td>
</tr>
<tr>
<td>GS HIV Ag/Ab Combo EIA (Bio-Rad)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Multispot HIV-1/2 Rapid Test (Bio-Rad)</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Clearview HIV 1/2 Stat-Pak (Alere)</td>
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<td>31</td>
</tr>
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</tr>
<tr>
<td>Ortho Vitros Anti-HIV 1+2 (all models)</td>
<td>-</td>
<td>29</td>
</tr>
<tr>
<td>Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)</td>
<td>-</td>
<td>18</td>
</tr>
</tbody>
</table>

| **SAMPLE 35 - 100% of participants reported reactive.**     |          |             |
| All Labs                                                   | 264      | -           |
| Architect HIV Ag/Ab Combo Assay (Abbott)                   | 22       | -           |
| Advia Centaur HIV 1/O/2 EHV (Siemens)                      | 44       | -           |
| Avioq HIV-1 Microelisa System (Avioq)                       | 1        | -           |
| GS HIV-1/HIV-2 Plus O (Bio-Rad)                            | 19       | -           |
| GS HIV Ag/Ab Combo EIA (Bio-Rad)                           | 1        | -           |
| Multispot HIV-1/2 Rapid Test (Bio-Rad)                     | 2        | -           |
| Clearview HIV 1/2 Stat-Pak (Alere)                         | 31       | -           |
| Reveal Rapid HIV-1 Antibody Test (MedMira)                  | 6        | -           |
| OraQuick Advance Rapid HIV-1/2 Antibody Test (Orasure)      | 91       | -           |
| Ortho Vitros Anti-HIV 1+2 (all models)                     | 29       | -           |
| Uni-Gold Recombigen HIV Rapid Test (Trinity Biotech)        | 18       | -           |
### Qualitative HIV-1 Ab - Confirmation Tests

<table>
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<tr>
<th>Primary Test Kit/Assay</th>
<th>Reactive</th>
<th>Nonreactive</th>
</tr>
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<tr>
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</tr>
<tr>
<td>All Labs</td>
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<tr>
<td>GS HIV-1 Western Blot (Bio-Rad)</td>
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<td><strong>SAMPLE 32 - 100% of participants reported reactive.</strong></td>
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<tr>
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<tr>
<td>GS HIV-1 Western Blot (Bio-Rad)</td>
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<td>-</td>
</tr>
<tr>
<td>Laboratory developed assay</td>
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<td>Cambridge Biotech HIV-1 WB (Maxim Biomedical)</td>
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<tr>
<td>GS HIV-1 Western Blot (Bio-Rad)</td>
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<td>-</td>
</tr>
<tr>
<td>Laboratory developed assay</td>
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<td>-</td>
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<tr>
<td>Cambridge Biotech HIV-1 WB (Maxim Biomedical)</td>
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<td>GS HIV-1 Western Blot (Bio-Rad)</td>
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<tr>
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<tr>
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### Qualitative HIV Ab Screening - Donor Tests

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<th>Primary Test Kit/Assay</th>
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<th>Nonreactive</th>
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<td>SAMPLE 96 - 100% of participants reported nonreactive.</td>
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<tr>
<td>All Labs</td>
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<tr>
<td>Abbott PRISM</td>
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<tr>
<td>Bio-Rad GS HIV-1/HIV-2 Plus O</td>
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<tr>
<td>SAMPLE 97 - 100% of participants reported reactive.</td>
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<td>All Labs</td>
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<td>SAMPLE 98 - 100% of participants reported reactive.</td>
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<td>All Labs</td>
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<td>SAMPLE 100 - 100% of participants reported nonreactive.</td>
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### Qualitative HIV-1 Ab Confirmation - Donor Tests

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<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
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<td>All Labs</td>
<td>Reactive</td>
</tr>
<tr>
<td>Bio-Rad GS HIV-1 Western Blot</td>
<td>-</td>
</tr>
<tr>
<td>Sanochemias Fluorognost IFA HIV-1</td>
<td>-</td>
</tr>
<tr>
<td><strong>SAMPLE 97 - 100% of participants reported reactive.</strong></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
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<tr>
<td>Bio-Rad GS HIV-1 Western Blot</td>
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<td>All Labs</td>
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<tr>
<td>Bio-Rad GS HIV-1 Western Blot</td>
<td>7</td>
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<tr>
<td>Sanochemias Fluorognost IFA HIV-1</td>
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<tr>
<td><strong>SAMPLE 99 - 100% of participants reported reactive.</strong></td>
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<tr>
<td>All Labs</td>
<td>11</td>
</tr>
<tr>
<td>Bio-Rad GS HIV-1 Western Blot</td>
<td>7</td>
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<tr>
<td>Sanochemias Fluorognost IFA HIV-1</td>
<td>4</td>
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<tr>
<td><strong>SAMPLE 100 - 100% of participants reported nonreactive.</strong></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
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</tr>
<tr>
<td>Bio-Rad GS HIV-1 Western Blot</td>
<td>-</td>
</tr>
<tr>
<td>Sanochemias Fluorognost IFA HIV-1</td>
<td>-</td>
</tr>
</tbody>
</table>
Samples #36 and #39 are not validated, the expected result is positive. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.

## Qualitative HTLV-1 Ab - Diagnostic Services

<table>
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<th>Participant Results</th>
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<tr>
<td>SAMPLE 36 - 50% of participants reported positive.*</td>
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<td>SAMPLE 39 - 100% of participants reported positive.*</td>
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* Samples #36 and #39 are not validated, the expected result is positive. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.
### Qualitative HTLV-1 Ab - Donor Services

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<th>Primary Test Kit/Assay</th>
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### Qualitative Infectious Mononucleosis - Diagnostic Services

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**SAMPLE 27 - 99% of participants reported negative.**
## Qualitative Infectious Mononucleosis - Diagnostic Services

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<tr>
<td>Polymedco PolyStat Mono</td>
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<td>Quidel QuickView Mono</td>
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SAMPLE 28 - 100% of participants reported negative.
## Qualitative Infectious Mononucleosis - Diagnostic Services

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### Qualitative Infectious Mononucleosis - Diagnostic Services

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<td>Clearview Mono</td>
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<td>Fisher Sure-Vue Color Mono Latex Test Kit</td>
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SAMPLE 30 - 98% of participants reported negative.
### Qualitative Lyme Disease Ab - Diagnostic Services

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<tr>
<td>Bio-Rad Platelia Lyme IgG/IgM</td>
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<tr>
<td>bioMerieux VIDAS/mini VIDAS Systems</td>
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<tr>
<td>DiaSorin Liaison B. burgdorferi Chemiluminescent Assay</td>
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</tr>
<tr>
<td>Immunetics C6 B. burgdorferi EIA Test</td>
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<tr>
<td>Laboratory developed assay</td>
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<td>MarDx Lyme Disease EIA (IgM &amp; IgG)</td>
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<tr>
<td>Meridien Premier LYME EIA</td>
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<td>Trinity Biotech B. burgdorferi IgG/IgM</td>
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</tr>
<tr>
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</table>

| **SAMPLE 42 - 100% of participants reported positive.**                              | Positive | Negative |
| All Labs                                                                             | 96       | -        |
| Bio-Rad Evolis                                                                       | 1        | -        |
| Bio-Rad PhD EIA System                                                               | 2        | -        |
| Bio-Rad Platelia Lyme IgG/IgM                                                        | 1        | -        |
| bioMerieux VIDAS/mini VIDAS Systems                                                   | 28       | -        |
| DiaSorin Liaison B. burgdorferi Chemiluminescent Assay                               | 14       | -        |
| Immunetics C6 B. burgdorferi EIA Test                                                | 18       | -        |
| Laboratory developed assay                                                           | 2        | -        |
| MarDx Lyme Disease EIA (IgM & IgG)                                                   | 5        | -        |
| Meridien Premier LYME EIA                                                            | 1        | -        |
| Trinity Biotech B. burgdorferi IgG/IgM                                               | 1        | -        |
| Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)                                  | 23       | -        |

<p>| <strong>SAMPLE 43 - 100% of participants reported negative.</strong>                              | Positive | Negative |
| All Labs                                                                             | -        | 96       |
| Bio-Rad Evolis                                                                       | -        | 1        |
| Bio-Rad PhD EIA System                                                               | -        | 2        |
| Bio-Rad Platelia Lyme IgG/IgM                                                        | -        | 1        |
| bioMerieux VIDAS/mini VIDAS Systems                                                   | -        | 28       |
| DiaSorin Liaison B. burgdorferi Chemiluminescent Assay                               | -        | 14       |
| Immunetics C6 B. burgdorferi EIA Test                                                | -        | 18       |
| Laboratory developed assay                                                           | -        | 2        |
| MarDx Lyme Disease EIA (IgM &amp; IgG)                                                   | -        | 5        |
| Meridien Premier LYME EIA                                                            | -        | 1        |
| Trinity Biotech B. burgdorferi IgG/IgM                                               | -        | 1        |
| Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)                                  | -        | 23       |</p>
<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>SAMPLE 44 - 100% of participants reported negative.</td>
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<tr>
<td>All Labs</td>
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<tr>
<td>Bio-Rad Evolis</td>
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</tr>
<tr>
<td>Bio-Rad PhD EIA System</td>
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<tr>
<td>Bio-Rad Platelia Lyme IgG/IgM</td>
<td></td>
</tr>
<tr>
<td>bioMerieux VIDAS/mini VIDAS Systems</td>
<td></td>
</tr>
<tr>
<td>DiaSorin Liaison B. burgdorferi Chemiluminescent Assay</td>
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<tr>
<td>Immunetics C6 B. burgdorferi EIA Test</td>
<td></td>
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<tr>
<td>Laboratory developed assay</td>
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</tr>
<tr>
<td>MarDx Lyme Disease EIA (IgM &amp; IgG)</td>
<td></td>
</tr>
<tr>
<td>Meriden Premier LYME EIA</td>
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<tr>
<td>Trinity Biotech B. burgdorferi IgG/IgM</td>
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<tr>
<td>Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)</td>
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</table>

| SAMPLE 45 - 100% of participants reported negative.         |          |          |
| All Labs                                                    |          | 96       |
| Bio-Rad Evolis                                              |          | 1        |
| Bio-Rad PhD EIA System                                      |          | 2        |
| Bio-Rad Platelia Lyme IgG/IgM                               |          | 1        |
| bioMerieux VIDAS/mini VIDAS Systems                         |          | 28       |
| DiaSorin Liaison B. burgdorferi Chemiluminescent Assay      |          | 14       |
| Immunetics C6 B. burgdorferi EIA Test                       |          | 18       |
| Laboratory developed assay                                  |          | 2        |
| MarDx Lyme Disease EIA (IgM & IgG)                          |          | 5        |
| Meriden Premier LYME EIA                                    |          | 1        |
| Trinity Biotech B. burgdorferi IgG/IgM                      |          | 1        |
| Wampole/Zeus B. burgdorferi IgG/IgM EIA Tests (any)         |          | 23       |
## Qualitative Lyme Western Blot IgG - Diagnostic Services

<table>
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<tr>
<th>Primary Test Kit/Assay</th>
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<tr>
<td><strong>SAMPLE 41 - 100% of participants reported negative.</strong></td>
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<tr>
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<tr>
<td>MarDx Lyme Disease (IgG) Marblot Strip Test</td>
<td>-</td>
</tr>
<tr>
<td>Viroblot Borrelia B-31 IgG/IgM</td>
<td>-</td>
</tr>
<tr>
<td><strong>SAMPLE 42 - 100% of participants reported positive.</strong></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
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<td>MarDx Lyme Disease (IgG) Marblot Strip Test</td>
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</tr>
<tr>
<td>Viroblot Borrelia B-31 IgG/IgM</td>
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<tr>
<td><strong>SAMPLE 43 - 100% of participants reported negative.</strong></td>
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<tr>
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<tr>
<td>MarDx Lyme Disease (IgG) Marblot Strip Test</td>
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<td><strong>SAMPLE 44 - 100% of participants reported negative.</strong></td>
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<tr>
<td>MarDx Lyme Disease (IgG) Marblot Strip Test</td>
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</tr>
<tr>
<td>Viroblot Borrelia B-31 IgG/IgM</td>
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<tr>
<td><strong>SAMPLE 45 - 100% of participants reported negative.</strong></td>
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</tr>
<tr>
<td>All Labs</td>
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<tr>
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<tr>
<td>MarDx Lyme Disease (IgG) Marblot Strip Test</td>
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<td>Viroblot Borrelia B-31 IgG/IgM</td>
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### Qualitative Lyme Western Blot IgM - Diagnostic Services

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<th>Negative</th>
<th>Equivocal</th>
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<tbody>
<tr>
<td><strong>SAMPLE 41</strong> - 100% of participants reported negative.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>All Labs</td>
<td>-</td>
<td>34</td>
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<td>-</td>
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<tr>
<td>MarDx Lyme Disease (IgM) Marblot Strip Test</td>
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<td>28</td>
<td>-</td>
</tr>
<tr>
<td>Viroblot Borrelia B-31 IgG/IgM</td>
<td>-</td>
<td>4</td>
<td>-</td>
</tr>
</tbody>
</table>

| **SAMPLE 42** - 41% of participants reported positive. * | | | |
| All Labs | 14 | 17 | 3 |
| Laboratory developed assay | 2 | - | - |
| MarDx Lyme Disease (IgM) Marblot Strip Test | 9 | 16 | 3 |
| Viroblot Borrelia B-31 IgG/IgM | 3 | 1 | - |

| **SAMPLE 43** - 100% of participants reported negative. | | | |
| All Labs | - | 34 | - |
| Laboratory developed assay | - | 2 | - |
| MarDx Lyme Disease (IgM) Marblot Strip Test | - | 28 | - |
| Viroblot Borrelia B-31 IgG/IgM | - | 4 | - |

| **SAMPLE 44** - 100% of participants reported negative. | | | |
| All Labs | - | 34 | - |
| Laboratory developed assay | - | 2 | - |
| MarDx Lyme Disease (IgM) Marblot Strip Test | - | 28 | - |
| Viroblot Borrelia B-31 IgG/IgM | - | 4 | - |

| **SAMPLE 45** - 100% of participants reported negative. | | | |
| All Labs | - | 34 | - |
| Laboratory developed assay | - | 2 | - |
| MarDx Lyme Disease (IgM) Marblot Strip Test | - | 28 | - |
| Viroblot Borrelia B-31 IgG/IgM | - | 4 | - |

* Sample #42 is not validated, the expected result is negative. When a consensus agreement cannot be reached among all participants, by regulation requirements, the sample cannot be scored and all participating laboratories get credit for this sample.
### Qualitative Rheumatoid Factor - Diagnostic Services

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
</tr>
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<tbody>
<tr>
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<tr>
<td><strong>SAMPLE 26 - 99% of participants reported positive.</strong></td>
<td></td>
</tr>
<tr>
<td>All Labs</td>
<td>96</td>
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<tr>
<td>Abbott Aeroset</td>
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</tr>
<tr>
<td>Arlington Scientific RF Latex Test</td>
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</tr>
<tr>
<td>Beckman Coulter Immage</td>
<td>2</td>
</tr>
<tr>
<td>Beckman Coulter AU System</td>
<td>1</td>
</tr>
<tr>
<td>Becton Dickinson RF Scan Latex</td>
<td>2</td>
</tr>
<tr>
<td>Biokit Rheumajet RF Latex</td>
<td>13</td>
</tr>
<tr>
<td>Cardinal Health SP RF Latex</td>
<td>3</td>
</tr>
<tr>
<td>Diamedix RF EIA Systems</td>
<td>1</td>
</tr>
<tr>
<td>Fisher Sure-Vue RF Latex</td>
<td>39</td>
</tr>
<tr>
<td>Ortho Vitros (all models)</td>
<td>2</td>
</tr>
<tr>
<td>Remel Seratest RF Latex Test</td>
<td>4</td>
</tr>
<tr>
<td>Roche Diagnostics Cobas (all systems)</td>
<td>2</td>
</tr>
<tr>
<td>Roche/Hitachi Modular Systems (all models)</td>
<td>2</td>
</tr>
<tr>
<td>Seradyn Color Slide RF</td>
<td>1</td>
</tr>
<tr>
<td>Siemens ADVIA 1200/1650/1800/2400</td>
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</tr>
<tr>
<td>Siemens Dimension VISTA</td>
<td>3</td>
</tr>
<tr>
<td>Siemens Nephelometer Systems (all models)</td>
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</tr>
<tr>
<td>Siemens (Dade Behring) RapiTex Latex Test</td>
<td>4</td>
</tr>
<tr>
<td>True Medix Diagnostics Trutest RF</td>
<td>3</td>
</tr>
<tr>
<td>Wampole Colorcard RF</td>
<td>1</td>
</tr>
<tr>
<td>Wampole Rheumatoid Factor ELISA</td>
<td>1</td>
</tr>
<tr>
<td>Wampole Rheumatex RF</td>
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</table>

**SAMPLE 27 - 99% of participants reported negative.**

<table>
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<th>Participant Results</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>All Labs</td>
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</tr>
<tr>
<td>Abbott Aeroset</td>
<td>-</td>
</tr>
<tr>
<td>Arlington Scientific RF Latex Test</td>
<td>-</td>
</tr>
<tr>
<td>Beckman Coulter Immage</td>
<td>-</td>
</tr>
<tr>
<td>Beckman Coulter AU System</td>
<td>-</td>
</tr>
<tr>
<td>Becton Dickinson RF Scan Latex</td>
<td>-</td>
</tr>
<tr>
<td>Biokit Rheumajet RF Latex</td>
<td>-</td>
</tr>
<tr>
<td>Cardinal Health SP RF Latex</td>
<td>-</td>
</tr>
<tr>
<td>Diamedix RF EIA Systems</td>
<td>-</td>
</tr>
<tr>
<td>Fisher Sure-Vue RF Latex</td>
<td>-</td>
</tr>
<tr>
<td>Ortho Vitros (all models)</td>
<td>-</td>
</tr>
<tr>
<td>Remel Seratest RF Latex Test</td>
<td>-</td>
</tr>
<tr>
<td>Roche Diagnostics Cobas (all systems)</td>
<td>-</td>
</tr>
<tr>
<td>Roche/Hitachi Modular Systems (all models)</td>
<td>-</td>
</tr>
<tr>
<td>Seradyn Color Slide RF</td>
<td>-</td>
</tr>
<tr>
<td>Siemens ADVIA 1200/1650/1800/2400</td>
<td>-</td>
</tr>
<tr>
<td>Siemens Dimension VISTA</td>
<td>-</td>
</tr>
<tr>
<td>Siemens Nephelometer Systems (all models)</td>
<td>-</td>
</tr>
<tr>
<td>Siemens (Dade Behring) RapiTex Latex Test</td>
<td>-</td>
</tr>
<tr>
<td>True Medix Diagnostics Trutest RF</td>
<td>-</td>
</tr>
<tr>
<td>Wampole Colorcard RF</td>
<td>-</td>
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<tr>
<td>Wampole Rheumatoid Factor ELISA</td>
<td>-</td>
</tr>
<tr>
<td>Wampole Rheumatex RF</td>
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</table>
## Qualitative Rheumatoid Factor - Diagnostic Services

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
<th></th>
</tr>
</thead>
</table>
| All Labs                                                    | Positive           | 96| Genuine
| Abbott Aeroset                                              | Negative           | 1 | Genuine
| Arlington Scientific RF Latex Test                          | All Labs            | 96| Genuine
| Beckman Coulter Immage                                      | Negative           | 1 | Genuine
| Beckman Coulter AU System                                   | Positive           | 2 | Genuine
| Becton Dickinson RF Scan Latex                              | Negative           | 2 | Genuine
| Biokit Rheumajet RF Latex                                   | Positive           | 13| Genuine
| Cardinal Health SP RF Latex                                 | Negative           | 3 | Genuine
| Diamedix RF EIA Systems                                     | Positive           | 1 | Genuine
| Fisher Sure-Vue RF Latex                                    | Negative           | 39| Genuine
| Ortho Vitros (all models)                                   | All Labs            | 2 | Genuine
| Remel Seratest RF Latex Test                                | Negative           | 4 | Genuine
| Roche Diagnostics Cobas (all systems)                       | Positive           | 2 | Genuine
| Roche/Hitachi Modular Systems (all models)                  | Negative           | 2 | Genuine
| Seradyn Color Slide RF                                       | Positive           | 1 | Genuine
| Siemens ADVIA 1200/1650/1800/2400                            | Negative           | 3 | Genuine
| Siemens Dimension VISTA                                     | Positive           | 3 | Genuine
| Siemens Nephelometer Systems (all models)                   | Negative           | 1 | Genuine
| Siemens (Dade Behring) RapiTex Latex Test                   | Positive           | 4 | Genuine
| True Medix Diagnostics Trutest RF                            | Negative           | 3 | Genuine
| Wampole Colorcard RF                                         | Positive           | 1 | Genuine
| Wampole Rheumatoid Factor ELISA                              | Negative           | 1 | Genuine
| Wampole Rheumatex RF                                         | Positive           | 1 | Genuine

### SAMPLE 29 - 99% of participants reported positive.

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>Participant Results</th>
<th></th>
</tr>
</thead>
</table>
| All Labs                                                    | Positive           | 96| Genuine
| Abbott Aeroset                                              | Negative           | 1 | Genuine
| Arlington Scientific RF Latex Test                          | All Labs            | 96| Genuine
| Beckman Coulter Immage                                      | Negative           | 1 | Genuine
| Beckman Coulter AU System                                   | Positive           | 2 | Genuine
| Becton Dickinson RF Scan Latex                              | Negative           | 2 | Genuine
| Biokit Rheumajet RF Latex                                   | Positive           | 13| Genuine
| Cardinal Health SP RF Latex                                 | Negative           | 3 | Genuine
| Diamedix RF EIA Systems                                     | Positive           | 1 | Genuine
| Fisher Sure-Vue RF Latex                                    | Negative           | 39| Genuine
| Ortho Vitros (all models)                                   | All Labs            | 2 | Genuine
| Remel Seratest RF Latex Test                                | Negative           | 4 | Genuine
| Roche Diagnostics Cobas (all systems)                       | Positive           | 2 | Genuine
| Roche/Hitachi Modular Systems (all models)                  | Negative           | 2 | Genuine
| Seradyn Color Slide RF                                       | Positive           | 1 | Genuine
| Siemens ADVIA 1200/1650/1800/2400                            | Negative           | 3 | Genuine
| Siemens Dimension VISTA                                     | Positive           | 3 | Genuine
| Siemens Nephelometer Systems (all models)                   | Negative           | 1 | Genuine
| Siemens (Dade Behring) RapiTex Latex Test                   | Positive           | 4 | Genuine
| True Medix Diagnostics Trutest RF                            | Negative           | 3 | Genuine
| Wampole Colorcard RF                                         | Positive           | 1 | Genuine
| Wampole Rheumatoid Factor ELISA                              | Negative           | 1 | Genuine
| Wampole Rheumatex RF                                         | Positive           | 2 | Genuine
## Qualitative Rheumatoid Factor - Diagnostic Services

<table>
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<th>Negative</th>
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<tbody>
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<td>Beckman Coulter AU System</td>
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<td>Becton Dickinson RF Scan Latex</td>
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<td>Biokit Rheumajet RF Latex</td>
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<td>Cardinal Health SP RF Latex</td>
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<td>Fisher Sure-Vue RF Latex</td>
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<td>Ortho Vitros (all models)</td>
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<td>True Medix Diagnostics Trutest RF</td>
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SAMPLE 30 - 100% of participants reported negative.
## Rheumatoid Factor Titers - Diagnostic Services

The number of laboratories that reported titers is listed for positive test samples 26, 28 and 29.

<table>
<thead>
<tr>
<th>Primary Test Kit/Assay</th>
<th>No. Labs</th>
<th>Sample 26 Titers</th>
<th>Sample 28 Titers</th>
<th>Sample 29 Titers</th>
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<tbody>
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<td>&lt; 1:1 1:1 1:2 1:4 1:8 &gt;=1:16</td>
<td>&lt; 1:1 1:1 1:2 1:4 1:8 &gt;=1:16</td>
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<td>- - - 1 1 2</td>
<td>- - - 2 2</td>
<td>- - - 3 3</td>
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<td>- - - - 1 -</td>
<td>- - - - 1 -</td>
</tr>
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<td>- - - - 4 -</td>
<td>- - - - 4 -</td>
<td>- - - - 4 -</td>
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<tr>
<td>Cardinal Health SP RF Latex</td>
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<td>- - - - - -</td>
<td>- - - - - -</td>
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<td>- - - 7 4 1</td>
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<td>- - - - - 1</td>
<td>- - - - - 1</td>
</tr>
<tr>
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<td>- - - 1 1 -</td>
<td>- - - 1 1 -</td>
<td>- - - 2 2 -</td>
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<td>1 - - - - -</td>
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</tbody>
</table>

**Sample 26 Titers**

<table>
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<tr>
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**Sample 28 Titers**

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**Sample 29 Titers**

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### Semi-Quantitative Rheumatoid Factor - Diagnostic Services

The number of laboratories reporting semi-quantitative results for positive samples 26, 28 and 29.

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

Results are summarized for positive test samples 26, 28 and 29. Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

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<th>Sample 26 Method</th>
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Quantitative Rheumatoid Factor (RF) IU/ml - Diagnostic Services

Results are summarized for positive test samples 26, 28 and 29. Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

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<th>Sample 29 Method</th>
<th>Primary Test Kit/Assay</th>
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### Qualitative Rubella Ab - Diagnostic Services

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<th>SAMPLE 12 - 99% of participants reported positive.</th>
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*One laboratory reported an equivocal result.*
Qualitative Rubella Ab - Diagnostic Services

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<th>Participant Results</th>
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<td>Bio-Rad Rubella IgG EIA</td>
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<td>Diasorin Liaison Rubella IgG</td>
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*One laboratory reported an equivocal result.
## Qualitative Rubella Ab - Diagnostic Services

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* One laboratory reported an equivocal result.
Quantitative Rubella Ab IU/ml - Diagnostic Services

Results are summarized for positive test samples 12 and 15. Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

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Qualitative Rubella IgM Specific - Diagnostic Services

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<th>Participant Results</th>
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<tbody>
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</table>

**SAMPLE 56 - 100% of participants reported negative.**

| All Labs                |          | 15       |
| Diamedix Rubella EIA Systems IgM |          | 1        |
| Rubella IgM EIA Systems   |          | 1        |
| Siemens ADVIA Centaur    |          | 2        |
| Siemens Immulite Systems (all models) |          | 10       |
| Zeus Rubella IgM EIA     |          | 1        |

**SAMPLE 57 - 100% of participants reported negative.**

| All Labs                |          | 15       |
| Diamedix Rubella EIA Systems IgM |          | 1        |
| Rubella IgM EIA Systems   |          | 1        |
| Siemens ADVIA Centaur    |          | 2        |
| Siemens Immulite Systems (all models) |          | 10       |
| Zeus Rubella IgM EIA     |          | 1        |

**SAMPLE 58 - 100% of participants reported negative.**

| All Labs                |          | 15       |
| Diamedix Rubella EIA Systems IgM |          | 1        |
| Rubella IgM EIA Systems   |          | 1        |
| Siemens ADVIA Centaur    |          | 2        |
| Siemens Immulite Systems (all models) |          | 10       |
| Zeus Rubella IgM EIA     |          | 1        |

**SAMPLE 59 - 100% of participants reported negative.**

| All Labs                |          | 15       |
| Diamedix Rubella EIA Systems IgM |          | 1        |
| Rubella IgM EIA Systems   |          | 1        |
| Siemens ADVIA Centaur    |          | 2        |
| Siemens Immulite Systems (all models) |          | 10       |
| Zeus Rubella IgM EIA     |          | 1        |

**SAMPLE 60 - 100% of participants reported positive.**

| All Labs                |          |          |
| Diamedix Rubella EIA Systems IgM |          | 1        |
| Rubella IgM EIA Systems   |          | 1        |
| Siemens ADVIA Centaur    |          | 2        |
| Siemens Immulite Systems (all models) |          | 10       |
| Zeus Rubella IgM EIA     |          | 1        |
### Qualitative Syphilis Reagin Ab - Diagnostic Services

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<th>Nonreactive</th>
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## Qualitative Syphilis Reagin Ab - Diagnostic Services

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Syphilis Reagin Ab (RPR) Titers - Diagnostic Services

The number of laboratories that reported titers is listed for reactive test samples 03 and 04.

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## Qualitative Syphilis Reagin Ab - Donor Services

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## Qualitative Syphilis Treponemal Ab - Diagnostic Services

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### Qualitative Syphilis Treponemal Ab - Diagnostic Services

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

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

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

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

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

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

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

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

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

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

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

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Quantitative Complement C4 (mg/dl) - Diagnostic Services
Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

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Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services
Acceptable ranges are given where 10 or more laboratories reported quantitative results. * Outlier values and values with qualifiers are omitted from statistics.

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

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Quantitative Immunoglobulin A (mg/dl) - Diagnostic Services

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Quantitative Immunoglobulin E (IU/ml) - Diagnostic Services

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

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

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

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

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

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

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Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

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

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

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

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Quantitative Immunoglobulin G (mg/dl) - Diagnostic Services

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

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

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

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  *Beckman Coulter Immage* | 13   | 12   | 7.16 | 12.03 | 9.60 | 0.81  |

  *Siemens Dimension/Vista/Xpand (all models)* | 11   | 4    | -    | -    | 9.82 | -     |

  *Siemens Nephelometer Systems (all models)* | 13   | 9    | -    | -    | 9.74 | -     |

| Turbidimetry Total |                        | 68         |                  | 37   | 5.96 | 16.13 | 11.05 | 1.70  |

  *Beckman Coulter Synchron LX/Unicel Systems (all models)* | 13   | 5    | 7.85 | 13.55 | 10.70 | 0.95  |

  *Beckman Coulter (formerly Olympus) AU System* | 11   | 5    | -    | -    | 10.00 | -     |

  *Ortho Vitros (all models)* | 5    | 1    | -    | -    | 10.00 | -     |

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  *Beckman Coulter Immage* | 13   | 13   | 129.87 | 168.13 | 149.00 | 6.38  |

  *Siemens Dimension/Vista/Xpand (all models)* | 11   | 11   | 139.06 | 180.22 | 159.64 | 6.86  |

  *Siemens Nephelometer Systems (all models)* | 13   | 13   | 137.79 | 177.54 | 157.67 | 6.62  |

| Turbidimetry Total |                        | 68         |                  | 68   | 117.88 | 170.01 | 143.95 | 8.69  |

  *Abbott Architect* | 5    | 5    | -    | -    | 143.20 | -     |

  *Beckman Coulter Synchron LX/Unicel Systems (all models)* | 7    | 7    | -    | -    | 139.71 | -     |

  *Beckman Coulter (formerly Olympus) AU System* | 11   | 11   | 117.55 | 147.88 | 132.71 | 5.05  |

  *Ortho Vitros (all models)* | 5    | 5    | -    | -    | 148.64 | -     |

  *Roche Diagnostics Cobas (all systems)* | 16   | 16   | 145.00 | 163.31 | 154.15 | 3.05  |

  *Roche/Hitachi Modular Systems (all models)* | 13   | 13   | 123.22 | 162.89 | 143.06 | 6.61  |

  *Siemens ADVIA 1200/1650/1800/2400* | 8    | 8    | -    | -    | 144.14 | -     |

  *Siemens Dimension/Vista/Xpand (all models)* | 3    | 3    | -    | -    | 160.33 | -     |
# Quantitative Immunoglobulin M (mg/dl) - Diagnostic Services

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

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<th>Acceptable Range</th>
<th>Primary Test Kit/Assay</th>
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