510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM

A. 510(k) Number:

K152013

B. Purpose for Submission:

New device

C. Measurand:

Anti-dsDNA antibodies (IgG)

D. Type of Test:

Quantitative chemiluminescent immunoassay (CIA)

E. Applicant:

INOVA Diagnostics, Inc.

F. Proprietary and Established Names:

QUANTA Flash® dsDNA
QUANTA Flash® dsDNA Calibrators
QUANTA Flash® dsDNA 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:

   LSW – Anti-DNA Antibody, Antigen and Control
   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 dsDNA is a chemiluminescent immunoassay for the quantitative determination of IgG anti-double stranded deoxyribonucleic acid (dsDNA) antibodies in human serum. The presence of anti-dsDNA antibodies, in conjunction with clinical findings and other laboratory tests, is an aid in the diagnosis of Systemic Lupus Erythematosus (SLE).

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

   QUANTA Flash dsDNA Controls are intended for use with the QUANTA Flash dsDNA chemiluminescent immunoassay for quality control in the determination of IgG anti-dsDNA antibodies 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 dsDNA kit includes one QUANTA Flash dsDNA Reagent Cartridge with the following reagents for 50 determinations:

a. dsDNA antigen coated paramagnetic beads in a suspension
b. Assay Buffer
c. Tracer IgG – Isoluminol labeled anti-human IgG antibodies in buffer

The QUANTA Flash dsDNA Calibrators kit is sold separately and contains:

a. Calibrator 1: Two barcode labeled tubes containing 0.7 mL prediluted, ready to use reagent.
b. Calibrator 2: Two barcode labeled tubes containing 0.7 mL prediluted, ready to use reagent.

The QUANTA Flash dsDNA Controls kit is sold separately and contains:

a. Negative Control: Two barcode labeled tubes containing 0.7 mL, ready to use reagent. Negative control contains human antibodies to dsDNA in buffer.
b. Positive Control: Two barcode labeled tubes containing 0.7 mL, ready to use reagent. Positive control contains human antibodies to dsDNA in buffer.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   QUANTA Lite® dsDNA SC ELISA

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

   K993727

2. Comparison with predicate:

QUANTA Flash dsDNA Reagent Kit:

Similarities		
Item	Device QUANTA Flash dsDNA	Predicate QUANTA Lite dsDNA
Intended Use	For quantitative determination of IgG anti-double stranded deoxyribonucleic acid (dsDNA) antibodies in human serum. The presence of anti-dsDNA antibodies, in conjunction with clinical findings and other laboratory tests, is an aid in the diagnosis of Systemic Lupus Erythematosus (SLE).	For the in-vitro measurement of specific IgG autoantibodies against double stranded deoxyribonucleic acid (dsDNA) present in human serum, as an aid to the diagnosis of systemic lupus erythematosus (SLE), in conjunction with other clinical findings.
Sample Type	Serum	Same
Traceability	Traceable to the first international standard preparation for dsDNA (WHO code: Wo/80)	Same
Shelf Life	One year at 2–8°C	Same

Differences		
Item	Device QUANTA Flash dsDNA	Predicate QUANTA Lite dsDNA
Detection	Chemiluminescent immunoassay	Enzyme-linked immunosorbent assay
Solid Phase	Paramagnetic microparticles (beads)	96-well plate
Antigen	Synthetic dsDNA	Calf thymus dsDNA
Conjugate	Isoluminol conjugated anti-human IgG	Horseradish peroxidase conjugated anti-human IgG
Calibration	Lot specific Master Curve and two Calibrators (Sold separately)	Five lot specific calibrators included in the kit
Cut-off	Negative: < 27 IU/mL Indeterminate: 27–35 IU/mL Positive: > 35 IU/mL	Negative: < 30 IU/mL Borderline: 30–75 IU/mL Positive: > 75 IU/mL
Assay Measuring Range (AMR)	9.8–666.9 IU/mL	12.3–1000.0 IU/mL

QUANTA Flash dsDNA Calibrators:

Similarities		
Item	Device QUANTA Flash dsDNA Calibrators	Predicate
Analyte	Anti-dsDNA 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 dsDNA Calibrators	Predicate
Intended Use	For use with QUANTA Flash dsDNA chemiluminescent immunoassay for the determination of IgG anti-dsDNA 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.

QUANTA Flash dsDNA Controls:

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

Differences		
Item	Device QUANTA Flash dsDNA Controls	Predicate
Intended Use	QUANTA Flash dsDNA Controls are intended for use with the QUANTA Flash dsDNA reagents for quality control in the determination of IgG anti-dsDNA antibodies in human serum.	No separate intended use; controls are part of the kit.
Levels	2 (low and high)	2 (negative and positive)

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

- EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline, Second Edition.
- EP6-A, Evaluation of Linearity of Quantitative Measurement, Approved Guideline.
- EP07-A2, Interference Testing in Clinical Chemistry, Approved Guideline, Second Edition
- EP09-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline, Third Edition.
- 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 dsDNA 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 dsDNA assay utilizes a reagent cartridge format, which is compatible with the BIO-FLASH instrument.

Synthetic dsDNA antigen is coated onto paramagnetic beads, which are stored in the reagent cartridge in suspension. When the assay cartridge is ready to be used for the first time, the entire cartridge is inverted several times to thoroughly mix the reagents. The sealed reagent tubes are then pierced with the reagent cartridge lid. 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- dsDNA antibodies bound to the corresponding dsDNA on the beads.

For quantitation, the QUANTA Flash dsDNA 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 dsDNA Calibrators. The Master Curve is created during manufacturing by using in-house standards that are traceable to the First International Standard Preparation for dsDNA (WHO code: Wo/80). 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 international units (IU)/mL from the instrument signal (RLU) obtained for each sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance: All results presented below were within the sponsor's pre-determined acceptance criteria for each study.

   a. Precision/Reproducibility:

   Precision: The precision of the QUANTA Flash dsDNA assay was evaluated on nine serum samples containing various concentrations of dsDNA antibodies. Each sample was run in duplicate, twice a day, for 20 or 21 days with one reagent lot (total of 80 or 84 replicates per sample). Data were analyzed for within run, between run, between day and total precision. The results are summarized in the table below.

Sample	N	Mean (IU/mL)	Within-Run		Between-Run		Between-Day		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
1	80	14.1	0.5	3.3	0.3	2.1	0.3	2.1	0.6	4.4
2	84	27.3	1.5	5.4	1.1	3.9	0.8	2.9	2.0	7.3
3	80	35.6	0.8	2.3	0.8	2.2	0.6	1.7	1.3	3.6
4	84	49.0	2.4	4.9	2.2	4.5	1.2	2.5	3.5	7.1
5	84	86.4	4.0	4.7	3.5	4.0	3.1	3.5	6.1	7.1
6	84	132.4	6.8	5.1	6.6	4.9	5.3	4.0	10.8	8.2
7	84	137.6	6.5	4.7	2.9	2.1	5.5	4.0	9.0	6.6
8	84	344.8	23.1	6.7	2.4	0.7	8.0	2.3	24.6	7.1
9	84	402.8	27.9	6.9	0.0	0.0	14.1	3.5	31.2	7.8

Site-to-site Reproducibility: A total of five samples were tested at three different locations using one reagent lot. Three samples were run in quadruplicate, twice a day, for 10 days, to generate 80 data points per site per sample, or a total of 240 measurements. Two additional samples were tested in replicates of five, once a day, for five days, to generate 25 data points for each sample at each site, or a total of 75 measurements. Data were analyzed for within run, between run, within site, between site and total precision. The results are summarized in the table below.

Sample	N	Mean (IU/mL)	Within-Day		Between-Day		Between-Sites		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
1	75	13.2	0.4	3.1	0.4	3.4	0.0	0.0	0.6	4.6
2	240	32.6	1.6	4.8	1.9	5.8	2.0	6.1	3.2	9.7
3	240	52.9	2.3	4.4	1.8	3.5	1.3	2.5	3.2	6.1
4	240	142.7	4.9	3.4	5.8	4.1	3.9	2.8	8.5	6.0
5	75	466.1	20.9	4.5	12.9	2.8	24.8	5.3	34.9	7.5

Lot-to-lot Reproducibility: To evaluate lot-to-lot reproducibility, five samples with anti-dsDNA antibody concentrations at various levels across the measuring range (13.9, 25.7, 33.1, 85.9, and 349.3 IU/mL) were tested. Each sample was tested in replicates of five, one run per day for five days using three difference reagent lots. Mean and %CV for each sample were calculated and %CV values were from 0.7% to 7.5% for all samples.

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 (9.8–666.9 IU/mL). The linearity across this range was evaluated by a study according to CLSI EP6-A. Serially diluted samples with dsDNA concentrations ranging from 5.6 to 716.1 IU/mL were prepared by diluting each of five high positive serum samples with analyte free serum. Each dilution was

tested in duplicate. The linear regression analysis with only samples within AMR resulted in the following equation:

Sample	Range (IU/mL)	Slope (95% CI)	Y-intercept (95% CI)	R^2	Recovery %
1	5.6–56.1	0.97 (0.93–1.01)	1.85 (0.40–3.30)	0.99	98.4–111.4
2	20.0–200.2	1.00 (0.98–1.02)	1.31 (-1.57–4.18)	1.00	98.7–105.1
3	54.9–549.2	1.02 (0.98–1.06)	-1.31 (-13.83–11.21)	0.99	97.0–108.9
4	71.6–716.1	1.08 (1.02–1.15)	-11.62 (-38.18–14.94)	0.99	90.8–113.0
5	65.1–650.9	1.00 (0.97–1.03)	-0.73 (-12.9–11.5)	1.00	96.4–108.7

Auto-rerun: To validate the auto-rerun function at a 1:10 dilution, eight high positive specimens with anti-dsDNA antibody concentrations above the assay measuring range (731.8, 737.7, 740.3, 786.1, 946.6, 986.6, 1030.0, and 4353.0 IU/mL) were run with the auto-rerun function enabled on the BIO-FLASH. The same set of samples prepared manually with 1:10 fold dilution was used as reference. The % recovery values for individual results obtained with the auto-rerun results compared to results obtained with the manual dilution were between 83.5% and 105.9%.

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

Traceability: The master curve standards are traceable to the First International Standard Preparation for dsDNA (WHO code: Wo/80). Based upon this standardization, results are reported in International Units (IU)/mL. Calibrator and Control values are directly traceable to in-house Standards that are used to create the Master Curves for the QUANTA Flash dsDNA assay.

Value assignment: The QUANTA Flash dsDNA Calibrators and Controls are manufactured by diluting human serum that contains a high titer of anti-dsDNA antibodies. The target IU/mL 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 (IU/mL)	Target Range (IU/mL)
QUANTA Flash dsDNA Calibrators		
Calibrator 1	19	17–21
Calibrator 2	189	169–209

	Target Value (IU/mL)	Target Range (IU/mL)
QUANTA Flash dsDNA Controls		
Low control	22	19–25
High control	90	81–99

Stability:

Kit stability (unopened): The accelerated stability study was performed using three lots of kits (with three different lots of dsDNA 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 nine 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 5ºC ± 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 6 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	60 days on-board

Sample stability: The study was performed with 13 samples, encompassing negative, equivocal and low to high positive samples, 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 six cycles. The results support sample stability up to 48 hours of storage at RT, up to 10 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 three replicates per sample over six days with two reagent lots. A total of 72 data points per lot were generated. LoB for each lot was calculated separately at the 95th percentile. The LoB for two lots was determined to be 519.8 RLU and 432.9 RLU. The claimed LoB value is 520 RLU.

The Limit of Detection (LoD) was determined by assaying five samples with anti-dsDNA antibody concentration between LoB and approximately four times of LoB. Each sample was tested in four 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 dsDNA assay for the two lots were determined to be 785.8 and 762.6 RLU. The claimed LoD is 785.8 RLU.

The Limit of Quantitation (LoQ) was determined based on the analysis of total impression of the LoD study with a total error goal of 20%. The LoQ of the QUANTA Flash dsDNA assay for the two lots were determined to be 1525 RLU and 1805 RLU, which are below the value of the lowest QUANTA Flash dsDNA Master Curve standard (2952 RLU/9.8 IU/mL), and therefore below the Analytical Measuring Range of the assay. The claimed LoQ is 1805 RLU.

e. Analytical specificity:

Endogenous Interference: Six serum samples with antibody concentration at 24.3 IU/mL (negative), 30.9 IU/mL (within the indeterminate range), 37.9 IU/mL (near/above high limit of the indeterminate range), 41.5 IU/mL (low positive), 132.3 IU/mL (mid high positive), and 375.6 IU/mL (high positive),were spiked with known quantities of conjugated 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). Each sample was tested in triplicate and the recovery was calculated by comparing to control samples spiked with the same volume of diluents. For rheumatoid factor (RF) interference, six additional samples with concentration at 21.4, 32.0, 40.3, 43.9, 140.3, and 364.0 IU/mL were tested by spiking them with different proportions of a high positive RF IgM serum sample (1894 IU/mL). Each sample was tested triplicate and the recovery was calculated by comparing to control samples spiked with the same proportions of a negative serum. No interference was detected in the samples up to the concentrations listed in the table below:

Potential Interfering Substances	**Maximum Concentration**
Bilirubin (conjugated)	10 mg/dL
Hemoglobin	200 mg/dL
Triglycerides	1000 mg/dL
Cholesterol	224.3 mg/dL
RF IgM	947.1 IU/mL

Analytical cross-reactivity: Cross reactivity of the QUANTA Flash dsDNA was investigated using 12 reference sera from the Center of Disease Control and Prevention (CDC) with one lot of QUANTA Flash dsDNA reagents. The ANA human reference serum #1 (for human antibodies to dsDNA) tested positive (50.7 IU/mL). The reference serum #5 (for human antibodies to Sm) and #7 (for human antibodies to SS-A/Ro) tested negative with the value of 22.7 and 14.8 IU/mL, respectively. The other reference sera in the panel were below 9.8 IU/mL.

f. Assay cut-off:

The QUANTA Flash dsDNA cut-off was determined by testing samples from a reference population of 170 subjects (121 apparently healthy blood donors and 49 other control disease samples). The cut-off was established as 27 IU/mL based on the 95th percentile of the results obtained. The upper limit of the indeterminate range was established as 35 IU/mL based on the 99th percentile of the results. These data were used to set the assay cut-off for QUANTA Flash dsDNA as follows:

	Negative	**Indeterminate**	**Positive**
QUANTA Flash dsDNA	< 27 IU/mL	27–35 IU/mL	> 35 IU/mL

2. Comparison studies:

a. Method comparison with predicate device:

Samples for method comparison analysis are from the samples used in the clinical validation studies and tested with QUANTA Flash dsDNA and the predicate QUANTA Lite dsDNA. A total of 481samples within the assay measuring ranges of both assays were included in the method comparison analysis. The sample set includes 369 samples from SLE patients, four samples from drug induced lupus patients, 100 samples from patients with other autoimmune diseases (primary anti-phospholipid syndrome, Sjögren's syndrome, systemic sclerosis, autoimmune myositis, mixed connective tissue disease, Crohn's disease, Celiac disease, Graves' disease, Hashimoto thyroiditis, rheumatoid arthritis, vasculitis), and eight samples from patients with infectious diseases. The results are summarized below:

		QUANTA Lite SC dsDNA			
		Positive	Indeterminate	Negative	Total
QUANTA Flash dsDNA	Positive	183	34	19	236
	Indeterminate	9	28	14	51
	Negative	36	81	77	194
	Total	228	143	110	481

Indeterminate considered as positive:

Positive agreement: 68.5% (95% CI: 63.6–73.0%)
Negative agreement: 70.0% (95% CI: 60.9–77.8%)
Overall agreement: 68.8% (95% CI: 64.5–72.8%)

Indeterminate considered as negative:
Positive agreement: 80.3% (95% CI: 74.6–84.9%)
Negative agreement: 79.1% (95% CI: 73.6–83.6%)
Overall agreement: 79.6% (95% CI: 75.8–83.0%)

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity and Clinical Specificity:

A total of 1131 samples were included in the clinical evaluation for the QUANTA Flash dsDNA. This validation set of samples includes 644 samples from SLE patients, 22 samples from drug induced lupus patients, 429 samples from patients with other autoimmune diseases (primary anti-phospholipid syndrome (APS), Sjögren's syndrome, systemic sclerosis, autoimmune myositis, mixed connective tissue disease (MCTD), Crohn's disease, Celiac disease, Graves' disease, Hashimoto thyroiditis, Rheumatoid arthritis, vasculitis), and 58 samples from patients with infectious disease. Clinical sensitivity and specificity for SLE (with a total of 1109 samples after excluding 22 drug induced SLE samples) are summarized in the following tables:

		Clinical Diagnosis of SLE		
		Positive	Negative	Total
QUANTA Flash dsDNA	Positive	275	26	301
	Indeterminate	41	32	73
	Negative	328	407	735
	Total	644	465	1109

Indeterminate considered as positive:
Sensitivity: 49.1% (95% CI: 45.2–52.9%)
Specificity: 87.5% (95% CI: 84.2–90.2%)

Indeterminate considered as negative:
Sensitivity: 42.7% (95% CI: 38.9–46.6%)
Specificity: 94.4% (95% CI: 91.9–96.3%)

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

	QUANTA Flash dsDNA		
	N=	No (%) positive	
		Indeterminate as "positive"	**Indeterminate as "negative"**
Target Disease			
SLE	644	316 (49.1%)	275 (42.7%)
Control Diseases			
SLE–drug induced	22	2 (9.1%)	2 (9.1%)
Primary APS	20	5 (25.0%)	3 (15.0%)
Sjögren's syndrome	50	4 (8.0%)	3 (6.0%)
Celiac disease (CD)	20	3 (15.0%)	0 (0.0%)
Systemic sclerosis	40	7 (17.5%)	3 (7.5%)
Idiopathic Inflammatory Myopathy (IIM)	20	2 (10.0%)	0 (0.0%)
MCTD	20	6 (30.0%)	3 (15.0%)
Crohn's disease	20	1 (5.0%)	1 (5.0%)
Graves' Disease	21	1 (4.8%)	0 (0.0%)
Hashimoto thyroiditis	61	7 (11.5%)	3 (4.9%)
Rheumatoid arthritis	101	14 (13.9%)	8 (7.9%)
Vasculitis	34	5 (14.7%)	1 (2.9%)
Infectious disease	58	3 (1.7%)	1 (1.7%)
Total of Controls	**487**	**60 (12.3%)**	**28 (5.7%)**

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-dsDNA antibody levels were analyzed in a cohort of 300 apparently healthy blood donors (131 females and 169 males, ages 19 to 68 years, with an average age and median age of 44 years) using the QUANTA Flash dsDNA. The results showed a mean concentration of 11.6 IU/mL with the values ranging from <9.8 to 81.9 IU/mL. Six samples (2.0%) were tested with value in the indeterminate range (27–35 IU/mL), and four (1.3%) of the samples were positive (36.8 to 81.9 IU/mL).

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.