Rubella IgG

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>List Number</td>
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<td>Caution</td>
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<tr>
<td></td>
<td>Consult instructions for use</td>
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<td>Septum</td>
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<td>Replacement Caps</td>
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<td>Assay CD-ROM</td>
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<td>Control Number</td>
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<td>WARNING: SENSITIZER</td>
<td>Warning: Sensitizer</td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
NAME
ARCHITECT Rubella IgG

INTENDED USE
ARCHITECT Rubella IgG is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination and qualitative detection of IgG antibodies to rubella virus in human serum and plasma on the ARCHITECT i2000 System. The ARCHITECT Rubella IgG assay is intended to aid in the determination of immune status to rubella.

SUMMARY AND EXPLANATION OF TEST
Primary postnatal rubella virus infection is typically a mild self-limiting disease characterized by a maculopapular rash, fever, malaise and lymphadenopathy. In contrast to postnatal infections, primary prenatal infections may have devastating effects. In utero infections may severely damage the fetus, particularly if occurring during the first four months of gestation. The congenitally infected infant may exhibit one or more of a variety of defects collectively known as the congenital rubella syndrome (CRS). Among these are low birth weight, cataracts, deafness, congenital heart disease, and mental retardation. The World Health Organization (WHO) conducted a worldwide survey on rubella, CRS, and rubella vaccine infections may have devastating effects.

Variety of defects collectively known as the congenital rubella syndrome (CRS). Among these are low birth weight, cataracts, deafness, congenital heart disease, and mental retardation. The World Health Organization (WHO) conducted a worldwide survey on rubella, CRS, and rubella vaccine infections may have devastating effects.

Both naturally acquired and vaccine induced immunity to rubella virus antibodies associated with antibody persistence have been shown to provide protection from clinical rubella upon reinfection. The widespread use of highly effective and safe vaccines dramatically reduced the incidence of rubella and CRS in the United States. In spite of this reduction, rubella outbreaks continue to occur. The number of cases of rubella reported annually to the WHO Regional Office for Europe has remained fairly stable over the past decade, with 30,432 cases reported during 2003. These occurrences indicate a need for continued serological surveillance to identify susceptible individuals and reduce the potential risk to CRS. The presence of at least 10 International Units (IU) of antibody per mL of sample is indicative of past exposure to rubella virus. Antibody levels below 10 IU/mL may be insufficient to provide protection from clinical illness upon exposure to rubella virus.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE
The ARCHITECT Rubella IgG assay is a two-step immunoassay for the quantitative determination and qualitative detection of IgG antibodies to rubella virus in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex. In the first step, sample, assay diluent, and partially purified rubella virus coated paramagnetic microparticles are combined. IgG antibodies to rubella virus present in the sample bind to the rubella virus coated microparticles. After washing, anti-human IgG acridinium-labeled conjugate is added to create a reaction mixture in the second step. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of IgG antibodies to rubella in the sample and the RLUs detected by the ARCHITECT Assay System optoelectronics.

REAGENTS
Reagent Kit, 100 Tests/500 Tests
NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT Systems. Please contact your local distributor.
ARCHITECT Rubella IgG Reagent Kit (8C17)
- **MICROPARTICLES** 1 bottle (6.6 mL per 100 test bottle/27.0 mL per 500 test bottle) partially purified rubella virus coated microparticles in TRIS buffer with surfactant. Preservatives: sodium azide and ProClin 950.
- **CONJUGATE** 1 bottle (5.9 mL per 100 test bottle/26.3 mL per 500 test bottle) Anti-human IgG (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with surfactant and protein (bovine) stabilizer. Minimum concentration: 16 ng/mL. Preservatives: antimicrobial agents.

ASAY DILUENT 1 bottle (10.0 mL per 100 test bottle/50.9 mL per 500 test bottle) Assay Diluent in TRIS buffer with surfactant and protein (bovine, goat, mouse) stabilizers. Preservatives: ProClin 950 and ProClin 300.

Assay Diluent
ARCHITECT i2000 Multi-Assay Manual Diluent (No. 7D82-50)
- **MULTI-ASSAY MANUAL DILUENT** 1 bottle (100 mL) ARCHITECT i2000 Multi-Assay Manual Diluent containing phosphate buffered saline solution. Preservative: antimicrobial agent.

Other Reagents
ARCHITECT i2000 Pre-Trigger Solution
- Pre-trigger solution containing 1.32% (w/v) hydrogen peroxide.
ARCHITECT i2000 Trigger Solution
- Trigger solution containing 0.35 N sodium hydroxide.
ARCHITECT Assay Wash Buffer
- Wash buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

WARNINGS AND PRECAUTIONS

- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

**CAUTION:** This product contains human sourced and/or potentially infectious components. Refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. BioSafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

The Microparticles contain methylisothiazolones, which are components of ProClin, and are classified per applicable European Community (EC) Directives as: Irritant (XI). The following are the appropriate Risk (R) and Safety (S) phrases.

- R43 May cause sensitization by skin contact.
- S24 Avoid contact with skin.
- S35 This material and its container must be disposed of in a safe way.
- S37 Wear suitable gloves.
- S46 If swallowed, seek medical advice immediately and show this container or label.

The Assay Diluent contains methylisothiazolones, which are components of ProClin, and are classified per applicable European Community (EC) Directives as: Irritant (XII). The following are the appropriate Risk (R) and Safety (S) phrases.

- R36 Irritating to eyes.
- R43 May cause sensitization by skin contact.
- S24 Avoid contact with skin.
- S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S35 This material and its container must be disposed of in a safe way.
- S37/39 Wear suitable gloves and eye/face protection.
- S46 If swallowed, seek medical advice immediately and show this container or label.

- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
- This product contains sodium azide; for a specific listing, refer to the REAGENTS section. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.
- For information on the safe disposal of sodium azide and a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.
Handling Precautions
- Do not use reagent kits beyond the expiration date.
- Do not pool reagents within a kit or between reagent kits.
- Before loading the ARCHITECT Rubella IgG Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. For microparticle mixing instructions, refer to the PROCEDURE, Assay Procedure section of this package insert.
- Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.
- To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
- When handling conjugate vials, change gloves that have contacted human serum or plasma, since introduction of human IgG will result in a neutralized conjugate.
- Once a septum has been placed on the reagent bottle, do not invert the bottle as this will result in reagent leakage and may compromise assay results.
- Over time, residual liquids may dry on the septum surface. These are typically dried salts, which have no effect on assay efficacy.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration
When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PREPARATION
- The ARCHITECT Rubella IgG assay file must be installed on the ARCHITECT i System from the ARCHITECT i Assay CD-ROM Addition B before performing the assay. For detailed information on assay file installation and on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS
Specimen Types
The specimen collection tubes listed below were verified to be used with the ARCHITECT Rubella IgG assay. Other specimen collection tubes have not been tested with this assay:
- Human serum (including serum collected in serum separator tubes)
- Human plasma collected in:
  - Sodium EDTA
  - Lithium Heparin (plasma separator tube)
  - Potassium EDTA
  - Sodium Heparin
  - Lithium Heparin
  - Sodium Citrate*
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens. Sodium citrate specimens may result in a -16.8% bias when compared to serum specimens.
- The ARCHITECT i System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the ARCHITECT Rubella IgG assay.

Indications of Reagent Deterioration
- Do not use specimens with the following conditions:
  - heat-inactivated
  - pooled
  - grossly hemolyzed
  - obvious microbial contamination
  - cadaver specimens or any other body fluids
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- For optimal results, inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Specimen Conditions
- Follow the tube manufacturer’s processing instructions for serum and plasma collection tubes. Gravity separation is not sufficient for specimen preparation.
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at x 10000 RCF (Relative Centrifugal Force) for 10 minutes before testing if:
  - they contain fibrin, red blood cells, or other particulate matter,
  - they require repeat testing, or
  - they were frozen and thawed.
- Transfer clarified specimen to a sample cup or secondary tube for testing.
- Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.

Storage
- Specimens may be stored on or off the clot, red blood cell, or separator gel for up to 14 days refrigerated at 2-8°C.
- If testing will be delayed more than 14 days, remove serum or plasma from clot, red blood cells, or separator gel and store frozen (-10°C or colder).
- Specimens stored frozen for 1 month showed acceptable performance. Avoid multiple freeze/thaw cycles.

Shipping
- Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells, or separator gel.
- When shipping specimens, package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Specimens may be shipped on wet or dry ice. Do not exceed the storage time limitations listed above.
PROCEDURE

Materials Provided
- ARCHITECT Rubella IgG Reagent Kit
- Pipettes or pipette tips (optional)
- Multi-Assay Manual Diluent
- Multi-Assay Manual

Materials Required but not Provided
- ARCHITECT / System
- Pre-trigger Solution
- Trigger Solution
- Wash Buffer
- Reaction Vessels
- Sample Cups
- Septum
- Replacement Caps

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

1. Before loading the ARCHITECT Rubella IgG Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
   - Invert the microparticle bottle 30 times.
   - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles remain adhered to the bottle, continue inverting the bottle until the microparticles have been completely resuspended.
   - If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.

2. Once the microparticles have been resuspended, place a septum on the bottle. For instructions on placing septums on bottles, refer to the Handling Precautions section of this package insert.

3. Load the ARCHITECT Rubella IgG Reagent Kit on the ARCHITECT / System.
   - Verify that all necessary assay reagents are present.
   - Ensure that septums are present on all reagent bottles.

4. Order calibration, if necessary.
   - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 8.

5. Order tests.
   - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.

6. The minimum sample cup volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation, verify adequate sample cup volume is present before running the test.
   - Priority: 70 μL for the first ARCHITECT Rubella IgG test plus 20 μL for each additional ARCHITECT Rubella IgG test from the same sample cup.
   - ≤ 3 hours on board: 150 μL for the first ARCHITECT Rubella IgG test plus 25 μL for each additional ARCHITECT Rubella IgG test from the same sample cup.
   - > 3 hours on board: additional sample volume is required. For information on sample evaporation and volumes, refer to the ARCHITECT System Operations Manual, Section 5.
   - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.

7. Prepare calibrators and controls.
   - Mix ARCHITECT Rubella IgG Calibrators and Controls by gentle inversion before use.
   - To obtain the recommended volume requirements for the ARCHITECT Rubella IgG Calibrators and Controls, hold the bottles vertically and dispense 5 drops of each calibrator or 5 drops of each control into each respective sample cup.

8. Load samples.
   - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
   - For additional information on principles of operation, refer to the ARCHITECT System Operations Manual, Section 3.
   - For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 5. When a laboratory requires more frequent maintenance, follow those procedures.

Specimen Dilution Procedures

Specimens with concentrations greater than 500.0 IU/mL of IgG antibodies to rubella will be flagged as “>500.0 IU/mL,” and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

- If using the Automated Dilution Protocol, the system performs a 1:10 dilution of the specimen and automatically calculates the concentration of the specimen before dilution and reports the result.

- Manual dilutions should be performed as follows:
  - The suggested dilution for the ARCHITECT Rubella IgG assay is 1:10.
  - Add 20 μL of the patient specimen to 180 μL of ARCHITECT Rubella IgG Calibrator A or ARCHITECT / Multi-Assay Manual Diluent.
  - The operator must enter the dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The result (before the dilution factor is applied) should be greater than 5 IU/mL.

- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

- To perform an ARCHITECT Rubella IgG calibration, test calibrators A, B, C, D, E, and F in replicates of two. A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the control package insert. Calibrators should be priority loaded.

- Calibration Range: 0.0 to 500.0 IU/mL.

- Once an ARCHITECT Rubella IgG calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
  - A reagent kit with a new lot number is used.
  - Controls are out of range.

- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

QUALITY CONTROL PROCEDURES

The recommended control requirement for the ARCHITECT Rubella IgG assay is that a single sample of each control be tested once every 24 hours each day of use. If laboratory quality control procedures require more frequent use of controls to verify test results, follow those procedures.

The ARCHITECT Rubella IgG Control values must be within the acceptable ranges specified in the control package insert. If a control is out of its specified range, the associated test results are invalid and samples must be retested. Recalibration may be indicated.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT Rubella IgG assay belongs to method group 1.

ARCHITECT Rubella IgG Calibrators may be used when MasterCheck is not available. Refer to the ARCHITECT System Operations Manual, Appendix B.
RESULTS

Standardization

The ARCHITECT Rubella IgG assay is referenced to the World Health Organization (WHO) 1st International Standard (RUBI-1-94) for Anti-Rubella Immunoglobulin. The concentration values for Rubella IgG in a given specimen can vary based on assay method and standardization and should not be used interchangeably.

Calculation

The ARCHITECT Rubella IgG assay uses a 4 Parameter Logistic Curve fit (4PLC, Y-weighted) data reduction method to generate a calibration curve.

Interpretation of Results

For details on configuring the ARCHITECT i System to use grayzone interpretations, refer to the ARCHITECT System Operations Manual, Section 2.

Negative: 0.0 to 4.9 IU/mL
Grayzone (Equivocal): 5.0 to 9.9 IU/mL
Positive: ≥10.0 IU/mL

Flags

- Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays.\(^\text{12}\) Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA).\(^\text{13,14}\) Specimens containing HAMA may produce anomalous values when tested with assay kits (such as ARCHITECT Rubella IgG) that employ mouse monoclonal antibodies.\(^\text{13}\)

EXPECTED VALUES

The incidence of Rubella IgG antibodies varies among populations depending on vaccination practices. In this study, an asymptomatic population composed of 1253 specimens (fresh and frozen) from pregnant women, random individuals, and negative samples were tested. Of these specimens, 935 (75%) were positive, 74 (6%) were equivocal and, 244 (19%) were negative by ARCHITECT Rubella IgG assay. The distribution of this population is shown below.\(^\ast\)

[Graph showing distribution of ARCHITECT Rubella IgG (IU/mL) with bars for Pregnant Women, Random Individuals, and Prescreened Specimens]

\(\ast\) Representative data; results in individual laboratories may vary from these data.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT Rubella IgG assay is designed to have a precision of ≤ 10% total CV within the range of 15.0 to 180.0 IU/mL and ≤ 20% total CV from greater than 180.0 IU/mL to 500.0 IU/mL.

A study was performed with the ARCHITECT Rubella IgG assay based on guidance from the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) document EPS-A2.\(^\text{15}\) A total of six levels of panels and controls were assayed, using three lots of reagents, on three instruments, in replicates of two at two separate times per day for 20 days. Data from this study are summarized in the following table.\(^\ast\) The Negative Control concentration ranged from 0.0 to 0.1 IU/mL.

### Specific Performance Characteristics

<table>
<thead>
<tr>
<th>Sample</th>
<th>Reagent</th>
<th>Mean Conc. (IU/mL)</th>
<th>Within Run SD</th>
<th>Total SD</th>
<th>%CV</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>1</td>
<td>1 80</td>
<td>26.3</td>
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<tr>
<td>Control</td>
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<td>24.4</td>
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<td>6.2</td>
<td>1.9</td>
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<tr>
<td>1</td>
<td>3</td>
<td>80</td>
<td>25.6</td>
<td>1.5</td>
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<td>2</td>
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<td>80</td>
<td>27.1</td>
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<td>25.7</td>
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<td>5.1</td>
<td>1.7</td>
</tr>
</tbody>
</table>

\(\ast\) Representative data; results in individual laboratories may vary from these data.
Dilution Linearity
The ARCHITECT Rubella IgG assay is designed to be linear between 5 and 500 IU/mL based on a study performed with guidance from the CLSI document EP6-A.16

Functional Sensitivity
The ARCHITECT Rubella IgG assay is designed to have a 20% CV at the upper 95% confidence limit of less than 5.0 IU/mL.

In this study, 11 human serum panels ranging in Rubella IgG concentrations from 0.2 - 2.2 IU/mL were tested in replicates of two over ten days on two instruments using two reagent lots and three calibrations for a total of 40 replicates per panel. At the upper 95% confidence limit, the lowest ARCHITECT Rubella IgG assay value exhibiting a 20% CV was calculated to be 1.2 IU/mL, as shown in the graph below.*

* Representative data; results in individual laboratories may vary from these data.

Interference
Potential interference in the ARCHITECT Rubella IgG assay from bilirubin, hemoglobin, total protein, and triglycerides at the levels indicated below is designed to be ≤10% as demonstrated by a study based on guidance from the CLSI document EP7-A2.17 Data from this study are summarized in the following table.*

<table>
<thead>
<tr>
<th>Potentially Interfering Substance</th>
<th>Concentration</th>
<th>% Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>20 mg/dL</td>
<td>≤10.0</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>500 mg/dL</td>
<td>≤10.0</td>
</tr>
<tr>
<td>Red Blood Cells</td>
<td>0.4% v/v</td>
<td>≤10%</td>
</tr>
<tr>
<td>Total protein</td>
<td>3 to 12 g/dL</td>
<td>≤10.0</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>3000 mg/dL</td>
<td>≤10.0</td>
</tr>
</tbody>
</table>

* Representative data; results in individual laboratories may vary from these data.

Other Potential Interferents
Additional studies were performed to evaluate other potential interfering disease states on the ARCHITECT Rubella IgG assay.*

<table>
<thead>
<tr>
<th>Potential Interfering Disease States</th>
<th>% Agreement a</th>
<th>Number of specimens b</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANA</td>
<td>100.0</td>
<td>9</td>
</tr>
<tr>
<td>Epstein-Barr Virus</td>
<td>96.0</td>
<td>25</td>
</tr>
<tr>
<td>HAMA</td>
<td>100.0</td>
<td>9</td>
</tr>
<tr>
<td>Herpes Simplex Virus</td>
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</tr>
<tr>
<td>Hyper IgG</td>
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<td>9</td>
</tr>
<tr>
<td>Hyper IgM</td>
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<tr>
<td>Influenza Vaccines</td>
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<tr>
<td>Measles Virus</td>
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<tr>
<td>Systemic Lupus Erythematosis</td>
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<td>6</td>
</tr>
<tr>
<td>Varicella Zoster Virus</td>
<td>100.0</td>
<td>10</td>
</tr>
</tbody>
</table>

a Compared to a commercially available Rubella IgG assay.
b Specimens giving equivocal results removed.

* Representative data; results in individual laboratories may vary from these data.

CDC Panel Results
The following information is from a panel of coded serum specimens (n=100) provided by the Center for Disease Control (CDC) and tested in a blind study. The sera panel was titered by Hemagglutination Inhibition. The ARCHITECT Rubella IgG assay results on this sera panel consists of 82 positive tests on 82 positive sera and 18 negative tests on 18 negative sera. This does not imply an endorsement of the assay by the CDC.

Initial Relative Agreement
The presence of IgG antibodies to rubella virus in 1253 specimens (fresh and frozen) was determined at three sites using the ARCHITECT Rubella IgG assay. In addition, each specimen was tested using another commercially available Rubella IgG assay. Of the 1253 specimens evaluated, 113 were equivocal by ARCHITECT and/or the commercially available assay and removed from analysis. Seventeen specimens yielded discordant results between ARCHITECT and the commercially available assay. The relative agreement was 98.5% (1123/1140) (95% confidence interval: 97.6% to 99.1%).

Initial Relative Sensitivity
The initial relative sensitivity was 98.4% (932/947) (95% confidence interval: 97.4% to 99.1%).

Initial Relative Specificity
The initial relative specificity was 99.0% (191/193) (95% confidence interval: 96.3% to 99.9%).

Comparison of ARCHITECT Rubella IgG with another commercially available Rubella IgG assay.*

<table>
<thead>
<tr>
<th>Initial Relative Agreement (%)</th>
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</thead>
<tbody>
<tr>
<td>Site I</td>
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<tr>
<td>Mean</td>
</tr>
<tr>
<td>95% CI</td>
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<tr>
<th>Initial Relative Sensitivity (%)</th>
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<th>Initial Relative Specificity (%)</th>
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<tr>
<td>95% CI</td>
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NOTE: Specimens giving equivocal results using ARCHITECT and another commercially available assay were not included in the calculation of relative agreement, relative sensitivity and relative specificity.
a Specificity 100% following consensus testing.

* Representative data; results in individual laboratories may vary from these data.
Consensus Testing

Further evaluation of the 17 discordant samples was performed using another commercially available Rubella IgG assay (Comparison Assay). From this testing, two samples were equivocal, 13 were negative and two were positive.

<table>
<thead>
<tr>
<th>ARCHITECT Result</th>
<th>Comparison Assay</th>
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<tr>
<td>+</td>
<td>2</td>
</tr>
<tr>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>13</td>
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After this additional testing, the consensus relative sensitivity of the ARCHITECT Rubella IgG assay was 100% (95% CI: 99.4%-100%), the consensus relative specificity was 100% (95% CI: 98.5%-100%), and the consensus relative agreement was 100% (95% CI: 99.5%-100%).

* Representative data; results in individual laboratories may vary from these data

BIBLIOGRAPHY