June 20, 2025

Abbott Laboratories
Laura Fraczek
Regulatory Affairs Senior Specialist
100 Abbott Park Road
Abbott Park, Illinois 60064

Re: K243168
Trade/Device Name: Alinity i Rubella IgG
Regulation Number: 21 CFR 866.3510
Regulation Name: Rubella Virus Serological Reagents
Regulatory Class: Class II
Product Code: LFX
Dated: May 22, 2025
Received: May 22, 2025

Dear Laura Fraczek:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JORGE L. MUNOZ -S
Digitally signed by JORGE L. MUNOZ -S
Date: 2025.06.20 13:41:14 -04'00'

Jorge L. Munoz, Ph.D.
Deputy Branch Chief
Division of Microbiology Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243168

Device Name
Alinity i Rubella IgG

Indications for Use *(Describe)*
The Alinity i Rubella IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of IgG antibodies to rubella virus in human serum, serum separator, and plasma tubes (lithium heparin, lithium heparin separator, and tripotassium EDTA) on the Alinity i system.

The Alinity i Rubella IgG assay is to be used as an aid in the determination of immune status to rubella in individuals including women of child-bearing age.

The Alinity i Rubella IgG assay has not been cleared for use in screening blood, plasma, or tissue donors.

The performance of this device has not been established for cord blood or neonatal samples. Likewise, performance has not been established for populations of immunocompromised or immunosuppressed individuals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. 510(k) Number

K243168

II. Applicant Name

Abbott Laboratories
Department 09AA
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Primary contact person for all communications:

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Date summary prepared: June 19, 2025

III. Device Name

Alinity i Rubella IgG

Reagents

Trade Name: Alinity i Rubella IgG Reagent Kit
Device Classification: Class II
Classification Name: Rubella virus serological reagents
Governing Regulation: 21 CFR 866.3510
Code: LFX

Calibrator

Trade Name: Alinity i Rubella IgG Calibrators
Device Classification: Class II
Classification Name: Rubella virus serological reagents
Governing Regulation: 21 CFR 866.3510
Code: LFX

Controls

Trade Name: Alinity i Rubella IgG Controls
Device Classification: Class II
Classification Name: Rubella virus serological reagents
Governing Regulation: 21 CFR 866.3510
Code: LFX

IV. Predicate Device

bioMérieux VIDAS RUB IgG assay (K080766)

V. Description of Device

Reagents

The kit configuration of the Alinity i Rubella IgG Reagent Kit is described below.

List Number (LN)	**04W0222**
Tests per cartridge	100
Number of cartridges per kit	2
Tests per kit	200
Microparticles	6.6 mL
Conjugate	6.1 mL
Assay Diluent	10.4 mL

- **Microparticles:** Partially purified rubella virus coated microparticles in TRIS buffer with surfactant. Minimum concentration: 0.12% solids. Preservatives: ProClin 950 and sodium azide.
- **Conjugate:** Anti-human IgG (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer and surfactant. Minimum concentration: 16 ng/mL. Preservatives: antimicrobial agents.
- **Assay Diluent:** TRIS buffer with protein (caprine, bovine, murine) stabilizers and surfactant. Preservatives: ProClin 300 and ProClin 950.

Calibrators

The Alinity i Rubella IgG Calibrators are described below.

- **Calibrator A:** Contains recalcified human plasma with protein (ovine) stabilizer.
- **Calibrator B – F:** Contain recalcified human plasma (reactive for IgG antibodies to rubella virus [anti-rubella IgG]) with protein (ovine) stabilizer.
- Preservatives: ProClin 950 and sodium azide.

The target concentrations for the calibrators are provided in the following table.

Calibrator	Quantity	Anti-Rubella IgG Concentration (IU/mL)
Calibrator A	1 x 3.0 mL	0.0
Calibrator B	1 x 3.0 mL	5.5
Calibrator C	1 x 3.0 mL	16.5
Calibrator D	1 x 3.0 mL	82.5
Calibrator E	1 x 3.0 mL	275.0
Calibrator F	1 x 3.0 mL	550.0

The Alinity i Rubella IgG Calibrator B through F are referenced to the World Health Organization (WHO) International Standard (RUBI-1-94) for Anti-Rubella Immunoglobulin at each concentration level.

Controls

The Alinity i Rubella IgG Controls are described below.

- **Negative Control:** Contains recalcified human plasma with protein (ovine) stabilizer.
- **Positive Control 1 and 2:** Contain recalcified human plasma (reactive for anti-rubella IgG) with protein (ovine) stabilizer.
- Preservatives: ProClin 950 and sodium azide.

The target concentrations and ranges for the controls are provided in the table below.

Control	Quantity	Anti-Rubella IgG	
		Concentration (IU/mL)	**Range (IU/mL)**
Negative Control	1 x 8.0 mL	0.0	< 4.4
Positive Control 1	1 x 8.0 mL	30.7	18.5 – 42.9
Positive Control 2	1 x 8.0 mL	348.8	209.3 – 488.3

The Alinity i Rubella IgG positive controls are traceable to the WHO International Standard (RUBI-1-94) for Anti-Rubella Immunoglobulin at each concentration.

Biological Principles of the Procedure

The Alinity i Rubella IgG assay is an automated, two-step immunoassay for the quantitative determination of anti-rubella IgG in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Sample, partially purified rubella virus-coated paramagnetic microparticles, and assay diluent are combined and incubated. The anti-rubella IgG present in the sample bind to the rubella virus coated microparticles. The mixture is washed. Anti-human IgG acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of anti-rubella IgG in the sample and the RLU detected by the system optics.

VI. Intended Use of the Device

The Alinity i Rubella IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of IgG antibodies to rubella virus in human serum, serum separator, and plasma tubes (lithium heparin, lithium heparin separator, and tripotassium EDTA) on the Alinity i system.

The Alinity i Rubella IgG assay is to be used as an aid in the determination of immune status to rubella in individuals including women of child-bearing age.

The Alinity i Rubella IgG assay has not been cleared for use in screening blood, plasma, or tissue donors.

The performance of this device has not been established for cord blood or neonatal samples. Likewise, performance has not been established for populations of immunocompromised or immunosuppressed individuals.

VII. Comparison of Technological Characteristics

The Alinity i Rubella IgG assay (subject device) utilizes a CMIA methodology for the quantitative determination of IgG antibodies to rubella virus and is intended for use on the Alinity i system.

The similarities and differences between the subject device and the predicate device are presented in the following tables.

Assay Similarities

Characteristics	Subject Device Alinity i Rubella IgG (K243168)	Predicate Device bioMérieux VIDAS RUB IgG (K080766)
Intended Use and Indications for Use	The Alinity i Rubella IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of IgG antibodies to rubella virus in human serum, serum separator, and plasma tubes (lithium heparin, lithium heparin separator, and tripotassium EDTA) on the Alinity i system. The Alinity i Rubella IgG assay is to be used as an aid in the determination of immune status to rubella in individuals including women of child-bearing age. The Alinity i Rubella IgG assay has not been cleared for use in screening blood, plasma, or tissue donors. The performance of this device has not been established for cord blood or neonatal samples. Likewise, performance has not been established for populations of immunocompromised or immunosuppressed individuals.	The VIDAS® RUB IgG (RBG) assay uses Enzyme Linked Fluorescent Assay (ELFA) technology on the VIDAS® automated instruments for the *in vitro* quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum. The VIDAS® RUB IgG assay is intended as an aid in the determination of immune status to rubella. The performance of this device has not been established for screening of cord blood, or for neonatal samples. Likewise, performance characteristics of the assay have not been established for immunocompromised or immunosuppressed individuals.
Interpretation of Results	Nonreactive: < 5.0 IU/mL Grayzone/Equivocal: 5.0 to < 10.0 IU/mL Reactive: ≥ 10.0 IU/mL	Negative: < 5 IU/mL Equivocal: 5 to < 10 IU/mL Positive: ≥ 10 IU/mL
Antigen and Antibody Used	• Rubella virus antigen • Anti-human IgG antibody (mouse, monoclonal)	• Rubella virus antigen (Strain MR 383) • Anti-human IgG antibodies (mouse, monoclonal)

Assay Differences

Characteristics	Subject Device Alinity i Rubella IgG (K243168)	Predicate Device bioMérieux VIDAS RUB IgG (K080766)
Calibrator(s)	6 Calibrators	1 Calibrator
Control(s)	3 (1 Negative, 2 Positives)	2 (1 Negative, 1 Positive)
Type of Specimen	Serum and Plasma	Serum
Methodology	Chemiluminescent microparticle immunoassay (CMIA)	Enzyme-linked fluorescent assay (ELFA)
Components	Microparticles – Partially purified rubella virus coated microparticles in TRIS buffer with surfactant. Minimum concentration: 0.12% solids. Preservatives: ProClin 950 and sodium azide. Conjugate – Anti-human IgG (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer and surfactant. Minimum concentration: 16 ng/mL. Preservatives: antimicrobial agents. Assay Diluent – TRIS buffer with protein (caprine, bovine, murine) stabilizers and surfactant. Preservatives: ProClin 300 and ProClin 950.	RBG SPRs – Solid Phase Receptacles (SPR) coated with rubella antigen (Strain MR 383). Ready to use. Conjugate – Alkaline phosphatase labeled monoclonal anti-human IgG antibodies (mouse); 0.09% sodium azide. Sample Diluent and Wash Solution – TRIS buffer (50 mmol/L) pH 7.4; protein and chemical stabilizers; 0.09% sodium azide.
Calibration Storage	Maximum of 30 days	Maximum of 14 days

VIII. Summary of Nonclinical Performance

A. Within-Laboratory Precision (20-Day)

A 20-day within-laboratory precision study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 3 lots of the Alinity i Rubella IgG reagents, 3 lots of the Alinity i Rubella IgG Calibrators, 3 lots of the Alinity i Rubella IgG Controls, and 1 instrument. Three controls and 7 recalcified human plasma panels (representing serum matrix) were tested in 3 replicates at 2 separate times per day on 20 different days using 3 reagent lot/calibrator lot combinations, where a unique reagent lot and a unique calibrator lot are paired. The performance is shown in the following table.

Sample	n	Mean (IU/mL)	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Lot[a]		Overall Within-Laboratory[b]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control	360	0.0	0.06	NA[c]	0.00	NA[c]	0.00	NA[c]	0.00	NA[c]	0.06	NA[c]
Positive Control 1	360	30.4	1.04	3.4	0.39	1.3	0.37	1.2	0.94	3.1	1.50	4.9
Positive Control 2	360	342.7	18.14	5.3	7.58	2.2	4.26	1.2	8.55	2.5	21.86	6.4
Panel 1	359[d]	0.0	0.03	NA[c]	0.01	NA[c]	0.02	NA[c]	0.02	NA[c]	0.04	NA[c]
Panel 2	360	3.0	0.14	NA[c]	0.04	NA[c]	0.04	NA[c]	0.19	NA[c]	0.24	NA[c]
Panel 3	358[d]	8.0	0.33	NA[c]	0.08	NA[c]	0.01	NA[c]	0.34	NA[c]	0.49	NA[c]
Panel 4	360	12.6	0.47	3.7	0.17	1.4	0.17	1.4	0.51	4.0	0.73	5.8
Panel 5	360	25.1	1.05	4.2	0.21	0.8	0.00	0.0	0.76	3.0	1.31	5.2
Panel 6	360	234.8	10.98	4.7	5.52	2.3	0.00	0.0	8.22	3.5	14.79	6.3
Panel 7	360	398.1	29.74	7.5	7.18	1.8	0.00	0.0	9.19	2.3	31.94	8.0

[a] Alinity i Rubella IgG reagent lot and Alinity i Rubella IgG calibrator lot are confounded, and the confounding effect is represented by between-lot.

[b] Overall within-laboratory variability contains repeatability (within-run), between-run, between-day, and between-lot variance components.

[c] Not applicable

[d] In cases where n < 360, replicate(s) were excluded due to an instrument error and no results were reported.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

B. Reproducibility Study (5-Day)

A 5-day reproducibility study was conducted at 3 US sites based on guidance from CLSI EP05-A3* using 3 controls and 7 recalcified human plasma panels (representing serum matrix). Four replicates per sample were evaluated in 2 runs per day over 5 days. Testing was conducted using 3 lots of the Alinity i Rubella IgG reagents, 2 lots of the Alinity i Rubella IgG Calibrators, and 2 lots of the Alinity i Rubella IgG Controls at each of the 3 testing sites.

Sample	n	Mean (IU/mL)	Repeatability		Between-Run		Between-Day		Between-Site		Between-Lot[a]		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control	359[d]	0.0	0.00	NA[c]	0.00	NA[c]	0.00	NA[c]	0.00	NA[c]	0.00	NA[c]	0.00	NA[c]
Positive Control 1	359[d]	29.4	0.89	3.0	0.26	0.9	0.35	1.2	0.13	0.5	0.23	0.8	1.03	3.5
Positive Control 2	360	349.1	15.63	4.5	5.03	1.4	14.66	4.2	4.01	1.1	9.33	2.7	24.25	6.9
Panel 1	360	0.0	0.02	NA[c]	0.00	NA[c]	0.01	NA[c]	0.01	NA[c]	0.01	NA[c]	0.02	NA[c]
Panel 2	359[d]	2.8	0.10	NA[c]	0.07	NA[c]	0.04	NA[c]	0.07	NA[c]	0.01	NA[c]	0.14	NA[c]
Panel 3	360	7.6	0.33	NA[c]	0.04	NA[c]	0.10	NA[c]	0.14	NA[c]	0.09	NA[c]	0.38	NA[c]
Panel 4	360	12.1	0.32	2.6	0.25	2.1	0.18	1.5	0.06	0.5	0.13	1.1	0.47	3.9
Panel 5	360	24.8	0.69	2.8	0.59	2.4	0.27	1.1	0.11	0.5	0.30	1.2	1.00	4.0
Panel 6	360	245.2	10.53	4.3	6.31	2.6	5.68	2.3	1.62	0.7	7.21	2.9	15.41	6.3
Panel 7	356[d]	410.9	22.94	5.6	11.15	2.7	20.94	5.1	8.39	2.0	4.33	1.1	34.32	8.4

[a] Alinity i Rubella IgG reagent lot and Alinity i Rubella IgG calibrator lot are confounded, and the confounding effect is represented by between-lot.

[b] Reproducibility contains repeatability, between-run, between-day, between-site, and between-lot variance components.

[c] Not applicable

[d] In cases where n < 360, replicate(s) were excluded due to an instrument error and no results were reported.

C. Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.† Testing was conducted using 3 lots of the Alinity i Rubella IgG reagents on each of

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

† Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

2 instruments over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

	IU/mL
LoB[a]	0.1
LoD[b]	0.3
LoQ[c]	0.7

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20 %CV and a maximum allowable bias of 15% were independently met. The LoQ was determined from n ≥ 60 replicates of low-analyte level samples.

D. Linearity

A study was performed based on guidance from CLSI EP06, 2nd ed.[*]

This assay is linear across the analytical measuring interval of 1.0 to 500.0 IU/mL.

E. Analytical Specificity / Interference

Potentially Interfering Endogenous Substances

The Alinity i Rubella IgG assay was evaluated for potential interference caused by endogenous substances based on guidance from CLSI EP07, 3rd ed.,[†] and CLSI EP37, 1st ed.[‡] Each substance was evaluated using samples containing anti-rubella IgG at the target ranges of 5.0 to 9.9 IU/mL and 10.0 to 20.0 IU/mL.

No significant interference (interference within ± 1.0 IU/mL for samples < 10.0 IU/mL and within ± 10% for samples ≥ 10.0 IU/mL) was observed at the following concentrations.

[*] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures*. 2nd ed. CLSI Guideline EP06. Wayne, PA: CLSI; 2020.

[†] Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

[‡] Clinical and Laboratory Standards Institute (CLSI). *Supplemental Tables for Interference Testing in Clinical Chemistry*. 1st ed. CLSI supplement EP37. Wayne, PA: CLSI; 2018.

No Significant Interference	
Potentially Interfering Substance	**Interferent Level**
Conjugated Bilirubin	40 mg/dL
Unconjugated Bilirubin	40 mg/dL
Hemoglobin	1000 mg/dL
Total Protein	15 g/dL
Triglycerides	3000 mg/dL

Potentially Interfering Drugs and Other Substances

The Alinity i Rubella IgG assay was evaluated for potential interference caused by exogenous substances based on guidance from CLSI EP07, 3rd ed., and CLSI EP37, 1st ed. Each substance was evaluated using samples containing anti-rubella IgG at the target ranges of 5.0 to 9.9 IU/mL and 10.0 to 20.0 IU/mL.

No significant interference (interference within ± 1.0 IU/mL for samples < 10.0 IU/mL and within ± 10% for samples ≥ 10.0 IU/mL) was observed at the following concentrations.

No Significant Interference	
Potentially Interfering Substance	**Interferent Level**
Acetaminophen	250 mg/L
Acetylsalicylic Acid	1000 mg/L
Ascorbic Acid	300 mg/L
Biotin	4250 ng/mL
Folic Acid	100 nmol/L
Ibuprofen	500 mg/L

Potential Cross-Reactivity

Potential cross-reactivity for the Alinity i Rubella IgG assay was determined by testing a total of 126 serum specimens from individuals with other medical conditions unrelated to rubella virus, in addition to individual(s) with IgM antibodies to rubella virus. The results are shown in the following table.

Category	n	Number of Alinity i Rubella IgG Reactive Results	Number of Alinity i Rubella IgG Grayzone/ Equivocal Results
Anti-dsDNA Antibodies	4	0	0
Anti-nuclear Antibody (ANA)	5	0	0
Cytomegalovirus (IgG)	7	0	0
Epstein-Barr Virus (EBV) IgG	5	0	0
HAMA	3	0	1[a]
Hepatitis B Antibodies	10	0	0
Hepatitis C Antibodies	4	0	0
Herpes Simplex Virus Type 1 (IgG)	10	0	0
Herpes Simplex Virus Type 2 (IgG)	5	0	0
Human Immunodeficiency Virus (HIV)	5	0	0
Human Chorionic Gonadotropin	5	0	1[b]
Hyper IgG	5	0	1[b]
Measles (IgG)	7	0	0
Mumps (IgG)	4	0	0
Parvovirus B19 (IgG)	4	0	0
Rheumatoid Factor (RF)	5	0	0
Rubella (IgM)	1	0	0
SARS-CoV-2 IgG	3	0	0
Syphilis	10	0	1[b]
Systemic Lupus Erythematosus	8	0	0
Toxoplasmosis (IgG)	6	0	0
Varicella Zoster Virus (IgG)	10	0	0
Total	126	0	4

[a] Positive result obtained on the comparator assay.

[b] Equivocal results obtained on the comparator assay.

F. Matrix Equivalency

A study was performed to evaluate whether specific blood collection tube types are suitable for use with the Alinity i Rubella IgG assay. The matrix collection tube type equivalency study was conducted including 42 donors of reactive (29 donors) and nonreactive (13 donors) samples in 5 types of blood collection tubes (serum, serum separator, lithium heparin plasma, lithium heparin plasma separator, and

tripotassium EDTA plasma) for use with the Alinity i Rubella IgG assay. Data was analyzed using regression analysis comparing concentrations of all matrices to serum to evaluate any potential bias. All of the blood collection tube types tested are acceptable for use with the Alinity i Rubella IgG assay. Statistical evaluation data are summarized below.

Collection Tube	Slope (95% CI) (IU/mL)	Intercept (95% CI) (IU/mL)	Correlation Coefficient (r)
Serum separator	1.01 (0.98, 1.02)	-0.3 (-0.5, 0.2)	1.00
Lithium heparin plasma	0.99 (0.97, 1.01)	-0.1 (-0.5, 0.2)	1.00
Lithium heparin plasma separator	1.00 (0.97, 1.02)	-0.2 (-0.7, 0.1)	1.00
Tripotassium EDTA plasma	0.96 (0.94, 0.98)	-0.1 (-0.4, 0.0)	1.00

G. CDC Panel Agreement

The Centers for Disease Control and Prevention (CDC) Rubella Reference Sera Panel (collected in 2014) was tested using the Alinity i Rubella IgG assay. The Alinity i Rubella IgG assay results were submitted to the CDC for data analysis and for the result interpretation for each sample. The panel consisted of 82 true positive rubella specimens and 18 true negative rubella specimens. Out of the 82 positive specimens, the Alinity i Rubella IgG assay detected 77 as reactive and 5 as equivocal, while all 18 negative specimens were detected as nonreactive. The CDC performed kit sensitivity (positive percent agreement [PPA]) and kit specificity (negative percent agreement [NPA]) analyses and sent the results to Abbott.

The percent agreement of the Alinity i Rubella IgG assay relative to the CDC results was calculated. The PPA was 93.9% with a 95% confidence interval (CI) of 86.51% to 97.37%. The NPA was 100.0% with a 95% CI of 82.41% to 100.00%.

The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply endorsement of the assay by the CDC.

Alinity i Rubella IgG Interpretation	CDC Interpretation		Positive % Agreement (95% CI)[a]	Negative % Agreement (95% CI)[a]
	Positive	Negative		
Reactive	77	0	93.9 (77/82) (86.51, 97.37)	100.0 (18/18) (82.41, 100.00)
Grayzone/Equivocal	5	0		
Nonreactive	0	18		

[a] The 95% CI for PPA and NPA were estimated using the Wilson score method.

H. CDC Low Titer Standard

The ability of the Alinity i Rubella IgG assay to detect and measure low levels of anti-rubella IgG antibodies was verified by testing the CDC Low-Titer Anti-Rubella Human Reference Serum - CDC Biological Standard (catalog number: IS2153 at 21.0 IU/mL). The mean concentration was 18.2 IU/mL for the resuspended CDC low titer standard and 8.6 IU/mL for the 1:2 dilution of the standard.

IX. Summary of Clinical Performance

A. Clinical Agreement

A clinical method comparison study was conducted to evaluate the clinical performance of the Alinity i Rubella IgG assay based on guidance from CLSI EP12-A2[*] using specimens collected from individuals included in the following categories.

- The Routine Order category was comprised of consecutively collected remnant specimens from individuals (non-pregnant) with a physician's routine order for anti-rubella IgG, including specimens collected in the US (n=946) and outside of the US (OUS) (n=457).
- The Pregnant Females (US) category was comprised of 435 specimens collected from pregnant females in the US.

[*] Clinical and Laboratory Standards Institute (CLSI). *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline–Second Edition*. CLSI Document EP12-A2. Wayne, PA: CLSI; 2008.

- The Supplemental Preselected Negative Pregnant Female category was comprised of specimens that were additionally obtained to supplement the small number of negative subjects in the Pregnant Females (US) category. These specimens were from pregnant females who had a negative anti-rubella IgG test result with the comparator assay. They were collected in the US (n=52) and outside of the US (OUS) (n=59).
- The Preselected Negative (OUS) category was comprised of 135 consecutively collected remnant specimens from individuals (non-pregnant) with a physician's routine order for anti-rubella IgG and a negative anti-rubella IgG test result.

Demographic information for specimens from the intended use population collected in the US (n=1433) is shown in the table below.

Specimen	Age	Female (n)	Male (n)	Unknown (n)	Total (n)
Routine Order (US) (n=946)	≤ 5 years	1	1	0	2
	6 to 21 years	92	29	0	121
	22 to 59 years	666	121	3	790
	≥ 60 years	17	16	0	33
	Total	776	167	3	946
Pregnant Females (US) (n=435)	≤ 5 years	0	0	0	0
	6 to 21 years	28	0	0	28
	22 to 59 years	404	0	0	404
	≥ 60 years	0	0	0	0
	Unknown	3	0	0	3
	Total	435	0	0	435
Supplemental Preselected Negative Pregnant Females (US) (n=52)	≤ 5 years	0	0	0	0
	6 to 21 years	5	0	0	5
	22 to 59 years	47	0	0	47
	≥ 60 years	0	0	0	0
	Total	52	0	0	52
Total (US) (n=1433)	≤ 5 years	1	1	0	2
	6 to 21 years	125	29	0	154
	22 to 59 years	1117	121	3	1241
	≥ 60 years	17	16	0	33
	Unknown	3	0	0	3
	Total	1263	167	3	1433

The clinical performance of the Alinity i Rubella IgG assay was evaluated comparing the results of the Alinity i Rubella IgG assay and the results of a composite comparator method comprised of 3 FDA-cleared anti-rubella IgG assays. Specimens with initially equivocal results on the comparator device (5 to < 10 IU/mL) were tested with 2 additional FDA-cleared devices, and the final 2 out of 3 consensus results were used for performance evaluation. The positive percent agreement (PPA) and negative percent agreement (NPA) between the Alinity i Rubella IgG investigational assay and the composite comparator method anti-rubella IgG assays were calculated.

The PPA and NPA for each specimen category are shown in the following 3 by 3 table.

Specimen Category	**Alinity i Rubella IgG Result[a]**	**Composite Comparator Anti-Rubella IgG Result**			**PPA (95% CI)[b]**	**NPA (95% CI)[b]**
		Positive	**Equivocal**	**Negative**		
Routine Order (US) (n=946)	**Reactive**	822	2	0	93.94 (822/875) (92.16, 95.34)	86.67 (26/30) (70.32, 94.69)
	Grayzone/Equivocal	36	41	2		
	Nonreactive	4	13	26		
Routine Order (OUS) (n=457)	**Reactive**	378	3	0	97.42 (378/388) (95.32, 98.59)	88.37 (38/43) (75.52, 94.93)
	Grayzone/Equivocal	9	26	2		
	Nonreactive	0	1	38		
Pregnant Females (US) (n=435)	**Reactive**	360	2	0	93.02 (360/387) (90.04, 95.16)	77.78 (14/18) (54.79, 91.00)
	Grayzone/Equivocal	17	30	2		
	Nonreactive	1	9	14		
Supplemental Preselected Negative Pregnant Females (US) (n=52)	**Reactive**	0	0	0	NA[c]	100.00 (52/52) (93.12, 100.00)
	Grayzone/Equivocal	0	0	0		
	Nonreactive	0	0	52		

Specimen Category	Alinity i Rubella IgG Result[a]	Composite Comparator Anti-Rubella IgG Result			PPA (95% CI)[b]	NPA (95% CI)[b]
		Positive	Equivocal	Negative		
Supplemental Preselected Negative Pregnant Females (OUS) (n=59)	**Reactive**	0	0	1[d]	NA[c]	98.31 (58/59) (91.00, 99.70)
	Grayzone/Equivocal	0	0	0		
	Nonreactive	0	0	58		
Preselected Negative (OUS) (n=135)	**Reactive**	0	0	0	0.00 (0/5) (0.00, 43.45)	99.23 (129/130) (95.77, 99.86)
	Grayzone/Equivocal	0	0	1		
	Nonreactive	3	2	129		

[a] The interpretation for Alinity i Rubella IgG results is ≥ 10.0 IU/mL for reactive, 5.0 to < 10.0 IU/mL for grayzone/equivocal, and < 5.0 IU/mL for nonreactive.

[b] The 95% CI for PPA and NPA were estimated using the Wilson score method.

[c] Not applicable.

[d] One sample was discordant between Alinity i Rubella IgG (19.0 IU/mL) and the comparator (4 IU/mL). After retesting, the results with Alinity i Rubella IgG were 18.4 and 18.5 IU/mL, and the results with the comparator were 24 and 26 IU/mL.

An additional assessment of the PPA and NPA between the Alinity i Rubella IgG assay and the composite comparator, relative to the medical decision point of 10 IU/mL antibody level considered to provide immunity from Rubella infection, is provided in the following 2 by 2 table.

Specimen Category	Alinity i Rubella IgG Result (IU/mL)[a]	Composite Comparator Anti-Rubella IgG Result		PPA (95% CI)[b]	NPA (95% CI)[b]
		Positive	Negative or Equivocal		
Routine Order (US) (n=946)	≥ 10.0	822	2	95.36 (822/862) (93.74, 96.57)	97.62 (82/84) (91.73, 99.34)
	< 10.0	40	82		
Routine Order (OUS) (n=457)	≥ 10.0	378	3	97.67 (378/387) (95.64, 98.77)	95.71 (67/70) (88.14, 98.53)
	< 10.0	9	67		

Specimen Category	Alinity i Rubella IgG Result (IU/mL)[a]	Composite Comparator Anti-Rubella IgG Result		PPA (95% CI)[b]	NPA (95% CI)[b]
		Positive	Negative or Equivocal		
Pregnant Females (US) (n=435)	≥ 10.0	360	2	95.24 (360/378) (92.60, 96.97)	96.49 (55/57) (88.08, 99.03)
	< 10.0	18	55		
Supplemental Preselected Negative Pregnant Females (US) (n=52)	≥ 10.0	0	0	NA[c]	100.00 (52/52) (93.12, 100.00)
	< 10.0	0	52		
Supplemental Preselected Negative Pregnant Females (OUS) (n=59)	≥ 10.0	0	1	NA[c]	98.31 (58/59) (91.00, 99.70)
	< 10.0	0	58		
Preselected Negative (OUS) (n=135)	≥ 10.0	0	0	0.00 (0/3) (0.00, 56.15)	100.00 (132/132) (97.17, 100.00)
	< 10.0	3	132		

[a] The interpretation for Alinity i Rubella IgG results is ≥ 10.0 IU/mL for reactive and < 10.0 IU/mL for grayzone/equivocal and nonreactive.

[b] The 95% CI for PPA and NPA were estimated using the Wilson score method.

[c] Not applicable.

X. Conclusion Drawn from Nonclinical and Clinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the subject device (Alinity i Rubella IgG, K243168) performance is substantially equivalent to the predicate assay (bioMérieux VIDAS RUB IgG assay, K080766).