ARCHITECT

SYSTEM

E

Rubella IgM

REF 6C18

34-8771/R3

B6C180

Read Highlighted Changes
Revised December, 2007

Rubella IgM

Customer Service
For additional product information,
please contact your local customer service organization.

This package insert must be read carefully prior to use. 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

REF	List Number	**ASSAY CD-ROM**	Assay CD-ROM
IVD	*In Vitro* Diagnostic Medical Device	**SN**	Serial Number
LOT	Lot Number	**CONTROL NO.**	Control Number
	Expiration Date	**REAGENT LOT**	Reagent Lot
2°C 8°C	Store at 2-8°C	**REACTION VESSELS**	Reaction Vessels
	CAUTION: Consult accompanying documents	**SAMPLE CUPS**	Sample Cups
	Manufacturer	**SEPTUM**	Septum
		REPLACEMENT CAPS	Replacement Caps

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

ABBOTT
Diagnostics Division

NAME

ARCHITECT Rubella IgM

INTENDED USE

The ARCHITECT Rubella IgM assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgM antibodies to Rubella virus in human serum and plasma.

SUMMARY AND EXPLANATION OF TEST

Primary postnatal Rubella infection is typically a mild self-limiting disease characterized by a macropapular rash, fever, malaise and lymphadenopathy.[1] In contrast to postnatal infections, primary prenatal infections may have devastating effects.[1-4] *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.[1,3]

Since Rubella does not have typical symptomatology, the clinical picture can be quite variable. The disease is often difficult or impossible to diagnose from symptoms alone.[1,3,5] The ability to detect the IgM class of anti-Rubella antibody in a single sample overcomes some of the problems associated with paired sera analysis of specific IgG and provides a clearer serodiagnosis picture.

A primary infection is associated with the pronounced IgM antibody response to the Rubella virus.[6] In cases of acute primary infection during pregnancy, IgM has been detected 4 to 15 days after appearance of the rash in nearly 100% of the cases. IgM levels begin to decline after 36 to 70 days, and are infrequently detected after 180 days.[8]

IgM antibody reactive with Rubella virus has been observed following reinfection, however, the levels are low and not detectable by all IgM assays.[1,4,6] Such asymptomatic reinfection of immune pregnant women, generally believed to be harmless to the fetus, is characterized serologically usually only by a significant rise in IgG antibody titer.

Although the clinical utility of Rubella IgM detection is usually associated with testing pregnant women, testing of nonpregnant individuals for IgM antibodies to Rubella virus is a useful aid in diagnosis of acute infection.

The ARCHITECT Rubella IgM assay is a qualitative method for the detection of Rubella specific IgM antibodies in human serum and plasma. In situations where primary infection is suspected, the optimum time for specimen collection has been reported to be 1 to 2 weeks after the onset of the rash.[1]

A value of a sample equal to or greater than 1.60 Index (1.00 S/CO) is considered reactive for IgM antibodies to Rubella. Samples reading between 1.20 Index (0.75 S/CO) and less than 1.60 Index (1.00 S/CO) are considered grayzone. Any sample with a value less than 1.20 Index (0.75 S/CO) is considered nonreactive.

Reactivity for IgM antibodies to Rubella may indicate current infection, reactivation or recent vaccination.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Rubella IgM assay is a two-step immunoassay for the qualitative detection of IgM antibodies to Rubella virus in human serum and plasma with flexible assay protocols, referred to as Chemiflex.[7]

Sample and pretreatment reagent are combined. An aliquot of the pretreated sample, assay diluent, and Rubella whole virus (strain HPV 77) coated paramagnetic microparticles are combined. Anti-Rubella IgM present in the sample binds to the Rubella whole virus coated microparticles. After washing, murine acridinium-labeled anti-human IgM 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 anti-Rubella IgM in the sample and the RLUs detected by the ARCHITECT *i* System optics. The presence or absence of anti-Rubella IgM in the sample is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from a previous calibration. If the chemiluminescent signal in the specimen is greater than or equal to the cutoff signal, the sample is considered reactive for anti-Rubella IgM.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Reagent Kit, 100 Tests

NOTE: This kit may not be available for use on all ARCHITECT *i* Systems. Please contact your local distributor.

ARCHITECT Rubella IgM Reagent Kit (6C18)

- **MICROPARTICLES** 1 Bottle (6.6 mL) Microparticles: Rubella whole virus (strain HPV 77) coated microparticles in TRIS buffered saline with protein stabilizer. Minimum concentration: 0.08% solids. Preservatives: ProClin 950 and sodium azide.
- **CONJUGATE** 1 Bottle (5.9 mL) Conjugate: Murine acridinium-labeled anti-human IgM in MES buffer. Minimum concentration: 23 ng/mL. Preservatives: ProClin 300 and antimicrobial agents.
- **ASSAY DILUENT** 1 Bottle (5.9 mL) Assay Diluent: Rubella IgM assay diluent containing citrate buffer. Preservative: ProClin 300.
- **PRE-TREATMENT** 1 Bottle (10.0 mL) Pretreatment: Rubella IgM pretreatment reagent containing goat anti-human IgG in TRIS buffer. Preservative: ProClin 300.

Other Reagents

ARCHITECT *i* Pre-Trigger Solution

- **PRE-TRIGGER SOLUTION** Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

ARCHITECT *i* Trigger Solution

- **TRIGGER SOLUTION** Trigger Solution containing 0.35 N sodium hydroxide.

ARCHITECT *i* Wash Buffer

- **WASH BUFFER** Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

WARNINGS AND PRECAUTIONS

- **IVD** **For *In Vitro* Diagnostic Use.**

Safety Precautions

- ⚠ **CAUTION:** This product contains human-sourced infectious 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, it is recommended that all human-sourced materials be considered potentially infectious and handled with appropriate biosafety practices.
- All components of this kit contain methylisothiazolones, which are components of ProClin. These components 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.

- Some components of this product contain sodium azide. For a specific listing, refer to the **REAGENTS** section of this package insert. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.
- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
- 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 IgM 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 IgM 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 7.

Storage Instructions

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The ARCHITECT Rubella IgM Reagent Kit must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.
- When stored and handled as directed, reagents are stable until the expiration date.
- The ARCHITECT Rubella IgM Reagent Kit may be stored on board the ARCHITECT *i* System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.
- Reagents may be stored on or off the ARCHITECT *i* System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** After reagents are removed from the system, initiate a reagent scan to update the onboard stability timer.
- It is recommended that the assay is calibrated every 30 days.

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 PROCEDURE

- The ARCHITECT Rubella IgM assay file must be installed on the ARCHITECT *i* System from the ARCHITECT *i* Assay CD-ROM 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 IgM 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:
  - Plasma separator tubes (lithium heparin)
  - Potassium EDTA
  - Sodium citrate
  - Lithium heparin
  - Sodium heparin
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient 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 IgM assay.

Specimen Conditions

- Do not use specimens with the following conditions:
  - heat-inactivated
  - pooled
  - grossly hemolyzed (> 500 mg/dL)
  - 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.

Preparation for Analysis

- 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 ≥ 10,000 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 cells, 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 the clot, red blood cells, or separator gel and store frozen (-10°C or colder).
- No qualitative performance differences were observed between experimental controls and nonreactive or reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

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 ice or dry ice. Do not exceed the storage time limitations listed above.

PROCEDURE

Materials Provided

- 6C18 ARCHITECT Rubella IgM Reagent Kit

Materials Required but not Provided

- ARCHITECT *i* System
- ARCHITECT *i* System Assay CD-ROM
- 6C18-01 ARCHITECT Rubella IgM Calibrator
- 6C18-10 ARCHITECT Rubella IgM Controls
- ARCHITECT *i* **PRE-TRIGGER SOLUTION**
- ARCHITECT *i* **TRIGGER SOLUTION**
- ARCHITECT *i* **WASH BUFFER**
- ARCHITECT *i* **REACTION VESSELS**
- ARCHITECT *i* **SAMPLE CUPS**
- ARCHITECT *i* **SEPTUM**
- ARCHITECT *i* **REPLACEMENT CAPS**
- Pipettes or pipette tips (optional) to deliver the volumes specified in the protocol.

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

Assay Procedure

- Before loading the ARCHITECT Rubella IgM Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend the 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.**
  - 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.
- Load the ARCHITECT Rubella IgM Reagent Kit on the ARCHITECT *i* System.
  - Verify that all necessary assay reagents are present.
  - Ensure that septums are present on all reagent bottles.
- Order calibration, if necessary.
  - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.
- Order tests.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- 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 IgM test plus 20 µL for each additional ARCHITECT Rubella IgM test from the same sample cup.
  - ≤ 3 hours on board: 150 µL for the first ARCHITECT Rubella IgM test plus 20 µL for each additional ARCHITECT Rubella IgM test from the 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.
- Prepare calibrator and controls.
  - Mix ARCHITECT Rubella IgM Calibrator 1 and Controls by gentle inversion before use.
  - To obtain the recommended volume requirements for the ARCHITECT Rubella IgM Calibrator 1 and Controls, hold the bottles **vertically** and dispense 4 drops of Calibrator 1 or 4 drops of each control into each respective sample cup.
- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN.
- 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 9. When a laboratory requires more frequent maintenance, follow those procedures.

Specimen Dilution Procedures

Specimens cannot be diluted for the ARCHITECT Rubella IgM assay.

Calibration

- To perform an ARCHITECT Rubella IgM calibration, test Calibrator 1 in replicates of three. A single sample of each ARCHITECT Rubella IgM 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. Calibrator 1 should be priority loaded.
- Once an ARCHITECT Rubella IgM 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.
- It is recommended that the assay is calibrated every 30 days.
- 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 IgM 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 IgM 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 Operations Manual, Appendix B. The ARCHITECT Rubella IgM belongs to method group 5 (except functional sensitivity).

RESULTS

Calculation

The ARCHITECT *i* System calculates the calibrator mean chemiluminescent signal from three Calibrator 1 replicates and stores the result. Results are reported by dividing sample result by the stored calibrator result.

The default result unit for the ARCHITECT Rubella IgM assay is Index. Sample results may also be reported as sample to cutoff (S/CO). Index value divided by 1.6 equals S/CO value.

Interpretation of Results

- Specimens with concentration values < 1.20 Index (< 0.75 S/CO) are considered nonreactive for IgM antibodies to Rubella. Individuals with such results are presumed to be not currently infected with Rubella.
- Specimens with a concentration value between ≥ 1.20 Index (≥ 0.75 S/CO) and < 1.60 Index (< 1.00 S/CO) are considered grayzone.
- Specimens with concentration values ≥ 1.60 Index (≥ 1.00 S/CO) are considered reactive for IgM antibodies to Rubella. Reactivity for IgM antibodies to Rubella may indicate current infection, reactivation or recent vaccination.

NOTE: It is recommended to confirm results of specimens with Index values equal to or greater than 1.20 Index (≥ 0.75 S/CO) and less than 1.60 Index (< 1.00 S/CO) by testing Rubella IgG. Consider to take a second sample, if possible, within an appropriate period of time (*e.g.,* two weeks) to confirm levels of IgM and IgG.

- For details on configuring the ARCHITECT *i* System to use gray zone interpretations, refer to the ARCHITECT System Operations Manual, Section 2.

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

- If the Rubella IgM results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.[8]
- For diagnostic purposes, results should be used in conjunction with other data; *e.g.*, symptoms, results of other tests, clinical impressions, etc.
- IgM rheumatoid factor (RF) in combination with Rubella specific IgG can lead to false reactive results in IgM detecting assays. The pretreatment of samples in the ARCHITECT Rubella IgM assay minimizes RF interference, however, in rare cases interference caused by high concentrations of RFs and Rubella specific IgG cannot be excluded.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.[9] 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).[10,11] Specimens containing HAMA may produce anomalous values when tested with assay kits that employ mouse monoclonal antibodies.[10]

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT Rubella IgM assay is designed to show a precision of ≤ 10% total** CV for the Positive Control.

A study was performed with the ARCHITECT Rubella IgM assay based on guidance from the Clinical and Laboratory Standards Institute. Controls were tested with 3 reagent lots at the internal site and with 2 reagent lots at the external evaluation site. Controls were tested on 2 instruments in replicates of 5 at 2 separate times per day for 5 days. Data from this study are summarized in the following table.*

			Within Run		Total **	
Sample	n	Mean Index	Index SD	Index %CV	Index SD	Index %CV
NC	500	0.07	0.008	10.908	0.008	11.335
PC	500	3.78	0.116	3.061	0.117	3.100

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

** Total is an accumulation of within run, between run and between day.

Seroconversion Sensitivity

The ARCHITECT Rubella IgM assay is designed to show a comparable seroconversion sensitivity to a commercially available diagnostic kit. Three commercially available seroconversion panels derived from vaccinated individuals were obtained and tested. The following table shows data from three seroconversion panels.*

Panel	Day after 1st draw	ARCHITECT Rubella IgM (Index) Cutoff: 1.60 Index	Commercially available diagnostic kit (Index) Cutoff: 0.800 Index
RP-001 (Profile Diagnostics)	0	0.09 (nonreactive)	0.170 (negative)
	2	0.08 (nonreactive)	0.099 (negative)
	7	0.07 (nonreactive)	0.140 (negative)
	9	0.09 (nonreactive)	0.082 (negative)
	14	0.18 (nonreactive)	0.103 (negative)
	17	**1.61 (reactive)**	0.373 (negative)
	21	**9.27 (reactive)**	**3.028 (positive)**
	24	**7.29 (reactive)**	**2.361 (positive)**
	28	**5.73 (reactive)**	**1.425 (positive)**
	31	**3.72 (reactive)**	**1.573 (positive)**
	35	**3.18 (reactive)**	**1.222 (positive)**
	38	**2.74 (reactive)**	**0.977 (positive)**
	42	**2.17 (reactive)**	0.744 (grayzone)
	45	**1.93 (reactive)**	0.537 (negative)
	50	1.56 (grayzone)	0.445 (negative)
RP-011 (Profile Diagnostics)	0	0.08 (nonreactive)	0.100 (negative)
	3	0.07 (nonreactive)	0.120 (negative)
	9	0.07 (nonreactive)	0.130 (negative)
	12	0.09 (nonreactive)	0.112 (negative)
	16	**1.64 (reactive)**	0.647 (grayzone)
	19	**6.19 (reactive)**	**2.792 (positive)**
	24	**5.61 (reactive)**	**3.904 (positive)**
	27	**4.17 (reactive)**	**3.263 (positive)**
	31	**3.24 (reactive)**	**2.260 (positive)**
	36	**2.11 (reactive)**	**1.332 (positive)**
	39	**1.66 (reactive)**	**1.050 (positive)**
	43	1.14 (nonreactive)	0.664 (grayzone)
	46	0.96 (nonreactive)	0.505 (negative)
	50	0.73 (nonreactive)	0.402 (negative)
	53	0.60 (nonreactive)	0.321 (negative)
	57	0.44 (nonreactive)	0.288 (negative)
	60	0.42 (nonreactive)	0.231 (negative)
	64	0.39 (nonreactive)	0.206 (negative)
	67	0.33 (nonreactive)	0.170 (negative)
	71	0.30 (nonreactive)	0.205 (negative)
RP-014 (Profile Diagnostics)	0	0.05 (nonreactive)	0.100 (negative)
	5	0.05 (nonreactive)	0.088 (negative)
	7	0.05 (nonreactive)	0.098 (negative)
	12	0.10 (nonreactive)	0.119 (negative)
	14	0.55 (nonreactive)	0.200 (negative)
	19	**3.37 (reactive)**	**0.967 (positive)**
	21	**3.55 (reactive)**	**1.108 (positive)**
	26	**3.13 (reactive)**	**1.001 (positive)**
	28	**2.67 (reactive)**	**0.874 (positive)**
	33	1.54 (grayzone)	0.785 (grayzone)
	35	**1.65 (reactive)**	0.494 (negative)
	40	1.16 (nonreactive)	0.404 (negative)
	42	1.05 (nonreactive)	0.463 (negative)

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

Resolved Relative Specificity

The ARCHITECT Rubella IgM assay is designed to show a comparable resolved relative specificity to a commercially available diagnostic kit. From the 1345*** specimens evaluated 9 specimens were confirmed positive.

***Note: Specimens that could not be resolved or showed grayzone result interpretation were not included in the evaluation of resolved relative specificity.

Data for resolved relative specificity are summarized in the following table.*

	Resolved Relative Specificity			
	ARCHITECT Rubella IgM		Commercially available diagnostic kit	
Sample Type	Observed	Lower 95% Confidence Limit	Observed	Lower 95% Confidence Limit
Blood Donors (Serum)	99.52% (208/209)	97.36%	100.00% (209/209)	98.25%
Blood Donors (Plasma)	100.00% (218/218)	98.32%	99.54% (217/218)	97.47%
Pregnant Women	100.00% (509/509)	99.28%	100.00% (509/509)	99.28%
Diagnostic/ Hospital Patients	98.75% (395/400)	97.11%	99.50% (398/400)	98.21%
Total	99.55% (1330/1336)	99.03%	99.78% (1333/1336)	99.35%

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

Interference

No interference was observed between experimental controls and nonreactive or reactive specimens tested with elevated levels of bilirubin (20 mg/dL), triglycerides (3000 mg/dL), protein (12 g/dL), red blood cells (0.4% v/v), or hemoglobin (500 mg/dL).

The interference of the ARCHITECT Rubella IgM assay was further evaluated on 138 specimens positive for anti-nuclear antibody, systemic lupus erythematosus, rheumatoid factor, herpes simplex virus, Epstein-Barr virus, measles, parvovirus B19, varicella zoster virus, hyperpolyclonal IgG, hyperpolyclonal IgM, human anti-mouse antibody, high titer Rubella IgG, and influenza vaccine recipients. With these specimens, ARCHITECT Rubella IgM and a commercially available diagnostic kit showed 98.55% agreement (136/138) (lower 95% confidence limit: 94.86%).

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The following US Patents are relevant to the ARCHITECT *i* System or its components. There are other such patents and patent applications in the United States and worldwide.

5 468 646	5 543 524	5 545 739
5 565 570	5 669 819	5 783 699

ProClin is property of its respective owner.

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