

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM**

A. 510(k) Number:

k141655

B. Purpose for Submission:

New device

C. Measurand:

Anti-SS-A 52 (Ro52) IgG autoantibodies

D. Type of Test:

Semi-quantitative chemiluminescent immunoassay (CIA)

E. Applicant:

INOVA Diagnostics, Inc.

F. Proprietary and Established Names:

QUANTA Flash® Ro52
QUANTA Flash® Ro52 Calibrators
QUANTA Flash® Ro52 Controls

G. Regulatory Information:

1. Regulation section:

21 CFR §866.5100 – Antinuclear Antibodies Immunological Test System
21 CFR §862.1150 – Calibrator
21 CFR §862.1660 – Quality Control Material (Assayed and Unassayed)

2. Classification:

Class II – Assay and Calibrators
Class I – Control

3. Product code:

OBE – Anti-SS-A 52 Autoantibodies
JIT – Calibrator, Secondary

JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

Immunology (82) (Assay)

Clinical Chemistry (75) (Calibrators and Controls)

H. Intended Use:

1. Intended use(s):

QUANTA Flash® Ro52 is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-Ro52 autoantibodies in human serum. The presence of anti-Ro52 autoantibodies, in conjunction with clinical findings and other laboratory tests, is an aid in the diagnosis of Systemic Lupus Erythematosus (SLE), Sjögren's Syndrome, Systemic Sclerosis, Idiopathic Inflammatory Myopathies.

QUANTA Flash® Ro52 Calibrators are intended for use with the QUANTA Flash® Ro52 Reagents for the determination of IgG anti-Ro52 autoantibodies in human serum. Each calibrator establishes a point of reference for the working curve that is used to calculate unit values.

QUANTA Flash® Ro52 Controls are intended for use with the QUANTA Flash® Ro52 Reagents for quality control in the determination of IgG anti-Ro52 autoantibodies in human serum.

2. Indication(s) for use:

Same as Intended Use

3. Special conditions for use statement(s):

For Prescription Use only

4. Special instrument requirements:

BIO-FLASH® chemiluminescent analyzer (k083518)

I. Device Description:

The QUANTA Flash® Ro52 Kit includes the following components:

- a. One (1) QUANTA Flash® Ro52 Reagent Cartridge with the following reagents for 50 determinations:
 - Ro52 antigen coated paramagnetic beads, lyophilized
 - Assay Buffer

- Tracer IgG – Isoluminol labeled anti-human IgG antibodies in buffer.
- b. One (1) vial of Suspension buffer
- c. One (1) Transfer pipette

The QUANTA Flash® Ro52 Calibrators set is sold separately and contains:

- a. Calibrator 1: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrator 1 contains human antibodies to Ro52 in buffer with concentration of 10 CU.
- b. Calibrator 2: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrator 2 contains human antibodies to Ro52 in buffer with concentration of 400 CU.

The QUANTA Flash® Ro52 Controls set contains is sold separately and contains:

- a. Negative Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Negative control contains human antibodies to Ro52 in buffer with concentration of 10 CU.
- b. Positive Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Positive control contains human antibodies to Ro52 in buffer with concentration of 55 CU.

J. Substantial Equivalence Information:

- 1. Predicate device name(s):

QUANTA Lite® SS-A 52 ELISA

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

k063565

- 2. Comparison with predicate:

QUANTA Flash® Ro52 Reagent Kit:

Similarities		
Item	Device QUANTA Flash® Ro52	Predicate QUANTA Lite SS-A 52
Intended Use	Semi-quantitative determination of anti-Ro52 antibodies in human serum.	Same
	Aid in the diagnosis of SLE, Sjögren’s syndrome (SS), Systemic Sclerosis (SSc), and Idiopathic Inflammatory Myopathies (IIM)	Aid in the diagnosis of SLE, SS, SSc, polymyositis (PM) and dermatomyositis (DM)

Similarities		
Item	Device QUANTA Flash® Ro52	Predicate QUANTA Lite SS-A 52
Antigen	Purified recombinant Ro52	Same
Sample Type	Serum	Same
Traceability	International Reference preparation is not available. Results are traceable to in-house standards	Same
Shelf Life	One year at 2 – 8°C	Same

Differences		
Item	Device: QUANTA Flash® Ro52	Predicate: QUANTA Lite SS-A 52
Detection	Chemiluminescent immunoassay	Enzyme-linked immunosorbent assay
Solid Phase	Paramagnetic microparticles (beads)	96-well plate
Conjugate	Isoluminol conjugated anti-human IgG	HRP conjugated anti-human IgG
Calibration	Lot specific Master Curve and two Calibrators (Sold separately)	Single standard included in the kit
Cut-off	Negative: < 20 CU Positive: > 20 CU	Negative: < 20 Unit Weak positive: 20 – 39 Unit Moderate positive: 40 – 80 Unit Strong positive: > 80 Unit
Assay Measuring Range (AMR)	2.3 – 1685.3 CU	No claim for the reportable range

QUANTA Flash® Ro52 Calibrators:

Similarities		
Item	Device QUANTA Flash® Ro52 Calibrators	Predicate
Analyte	Anti-Ro52 antibodies	Same
Matrix	Human serum, buffers, stabilizers and preservative	Same
Physico-chemical characteristics	Liquid, prediluted, ready to use	Same
Shelf Life/Storage	One year at 2 – 8°C	Same

Differences		
Item	Device: QUANTA Flash® Ro52 Calibrators	Predicate:
Intended Use	For use with QUANTA Flash® Ro52 reagents for determination of IgG anti-Ro52 antibodies in human serum. Each calibrator establishes a point of reference for the working curve that is used to calculate unit values.	No separate intended use; calibrator is part of the kit.
Unit	CU (Chemiluminescent units)	Units

QUANTA Flash® Ro52 Controls:

Similarities		
Item	Device QUANTA Flash® Ro52 Controls	Predicate
Analyte	Anti-Ro52 antibodies	Same
Matrix	Human serum, buffer, stabilizer, and preservative	Same
Physico- chemical characteristics	Liquid, ready to use	Same
Levels	2 (negative and positive)	Same
Shelf Life/Storage	One year at 2 – 8°C	Same

Differences		
Item	Device: QUANTA Flash® Ro52 Controls	Predicate:
Intended Use	QUANTA Flash® Ro52 Controls are intended for use with the QUANTA Flash® Ro52 reagents for quality control in the determination of IgG anti-SS-B autoantibodies in human serum.	No separate intended use; controls are part of the kit.
Unit	CU (arbitrary)	Units (arbitrary)

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

EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline, Second Edition.

EP06-A, Evaluation of Linearity of Quantitative Measurement, Approved Guideline, Second Edition.

EP07-A2, Interference Testing in Clinical Chemistry, Approved Guideline, Second Edition

EP09-A2-IR, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, Second Edition (Interim Revision).

EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition
C28-A3, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline, Third Addition

L. Test Principle:

The QUANTA Flash® Ro52 assay is a microparticle chemiluminescent immunoassay designed for use on the BIO-FLASH® instrument. The instrument platform is a fully automated closed system with continuous load and random access capabilities that automatically processes the samples, runs the assay and reports the results. It includes liquid handling hardware, luminometer and computer with software-user interface. The QUANTA Flash® Ro52 assay utilizes a reagent cartridge format, which is compatible with the BIO-FLASH® instrument.

Purified recombinant Ro52 antigen is coated onto paramagnetic beads. The bead suspension is lyophilized and stored in the bead tube. Prior to use in the BIO-FLASH® system, the sealed reagent tubes are pierced with the reagent cartridge lid and the beads are rehydrated and resuspended using resuspension buffer by pipetting up and down with a transfer pipette. The reagent cartridge is then loaded onto the BIO-FLASH® instrument. Samples are also loaded onto the instrument in sample racks. A patient serum sample is prediluted by the BIO-FLASH® with system rinse in a small disposable plastic cuvette. Small amounts of the diluted patient serum, the beads, and assay buffer are all combined into a second cuvette, and mixed. This cuvette is then incubated at 37°C. The beads are magnetized and washed several times. Isoluminol conjugated anti-human IgG antibodies are then added to the cuvette, and again incubated at 37°C. The beads are magnetized and washed repeatedly. The isoluminol conjugate is oxidized when Trigger 1 and Trigger 2 are added to the cuvette, and the flash of light produced from this reaction is measured as Relative Light Units (RLU) by the BIO-FLASH® optical system. The RLU are proportional to the amount of isoluminol conjugate that is bound to the human IgG, which is in turn proportional to the amount of anti-Ro52 antibodies bound to the corresponding Ro52 on the beads.

For determining the amount of antibody in a sample, the QUANTA Flash® Ro52 assay utilizes a predefined lot specific Master Curve that is uploaded onto the instrument through the reagent cartridge barcode. Every new lot number of reagent cartridge must be calibrated before first use, with the QUANTA Flash® Ro52 Calibrators. Based on the results obtained with the two Calibrators included in the Calibrator Set, an instrument specific Working Curve is created, which is used to calculate chemiluminescent units (CU) from the instrument signal (RLU) obtained for each sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision: The precision of the QUANTA Flash® Ro52 assay was evaluated on nine serum samples containing various concentrations of Ro52 antibodies. Each sample was run in duplicate, twice a day, for 21 days with one reagent lot (total of 84 replicates per sample). Data were analyzed for within run, between run, between day and total precision. All %CV values were within the manufacturer’s pre-determined acceptance limit of <10%. The results are summarized in the table below.

Sample	Mean (CU)	Within-Run		Between-Run		Between-Day		Total	
		SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
1	14.0	0.5	3.4	0.4	3.2	0.4	3.0	0.8	5.5
2	18.8	0.6	3.4	0.4	2.1	0.9	4.6	1.1	6.1
3	20.5	0.7	3.4	0.6	3.1	1.2	5.8	1.5	7.4
4	27.2	1.0	3.6	0.7	2.6	1.5	5.5	1.9	7.1
5	140.5	8.3	5.9	2.0	1.5	8.4	6.0	12.0	8.5
6	343.3	8.6	2.5	6.2	1.8	17.0	4.9	20.0	5.8
7	638.2	29.1	4.6	0.0	0.0	38.7	6.1	48.5	7.6
8	1081.3	48.7	4.5	30.6	2.8	50.7	4.7	76.7	7.1
9	1537.5	68.2	4.4	65.3	4.2	79.4	5.2	123.4	8.0

Reproducibility: Six samples were tested on two different reagent lots, using two different lots of calibrators, by two operators. Samples were run in quadruplicate, twice a day, for 10 days, to generate 80 data points per sample. Data were analyzed for within run, between reagent lots, between calibrator lots, between operators and total precision. All %CV values were within the manufacturer’s pre-determined acceptance limit, 10%. The results are summarized in the tables below.

Sample	Mean (CU)	Within-Run		Between-Lot		Between-Calibrator		Between Operator		Total	
		SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
1	9.8	0.3	3.3	0.4	4.5	0.4	4.2	0.2	2.5	0.4	4.3
2	22.4	0.6	2.8	1.1	4.7	1.3	5.8	0.7	3.0	1.1	4.9
3	96.9	2.2	2.3	8.5	8.7	6.1	6.3	3.8	3.9	6.5	6.7
4	847.6	28.6	3.4	51.7	6.1	21.4	2.5	23.9	2.8	38.8	4.6
5	1140.8	44.8	3.9	56.6	5.0	56.1	4.9	57.8	5.1	62.4	5.5
6	1472.2	61.9	4.2	54.2	3.7	57.4	3.9	57.8	3.9	66.9	4.5

b. Linearity/assay reportable range:

Linearity: The analytical measuring range of the assay is defined by the lowest and highest points on the master curve (2.3 – 1685.3 CU). The linearity across this range was evaluated by a study according to CLSI EP6-A. Serially diluted samples with Ro52 concentrations ranging from 1.8 to 2414.7 CU were prepared by diluting each of four high positive serum samples with analyte free (stripped) serum. Each dilution

was tested in duplicate. The linear regression analysis gives the following equation:

Sample	Test Range (CU)	Slope (95% CI)	Y-intercept (95% CI)	R ²
1	231.2 – 1618.2	0.97 (0.93 – 1.01)	-4.83 (-44.50 – 34.85)	1.00
2	37.2 – 370.4	1.01 (0.98 – 1.04)	-4.69 (-11.24 – 1.87)	1.00
3	11.0 – 104.2	1.02 (0.99 – 1.04)	0.16 (-1.59 – 1.91)	1.00
4	3.8 – 17.0	0.92 (0.86 – 0.98)	1.07 (0.41 – 1.73)	0.99
All samples	3.8 – 1618.2	0.97 (0.96 – 0.97)	2.23 (-1.57 – 6.03)	1.00

Auto-rerun: To validate the auto-rerun function with 1:35 dilutions, five high positive specimens with anti-Ro52 antibody concentration above assay measuring range (2226.7, 8124.4, 10165.7, 21180.4, and 23004.7 CU) were run with the auto-rerun function enabled on the BIO-FLASH®. The same set of samples prepared manually with 1:35 fold dilution was used as reference. The % recovery values for results obtained with the auto-rerun results compared to results obtained with the manual dilution were between 87% and 97%.

Hook effect: The same set of five high positive samples used in the validation study for auto-rerun function and having anti-Ro52 antibody concentration above assay measuring range was examined to assess hook effect. No hook effect was observed up to 23004.7 CU.

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

Traceability: There is no recognized standard or reference material for anti-Ro52 autoantibodies. The calibrator and control values are directly traceable to in-house standards that are used to create the master curves for the QUANTA Flash® Ro52.

Value assignment: The QUANTA Flash® Ro52 Calibrators and Controls are manufactured by diluting human serum that contains high titer of anti-Ro52 antibodies. The target CU is achieved through trial dilutions on small scale. Once a dilution is selected, the Calibrators and Controls are bulked, tested, and adjusted. Upon completion of the manufacturing process, the Calibrators and Controls are tested on at least two instruments, on at least two lots of reagent cartridge, in replicates of 10 to determine final value assignment. The target values and ranges for the Calibrators and Controls are listed below:

	Target Value (CU)	Target Range (CU)
<i>QUANTA Flash® Ro52 Calibrators</i>		
Calibrator 1	10	8 – 12
Calibrator 2	400	360 – 440
<i>QUANTA Flash® Ro52 Controls</i>		
Negative control	10	8 – 12
Positive control	50	40 – 60

Stability:

Kit stability (unopened): The accelerated stability study was performed using three lots of Ro52 coupled beads, calibrators, and controls. Real-time stability is on-going; the results to date support a claim of 12 months stability for unopened kits, calibrators and controls stored at 2 – 8°C.

On-board (In-use) stability: On-board stability study was performed for calibrators, controls and reagent cartridge:

- i. **Calibrators:** Calibrators were placed uncapped, onboard the instrument, and calibration was performed five times over 8.5 hours. Controls and a panel of characterized patient specimens were run on each calibration curve. Each calibrator is measured in triplicate during calibration.
- ii. **Controls:** Two vials of each control were assayed twice a day for a total of 20 runs. The first run was used to establish baseline value, and then an additional 19 runs were performed. During runs, the Controls were left uncapped, onboard the instrument for 15 minutes per run. When not in use, the controls were capped, and stored at 5°C ± 3°C.
- iii. **Reagent Cartridge:** Three lots of cartridges were tested with four serum specimens (with different reactivity levels) along with the Negative and Positive Controls. The specimens were tested periodically up to 90 days. Percent recoveries were calculated compared to the day zero average values, and linear regression analysis was performed by plotting % recovery against the number of days.

All results met the manufacturer’s acceptance criteria and support the following stability claim:

Calibrators	8 hours on-board; up to 4 calibrations.
Controls	Up to 15 uses with 10 min on-board per use
Reagent Cartridge	36 days on-board

Sample stability: The study was performed with six samples (two negatives, two positives, and two around the cut-off), tested at 2 – 8°C, and room temperature (RT). In addition, the samples were tested for the stability after repeated freeze/thaw cycles up to three cycles. The results support sample stability up to 48 hours of storage at

RT, up to 144 days of storage at 2-8°C, and up to three freeze/thaw cycles when samples are stored at or below -20°C.

d. Detection limit:

Limit of Blank (LoB) was determined by assaying four blank samples in five replicates per sample over three days with two reagent lots. Sixty data points per lot were generated. LoB for each lot was calculated separately at the 95th percentile using the non-parametric method, as the dataset showed non-normal distribution (p values of 0.0068 and < 0.0001, respectively). The LoB for two lots was determined to be 308 RLU and 319 RLU. The claimed LoB value is 319 RLU.

The Limit of Detection (LoD) was determined by assaying five samples with anti-Ro52 antibody concentration between LoB and approximately four times of LoB. Each sample was tested in five replicates over three days on two reagent lots. LoD value was calculated as the LoB + 1.645 x SD of the replicates for the low level samples. The LoD of the QUANTA Flash® Ro52 assay for the two lots were determined to be 400 and 402 RLU, which are below the value of the lowest QUANTA Flash® Ro52 Master Curve standard (2.3 CU), and therefore below the Analytical Measuring Range of the assay. The claimed LoD is 402 RLU.

e. Analytical specificity:

Endogenous Interference: Three serum samples with antibody concentration at 16.5 CU (negative), 21.9 CU (around the cut-off), and 64.9 CU (positive) were spiked with known quantities of bilirubin (10, 5.0 or 2.5 mg/dL), hemoglobin (200, 100, or 50 mg/dL), triglycerides/cholesterol (1000/224.3, 500/112.2, or 250/56.1 mg/dL), or rheumatoid factor (RF) (about 500, 300, or 100 IU/mL). Each sample was tested in triplicate and the recovery was calculated by comparing to control samples spiked with the same volume of diluents. No interference (<15%) was detected in the samples up to the concentrations listed in the table below:

Potential Interfering Substances	Maximum Concentration	Range of % Recovery
Bilirubin	10 mg/dL	87 – 91%
Hemoglobin	200 mg/dL	89 – 93%
Triglycerides	1000 mg/dL	91 – 93%
Cholesterol	224.3 mg/dL	91 – 93%
RF	500 IU/mL	95 – 108%

Analytical cross-reactivity: Cross reactivity of the QUANTA Flash® Ro52 was investigated using 12 reference sera from the Center of Disease Control and Prevention (CDC). The Reference sera IS2105 ANA #7 (Anti-SS-A/Ro), IS2073 ANA #2 [IIF ANA (speckled pattern); anti-SS-B/La] and IS2187 ANA #10 (Anti-Jo1) showed a concentration of 32.4 CU, 40.7 CU and 443.7 CU, respectively. The other nine (9) reference sera in the panel were negative.

f. *Assay cut-off:*

The QUANTA Flash® Ro52 cut-off was determined by testing samples from a reference population of 155 subjects (115 apparently healthy blood donors and 40 other control disease samples). The cut-off was established as 20 CU based on the 97th percentile of the results obtained.

	Positive	Negative
QUANTA Flash® Ro52	≥ 20 CU	< 20 CU

2. Comparison studies:

a. *Method comparison with predicate device:*

Samples for method comparison analysis included 319 samples from the clinical validation study (see below), along with 27 additional samples characterized as having a speckled pattern on HEp-2 by ANA IIF. From the total sample size of 319, results for 283 samples were within the reportable range of the assay. These samples were tested on both the QUANTA Flash® Ro52 and on the predicate. The results are summarized below:

		QUANTA Lite SS-A52 ELISA		
		Positive	Negative	Total
QUANTA Flash® Ro52	Positive	100	10	110
	Negative	22	151	173
	Total	122	161	283

Positive agreement: 82.0% (95% CI: 74.0 – 88.3%)

Negative agreement: 93.8% (95% CI: 88.9 – 97.0%)

Overall agreement: 88.7% (95% CI: 84.4 – 92.1%)

b. *Matrix comparison:*

Not applicable

3. Clinical studies:

a. *Clinical Sensitivity and Clinical Specificity:*

A total of 600 samples were included in the clinical validation for the QUANTA Flash® Ro52. The validation set of samples includes 131 samples from patients diagnosed with SLE, 91 samples from patients diagnosed with SS, samples from patients diagnosed with SSc, 65 samples from patients diagnosed with IIM (8 DM, 19 PM, 27 PM/DM overlap syndrome, and 11 myosites with Jo-1 antibodies), and 233 samples from patients with other diseases including autoimmune and infectious diseases. Clinical sensitivity and specificity in this sample cohort are summarized in the following tables:

		Clinical Diagnosis of SLE		
		Positive	Controls (no SS, SSc, IIM)	Total
QUANTA Flash® Ro52	Positive	47	7	54
	Negative	84	212	296
	Total	131	219	350

Sensitivity: 35.9% (95% CI: 27.7 – 44.7%)

Specificity: 96.8% (95% CI: 93.5 – 98.7%)

		Clinical Diagnosis of SS		
		Positive	Controls (no SLE, SSc, IIM)	Total
QUANTA Flash® Ro52	Positive	26	7	33
	Negative	28	212	240
	Total	54	219	273

Sensitivity: 48.1% (95% CI: 34.3 – 62.2%)

Specificity: 96.8% (95% CI: 93.5 – 98.7%)

		Clinical Diagnosis of SSc		
		Positive	Controls (no SS, SLE, IIM)	Total
QUANTA Flash® Ro52	Positive	13	7	20
	Negative	67	212	279
	Total	80	219	299

Sensitivity: 16.3% (95% CI: 8.9 – 26.2%)

Specificity: 96.8% (95% CI: 93.5 – 98.7%)

		Clinical Diagnosis of IIM		
		Positive	Controls (no SS, SSc, SLE)	Total
QUANTA Flash® Ro52	Positive	26	7	33
	Negative	39	211	250
	Total	65	218	283

Sensitivity: 40.0% (95% CI: 28.0 – 52.9%)

Specificity: 96.8% (95% CI: 93.5 – 98.7%)

The distribution of the cohort and the Ro52 positivity rate for each clinical subgroup are summarized below:

Disease category	QUANTA Flash® Ro52		
	N	# of positive	% Positive
Target Diseases:			
Sjogren's syndrome	91	40	44.0%
SLE	131	47	35.9%
Systemic Sclerosis	80	13	16.3%
IIM	65	26	40.0%
Dermatomyositis (DM)	8	5	62.5%
Polymyositis (PM)	19	5	26.3%
PM/DM Overlap	27	7	25.9%
Myositis	11	9	81.8%
Control Diseases:			
Graves' Disease	10	0	0.0%
Hashimoto Thyroiditis	10	0	0.0%
Celiac Disease	11	0	0.0%
Crohn's Disease	20	0	0.0%
Ulcerative Colitis	20	0	0.0%
HCV	6	1	16.7%
HBV	6	0	0.0%
CMV	11	1	9.1%
EBV	12	2	16.7%
HIV	5	0	0.0%
Syphilis	5	0	0.0%
Primary APS	15	0	0.0%
Secondary APS*	14	6	42.9%
Vasculitis	17	0	0.0%
Rheumatoid arthritis	50	2	4.0%
Osteoarthritis	20	1	5.0%
Behçet's disease	1	0	0.0%
Total controls	233	13	5.6%

* Patients may have SLE

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

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected value in the normal population is “negative”. Anti-Ro52 antibody levels were analyzed in a cohort of 111 apparently healthy blood donors (90 females and 21 males, ages 17 to 60 years, with an average age of 32.6 years and median age of 31 years) using the QUANTA Flash® Ro52. The results showed a mean concentration of 8 CU with the values ranging from <2.3 to 19.3 CU. None of the samples were positive on the QUANTA Flash® Ro52.

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.