510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number: K080766

B. Purpose for Submission: Clearance of new device

C. Measurand: Rubella-specific IgG in human serum

D. Type of Test: Enzyme-linked Fluorescent Assay (ELFA)

E. Applicant: bioMérieux, Inc.

F. Proprietary and Established Names: VIDAS® RUB IgG

G. Regulatory Information:

1. <u>Regulation section:</u> 21CFR §866.3510, Rubella virus serological reagents

2. <u>Classification:</u> Class II

3. <u>Product code:</u> LFX (Enzyme Linked Immunoabsorbent Assay, Rubella)

4. <u>Panel:</u> Microbiology (83)

H. Intended Use:

1. <u>Intended use(s):</u>

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.

2. <u>Indication(s) for use:</u>

Same as intended use

3. Special conditions for use statement(s):

   For professional use only

4. Special instrument requirements:

   VIDAS® instruments, cleared with: K923579, K891385

I. Device Description:

The VIDAS® RUB IgG assay is an enzyme-linked fluorescent immunoassay (ELFA) that consists of a two-step enzyme immunoassay sandwich method and a fluorescent detection. All assay steps are automated by the VIDAS® instrument. The main components of the device are a Solid Phase Receptacle (SPR®), which is a pipette tip-like disposable device that serves as solid phase as well as a pipettor for the assay; and a Reagent Strip, which consists of sealed wells containing the ready-to-use reagents for the assay. The assay reactions take place by pipetting up and down the reaction medium with the Solid Phase Receptacle (SPR®) through the wells of the reagent strip. The sample is initially diluted, and follows a first incubation step in the SPR®, where anti-Rubella IgG antibodies present in the sample bind to the rubella antigen coating the interior of the SPR®. After a wash step to eliminate any unbound component, a second incubation is performed using a monoclonal anti-human IgG alkaline phosphatase conjugate. Following another wash step, the detection substrate (4-methyl-umbelliferyl phosphate) is added to the SPR. The enzyme conjugate catalyzes the hydrolysis of the substrate into a fluorescent product (4-methyl-umbelliferone), and its fluorescence is measured by the VIDAS® instrument. The intensity of the fluorescence is proportional to the concentration of rubella antibodies present in the sample. Results are automatically determined by the instrument based on the stored calibration curve and according to the CLSI I/LA6-A recommended cut-off of 10 IU/mL. The assay is calibrated against the WHO 1st International Standard for anti-Rubella Immunoglobulin, Human, Rubi 1-94, (1997). The test results are to be used in conjunction with other clinical information and history to suggest immune status against rubella virus.

J. Substantial Equivalence Information:

1. Predicate device name(s): Abbott Labs. AxSYM Rubella IgG Antibody Assay

2. Predicate K number(s):   K954045

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	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.	The AxSYM Rubella IgG assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum or plasma (EDTA, heparin or sodium citrate) to aid in the determination of immune status to rubella.
Sample handling/processing	Automated	Automated
Indications for Use	Aid in the determination of immune status to rubella	Aid in the determination of immune status to rubella
Assay Principle	Two step antibody binding of Rubella antibodies. An antigen is bound to a solid phase and anti-human IgG is in liquid form and is labeled with fluorescent compound	Two step antibody binding of Rubella antibodies. An antigen is bound to a solid phase and anti-human IgG is in liquid form and is labeled with fluorescent compound
Detection Substrate	4-methyl-umbelliferyl phosphate	4-methyl-umbelliferyl phosphate
Unit of Measure	IU/mL	IU/mL
Cut-off	10 IU/mL	10 IU/mL
Equivocal Zone	5-<10 IU/mL	5.0 – 9.9 IU/mL
Linearity	Quantitative and qualitative assay	Quantitative and qualitative assay
CDC Rubella Panel evaluation	Yes	Yes
CLSI Standards Used	I/LA6, EP5	I/LA6, EP5

Differences		
Item	Device	Predicate
Sample Type	Serum	Serum or plasma (EDTA, heparin or sodium citrate)
Antigen Used	Rubella virus (strain MR 383)	Rubella virus (strain HPV 77)
Antibody Detector	Mouse monoclonal anti-human IgG	Goat anti-human IgG
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Microparticle enzyme immunoassay (MEIA)
Sample Volume	100 µL	180 µL
Traceability/ Standardization	Master curve for each kit lot and each calibrator lot are traceable to the World Health Organization (WHO) 1st International Rubella Reference Standard, RUBI-1-94	Each calibrator lot is traceable to the 2nd preparation of the International Standard for Anti-Rubella Immunoglobulin
Measurement Range	0 – 274 IU/mL	0 – 500 IU/mL

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

CLSI 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 EP7-A2, "Interference Testing in Clinical Chemistry"

CLSI EP5-A2, "Evaluation of Precision Performance of Quantitative Measurement Methods"

CLSI EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach"

CLSI EP17-A, "Protocols for Determination of Limits of Detection"

L. Test Principle:

The VIDAS® RUB IgG II (RBG) Assay is performed in the automated VIDAS® instruments. All assay parameters are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR®), serves as the solid phase as well as a pipettor for the assay. Reagents for the assay are provided in sealed RBG Reagent Strips. The first well of the Reagent Strip is perforated to include the sample to be tested. The last well of the Strip corresponds to a cuvette that is used for fluorescent detection by the instrument. The SPR® performs the sample processing for the assay while moving from well to well of the Reagent Strip. Anti-Rubella IgG antibodies present in the sample will bind to the Rubella antigen coating the interior of the SPR®. A monoclonal anti-human IgG alkaline phosphatase conjugate is used in conjunction with the substrate 4-methylumbelliferyl phosphate for fluorescent detection.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

    a. *Precision/Reproducibility:*
    Four serum samples were tested in duplicate twice a day (2 runs per day over 10 days) on each of the 2 reagent lots using a single instrument at each of three sites (N = 240). The repeatability (intra-run precision), inter-run precision, between-site precision and total precision were calculated according to the CLSI® EP5-A2 document.

Sample	Mean conc. IU/mL	Repeatability		Inter-run precision		Between site precision		Total precision	
		Standard deviation	CV (%)	Standard deviation	CV (%)	Standard deviation	CV (%)	Standard deviation	CV (%)
Sample 1	7.8	0.58	7.4	0.58	7.4	0.20	2.5	0.84	10.8
Sample 2	8.8	0.57	6.4	0.66	7.4	0.22	2.5	0.89	10.2
Sample 3	29.8	1.46	4.9	2.62	8.8	0.95	3.2	3.14	10.6
Sample 4	154.6	10.58	6.8	18.49	12.0	0.00	0.0	21.30	13.8

Quality Control:
The VIDAS® RUB IgG Assay quality controls used for the clinical performance study included two levels: Negative (kit control C2) and high positive (kit control C1) and were included in each run of the VIDAS® instrument used for the clinical performance study. These controls must be assayed immediately after opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using these controls. At a minimum, the VIDAS® calibration was performed every 14 days during the clinical study.

b. *Linearity/assay reportable range:*
VIDAS® RUB IgG Assay linearity studies were conducted according to CLSI® EP6-A guidelines. One high concentration serum sample (> 250 IU/mL) and the Anti-Rubella Immunoglogulin WHO International Standard (RUBI-1-94) were each serially diluted in a negative serum over the measurement range. Each dilution was tested in triplicate. The VIDAS® RUB IgG assay was was demonstrated to be linear from 0 IU/mL to 274 IU/mL. The linear regression curve is:
Observed concentration = -1.608 + 0.996 * expected concentration, $r^2 = 0.99$.

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

Traceability:
Concordance of the assay with the WHO International Standard was evaluated using serial dilutions of the standard preparation into a negative serum sample. The dilutions were tested with two lots of the VIDAS® RUB IgG Assay. Linear regression for WHO doses (IU/mL) vs. VIDAS® results:
Observed concentration = 2.656 + 0.981 * expected concentration, $r^2 = 0.98$.

Stability: Kit and Controls:
    Storage:
Storage of the VIDAS® RUB IgG kit is recommended at 2-8°C. Do not freeze reagents. Store all opened unused reagents at 2-8°C.
Kit shelf-life is lot specific. If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label.

Heat inactivation:
Twenty-two serum samples were heated to a temperature of 56-58 °C for 30 minutes to verity the effect on assay results of heat inactivation. Each sample was tested before and after heat inactivation and the results were compared using a linear regression. Acceptance criteria: heat treated sample titer is in a range +/- 3 SD of the untreated sample. Results for six of the samples were found to be significantly higher after treatment. It was concluded that heat inactivated samples should not be used.

d. *Detection limits:*

LoB, LoD, and LoQ were evaluated for the VIDAS® RUB IgG Assay according to CLSI EP17-A guideline, using one instrument one kit lot, and 6 human samples (one negative or blank, and 5 low levels). The blank sample was tested in 12 replicates in a single run per day for 5 days; each low level sample was tested in 4 replicates in a single run per day for 5 days. The determination of LoB, LoD, and LoQ was based on 160 results (60 from blank, and 100 from low level samples). To determine their accepted reference value, each low level sample was tested in 4 replicates and two runs on two different VIDAS® systems. All the four runs were tested on the same day. LoB was determined to be = 0.24 IU/mL; LoD = 0.47 IU/mL; and LoQ = 0.80 IU/mL. All are reported at 0 IU/mL by the VIDAS® systems, and all meet the clinical requirements of the test.

e. *Analytical specificity:*

Cross-reactivity:
The cross-reactivity of the VIDAS® RUB IgG assay was evaluated according to CLSI® document EP7-A2 comparative measurement procedure. Patient specimens were used to test for potential cross reactivity due to endogenous antibodies generated by other disease states. 138 samples found by a different commercially available test to have rubella IgG levels spanning the measuring range of the VIDAS assay and demonstrating immunological reactivity to the following 14 disease states using FDA-Cleared devices were evaluated on the VIDAS and by the predicate assay. Comparative results between the different disease states and healthy donors showed no bias. No cross-reactivity was observed. Due to low prevalence of rubella antibody negative/cross-reacting condition positive patients, cross-reactivity could not be adequately assessed in other disease states. The end user should establish cross-reactivity performance in these situations.

Organism / condition	Number of samples	VIDAS negative results	AxSYM device negative results (on same VIDAS negative samples)	Concordance of positive results (VIDAS positive / AxSYM positive)
Anti-Nuclear Antibody	9	2	2	7/7
Rheumatoid factor	10	0	0	10/10
Epstein-Barr Virus	9	0	0	9/9
Measles IgG	10	0	0	10/10
Parvovirus B19	10	1	0	9/10
Herpes Simplex Virus	10	0	0	10/10
CytoMegaloVirus	10	2	1	8/9
Varicella-Zoster Virus	10	0	0	10/10
Influenza Virus	9	0	0	9/9
Mumps	10	0	0	10/10
Toxoplasma positive IgG	10	2	2	8/8
Toxoplasma positive IgM	8	0	0	8/8
Hyper-Immune IgG	10	3	3	7/7
Hyper-Immune IgM	9	1	1	8/8

NOTE: Assessment of potential cross-reactivity due to circulating HAMA was not established. The user is responsible for establishing cross-reactivity performance with these antibodies.

Interference:
Testing for interfering substances was conducted according to CLSI Protocol EP7-A2 (Vol. 25, No. 27) using 3 human serum samples with values between 0.34 to 124.54 IU/mL. Test and control samples were evaluated in replicates of 3 using 5 levels of the interferent substance. Acceptance criterion: Recovery of positive samples within ± 15% of initial value. No significant change in the quantitative and qualitative results of the VIDAS® RUB IgG kit was observed in the substances tested at the specific levels indicated.

Interferent Material Tested	Tested Concentration
Hemoglobin	Up to 3.8 g/L Hemoglobin (239 µmol/L monomer hemoglobin)
Lipids	Lipids up to 30 g/L equivalent in triglycerides
Bilirubin	Up to 540 µmol/L

Interpretation method: Doses were calculated with systematic recalibration. The mean of the doses was obtained for each potential interfering substance concentration level. The linear regression line coefficients were determined between the observed analyte values and the associated interfering substance concentrations. 95% confidence ranges were also determined and added to the data sets. A test of the hypothesis, whereby the line slope is zero, was

evaluated and interpreted. If it was not possible to exclude the hypothesis at a 5% risk, it was determined to be possible to admit that no detrimental effect on the assay was experienced with the interfering substance. If it was possible to exclude it, a repeat of the analysis with lower interfering substance concentrations was performed until no interfering effect on the assay was found. The study concluded that no significant systematic effects on the assay were detected for each potentially interfering substance at the described levels.

f. *Assay cut-off:*

The cut-off for the VIDAS® Rub IgG assay was set at 10 IU/mL based on the WHO 1st International Standard for anti-Rubella Immunoglobulin, Human, RUBI-1-94 (1997) in accordance to the CLSI guideline I/LA6-A (1997).

ROC curve analysis was performed in order to determine the accuracy of the assay's cutoff. The assay's cut-off was set based on the CLSI Guideline and evaluated on the observed results to guarantee the best levels of specificity, without compromising the sensitivity. A grey zone between 5 and 10 IU/mL was established due to observed assay imprecision. A sample is defined as positive if the test value is equal to or greater than 10 IU/mL, and defined as negative if the Index value is lower than 5 IU/mL. Samples with results between 5 and 10 IU/mL are classified as equivocal.

WHO Metrological Traceability:
The international preparation (RUBI-1-94, WHO 1st International Standard for anti-Rubella Immunoglobulin, Human, 1997) was used to prepare a dilution curve in serum matrix to cover the assay range.
The metrological traceability process includes four levels:
    RUBI-1-94 as reference standard for the assay. 10 data points, ranging from 0 to 500 IU/ml, were generated by dilution of the RUBI-1-94 in a pool of rubella IgG negative human serum.
    Working standard and adjustment panel. The working standard (7 data points) is the secondary standard which has values assigned based on RUBI-1-94, and it is used together with the adjustment panel (6 data points) to generate master calibration curves for each reagent lot.
    Kit calibrator (S1), run by the users to provide instrument-specific calibration curves and to compensate for possible minor variations in assay signal throughout the shelf-life of the kit.
    Patient samples, a panel of six samples representing the range of the assay. The concentration of the working standard and adjustment panel was assessed using the reference standard (RUBI-1-94) to generate a master curve. The measurement of each data point was performed in duplicate, in 5 series for each of two reagent lots. The final assigned values were the mean of the values obtained on the two lots. There was no bias between concentrations obtained from reference standard and working standard.

The analytical sensitivity was based on a dilution curve plotted with the mean of each standard point. Regression analysis of the VIDAS® RUB IgG assay results versus the calculated WHO standard concentration of each dilution was evaluated (IU/mL).

2. Comparison studies:

    a. *Method comparison with predicate device:*
        The performance of the VIDAS® RUB IgG assay was determined by percent agreement among negative samples and percent agreement among positive samples, against a reference method, in specific populations. The relevant 95% confidence limits were computed by applying the exact method.
        All specimens were tested using the VIDAS® RUB IgG assay and three other FDA-cleared Rubella IgG EIA assays according to their respective package inserts. All testing was performed on a single specimen from the patient. Samples with results above the reportable range of the VIDAS® RUB IgG assay or the reportable range of the commercial assays were diluted according to the respective package insert and re-assayed after dilution. Equivocal results that remained equivocal after being re-tested, were considered equivocal for the performance analysis.
        The performance of the VIDAS® RUB IgG assay was determined by comparison to a testing algorithm (Consensus Comparator) that utilizes a two out of three results consensus as the final outcome for the predicate (using the three FDA cleared devices): i.e. a sample with a concordant result by at least two of the three commercial devices was defined as the consensus predicate result. If the results by the three devices were either discordant among themselves or concordant equivocal, the sample was classified as equivocal. Specimens that were equivocal by both, the VIDAS® RUB IgG assay and the consensus from the three commercial tests (total of 12 out of the 1,130), and samples with quantity not sufficient for the 2/3 consensus method (8/1,130) were not included in the percent agreement calculation. Positive or negative results from the VIDAS® RUB IgG assay were considered as non-agreements in the calculation of percent positive agreement and percent negative agreement when the corresponding consensus comparator result was equivocal. Comparison method: compared number of samples positive on both tests to sum of all positive samples on the reference method + samples equivocal on the comparator method and negative on the VIDAS® RUB IgG assay. Compared number of samples negative on both tests to sum of all negative samples on the reference method + samples equivocal on the comparator method and positive on the VIDAS® RUB IgG assay.

        Bias estimation:
        The comparison study was based on the CLSI EP9-A2 guideline "Method Comparison and Bias Estimation Using patient samples". A total of 80 samples were tested in duplicate (within the same run) with the VIDAS® RUB IgG and the Abbott AxSYM Rubella IgG assays. 40 of these samples were

pre-selected negative sera with concentrations <10 IU/mL and 40 were pre-selected low-positive sera (10-20 IU/mL). This same data set was also used to determine the % reproducibility of VIDAS® RUB IgG assay at the <10 IU/mL and 10-20 IU/mL levels. The Passing-Bablok regression method was used to estimate the intercept and the slope, and simple linear regression was used to estimate the expected (average) bias and the confidence interval for the expected bias at the 10 IU/mL medical decision level (reference point defining immunity).

There is no significant constant bias, but there is a significant proportional bias. This proportional bias of 67.8% is justified by bioMérieux as expected because of the AxSYM being calibrated to the 2nd preparation of the rubella International Standard whereas the VIDAS® is calibrated to the 3rd preparation of the International Standard (i.e., 1st WHO International Standard, or RUBI-1-94). Despite the bias, performance of the VIDAS® RUB IgG assay is satisfactory and meets agreement requirements (see clinical studies performance below).

b. *Matrix comparison:* N/A

3. Clinical studies:

a. *Clinical Sensitivity:* N/A

b. *Clinical specificity:* N/A

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

Percent positive and percent negative agreement with a consensus comparator method was determined as specified under Comparison Studies (see above). A total of 1001 specimens were included in the original study. The trial population consisted of 505 prospectively collected specimens (fresh and frozen) and 496 retrospective specimens (frozen repository). The prospectively collected specimens included 325 samples from pregnant women and 180 samples from the general population. The general population is defined here as predominantly adults for whom anti-rubella testing had been ordered per clinical routine, excluding pregnant women. The retrospective specimens consisted of 200 specimens from pregnant women and 296 samples from the general population (as defined above).

Supplementary Study: Given the lack of statistical power to properly assess the negative agreement in the pregnant women population using prospective samples, an unbiased blinded test of 104 pre-selected additional pregnant negative specimens and 25 pre-selected additional pregnant positive samples was performed and analyzed following the same considerations mentioned above.

The following tables compare the results of the VIDAS® RUB IgG assay to the consensus comparator:

Prospective populations

VIDAS®	Prospective Pregnant Women 2/3 Consensus				Prospective General Population 2/3 Consensus			
	Pos	Equiv	Neg	Total	Pos	Equiv	Neg	Total
Pos	309	1	0	310	170	1	0	171
Equiv	10	3	0	13	3	1	0	4
Neg	0	0	2	2	0	2	2	4
Total	319	4	2	325	173	4	2	179*

	% Agreement	95% CI	% Agreement	95% CI
Positive	96.9% (309/319)	94.3 – 98.5	97.1% (170/175)	93.5 – 99.1
Negative	66.7% (2/3)**	9.4 – 99.2	66.7% (2/3)**	9.4 – 99.2

*One sample was defined as quantity not sufficient (QNS) and was excluded from the analysis
**Number of samples too low to reliably calculate % negative agreement. An additional analysis with pre-selected negative pregnant samples and retrospective samples was performed (for Pregnant and General Populations, respectively)

Retrospective populations

VIDAS®	Retrospective Pregnant Women 2/3 Consensus				Retrospective General Population 2/3 Consensus			
	Pos	Equiv	Neg	Total	Pos	Equiv	Neg	Total
Pos	179	0	0	179	169	0	0	169
Equiv	9	4	0	13	7	4	0	11
Neg	0	5	3	8	1	6	104	111
Total	188	9	3	200	177	10	104	291*
	% Agreement		95% CI		% Agreement		95% CI	
Positive	92.7% (179/193)		88.1 – 96.0		92.3% (169/183)		87.5 – 95.8	
Negative	100% (3/3)		29.2 – 100.0		100% (104/104)		96.5 – 100.0	

*Five samples were defined as QNS and were excluded from the analysis

Pre-selected Pregnant Women Population

VIDAS®	Pre-selected Pregnant Women 2/3 Consensus			
	Pos	Equiv	Neg	Total
Pos	23	0	0	23
Equiv	0	0	0	0
Neg	0	2	102	104
Total	23	2	102	127*
	% Agreement			95% CI
Positive	92.0% (23/25)			74.0 – 99.0
Negative	100% (102/102)			96.4 – 100.0

*Two samples were defined as QNS and were excluded from the analysis.

CDC Performance Panel Results

A serum panel obtained from the CDC containing 100 samples, which consisted of 50 pairs of duplicate samples titered by Hemagglutination Inhibition (HI) were evaluated. The sample pairs included 9 negative sera (representing 18 negative samples), and 41 positive sera (representing 82 positive samples). The VIDAS® RUB IgG assay identified 80/82 (97.6%) positive tests on 82 positive sera and 18/18 (100%) negative tests on 18 negative sera. One of the pairs of HI positive sera was reported as VIDAS® equivocal (both results).

CDC Biological Standard Results

The CDC low-titer (commercialized at 21.0 IU/mL) anti-Rubella antibody human standard was tested neat and at a ½ dilution as described in the CLSI® I/LA6-A guideline. The mean result of the neat standard was 17.3 IU/mL. The mean result of the two fold diluted standard was 8.0 IU/mL.

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:

Reference Range:

below 5 IU/mL	Negative
between =5 and <10 IU/mL	Equivocal
equal to or above 10 IU/mL	Positive

Expected Values

The VIDAS® RUB IgG assay was tested with 505 prospectively collected specimens (fresh and frozen) representing subjects for whom rubella IgG testing had been ordered per clinical routine. Of the 505 serum samples, 325 corresponded to pregnant women, and 180 samples corresponded predominantly to non pregnant adults and contained 85.5% females and 14.5% males. The distribution of results for IgG antibodies to rubella in these populations as determined by the VIDAS® RUB IgG assay is summarized as follows:

Prospectively collected samples from a General population

		N	Negative	Equivocal	Positive	Prevalence %
	Total	180	4	4	172	95.56
Gender	Female	129	3	2	124	96.12
	Male	51	1	2	48	94.12
Age	10 - 20	24	1	1	22	91.67
	21 – 39	90	2	2	86	95.56
	40 – 59	53	1	1	51	96.23
	$\geq$ 60	13	0	0	13	100.00

Prospectively collected samples from pregnant women

		N	Negative	Equivocal	Positive	Prevalence %
	Total	325	2	13	310	95.38
Age	10 – 20	29	0	2	27	93.10
	21 – 39	290	2	11	277	95.52
	$\geq$ 40	6	0	0	6	100.00

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.