SIEMENS Healthineers

Rubella IgG (Rub G)

Assay for the Detection of IgG Antibodies to Rubella Virus

Current Revision and Date[a]	Rev. 02, 2019-06	
Product Name	Atellica IM Rubella IgG (Rub G)	REF 10995670
Abbreviated Product Name	Atellica IM Rub G	
Test Name/ID	Rub_G	
Systems	Atellica IM Analyzer	
Materials Required but Not Provided	Atellica IM APW1	REF 10995458
Optional Materials	Atellica IM Rub G QC	REF 10995671
Specimen Types	Serum, EDTA plasma, heparinized plasma	
Sample Volume	10 µL	
Measuring Interval	0.2–500.0 IU/mL	

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

WARNING

The use of the Atellica IM Rubella IgG assay to diagnose recent infection by testing acute and convalescent samples is not recommended. The calculated values for rubella IgG in a given specimen, as determined by assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the rubella IgG assay used. Values obtained with different assay methods cannot be used interchangeably. The reported IgG level cannot be correlated to an endpoint titer.

Intended Use

The Atellica™ IM Rubella IgG (Rub G) assay is an IgG-antibody capture microparticle direct chemiluminescent *in vitro* diagnostic immunoassay for the quantitative and qualitative detection of IgG antibodies to the rubella virus in human serum and plasma (EDTA and heparin) using the Atellica™ IM Analyzer.

This assay is used as an aid in the assessment of immune status to rubella in individuals including women of child-bearing age.

Summary and Explanation

Rubella is a member of the togaviridae family. Primary infections are generally mild, with symptoms such as a mild rash, low-grade fever, and lymphadenopathy. In contrast, primary infections during pregnancy can pass transplacentally to the fetus and can lead to fetal death or congenital rubella syndrome (CRS); the risk of fetal infection is greatest during the first trimester of pregnancy. Babies born with CRS typically exhibit low birth weight, deafness, eye disease, mental retardation, and cardiac abnormalities.

A primary infection induces an IgM and an IgG response. Within 4–6 months, IgM levels become undetectable or very low. IgG decreases to low levels, but lasts indefinitely and confers lifelong immunity. A secondary infection exhibits a rising IgG antibody without significant levels of IgM.[1]

Only 1 serological type of rubella virus is found in the population.[2,3] Since the introduction of the rubella vaccine in the late 1960s, the incidence of CRS has dropped dramatically. However, outbreaks of rubella have still occurred and pose a potential risk to women of childbearing age. Immunity from the vaccination is shown to persist for more than 16 years.[4] An antibody level of 10 IU/mL is thought to be protective.[5]

Principles of the Procedure

The Atellica IM Rub G assay is a sandwich immunoassay using direct chemiluminescent technology. The mouse monoclonal anti-human IgG_{Fc} antibody is covalently coupled to paramagnetic particles in the Solid Phase. In the Lite Reagent, the rubella virus antigen is labeled with acridinium ester.

The sample is incubated simultaneously with Solid Phase and Lite Reagent. Antibody-antigen complexes will form if rubella IgG is present in the sample.

A direct relationship exists between the amount of rubella IgG activity present in the patient sample and the amount of relative light units (RLUs) detected by the system. A result of reactive, nonreactive, or equivocal is determined according to the clinical cut-off value established with the calibrators. Refer to *Interpretation of Results*.

Reagents

Material Description	Storage	Stability[a]
Atellica IM Rub G ReadyPack® primary reagent pack **Lite Reagent** 10.0 mL/reagent pack Inactivated rubella virus antigen (strain HPV 77) (~0.2 µg/mL) labeled with acridinium ester in protein buffer; surfactant; preservatives **Solid Phase** 20.0 mL/reagent pack Mouse monoclonal anti-human IgG_{Fc} antibody (~0.15 mg/mL) covalently coupled to paramagnetic particles in protein buffer; preservatives	Unopened at 2–8°C Onboard	Until expiration date on product 23 days
Atellica IM Rub G CAL 1.0 mL/vial Processed human plasma positive for rubella IgG antibodies; preservatives	At 2–8°C At room temperature Atellica™ Sample Handler[b]	Until expiration date on product 8 hours

Material Description	Storage	Stability[a]
Atellica IM APW1 ReadyPack ancillary reagent pack[c] 25.0 mL/pack 0.4 N sodium hydroxide	Unopened at 2–8°C	Until expiration date on product
	Onboard	14 days

[a] Refer to *Storage and Stability*.

[b] Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

[c] Refer to *Materials Required but Not Provided*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens.com/healthineers.

H317
P272, P280, P302+P352, P333+P313, P363, P501

Warning!
May cause an allergic skin reaction.
Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (in Atellica IM Rub G ReadyPack)

H290, H319, H315
P280, P264, P305+P351+P338, P310, P390, P501

Warning!
May be corrosive to metals. Causes serious eye irritation. Causes skin irritation.
Wear protective gloves/protective clothing/eye protection/face protection. Wash hands thoroughly after handling. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician. Absorb spillage to prevent material damage. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: sodium hydroxide (in Atellica IM APW1)

CAUTION POTENTIAL BIOHAZARD

Contains human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive). No test offers complete assurance that these or other infectious agents are absent; this material should be handled using good laboratory practices and universal precautions.[6–8]

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Note For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

Note For information about calibrator preparation, refer to *Preparing the Calibrators*.

Storage and Stability

Store reagents in an upright position. Protect the product from heat and light sources. Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

Store calibrators in an upright position. Calibrators are stable until the expiration date on the product when stored at 2–8°C. Calibrators are stable for 8 hours at room temperature.

Store Atellica IM APW1 in an upright position. Unopened Atellica IM APW1 is stable until the expiration date on the product when stored at 2–8°C.

Do not use products beyond the expiration date printed on the product labeling.

Onboard Stability

Reagents are stable onboard the system for 23 days. Discard reagents at the end of the onboard stability interval.

Note Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

Atellica IM APW1 is stable onboard the system for 14 days.

Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

Serum and plasma (EDTA and heparin) are the recommended sample types for this assay.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[8]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[9]
- Follow the instructions provided with your specimen collection device for use and processing.[10]
- Allow blood specimens to clot completely before centrifugation.[7]
- Keep tubes capped at all times.[7]

Storing the Specimen

- Store specimens at 2–8°C for up to 7 days. Specimens may be stored on the clot.
- Freeze samples, devoid of red blood cells, at ≤ -20°C for longer storage. Do not store in a frost-free freezer. When 10 weakly positive samples and 5 negative samples were subjected to 5 freeze-thaw cycles, no qualitative differences were observed.

CAUTION

Thoroughly mix thawed samples and centrifuge them at 10,000 x g for 10 minutes before using. Collect the supernatant into a clean vial.

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

Samples maintained at room temperature for up to 2 days or refrigerated for up to 7 days demonstrated no qualitative differences. Store samples at 2–8°C upon arrival. If shipment is expected to exceed 7 days, ship specimens frozen.

Preparing the Samples

This assay requires 10 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the online help.

Note Do not use specimens with apparent contamination.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

Note Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[7]

Note For a complete list of appropriate sample containers, refer to the online help.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
10995670	1 ReadyPack primary reagent pack containing Atellica IM Rub G Lite Reagent and Solid Phase Atellica IM Rub G master curve and test definition MC TDEF 1 vial Atellica IM Rub G CAL low calibrator CAL L 1 vial Atellica IM Rub G CAL high calibrator CAL H Atellica IM Rub G calibrator lot-specific value sheet CAL LOT VAL	100

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description	
	Atellica IM Analyzer[a]	
10995458	Atellica IM APW1 (probe wash)	2 ReadyPack ancillary reagent packs containing 25.0 mL/pack WASH

[a] Additional system fluids are required to operate the system: Atellica IM Wash, Atellica IM Acid, Atellica IM Base, and Atellica IM Cleaner. For system fluid instructions for use, refer to the Document Library.

Optional Materials

The following materials may be used to perform this assay, but are not provided:

REF	Description	
10995671	Atellica IM Rub G QC (quality control material)	2 x 2.7 mL negative quality control CONTROL –
		2 x 2.7 mL positive quality control low level CONTROL L +
		2 x 2.7 mL positive quality control high level CONTROL H +
		Quality control lot-specific value sheet CONTROL LOT VAL

Assay Procedure

The system automatically performs the following steps:

1. Dispenses 10 µL of sample into a cuvette.
2. Dispenses 200 µL of Solid Phase and 100 µL of Lite Reagent, then incubates the mixture for 17 minutes at 37°C.
3. Separates, aspirates, then washes the cuvette with Atellica IM Wash.
4. Dispenses 300 µL each of Atellica IM Acid and Atellica IM Base to initiate the chemiluminescent reaction.
5. Reports results.

Preparing the Reagents

All reagents are liquid and ready to use. Before loading primary reagent packs onto the system, mix them by hand and visually inspect the bottom of the reagent pack to ensure that all particles are resuspended. For information about preparing the reagents for use, refer to the online help.

Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. The system automatically mixes reagent packs to maintain homogeneous suspension of the reagents. For information about loading reagent packs, refer to the online help.

Master Curve Definition

Before initiating calibration on each new lot of reagent, load the assay master curve and test definition values by scanning the MC TDEF 2D barcodes. For loading instructions, refer to the online help.

Performing Calibration

For calibration of the Atellica IM Rub G assay, use the calibrators provided with each kit.

Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

Stability Interval	Days
Lot Calibration	53
Pack Calibration	14
Reagent Onboard Stability	23

For information about lot calibration and pack calibration intervals, refer to the online help.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

Preparing the Calibrators

Calibrators are liquid and ready to use. Gently mix and invert the vials to ensure homogeneity of the material.

Note Use calibrator material within the stability limits specified in *Storage and Stability* and discard any remaining material.

Calibration Procedure

The calibrators are provided in dropper vials. Each dispensed drop is approximately 50 µL.

The required sample volume for testing depends on several factors. For information about sample volume requirements, refer to the online help.

Use the following lot-specific materials to perform calibration:

- For the master curve and assay test definitions, refer to the lot-specific master curve and test definition sheet MC TDEF provided with the assay reagents.
- Calibrators provided in an assay kit must only be used with reagents from that assay kit lot. Do not use calibrators from one assay kit with reagents from a different assay kit lot.
- For the calibrator definitions, refer to the lot-specific value sheet CAL LOT VAL provided with the calibrator materials.
- Generate lot-specific barcode labels to use with the calibrator samples.

For instructions about how to perform the calibration procedure, refer to the online help.

Performing Quality Control

For quality control of the Atellica IM Rub G assay, use the Atellica IM Rub G QC or an equivalent product at least once during each work shift that samples are analyzed. Use the quality control material in accordance with the quality control instructions for use.

For the assigned values, refer to the lot-specific value sheet CONTROL LOT VAL provided. A satisfactory level of performance is achieved when the analyte values obtained are within the expected control interval for the system or within your interval, as determined by an appropriate internal laboratory quality control scheme. Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the online help.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Test quality control samples after a successful calibration.

Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the online help. Refer to *Interpretation of Results*.

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

Interpretation of Results

The system reports rubella IgG antibody results in IU/mL and as Nonreactive (negative), Reactive (positive), or Equivocal:

- **Nonreactive:** Samples with a value of < 5.0 IU/mL are considered negative for IgG antibodies to rubella virus.
- **Reactive:** Samples with a value of ≥ 10.0 IU/mL are considered positive for IgG antibodies to rubella virus.
- **Equivocal:** Samples with a value of ≥ 5.0 IU/mL and < 10.0 IU/mL are considered equivocal. Obtain a new specimen and test using the Atellica IM Rub G assay.

Results ≥ 10.0 IU/mL are considered positive in accordance with the CLSI guidelines and based on the WHO International Standard for Anti-Rubella serum as an indicator of immune status and a breakpoint to detect most seropositive persons.[5] The cut-off value for the assay was verified based on results of the receiver operating characteristic (ROC) curve and positive/negative predictive values generated from the results of clinical studies.

Note If the controls are out of range, the sample results are invalid. Do not report results.

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Limitations

The following information pertains to limitations of the assay:

- The Atellica IM Rub G assay is limited to the detection of IgG antibodies to rubella virus in human serum and plasma.
- The use of the Atellica IM Rub G assay to diagnose recent infection by testing acute and convalescent serum samples has not been validated.

- Specimens taken early during the acute phase of infection may not contain detectable levels of IgG antibodies to rubella virus.
- For patient samples measuring at or around the cut-off value of 10.0–15.0 IU/mL, significantly elevated or increasing concentrations of total IgG may change a positive qualitative interpretation to equivocal or, rarely, may result in a negative interpretation.
- Do not use heat-inactivated specimens.
- The performance of the assay has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic fluid, or pleural fluid.
- The performance of the assay has not been established for populations of immunocompromised or immunosuppressed patients.
- Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay is designed to minimize interference from heterophilic antibodies.[11,12] Additional information may be required for diagnosis.

Expected Values

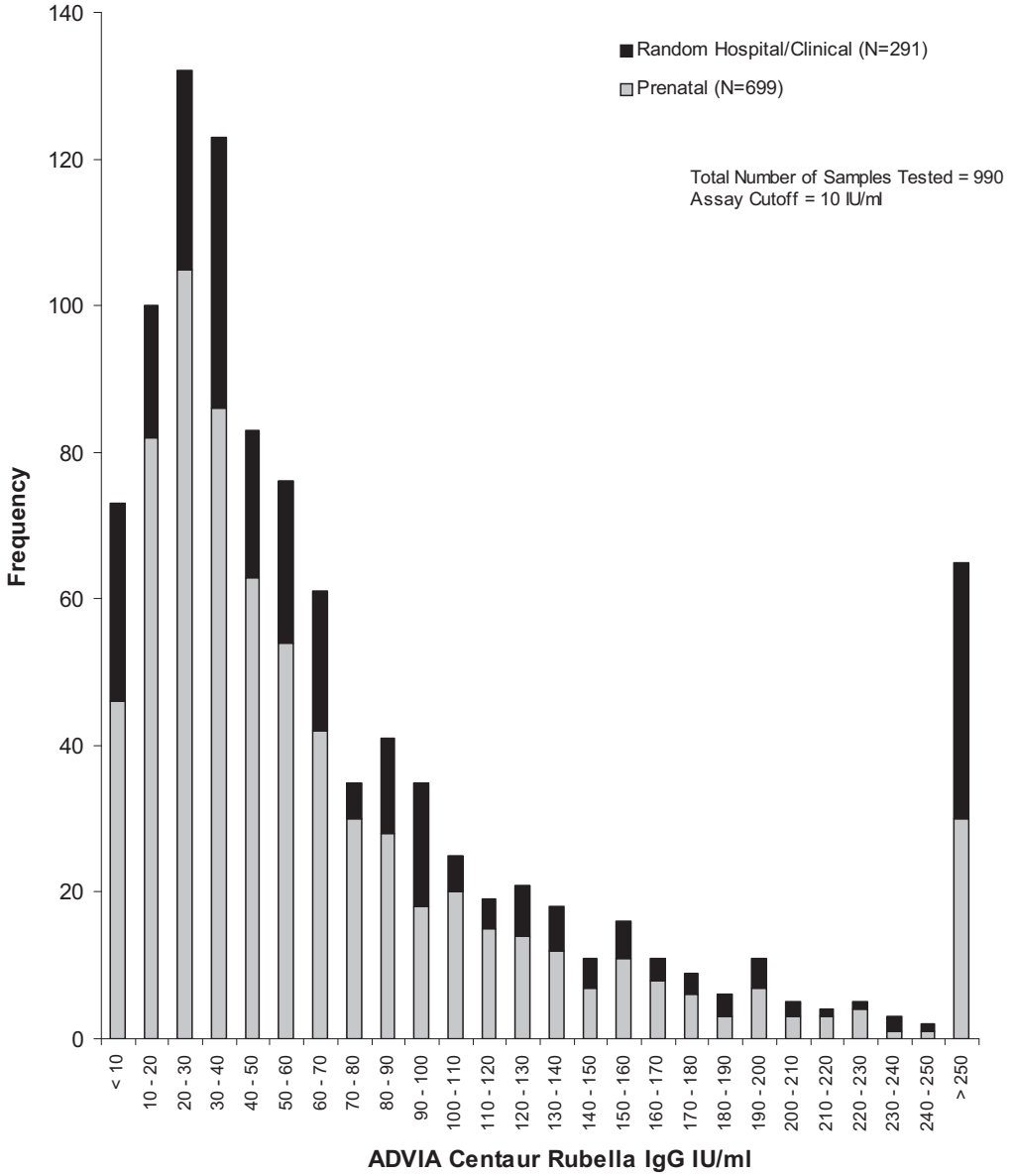
The reagent formulations used on the Atellica IM Analyzer are the same as those used on the ADVIA Centaur® system. Expected values were established using the ADVIA Centaur system and confirmed by assay comparison. Refer to *Performance Characteristics on the Atellica IM Analyzer*.

Among populations, the occurrence of IgG antibody to the rubella virus varies. The level of seropositivity ranges widely.[13-15] Data were obtained on 990 samples from prenatal women and random individuals. Of these samples, 918 (92.7%) were positive, 35 (3.5%) were equivocal, and 37 (3.7%) were negative.[16]

Population	N[a]	Negative	Equivocal	Positive
Prenatal women	699	22 (3.1%)	23 (3.3%)	654 (93.6%)
Random individuals	291	15 (5.2%)	12 (4.1%)	264 (90.7%)

[a] Number of samples tested.

ADVIA Centaur Rubella IgG – Population Observed Values



As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.[17] Consider these values as guidance only.

Performance Characteristics

The reagent formulations used on the Atellica IM Analyzer are the same as those used on the ADVIA Centaur system. Some performance characteristics for the Atellica IM assay were established using the ADVIA Centaur system.

Performance Characteristics on the ADVIA Centaur System

Specificity

To evaluate the specificity of the assay, 100 specimens from individuals with the various disease states listed below were tested. The rubella IgG status of the specimens was confirmed using an alternate method. The results are shown in the following table:

		ADVIA Centaur Rubella G Assay Result	
Disease State	**Rubella IgG Status by Alternate Method**	**< 10.0 (IU/mL)**	**≥ 10.0 (IU/mL)**
Cytomegalovirus	Negative	3	0
	Positive	1[a]	6
Epstein-Barr virus	Negative	0	0
	Positive	0	10
Herpes simplex virus	Negative	3	0
	Positive	1[a]	6
Influenza vaccinees	Negative	0	0
	Positive	0	10
Measles virus	Negative	0	0
	Positive	0	10
Parvovirus B19	Negative	0	0
	Positive	0	10
Syphilis	Negative	1	0
	Positive	1[a]	8
Varicella zoster virus	Negative	1	0
	Positive	0	9
Multiple myeloma	Negative	2	0
	Positive	5[b]	3
Rheumatoid factor	Negative	0	0
	Positive	0	5
ANA	Negative	1	0
	Positive	1[a]	3

[a] Equivocal result on ADVIA Centaur Rub G assay.

[b] IgG concentration was > 25 mg/mL.

Assay results obtained at individual laboratories may vary from the data presented.

Percent Agreement

The presence of rubella IgG antibody in 1337 frozen and fresh specimens was evaluated at 3 U.S. sites using the ADVIA Centaur Rubella G assay and a commercially available rubella IgG EIA. Prenatal and random hospital and clinical specimens were obtained from the mid-Atlantic and Midwest regions of the United States as well as Canada and Germany. Of the 1337 specimens tested, 43 were equivocal by the ADVIA Centaur Rubella G assay. Discordant results were found on 9 specimens. Further evaluation was performed with the discordant samples using other commercially available tests for rubella IgG.

Assay results obtained at individual laboratories may vary from the data presented.

Positive Percent Agreement

Using the alternative method, 1029/1337 tested positive for rubella IgG antibody. Of the specimens that tested positive, 23 were equivocal, 1000 were positive, and 6 were negative using the ADVIA Centaur Rubella G assay. The positive percent agreement was 99.4%.

Negative Percent Agreement

Using the alternative method, 245/1337 tested negative for rubella IgG antibody. Of the specimens that tested negative, 5 were equivocal, 242 were negative, and 3 were positive using the ADVIA Centaur Rubella G assay. The negative percent agreement was 98.8%.

Note *Percent Agreement* refers to the comparison of this assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison assay's accuracy to predict disease.

Percent Agreement before Resolution of Discordant Samples

Site	N	Positive Percent Agreement (%)	Negative Percent Agreement (%)	Overall Percent Agreement (%)
1	645	100 (466/466)	99.4 (152/153)	99.8 (618/619)
2	350	98.9 (269/272)	100 (49/49)	99.1 (318/321)
3	342	98.9 (265/268)	95.4 (41/43)	98.4 (306/311)
Total	1337	99.4 (1000/1006)	98.8 (242/245)	99.3 (1242/1251)

		Predicate Rubella IgG			
		Positive	Equivocal	Negative	Total
ADVIA Centaur Rubella G	**Positive**	1000	9	3	1012
	Equivocal	23	15	5	43
	Negative	6	34	242	282
	Total	1029	58	250	1337

Positive Percent Agreement = 99.4% (1000/1006), 95% CI (Confidence Interval) = 98.71%–99.78%

Negative Percent agreement = 98.8% (242/245), 95% CI = 96.46%–99.75%

Overall Percent Agreement = 99.3% (1242/1251), 95% CI = 98.64%–99.67%

Note Samples giving equivocal results were not included in the calculations of percent agreement.

Consensus Testing

Further analysis of the 9 specimens with discordant results was performed using an additional commercially available EIA for rubella IgG. Of the 3 that were positive by ADVIA Centaur and negative by EIA, 1 was equivocal and 2 were positive by consensus. Of the 6 that were negative by ADVIA Centaur and positive by EIA, 1 was equivocal, 1 was positive, and 4 were negative by consensus.

CDC Panel

A serum panel obtained from the Centers for Disease Control (CDC) was tested using the ADVIA Centaur Rubella G assay. The testing was performed to provide additional information about the performance of the ADVIA Centaur Rubella G assay with a characterized serum panel. This is not an endorsement of the assay by the CDC.

The panel consisted of 82 positive and 18 negative samples. The ADVIA Centaur Rubella G assay correctly identified all (100) panel members.

Interferences

Hemolysis, Icterus, Lipemia (HIL), and Other Interferences

Serum specimens that are . . .	Demonstrate ≤ 10% change in results . . .
hemolyzed	up to 500 mg/dL of hemoglobin
icteric	up to 60 mg/dL of conjugated bilirubin up to 40 mg/dL of unconjugated bilirubin
lipemic	up to 1000 mg/dL of triglycerides
hyperproteinemic	up to 12 g/dL of protein
hypoproteinemic	as low as 3 g/dL of protein

Note Samples with naturally occurring low protein (2.9–3.7 g/dL) and high protein (10.6–11.7 g/dL) levels yielded the same diagnosis as other assay methods.

Results were established using the ADVIA Centaur system.

Performance Characteristics on the Atellica IM Analyzer

Measuring Interval

The Atellica IM Rub G assay provides results from 0.2–500.0 IU/mL.

Positive Percent Agreement

Positive percent agreement was determined by comparing the Atellica IM Rub G assay using the Atellica IM Analyzer to the ADVIA Centaur Rubella G assay using the ADVIA Centaur XP system. A population of 182 samples that tested reactive using the ADVIA Centaur Rubella G assay was tested using the Atellica IM Rub G assay. The performance of the Atellica IM Rub G assay is shown in the following table:

Number	Nonreactive	Equivocal	Reactive	Positive Percent Agreement
182	0	4	178	100% (178/178)

The positive percent agreement of the Atellica IM Rub G assay is 100% (178/178) with a 95% confidence interval (CI) of 97.9%–100%.

Assay results obtained at individual laboratories may vary from the data presented.

Negative Percent Agreement

Negative percent agreement was determined by comparing the Atellica IM Rub G assay using the Atellica IM Analyzer to the ADVIA Centaur Rubella G assay using the ADVIA Centaur XP system. A population of 103 samples that tested nonreactive using the ADVIA Centaur Rubella G assay was tested using the Atellica IM Rub G assay. The performance of the Atellica IM Rub G assay is shown in the following table:

Number	Nonreactive	Equivocal	Reactive	Negative Percent Agreement
103	103	0	0	100% (103/103)

The negative percent agreement of the Atellica IM Rub G assay is 100% (103/103) with a 95% confidence interval of 96.4%–100%.

Assay results obtained at individual laboratories may vary from the data presented.

Percent Agreement

		ADVIA Centaur Rubella IgG			
		Positive	Equivocal	Negative	Total
Atellica IM Rub G	**Positive**	178	0	0	178
	Equivocal	4	31	0	35
	Negative	0	10	103	113
	Total	182	41	103	326

Positive Percent Agreement = 100.0% (178/178), 95% CI = 97.9%–100.0%

Negative Percent Agreement = 100.0% (103/103), 95% CI = 96.4%–100.0%

Overall Percent Agreement = 100.0% (281/281), 95% CI = 98.7%–100.0%

Note Samples giving equivocal results were not included in the calculations of percent agreement.

Precision

Precision was determined in accordance with CLSI Document EP05-A3.[18] Samples were assayed on an Atellica IM Analyzer in duplicate in 2 runs per day for 20 days. The assay was designed to have within-laboratory precision of ≤ 0.9 IU/mL SD for samples from 0.2–4.9 IU/mL, and ≤ 12.0% CV for samples from 5.0–500.0 IU/mL. The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Sample Type	**N[a]**	**Mean (IU/mL)**	**SD[b] (IU/mL)**	**CV[c] (%)**	**SD (IU/mL)**	**CV (%)**
Serum A	80	4.4	0.4	N/A[d]	0.6	N/A
Serum B	80	9.1	0.5	5.4	0.8	8.3
Serum C	80	163.8	4.5	2.7	7.8	4.8
Control 1	80	1.0	0.4	N/A	0.6	N/A

			Repeatability		Within-Laboratory Precision	
Sample Type	**N[a]**	**Mean (IU/mL)**	**SD[b] (IU/mL)**	**CV[c] (%)**	**SD (IU/mL)**	**CV (%)**
Control 2	80	18.5	0.7	4.0	1.0	5.5
Control 3	80	82.2	1.7	2.0	2.9	3.6

[a] Number of samples tested.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Not applicable.

Assay results obtained at individual laboratories may vary from the data presented.

Standardization

The Atellica IM Rub G assay standardization is traceable to the World Health Organization (WHO) 1st International Standard for human anti-rubella immunoglobulin (RUBI-1-94). Assigned values for calibrators and controls are traceable to this standardization.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens.com/healthineers

References

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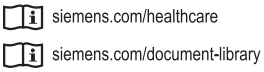
Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
 Rev. 01	Version of instructions for use
 siemens.com/healthcare siemens.com/document-library	Internet URL address to access the electronic instructions for use
Rev. REVISION	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Biological risks Potential biological risks are associated with the medical device.

Symbol	Symbol Title and Description
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.

Symbol	Symbol Title and Description
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
EC REP	Authorized Representative in the European Community
	Use-by date Use by the designated date.
LOT	Batch code
REF	Catalog number
	Recycle
	Printed with soy ink
CE	CE Mark
CE 0088	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
UNITS C	Common Units
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number

Symbol	Symbol Title and Description
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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