

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K063143

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Rubella-specific IgG in serum and plasma (heparin, EDTA, sodium citrate)

D. Type of Test:

Immunometric (ELISA)

E. Applicant:

Ortho-Clinical Diagnostics, Inc.

F. Proprietary and Established Names:

VITROS Immunodiagnostic Products Rubella IgG Reagent Pack

VITROS Immunodiagnostic Products Rubella IgG Calibrators

G. Regulatory Information:

1. Regulation section:

21CFR §866.3510, Rubella virus serological reagents

2. Classification:

Class II

3. Product code:

LFX

4. Panel:

H. Intended Use:

1. Intended use(s):

The VITROS Immunodiagnostic Products Rubella IgG assay is intended for the quantitative determination of IgG antibodies to rubella virus in human serum and plasma (heparin, EDTA or sodium citrate) using the VITROS Immunodiagnostic System.

2. Indication(s) for use:

The VITROS Rubella IgG assay is for use in the clinical laboratory to aid in the determination of immunity to rubella virus infection.

3. Special conditions for use statement(s):

For professional use

4. Special instrument requirements:

VITROS ECi/ECiQ Immunodiagnostic System (cleared K962919)

I. Device Description:

The VITROS Rubella IgG assay and calibrators are a test system to detect antibodies to the rubella virus, as an indicator of immunity to reinfection. The test is a standard automated ELISA that quantitatively detects IgG antibodies in serum or plasma, by means of binding of IgG in a specimen to antigen immobilized on a well surface. The bound IgG is detected by a secondary anti-human IgG labeled with HRP. The bound HRP generates a luminescent signal in the presence of substrate, and the signal is proportional to the amount of IgG bound to the plate well. The assay is calibrated by means of three calibrators (cleared with this submission) that are traceable to the WHO standard reference material for Rubella IgG. The test results are reported as International Units/mL (IU/mL) with an associated interpretation of “negative”, “low positive”, or “positive” for the presence of anti-rubella IgG at the cut-off value of 10 IU/mL. The test results are to be used in conjunction with other clinical information and history to suggest immune status versus rubella virus.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Abbott AXSYM Rubella IgG Assay

2. Predicate 510(k) number(s):

K954045

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	For in vitro diagnostic use only. The VITROS Immunodiagnostic Products Rubella IgG assay is intended for the quantitative determination of IgG antibodies to rubella virus in human serum and plasma (heparin, EDTA or sodium citrate) using the VITROS Immunodiagnostic System. The VITROS Rubella IgG assay is for use in the clinical laboratory as an aid in the determination of immunity to rubella virus infection.	The AxSym Rubella IgG assay is a Microparticle Enzyme Immunoassay (MIA) for the qualitative and quantitative measurement of IgG antibodies to rubella virus in serum or plasma (EDTA, heparin or sodium citrate) to aid in the determination of immune status to rubella.
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme-labeled	Enzyme-labeled
Instrumentation	Automated Immunoassay System	Automated Immunoassay System
Sample Type	Serum and plasma (EDTA, heparin, or sodium citrate)	Serum and plasma (EDTA, heparin, or sodium citrate)
Antigen Virus Strain	HPV-77	HPV-77
Calibrator Format	Liquid	Liquid
Linearity with W.H.O. 1st International standard-Assay range	Yes	Yes
CDC Rubella Panel evaluation	Yes	Yes

Similarities		
Item	Device	Predicate
Calibrators referenced to W.H.O.	Yes	Yes
CLSI Standards Used	I/L6, EP5	I/L6, EP5

Differences		
Item	Device	Predicate
Secondary Antibody	Mouse monoclonal anti-human IgG	Goat anti-human IgG
Sample Volume	10 µL	180 µL
Calibrator Levels	3	6
Reportable Range	0-350 IU/mL	1-500 IU/mL
Incubation time and temperature	35 min at 37° C	20 min at 37° C
Instrumentation	VITROS ECi/ECiQ Immunodiagnostic System	AxSYM System

K. Standard/Guidance Document Referenced (if applicable):

NCCLS I/L6-A, “Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of the Test Products in the Clinical Laboratory”.

CLSI EP5-A, “Evaluation of Precision Performance of Clinical Chemistry Devices”

CLSI EP6-A, “Evaluation of the Linearity of Quantitative Measurement Procedures”

CLSI EP7-A, “Interference Testing in Clinical Chemistry”

CLSI EP9-A2, “Method Comparison and Bias Estimation Using Patient Samples”

L. Test Principle:

The VITROS Rubella IgG assay is performed using the VITROS Immunodiagnostic Products Rubella IgG Reagent Pack and VITROS Immunodiagnostic Products Rubella IgG Calibrators on the VITROS Immunodiagnostic System. An immunometric technique is used. This involves the reaction of anti-rubella IgG present in the sample with rubella antigen coated onto the wells. After a wash step a horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal anti-human IgG) is added and this complexes with bound anti-rubella IgG. Unbound materials are removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an

electron transfer agent, is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the VITROS Immunodiagnostic System. The amount of HRP conjugate bound is directly proportional to the concentration of anti-rubella IgG present.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision was evaluated at three sites, using three master lots and four precision pools at 4 analyte levels on three VITROS systems, based on recommendations found in CLSI/NCCLS EP5-A and CLSI/NCCLS I/L6-A. Calibration was performed prior to initiating the studies and as needed subsequently. Quality controls were run in singleton on each day of the study. Within-run, within-calibration, and within-lab precision results were generated as follows:

	Units = IU/mL							No. Observ.
	Mean Rubella Conc	Within-run*		Within-calibration**		Within-lab***		
		SD	CV (%)	SD	CV (%)	SD	CV (%)	
Site 1	3.84	0.196	5.6	0.463	13.3	0.529	13.8	80
	8.24	0.227	2.8	0.649	8.1	0.736	8.4	80
	17.2	0.434	2.6	1.03	6.2	1.46	8.0	80
	72.4	1.91	2.8	5.04	7.3	6.80	8.7	80
Site 2	4.98	0.141	2.8	0.253	5.1	0.252	5.1	80
	10.3	0.342	3.3	0.579	5.6	0.572	5.6	80
	20.7	0.414	2.0	0.675	3.2	0.760	3.7	80
	77.7	2.29	2.9	5.24	6.7	5.49	7.1	80
Site 3	4.19	0.227	5.5	0.622	15.0	0.626	14.7	76
	8.70	0.244	2.8	0.879	10.2	0.889	10.1	76
	15.5	0.301	1.9	1.11	7.2	1.12	7.1	76
	74.0	2.74	3.7	9.60	13.0	8.44	11.4	76

* Within-run: Within-run precision was determined using duplicate determinations.

** Within-calibration: Total within-calibration precision was determined using a single lot of reagent over a single calibration interval.

*** Within-lab: Total within-lab precision was estimated using a single reagent lot calibrated weekly.

b. *Linearity/assay reportable range:*

The assay range is 0-350 IU/mL. Assay linearity was determined based on recommendations in CLSI/NCCLS EP6-A. Two analyte concentration ranges were constructed from two plasma pools with IgG titers near the extremes of the assay measurement limits that were mixed to 10 intermediate concentrations per tested range. One range spanned the assay measurement range, and the other was centered near the assay cut-off. The mean of each concentration was determined using six replicates from two master lots of reagent, and the means compared with the calculated concentrations. Linear regression indicated that the assay is linear around the cut-off (4-32 IU/mL) with $r^2 = 0.9988$. Across the entire range of the assay, the results are best fitted by second order polynomial regression with deviation from linearity in the range 32.5-296 IU/mL equal to or less than 10.9%

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Calibration of the VITROS Rubella IgG assay is traceable to in-house reference calibrators that have been value-assigned using a commercially available assay adjusted to optimize the clinical performance of the assay. Calibration is verified using Centers for Disease Control and Prevention (CDC) low titer Rubella standard.

Shelf-life and open on-board storage stability assessments were performed for reagents, and shelf-life and open off-board storage stability assessments were performed for calibrators.

Shelf-life: Shelf-life testing was performed at weeks 0, 4, 9, 13, 18, 22, 26, 30, and 36 using VITROS Rubella IgG Reagent Packs and VITROS Rubella IgG Calibrators that had been subject to simulated transport conditions of storage at +20° C for 2 days then returned to storage at 2-8° C prior to testing. Four runs were performed at each time point for three master lots. All tests for all timepoints yielded results within acceptance limits, and support a 30 week shelf-life for reagents and calibrators.

Open on-board storage: Open on-board storage stability was assessed at weeks 0, 2, 4, 8, and 12 weeks using 3 lots and four runs per lot at each time point, with reagents that had been subjected to simulated transport conditions and returned to storage at 2-8° C. Fresh reagents were tested at weeks 0 and 12. Reagent Packs were stored under simulated use conditions (stored in system Environmental Chamber, with warming to room temperature for ≥ 30 min on 6 separate occasions) for duration of the testing. All results for each time point were within acceptance limits, and support an on-board storage period of 12 weeks with typical Reagent Pack use.

Open off-board storage of calibrators: Off-board storage of calibrators was

assessed at storage temperatures 2-8° C and -20° C, at 0, 5, 10, and 13 weeks using pooled calibrators and three reagent kit lots and four runs per lot at each time point. Reagent Packs and calibrators were subjected to simulated transport conditions and returned to storage at 2-8° C prior to testing. Each run included singleton determinations of fresh, and pooled and stored calibrators (2-8° C and -20° C). All results were within acceptance limits, and support an open off-board storage at 2-8° C or -20° C for up to 13 weeks.

Sample stability was examined using matched samples drawn in serum glass, EDTA, heparin, and citrate plasma tubes from 9 IgG-positive donors and one IgG-negative donor. Samples were assayed fresh, after 5 and 7 days storage at 2-8° C, and after 4 weeks at -20° C. Three singleton determinations were made with one master lot of reagents, and the other 6 determinations were made with a different master lot on a second VITROS instrument. Three determinations for each sample type and storage condition were made. The table below shows the results for the IgG positive samples. There was no storage effect on the IgG negative samples.

Sample type	Mean % difference from fresh		
	2-8° C 5 days	2-8° C 7 days	-20° C 4 weeks
Serum	-5.1	-9.7	-11.0
Heparin	-3.2	-11.6	-7.9
EDTA	-6.2	-12.8	-10.5
Citrate	-2.6	-7.0	-3.6

d. Detection limit:

The detection limit of the assay is nominally 0 IU/mL. Performance data support a lower limit of linearity of 4 IU/mL. Two specimen pools with concentration = 4IU/mL were each tested 16 (pool 1a) or 20 (pool 1b) times, using two reagent lots.

Pool	Mean	SD	CV(%)	N
1a	3.90	0.257	6.6	16
1b	4.07	0.260	6.4	20

e. Analytical specificity:

Analytical specificity was demonstrated by testing of cross-reactivity with

specimens containing potentially cross-reacting subgroups, and by testing of specimens spiked with various potentially interfering substances.

Cross-reacting subgroups: 177 patient samples were determined in singleton using the VITROS Rubella IgG assay and the Abbott AxSym Rubella IgG assay, using 2 master lots of VITROS reagents and 2 VITROS instruments. Results were compared for agreement. Twenty-four of 177 samples were negative for IgG in both tests. 138 samples were positive in both tests. Eleven samples were positive or equivocal with AxSym and negative with VITROS. ANA/SLE was slightly over-represented in the discordant group. No evidence of specific cross-reactivity was seen.

Subgroup	N	Consensus
CMV IgG	7	7/7
CMV IgM	5	5/5
EBV IgG	5	5/5
EBV IgM	5	4/5
HSV1 IgG	5	5/5
HSV2 IgG	5	5/5
Measles IgG	5	4/5
Measles IgM	5	4/5
Toxoplasma IgG	2	1/2
Toxoplasma IgM	5	5/5
Anti-VZV	4	4/4
Anti-Parvo B19	5	5/5
ANA/SLE	26	20/26
Hyper IgG	9	7/9
Hyper IgM	3	2/2
RF	72	72/72
Heterophilic/HAMA	9	6/9

	#	%	CI
Pos. agreement-excl Equiv	138/149	92.6	87.2-96.3%
Neg. agreement-excl Equiv	24/24	100	85.8-100%
Pos. agreement-incl Equiv	138/152	90.8	85.0-94.9%
Neg. agreement-incl Equiv	24/25	96.0	79.6-99.9%

Overall agreement	162/173	93.6	88.9-96.8%
-------------------	---------	------	------------

Interfering substances: Four interfering substances were examined for their effects on Rubella IgG measurement using 12 replicates of an in-house QC pool with an IgG value near the cut-off, and 2 reagent master lots.

Substance	Conc.	Mean % interference	
		Lot 2	Lot 4
Azide	100 mg/dL	-3.8	-7.5
Bilirubin	20 mg/dL	-7.0	-3.5
Dipyron	100 mg/dL	2.3	4.1
Triolein	3000 mg/dL	-2.7	-6.8

The effect of hemolysis was also examined using 5 hemoglobin levels in 11 samples with 2 lots of reagents. An aliquot of serum was withdrawn from each sample (non-hemolyzed) and to various levels of hemoglobin (5.0, 2.5, 1.1, 0.5 g/L) were added to additional aliquots. Each prepared sample was analyzed in singleton, and % difference of samples with added hemoglobin compared to non-hemolyzed samples was determined. The following table contains results from bias calculations using only the highest level of hemoglobin (500 mg/dL). The mean percent differences for the two lots were -6.2 and -4.5, with ranges of 4.7 to -30.6 and 18.4 to -34.6

Sample	Lot 2		Lot 4	
	Non-hemolyzed IU/mL	Percent difference	Non-hemolyzed IU/mL	Percent difference
1	149	2.0	157	-6.4
2	0	0	0	0
3	263	21.7	244	18.4
4	319	-14.4	256	-12.1
5	40.4	4.7	43.2	0.5
6	211	-8.5	195	5.1
7	142	-30.6	162	-34.6
8	130	-11.5	121	-5.0
9	241	-22.4	225	-15.6
11	49.1	-5.5	52.2	0.2

12	213	2.8	192	4.7
Mean		-6.2		-4.5

An additional study using samples with values near the cut-off of 10 IU/mL was performed, using samples prepared by mixing Rubella IgG positive sera with Rubella IgG negative sera to generate samples of appropriate concentrations.

Sample	Lot 220		Lot 230	
	Non-hemolyzed IU/mL	% difference	Non-hemolyzed IU/mL	% difference
1	18.0	0.6	14.6	7.5
2	16.5	4.8	12.5	4.0
3	13.8	10.1	10.9	2.8
4	17.2	11.6	13.7	0.0
5	13.3	0	10.4	5.8
6	12.6	1.6	10.0	0.0
7	12.7	21.3	10.5	8.6
8	14.1	-12.8	11.0	-6.4
9	14.7	-1.4	11.0	7.3
10	14.1	10.6	11.8	0.0
11	11.2	8.0	10.6	-9.2
12	10.4	40.4	8.92	ND
Mean		7.9		1.9

f. Assay cut-off:

The assay is calibrated to yield a cut-off value for the presence of anti-rubella IgG at 10 IU/mL, by calibration to the WHO reference material. Ten dilutions of the WHO 1st International Rubella IgG standard (1579.7 IU/mL) were made, yielding calculated IgG concentrations of 1.04-15.3 IU/mL. Each dilution was measured in triplicate in two different master lots of reagent. The results were analyzed using linear regression

Linear regression	Values
R square	0.999
Intercept	0.987
Slope	0.840
WHO result at VITROS Rubella IgG cut-off	9.39 IU/mL

2. Comparison studies:

a. *Method comparison with predicate device:*

The VITROS Rubella IgG assay was compared to the Abbott AxSYM Rubella IgG over the claimed working ranges of the assays, using 88 archived samples, at two sites, with 2 master lots of reagents, and 2 VITROS instruments.

Deming's regression was performed on the IgG measurements from the two test systems, yielding $VITROS = 0.936 (\text{assay } X) + 6.11 \text{ IU/mL}$, correlation coefficient = 0.853.

	Parameter	SE	95% CI of coefficient
N	88		
r	0.8529		
r square	0.7274		
Intercept	6.1100	7.5159	-8.8311 to 21.0512
Slope	0.9357	0.0618	0.8129 to 1.0585

b. *Matrix comparison:*

Matrix comparison samples were prepared from matched samples drawn from 5 rubella IgG-positive donors and one rubella IgG-negative donor. Positive samples were diluted with negative serum to generate serum test samples with IgG concentrations near the cut-off of 10 IU/mL. Negative samples were also spiked with positive samples to achieve concentrations near the cutoff.

Matrices tested were heparin, EDTA, and sodium citrate plasma, and standard (glass-collected), SST, and silicon-coated serum tube samples. SST-collected serum samples were tested when serum was withdrawn within 24 hr and within 48 hr of specimen collection. Results from all matrix types were compared to glass-collected serum. Each sample was determined in triplicate, spit over two VITRO instruments and two reagent lots

Rubella IgG-positive plasma samples diluted with rubella IgG-negative plasma

Donor	Glass	Heparin		EDTA		Citrate		SST day 0		SST day 1		Silicon coated	
	Mean	Mean	% diff	Mean	% diff	Mean	% diff	Mean	% diff	Mean	% diff	Mean	% diff
1	14.0	14.0	0.0	13.9	-0.7	10.7	-23.6	13.5	-3.6	14.1	0.7	13.1	-6.4
3	16.7	15.8	-5.4	15.8	-5.4	12.4	-25.7	15.2	-9.0	14.7	-12.0	15.8	-5.4
5	13.5	14.6	8.1	14.6	8.1	13.7	1.5	13.8	2.2	15.9	17.8	13.6	0.7
6	12.5	14.0	12.0	13.6	8.8	12.2	-10.4	12.2	-2.4	13.0	4.0	12.2	-2.4
7	13.6	14.0	2.9	14.5	6.6	12.8	-19.9	12.8	-5.9	12.5	-8.1	14.0	2.9
Mean % difference			3.5		3.5		-15.6		-3.7		0.5		-2.1
Range		-5.4 to 12		-5.4 to 8.8		-25.7 to 1.5		-9 to 2.2		-12 to 17.8		-6.4 to 2.9	

Rubella IgG-negative samples spiked with rubella IgG-positive samples

Donor	Glass	Heparin		EDTA		Citrate		SST day 0		SST day 1		Silicon coated	
	Mean	Mean	% diff	Mean	% diff	Mean	% diff	Mean	% diff	Mean	% diff	Mean	% diff
1	14.0	14.0	0.0	13.9	-0.7	10.7	-23.6	13.5	-3.6	14.1	0.7	13.1	-6.4
3	16.7	15.8	-5.4	15.8	-5.4	12.4	-25.7	15.2	-9.0	14.7	-12.0	15.8	-5.4
5	13.5	14.6	8.1	14.6	8.1	13.7	1.5	13.8	2.2	15.9	17.8	13.6	0.7
6	12.5	14.0	12.0	13.6	8.8	12.2	-10.4	12.2	-2.4	13.0	4.0	12.2	-2.4
7	13.6	14.0	2.9	14.5	6.6	12.8	-19.9	12.8	-5.9	12.5	-8.1	14.0	2.9
Mean % difference			3.5		3.5		-15.6		-3.7		0.5		-2.1
Range		-5.4 to 12		-5.4 to 8.8		-25.7 to 1.5		-9 to 2.2		-12 to 17.8		-6.4 to 2.9	

An additional study was performed to further examine the effect of sodium citrate on assay performance, using fourteen samples generated by blending of positive and negative serum and citrate plasma to generate samples with IgG values near the cut-off. Values shown below are the measured increase in IgG as a result of subtracting the sample value after spiking from the sample value prior to spiking (result increase).

Donor number	Serum value (IU/mL)	Plasma value (IU/mL)	% difference
1	7.37	7.65	3.8
2	6.62	6.25	-5.6
3	9.55	8.95	-6.3
4	4.56	3.76	-17.5
5	8.48	7.97	-6.0

6	7.11	7.05	-0.8
7	7.37	5.25	-28.8
8	5.44	7.23	32.9
9	7.00	6.85	-2.1
10	9.44	8.34	-11.7
11	7.89	7.22	-8.5
12	4.13	7.30	76.8
13	5.46	6.02	10.3
14	10.3	6.08	-41.0
Mean % difference			-0.3
Range of % difference			-41.0 to 76.8

3. Clinical studies:

a. *Clinical Sensitivity:*

Percent positive and percent negative agreement with a predicate device (Abbott AxSYM Rubella IgG assay) was determined in two studies.

Study 1: A total of 871 prospectively collected, random clinical samples, including women of child-bearing age, healthcare workers, and people being screened for rubella infection were tested at three clinical sites in Europe. 295 were from Site 1 (France), 276 from site 2 (Netherlands), and 300 were from site 3 (Netherlands). Each sample was tested in singleton on each system (VITROS and AxSYM). The VITROS Rubella IgG assay classifies samples with IgG values ≥ 10 IU/mL as positive, and values < 10 IU/mL as negative. The AxSYM Rubella IgG assay classifies samples with IgG values ≥ 10 IU/mL as positive, values ≥ 5 but < 10 IU/mL as equivocal, and values < 5 IU/mL as negative.

Of the samples tested, 70 (8%) were negative and 801 (92.0%) were positive for rubella IgG.

Agreement was calculated with and without equivocal results.

Three clinical sites		EIA			Totals
		Positive	Equivocal	Negative	
VITROS	Positive	782	15	4	801

	Negative	11	18	41	70
	Total	793	33	45	871
Equivocal %			3.8		

Excluding equivocals:

	Percent agreement		95% CI	
Positive	98.6	782/793	97.5	99.3
Negative	91.1	41/45	78.8	97.5
Overall*	98.2	823/838	97.1	99.0

Including equivocals:

	Percent agreement		95% CI	
Positive	96.4	782/811	94.9	97.6
Negative	68.3	41/60	55.0	79.7
Overall*	98.2	823/838	97.1	99.0

* Overall percentage agreement calculated using the total number of samples measured, excluding those that read equivocal in the AxSYM assay.

Positive and negative agreement rate was similar between sites.

Study 2: A total of 572 blinded, randomized positive and negative retrospective frozen clinical samples from US sample suppliers were tested at two sites (300 samples at site 1 and 292 samples at site 2) in singleton on each system (VITROS and AxSYM). Sample status was confirmed by vendors prior to the study. The VITROS Rubella IgG assay classifies samples with IgG values ≥ 10 IU/mL as positive, and values < 10 IU/mL as negative. The AxSYM Rubella IgG assay classifies samples with IgG values ≥ 10 IU/mL as positive, values ≥ 5 but < 10 IU/mL as equivocal, and values < 5 IU/mL as negative.

Of the samples tested, 224 (37.8%) were negative and 868 (62.2%) were positive for rubella IgG.

Agreement was calculated with and without equivocal results.

		EIA			Totals
		Positive	Equivocal	Negative	
VITROS	Positive	347	18	3	368
	Negative	9	45	170	224
Total		356	63	173	592

Excluding equivocals:

	Percent agreement		95% CI	
	Positive	97.5	347/356	95.3
Negative	98.3	170/173	95.0	99.6
Overall*	97.7	517/529	96.1	98.8

Including equivocals:

	Percent agreement		95% CI	
	Positive	86.5	347/401	82.8
Negative	89.0	170/191	83.7	93.1
Overall*	97.7	517/529	96.1	98.8

* Overall percentage agreement calculated using the total number of samples measured, excluding those that read equivocal in the AxSYM assay.

b. *Clinical specificity:*

See Clinical Sensitivity section above.

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

The clinical cut-off for immunity to infection with rubella virus has been determined to be 10 IU/mL, as published in NCCLS I/L6-A, "Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of the Test Products in the Clinical Laboratory".

5. Expected values/Reference range:

<10 IU/mL = negative

≥ 10 IU/mL = positive

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.