510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K253817

B Applicant

Immunodiagnostics Systems Limited

C Proprietary and Established Names

IDS SS-A/Ro
IDS SS-A/Ro 60 kDa
IDS SS-B/La

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LLL OBE PET	Class II	21 CFR 866.5100 – Antinuclear Antibody Immunological Test System.	IM - Immunology

II Submission/Device Overview:

A Purpose for Submission:

New devices

B Measurand:

Anti-SS-A/Ro IgG autoantibodies
Anti-SS-A/Ro 60 kDa IgG autoantibodies
Anti-SS-B/La IgG autoantibodies

C Type of Test:

Automated semi-quantitative chemiluminescent immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

IDS SS-A/Ro

The IDS SS-A/Ro test is an automated *in vitro* diagnostic device intended for the semi-quantitative determination of SS-A/Ro (52 kDa and 60 kDa) IgG autoantibodies in human serum on the IDS system. Results are to be used in conjunction with other clinical and laboratory data as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE), Sjögren's Syndrome (SjS), and Systemic Sclerosis (SSc).

IDS SS-A/Ro 60 kDa

The IDS SS-A/Ro 60 kDa test is an automated *in vitro* diagnostic device intended for the semi-quantitative determination of SS-A/Ro 60 kDa IgG autoantibodies in human serum on the IDS system. Results are to be used in conjunction with other clinical and laboratory data as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE) and Sjögren's Syndrome (SjS).

IDS SS-B/La

The IDS SS-B/La test is an automated *in vitro* diagnostic device intended for the semi-quantitative determination of SS-B/La IgG autoantibodies in human serum on the IDS system. Results are to be used in conjunction with other clinical and laboratory data as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE), and Sjögren's Syndrome (SjS).

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

For use on IDS-iSYS Multi-Discipline Automated System (K091849)

IV Device/System Characteristics:

A Device Description:

IDS SS-A/Ro

The IDS SS-A/Ro kit consists of a reagent cartridge, 2 levels of calibrators, and a QR barcode contains data for the reagent kits.

The reagent cartridge contains following ready to use reagents for 100 determinations:

- MP (1 bottle, 2.5 mL): Magnetic particles coated with the SS-A/Ro antigen, in phosphate buffer containing stabilizing proteins and Pro-Clin 300 and sodium azide (< 0.1%) as preservatives.
- CONJ (1 bottle, 15 mL): Mouse monoclonal anti-human IgG antibody labelled with an acridine ester derivative (conjugate), in phosphate buffer containing stabilizers and sodium azide (< 0.1%) as preservative..
- DIL (1 bottle, 25 mL): Sample Dilution Solution: phosphate buffer containing bovine serum albumin, detergent, inert blue dye, and Pro-Clin 300 and gentamicin SO_4 as preservatives..

The lot specific calibrators are included with the kit:

- Two levels (CAL A and CAL B): 1 vial per level. The ready to use calibrators are human serum containing 1.6 mL human antibodies to SS-A/Ro IgG in phosphate buffer containing bovine serum albumin, detergent, inert blue dye, Pro-Clin 300 and gentamicin SO_4 as preservatives.

IDS SS-A/Ro 60 kDa

The IDS SS-A/Ro 60 kDa kit consists of a reagent cartridge, 2 levels of calibrators, and a QR barcode contains data for the reagent kits.

The reagent cartridge contains following ready to use reagents for 100 determinations:

- MP (1 bottle, 2.5 mL): Magnetic particles coated with the SS-A/Ro 60 antigen, in phosphate buffer containing stabilizing proteins and Pro-Clin 300 and sodium azide (< 0.1%) as preservatives.
- CONJ (1 bottle, 15 mL): Mouse monoclonal anti-human IgG antibody labelled with an acridine ester derivative (conjugate), in phosphate buffer containing stabilizers and sodium azide (< 0.1%) as preservative..
- DIL (1 bottle, 25 mL): Sample Dilution Solution: phosphate buffer containing bovine serum albumin, detergent, inert blue dye, and Pro-Clin 300 and gentamicin SO_4 as preservatives..

The lot specific calibrators are included with the kit:

- Two levels (CAL A and CAL B): 1 vial per level. The ready to use calibrators are human serum containing 1.6 mL human antibodies to SS-A/Ro 60 kDa IgG in phosphate buffer containing bovine serum albumin, detergent, inert blue dye, Pro-Clin 300 and gentamicin SO_4 as preservatives.

IDS SS-B/La

The IDS SS-B/La kit consists of a reagent cartridge, 2 levels of calibrators, and a QR barcode contains data for the reagent kits.

The reagent cartridge contains following ready to use reagents for 100 determinations:

- MP (1 bottle, 2.5 mL): Magnetic particles coated with the SS-B/La antigen, in phosphate buffer containing stabilizing proteins and Pro-Clin 300 and sodium azide (< 0.1%) as preservatives.
- CONJ (1 bottle, 15 mL): Mouse monoclonal anti-human IgG antibody labelled with an acridine ester derivative (conjugate), in phosphate buffer containing stabilizers and sodium azide (< 0.1%) as preservative..
- DIL (1 bottle, 25 mL): Sample Dilution Solution: phosphate buffer containing bovine serum albumin, detergent, inert blue dye, and Pro-Clin 300 and gentamicin SO_4 as preservatives..

The lot specific calibrators are included with the kit:

- Two levels (CAL A and CAL B): 1 vial per level. The ready to use calibrators are human serum containing 1.6 mL human antibodies to SS-B/La IgG in phosphate buffer containing bovine serum albumin, detergent, inert blue dye, Pro-Clin 300 and Gentamicin SO4 as preservatives.

B Principle of Operation:

The assays are based on chemiluminescence technology. Diluted samples, controls or calibrators are incubated with magnetic particles coated with the SS-A/Ro, SS-A/Ro 60 kDa, or SS-B/La antigens to allow reactive antibodies to bind. Following a washing step after the first incubation, a mouse anti-human IgG monoclonal antibody labelled with acridinium is added, followed by a subsequent incubation step. The magnetic particles are captured using a magnet and a wash step performed to remove any unbound antibodies. Trigger reagents are added; the resulting light emitted by the acridinium label is proportional to the level of anti-SS-A/Ro, SS-A/Ro 60 kDa, or SS-B/La antigen-reactive IgG antibodies in the sample.

V Substantial Equivalence Information:

A Predicate Device Name(s):

ORGENTEC ANTI-SS-A(RO) ELISA
QUANTA Flash Ro60
QUANTA Flash SS-B

B Predicate 510(k) Number(s):

K962054
K141328
K141210

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251440 (Candidate)	K962054 (Predicate)
Device Trade Name	IDS SS-A/Ro	ORGENTEC ANTI-SS-A(RO) ELISA
General Device Characteristic Similarities		
Intended Use/ Indications For Use	The IDS SS-A/Ro test is an automated in vitro diagnostic device intended for the semi-quantitative determination of SS-A/Ro (52 kDa and 60 kDa) IgG autoantibodies in human serum on the IDS system. Results are to be used in conjunction with other clinical and laboratory data as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE), Sjögren's Syndrome (SjS), and Systemic Sclerosis (SSc).	The Orgentec Anti-SS-A(Ro) ELISA is intended for the in vitro semi-quantitative determination of autoantibodies against cytoplasmic antigen, SS-A(Ro) in human serum or plasma to assist in the diagnosis of system lupus erythematosus (SLE) and other connective tissue diseases such as Sjögren's Syndrome.
Antigen	Purified recombinant Ro60 kDa and Ro52 kDa	Same
Shelf Life	12 months	Same
General Device Characteristic Differences		
Assay Principle	Chemiluminescent immunoassay	Enzyme-linked immunosorbent assay
Assay Format	Automatic	Manual
Sample Type(s)	Serum	Serum or plasma
Solid phase	Paramagnetic microparticles (beads)	96-well plate
Conjugate	Mouse monoclonal anti-human IgG antibody labelled with an acridinium ester derivative	Anti-human IgG HRP labelled
Assay Measuring Interval	5.3 – 640.0 AU/mL	0 – 200 U/mL
Cut-off	Negative: < 10.0 AU/mL Positive: ≥ 10.0 AU/mL	Negative: < 15 U/mL Equivocal: 15 to 25 U/mL Positive: > 25 U/mL
Unit	AU (arbitrary units)	U/mL (arbitrary units)

Device & Predicate Device(s):	K251440 (Candidate)	K141328 (Predicate)
Device Trade Name	IDS SS-A/Ro60 kDa	QUANTA Flash Ro60
General Device Characteristic Similarities		
Intended Use/ Indications For Use	The IDS SS-A/Ro 60 kDa test is an automated in vitro diagnostic device intended for the semi-quantitative determination of SS-A/Ro 60 kDa IgG autoantibodies in human serum on the IDS system. Results are to be used in conjunction with other clinical and laboratory data as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE) and Sjögren's Syndrome (SjS).	QUANTA Flash Ro60 is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-Ro60 autoantibodies in human serum. The presence of antiRo60 autoantibodies, in conjunction with clinical findings and other laboratory tests, is an aid in the diagnosis of Systemic Lupus Erythematosus and Sjögren's Syndrome.
Assay Methodology	Solid phase (heterogeneous) immunoassay	Same
Assay Principle	Chemiluminescent immunoassay	Same
Sample Type	Serum	Same
Antigen	Purified recombinant Ro60 antigen	Same
Shelf Life	12 months	Same
Assay Format	Automatic	Same
Solid Phase	Paramagnetic microparticles (beads)	Same
General Device Characteristic Differences		
Conjugate	Monoclonal mouse anti-human IgG antibody marked with an acridinium ester derivative.	Isoluminol conjugated anti-human IgG
Cut-off	Negative: < 10 AU/mL Positive: ≥ 10 AU/mL	Negative: < 20 CU Positive: ≥ 20 CU
Assay Measuring Range (AMR)	2.9 – 640.0 AU/mL	4.9 - 1374.8 CU
Unit	AU (arbitrary units)	CU (Chemiluminescent units) (arbitrary)

Device & Predicate Device(s):	K251440 (Candidate)	K141210 (Predicate)
Device Trade Name	IDS SS-B/La	QUANTA Flash SS-B
General Device Characteristic Similarities		
Intended Use/ Indications For Use	The IDS SS-B/La test is an automated *in vitro* diagnostic device intended for the semi-quantitative determination of SS-B/La IgG autoantibodies in human serum on the IDS system. Results are to be used in conjunction with other clinical and laboratory data as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE), and Sjögren's Syndrome (SjS).	QUANTA Flash SS-B is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-SS-B autoantibodies in human serum. The presence of anti-SS-B autoantibodies, in conjunction with clinical findings and other laboratory tests is an aid in the diagnosis of Sjögren's Syndrome and Systemic Lupus Erythematosus.
Assay Methodology	Solid phase (heterogeneous) immunoassay	Same
Assay Principle	Chemiluminescent immunoassay	Same
Sample Type	Serum	Same
Antigen	Purified recombinant SS-B antigen	Same
Shelf Life	12 months	Same
Assay Format	Automatic	Same
Solid Phase	Paramagnetic microparticles (beads)	Same
General Device Characteristic Differences		
Conjugate	Mouse monoclonal anti-human IgG antibody labelled with an acridinium ester derivative	Isoluminol conjugated anti-human IgG
Cut-off	Negative: < 10 AU/mL Positive: ≥ 10 AU/mL	Negative: < 20 CU Positive: ≥ 20 CU
Assay Measuring Range	4.6 – 640.0 AU/mL	3.3 – 1550 CU
Unit	AU (arbitrary units)	CU (Chemiluminescent units) (arbitrary)

VI Standards/Guidance Documents Referenced:

The following Clinical and Laboratory Standards Institute (CLSI) guidelines were used:

- CLSI EP05, 3rd Edition, Evaluation of Precision of Quantitative Measurement Procedures,

- CLSI EP06, 2nd Edition, Evaluation of the Linearity of Quantitative Measurement Procedures
- CLSI EP07, 3rd Edition, Interference Testing in Clinical Chemistry
- CLSI EP17, 2nd Edition, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
- CLSI EP25-A2, Evaluation of Stability of In Vitro Diagnostic Reagents
- CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory
- CLSI EP34, Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking
- CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision of the IDS SS-A/Ro, SS-A/Ro 60 kDa, and SS-B/La assays was evaluated following the CLSI Guideline EP05-A3.

Within-Laboratory Precision:

To evaluate within-laboratory precision of the IDS SS-A/Ro, SS-A/Ro 60 kDa, and SS-B/La assays, a total of seven serum samples spanning the analytical measuring interval (AMI) of each assay were tested in duplicate, twice a day for 20 days on one IDS system using one lot of assay reagent, yielding a total of 80 measurements per sample. The standard deviation (SD) and %CV of the within-run, between-run, between-day, and total within-laboratory imprecision were calculated for each sample. The results are summarized in the following tables.

IDS SS-A/Ro:

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Within-Day		Between-Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	80	8.0	0.5	6.5%	0.1	1.7%	0.6	7.6%	0.8	10.2%	0.5	6.5%
2	80	10.5	0.4	3.7%	0.4	3.5%	0.6	6.1%	0.8	8.0%	0.4	3.7%
3	80	16.0	0.9	5.9%	0.7	4.4%	0.8	5.1%	1.4	9.0%	0.9	5.9%
4	80	79.9	1.6	2.0%	1.4	1.7%	2.6	3.2%	3.3	4.2%	1.6	2.0%
5	80	140.3	3.1	2.2%	3.4	2.4%	3.2	2.3%	5.6	4.0%	3.1	2.2%
6	80	306.4	5.7	1.9%	4.5	1.5%	6.2	2.0%	9.6	3.1%	5.7	1.9%
7	80	509.7	12.7	2.5%	6.9	1.4%	14.9	2.9%	20.8	4.1%	12.7	2.5%

IDS SS-A/Ro 60 kDa:

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Within-Day		Between-Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	80	8.3	0.5	6.6%	0.5	5.7%	0.1	1.4%	0.7	8.8%	0.5	6.6%
2	80	10.5	0.5	4.4%	0.5	4.7%	0.7	6.8%	1.0	9.4%	0.5	4.4%
3	80	15.2	0.6	4.2%	1.1	7.5%	0.6	4.1%	1.4	9.5%	0.6	4.2%
4	80	66.3	1.7	2.5%	2.9	4.4%	2.4	3.7%	4.2	6.3%	1.7	2.5%
5	80	169.8	3.1	1.8%	4.4	2.6%	5.5	3.2%	7.6	4.5%	3.1	1.8%
6	80	338.2	8.0	2.4%	10.2	3.0%	8.7	2.6%	15.6	4.6%	8.0	2.4%
7	80	544.7	17.6	3.2%	20.5	3.8%	12.5	2.3%	29.8	5.5%	17.6	3.2%

IDS SS-B/La:

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Within-Day		Between-Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	80	7.1	0.6	9.2%	0.2	3.1%	0.4	6.3%	0.8	11.6%	0.6	9.2%
2	80	10.3	0.6	6.3%	0.6	6.1%	0.5	4.6%	1.0	9.9%	0.6	6.3%
3	80	13.7	0.7	4.8%	0.6	4.1%	0.7	5.2%	1.1	8.2%	0.7	4.8%
4	80	76.5	5.3	6.9%	0.0	0.0%	4.1	5.4%	6.7	8.7%	5.3	6.9%
5	80	135.7	9.5	7.0%	4.1	3.0%	3.3	2.5%	10.9	8.0%	9.5	7.0%
6	80	335.0	21.4	6.4%	11.9	3.5%	0.0	0.0%	24.5	7.3%	21.4	6.4%
7	80	497.6	42.8	8.6%	0.0	0.0%	15.6	3.1%	45.5	9.1%	42.8	8.6%

Between-Lot Imprecision:

To evaluate the lot-to-lot precision of the IDS SS-A/Ro, SS-A/Ro 60 kDa, and SS-B/La assays, a total of seven serum samples spanning the AMI of each assay were tested in five replicates, once a day for five days on one IDS system using three lots of reagents by one operator per system, yielding a total of 75 measurements per sample. The standard deviation (SD) and %CV of the within-run, between-run, between-lot, and total imprecision were calculated for each sample. The results are summarized in the following tables.

IDS SS-A/Ro:

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Between-Lot		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	75	8.2	0.6	7.2%	0.2	1.9%	0.3	3.2%	0.7	8.2%
2	75	9.9	0.8	7.9%	0.0	0.0%	0.2	2.0%	0.8	8.1%
3	75	13.8	0.8	5.9%	0.9	6.4%	0.2	1.6%	1.2	8.9%
4	75	88.8	2.6	2.9%	1.8	2.1%	7.5	8.4%	8.1	9.1%
5	75	159.5	3.3	2.1%	4.8	3.0%	12.7	7.9%	14.0	8.8%
6	75	343.0	6.4	1.9%	7.3	2.1%	29.9	8.7%	31.4	9.2%
7	75	563.5	14.9	2.6%	29.3	5.2%	14.5	2.6%	35.9	6.4%

IDS SS-A/Ro 60 kDa:

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Between-Lot		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	75	8.3	0.5	5.7%	0.4	5.1%	0.3	3.1%	0.7	8.2%
2	75	10.4	0.3	3.0%	0.3	2.8%	0.1	1.0%	0.4	4.2%
3	75	14.6	0.6	4.4%	0.3	2.4%	0.5	3.3%	0.9	6.0%
4	75	65.9	1.5	2.2%	2.0	3.1%	1.0	1.6%	2.7	4.1%
5	75	164.1	3.7	2.3%	1.2	0.7%	6.3	3.8%	7.4	4.5%
6	75	326.7	5.6	1.7%	8.7	2.7%	13.2	4.0%	16.8	5.1%
7	75	535.5	19.4	3.6%	14.7	2.7%	24.2	4.5%	34.3	6.4%

IDS SS-B/La:

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Between-Lot		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	75	7.6	0.7	9.1%	0.5	6.9%	0.1	1.6%	0.9	11.5%
2	75	10.9	0.8	7.1%	0.4	3.4%	0.7	6.2%	1.1	10.0%
3	75	16.5	1.5	9.2%	0.1	1.8%	0.8	3.3%	4.7	10.4%
4	75	76.5	4.8	6.2%	3.6	4.7%	5.3	6.9%	8.0	10.4%
5	75	137.8	9.6	7.0%	4.4	3.2%	7.3	5.3%	12.8	9.3%
6	75	335.9	24.3	7.2%	18.1	5.4%	11.4	3.4%	32.4	9.6%
7	75	513.5	36.3	7.1%	12.0	2.6%	8.6	1.7%	39.2	7.6%

Between-Instrument Reproducibility:

To evaluate the instrument-to-instrument precision of the IDS SS-A/Ro, SS-A/Ro 60 kDa, and SS-B/La assays, a total of seven serum samples spanning the AMI of each assay were tested in five replicates, once a day for five days using one lot of reagent on three IDS systems by one operator, for a total of 75 measurements per sample. The standard deviation (SD) and %CV of the within-run, between-run, between-instrument, and total imprecision (reproducibility) were calculated for each sample. The results are summarized in the following tables.

IDS SS-A/Ro

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Between-Instrument		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	75	8.1	0.8	9.8%	0.3	3.9%	0.5	6.2%	1.0	12.3%
2	75	10.1	0.8	8.2%	0.3	3.1%	0.2	2.1%	0.9	9.0%
3	75	15.6	0.8	5.4%	1.4	9.0%	0.5	3.1%	1.7	10.9%
4	75	97.3	3.3	3.4%	4.0	4.1%	2.5	2.6%	5.8	5.9%
5	75	173.6	3.8	2.2%	9.7	5.6%	4.2	2.4%	11.2	6.5%

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Between-Instrument		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
6	75	400.4	16.0	4.0%	10.9	2.7%	20.6	5.1%	28.3	7.1%
7	75	572.8	28.3	4.9%	11.4	2.0%	0.0	0.0%	30.5	5.3%

IDS SS-A/Ro 60 kDa:

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Between-Instrument		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	75	7.6	0.5	7.0%	0.5	6.6%	0.2	2.7%	0.8	10.0%
2	75	10.3	0.7	7.2%	0.3	3.3%	0.2	1.5%	0.8	8.0%
3	75	14.6	0.8	5.2%	0.9	6.4%	0.0	0.0%	1.2	8.2%
4	75	60.5	1.4	2.3%	2.5	4.1%	3.4	5.7%	4.5	7.4%
5	75	151.3	3.4	2.2%	4.0	2.6%	5.3	3.5%	7.5	4.9%
6	75	298.4	6.4	2.1%	8.4	2.8%	11.1	3.7%	15.3	5.1%
7	75	496.5	11.6	2.3%	8.0	1.6%	9.3	1.9%	16.8	3.4%

IDS SS-B/La

Sample	*N*	Mean (AU/mL)	Within-Run		Between-Run		Between-Instrument		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	75	7.3	0.5	6.7%	0.3	4.5%	0.3	4.1%	0.7	9.1%
2	75	10.8	0.6	5.8%	0.4	3.9%	0.2	2.2%	0.8	7.3%
3	75	17.7	1.3	7.6%	0.5	3.0%	0.0	0.0%	1.5	8.2%
4	75	77.0	3.1	4.0%	3.4	4.5%	1.0	1.3%	4.8	6.2%
5	75	141.6	6.2	4.4%	5.9	4.1%	2.1	1.5%	8.8	6.2%
6	75	338.5	13.4	4.0%	14.7	4.3%	6.2	1.8%	20.8	6.2%
7	75	509.2	27.1	5.3%	5.4	1.1%	10.6	2.1%	29.6	5.8%

2. Linearity:

Linearity for the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La assays was evaluated based on CLSI EP06, 2nd Ed. For each assay, two dilution series were prepared by mixing one High native serum sample with a Low native serum sample. Seven dilutions were made that overlapped other samples' dilution series. Each sample was tested with four or seven replicates on the IDS Instrument. The percent deviation from the weighted linear regression analysis was used to assess the fit of the regression for each sample and analyte. The results are summarized in the table below.

IDS SS-A/Ro:

Sample ID	Test Range (AU/mL)	Slope (95% CI)	R^2	% Deviation from Linearity
Panel - 1	0.5 – 53.9	1.02 (0.99 – 1.05)	0.99	-10.4% to 15.5%
Panel - 2	13.9 – 781.2	1.01 (0.97 – 1.04)	0.99	-9.5% to 12.3%

IDS SS-A/Ro 60 kDa:

Sample ID	Test Range (AU/mL)	Slope (95% CI)	R^2	% Deviation from Linearity
Panel - 1	2.6 – 53.5	1.00 (0.98 – 1.02)	0.99	-1.4% to 6.0%
Panel - 2	12.2 – 740.2	1.02 (1.00 – 1.04)	0.99	-10.2% to 3.0%

IDS SS-B/La

Sample ID	Test Range (AU/mL)	Slope (95% CI)	R^2	% Deviation from Linearity
Panel - 1	3.8 – 54.3	0.99 (0.96 – 1.01)	0.99	-2.1% to 6.2%
Panel - 2	16.1 – 771.2	1.02 (1.00 – 1.04)	0.99	-7.6% to 7.2%

The data support the linearity of the following analytical measuring interval of the assay:

- IDS SS-A/Ro (5.3 – 640.0 AU/mL)
- IDS SS-A/Ro 60 kDa (2.9 – 640.0 AU/mL)
- IDS SS-B/La (4.6 – 640.0 AU/mL).

3. Analytical Specificity/Interference:

The potential for interference with IDS SS-A/Ro, SS-A/Ro 60 kDa, and SS-B/La by exogenous and endogenous compounds were evaluated following the CLSI EP07, 3rd Ed. The studies were performed using three human serum specimens, one positive, one near the cutoff (borderline), and one negative. Interferent or blank buffer (≤10% v/v) were spiked into the tested serum specimens. The results of samples with interferent substance were compared to the control samples without interferent substance. No significant interference was observed when the interfering substances were tested at the following threshold concentrations:

Endogenous Interference:

Potential Interfering Substance	Tested Concentration
Albumin (Protein)	6 g/dL
Bilirubin, conjugated	40 mg/dL
Bilirubin, unconjugated	40 mg/dL
Cholesterol	400 mg/dL
Hemoglobin	1000 mg/dL
Human Anti-Mouse Antibody (HAMA)	200 ng/dL
Protein, Total	15 g/dL
Rheumatoid Factor (RhF)	540 IU/mL
Triglycerides	1500 mg/dL

Exogenous Interference:

Potential Interfering Substance	Tested Concentration
Acetaminophen	15.6 mg/dL
Acetylsalicylic Acid	3.0 mg/dL

Potential Interfering Substance	Tested Concentration
Alendronate	0.01025 mg/dL
Amoxicillin	12.9 mg/dL
Atenolol	0.009 mg/dL
Atorvastatin	0.0756 mg/dL
Azathioprine	0.258 mg/dL
Biotin	3.5 mg/dL
Diltiazem	0.075 mg/dL
Enalapril	0.0819 mg/dL
Erythromycin	13.8 mg/dL
Furosemide	1.59 mg/dL
Hydroxychloroquine	0.01509 mg/dL
Ibuprofen	21.9 mg/dL
Losartan	0.0672 mg/dL
Methotrexate	205 mg/dL
Naproxen	36.0 mg/dL
Omeprazole	0.84 mg/dL
Prednisone	0.01 mg/dL
Ranitidine	1.05 mg/dL
Rituximab	114.3 mg/dL

The CDC (Centers for Disease Controls and Prevention) ANA human reference sera panel samples were tested using the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La kit to demonstrate the specificity of the assay. The table below outlines the results obtained:

Sample ID	Catalog No.	CDC Description	IDS SS-A/Ro (AU/mL)	IDS SS-A/Ro 60 kDa (AU/mL)	IDS SS-B/La (AU/mL)
ANA-01	IS2072	ANA Homogeneous Positive; Anti-native DNA Positive	5.4 (NEG)	<2.9 (NEG)	<4.6 (NEG)
ANA-02	IS2073	ANA Speckled Positive; Anti-SSB Positive	306.1 (POS)	292.8 (POS)	>640.0 (POS)
ANA-03	IS2074	ANA Speckled Positive	138.7 (POS)	198.3 (POS)	83.8 (POS)
ANA-04	IS2075	ANA-U1 RNP Positive	9.3 (NEG)	5.7 (NEG)	<4.6 (NEG)
ANA-05	IS2076	Anti-Sm Positive	<5.3 (NEG)	<2.9 (NEG)	<4.6 (NEG)
ANA-07	IS2105	Anti-SS-A Positive	552.6 (POS)	>640.0 (NEG)	<4.6 (NEG)
ANA-08	IS2134	ANA Centromere Positive	<5.3 (NEG)	<2.9 (NEG)	<4.6 (NEG)
ANA-09	IS2135	Anti-Scl 70 Positive	<5.3(NEG)	8.6 (NEG)	<4.6 (NEG)
ANA-10	IS2187	Anti-Jo 1 Positive	232.0[±] (POS)	<2.9 (NEG)	<4.6 (NEG)
ANA-12	IS2706	Anti-Ribosomal P Positive	6.5 (NEG)	<2.9 (NEG)	<4.6 (NEG)

[±] Other immunoassay methods had shown that sample ANA-10 (IS2187) was positive for Ro52.

4. Detection Limit:

The limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) were determined following CLSI EP17-A2.

Two reagent lots of IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, or IDS SS-B/La were used. The LoB was determined with 80 replicates of four undetectable single donor serum samples per reagent lot using the parametric method. The LoD of each assay was determined with four low level serum samples. Each sample was measured in four replicates, once per day for five days resulting in a total 20 measurements per sample per IDS reagent lot: a total of 80 measurements per reagent lot using the parametric method. Similarly, the LoQs were determined with 160 replicates of four undetectable single donor serum samples and four serum samples with low antibodies level per reagent lot. The claimed LoQ is the highest concentration of the sample below the precision of 20% CV.

The claimed detection limits for each assay are summarized below:

	LoB (AU/mL)	LoD (AU/mL)	LoQ (AU/mL)
IDS SS-A/Ro	0.0	1.2	5.3
IDS SS-A/Ro 60 kDa	0.0	1.3	2.9
IDS SS-B/La	0.0	1.1	4.6

5. Assay Reportable Range

The assay reportable range is the same as the analytical measuring intervals (AMIs).

- IDS SS-A/Ro: The AMI is 5.3 – 640.0 AU/mL. Results lower than 5.3 AU/mL will be reported as "<5.3 AU/mL". Results greater than 640.0 AU/mL will be reported as ">640.0 AU/mL".

- IDS SS-A/Ro 60 kDa: The AMI is 2.9 – 640.0 AU/mL. Results lower than 2.9 AU/mL will be reported as "<2.9 AU/mL". Results greater than 640.0 AU/mL will be reported as ">640.0 AU/mL".

- IDS SS-B/La: 4The AMI is 4.6 – 640.0 AU/mL. Results lower than 4.6 AU/mL will be reported as "<4.6 AU/mL". Results greater than 640.0 AU/mL will be reported as ">640.0 AU/mL".

6. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

a. Traceability

There are no international reference materials available for anti-SSA-Ro, anti-SSA-Ro60, and anti-SSB/La. Calibrator and Control values are traceable to in-house materials for each assay.

b. Reagent Stability:

The reagent stability studies for IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La assays were designed and conducted following CLSI EP25, 2nd Ed.

Shelf-life stability: The stability of the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La reagent kit was evaluated with a real-time study. Three lots of the IDS reagent kit were stored under recommended conditions at 2 – 8°C and tested at different timepoints using two negative and five to six positive serum samples.

On-board stability: The on-board stability of the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La reagent kit was evaluated on-board the IDS instrument. One lot of the reagent kit was opened and stored on-board the IDS system and assessed over 12 time points using one to two negative and five positive serum samples.

In-use stability: The in-use stability of the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La reagent kit was evaluated with an open cartridge vial on the IDS instrument. One lot of the IDS reagent kit was opened and stored on-board the IDS system and assessed over 8 time points using four positive serum samples at 2 – 8°C. Reagent cartridges were removed from the system after each time point and stored at 2 – 8°C.

The studies support the following reagent stability claims for each assay:

	Reagent Stability Claim		
Storage Condition	**IDS SS-A/Ro**	**IDS SS-A/Ro 60 kDa**	**IDS SS-B/La**
Shelf-life (2 – 8°C)	12 months	12 months	12 months
On-board	56 days	56 days	42 days
In-use	56 days	56 days	42 days

c. *Sample Stability:*

On-board sample stability: The sample stability was evaluated to support the stability of samples when on-board the IDS system for the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La assays using one to two negative and six positive serum samples. Samples were tested at six time points when placed on-board the IDS system.

Sample stored at 5±3°C: The sample stability was evaluated to support the stability of samples when stored at 5±3°C for the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La assays using one negative and four to six positive serum samples. Samples were tested at four time points stored at refrigeration condition (5±3°C).

Sample stored at room temperature (20±5°C): The sample stability was evaluated to support the stability of samples when stored at room temperature (20±5°C) for the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La assays using one negative and four to five positive serum samples. Samples were tested at seven time points on the IDS system when stored at room temperature.

Sample stored at frozen condition (-20±5°C): The sample stability was evaluated to support the stability of samples when frozen (-20±5°C) for the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La assays using one negative and six to nine positive serum samples. Samples were tested at 10 time points when stored at frozen condition.

Sample stability under freeze/thaw cycle: The sample stability was evaluated to support the stability of samples when undergoing multiple freeze/thaw cycles using the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La reagent kit using one negative and five to six positive serum samples. Samples were aliquoted and tested with three freeze/thaw cycles on the IDS system.

The studies support the following sample stability claims for each assay:

Sample Stability Claim			
Storage Condition	**IDS SS-A/Ro**	**IDS SS-A/Ro 60 kDa**	**IDS SS-B/La**
On-board	8 hours	8 hours	8 hours
5±3°C	14 days	14 days	14 days
20±5°C (RT)	48 hours	48 hours	48 hours
-20±5°C	28 months	28 months	28 months
freeze/thaw	2 cycles	2 cycles	2 cycles

7. Assay Cut-Off:

The three assays have the same cut-off: 100 AU/mL, with the following result interpretation:

Negative: < 10.0 AU/mL
Positive: ≥ 10.0 AU/mL

B Comparison Studies:

1. Method Comparison with Predicate Device:

The method comparison for each of the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La assay, the was conducted by testing the native serum samples with the candidate device and its predicate. Of the tested samples, samples within the analytical measuring interval of both candidate device and its predicate were used in the data analysis. Positive percent agreement (PPA) and negative present agreement (NPA), with 95% confident intervals were calculated for each analyte comparison. The method comparison study results for each assay are summarized in the following table:

IDS SS-A/Ro:

		Predicate			
		Positive	**Equivocal**	**Negative**	**Total**
IDS SS-A/Ro	**Positive**	42	8	0	50
	Negative	0	5	77	82
	Total	42	13	77	132

Equivocal as Positive
PPA: 90.9% (50/55) (95% CI: 80.4 – 96.1%)
NPA: 100.0% (77/77) (95% CI: 95.2 – 100.0%

Equivocal as Negative
PPA: 100.0% (42/42) (95% CI: 91.6 – 100.0%)
NPA: 91.1% (82/90) (95% CI: 83.4 – 95.4%)

IDS SS-A/Ro 60 kDa:

		Predicate		
		Positive	**Negative**	**Total**
IDS SS-A/Ro 60 kDa	**Positive**	62	2	64
	Negative	7	77	84
	Total	69	79	148

PPA: 89.9% (62/69) (95% CI: 80.5 – 95.0%)
NPA: 97.5% (77/79) (95% CI: 91.2 – 99.3%)

IDS SS-B/La:

		Predicate		
		Positive	**Negative**	**Total**
IDS SS-B/La	**Positive**	75	1	76
	Negative	0	60	60
	Total	75	61	136

PPA: 100.0% (75/75) (95% CI: 95.1 – 100.0%)
NPA: 98.4% (60/61) (95% CI: 91.3 – 99.7%)

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity and Specificity:

To validate the clinical performance of the IDS SS-A/Ro, IDS SS-A/Ro 60 kDa. Amd IDS SS-B/La, a cohort of characterized samples were used. The study comprised a total of 824 samples including samples from patients diagnosed with systemic lupus erythematosus (SLE, n = 228), Sjögren's syndrome (SjS, n = 95), systemic sclerosis (SSc, n = 86), and other disease control samples (n= 415) from patients diagnosed with various autoimmune and infectious diseases. The results were summarized for each assay below.

IDS SS-A/Ro

		Diagnosis				
		SLE	**SjS**	**SSc**	**Controls**	**Total**
IDS SS-A/Ro	**Positive**	107	76	15	15	213
	Negative	121	19	71	400	611
	Total	228	95	86	415	824

		Point Estimate	(95% CI)
Systemic lupus erythematosus (SLE)	Sensitivity	46.9%	(40.6% to 53.4%)
Sjögren's syndrome (SjS)	Sensitivity	80.0%	(70.9% to 86.8%)
Systemic sclerosis (SSc)	Sensitivity	17.4%	(10.9% to 26.8%)
Target Indications (SLE+SjS+SSc)	Sensitivity	48.4%	(43.6% to 53.3%)
Differential diagnosis controls	Specificity	96.4%	(94.1% to 97.8%)

IDS SS-A/Ro - Distribution of the clinical study sample cohort and the antibody positive rate			
Disease Category	***N***	**# Positive**	**% Positive**
Target Diseases			
Systemic lupus erythematosus (SLE)	228	107	46.9%
Sjögren's syndrome (SjS)	95	76	80.0%
Systemic sclerosis (SSc)	86	15	17.4%
Control Diseases			
Antiphospholipid	22	1	4.5%
Atrophic gastritis	26	1	3.8%
Autoimmune liver disease	21	1	4.8%
Crohn's disease	30	1	3.3%
Cytomegalovirus	6	0	0.0%
Epstein Barr virus	5	0	0.0%
Granulomatosis w/polyangiitis	34	1	2.9%
Graves' disease	48	2	4.2%
Hashimoto's thyroiditis	33	1	3.0%
Hepatitis B	20	1	5.0%
Hepatitis C	21	0	0.0%
Idiopathic inflammatory myopathies	27	3	11.1%
Microscopic polyangiitis	31	1	3.2%
Primary biliary cholangitis	17	1	5.9%
Rheumatoid arthritis	54	1	1.9%
Ulcerative colitis	20	0	0.0%
Total controls	***415***	***15***	***3.6%***

IDS SS-A/Ro 60 kDa:

		Diagnosis			
		SLE	**SjS**	**Controls**	**Total**
IDS SS-A/Ro 60 kDa	**Positive**	105	71	9	185
	Negative	123	24	492	639
	Total	228	95	501	824

		Point Estimate	(95% CI)
Systemic lupus erythematosus (SLE)	Sensitivity	46.1%	39.7% to 52.5%
Sjögren's syndrome (SjS)	Sensitivity	74.7%	65.2% to 82.4%
Target Indications (SLE+SjS)	Sensitivity	54.5%	49.0% to 59.8%
Differential diagnosis controls	Specificity	98.2%	96.6% to 99.1%

IDS SS-A/Ro 60 kDa - Distribution of the clinical study sample cohort and the antibody positive rate			
Disease Category	***N***	**# of Positives**	**% Positive**
Target Diseases			
Systemic lupus erythematosus (SLE)	228	105	46.1%
Sjogren's syndrome (SjS)	95	71	74.7%
Control Diseases			
Systemic sclerosis (SSc)	86	2	2.3%
Antiphospholipid	22	1	4.5%
Atrophic gastritis	26	0	0.0%
Autoimmune liver disease	21	1	4.8%
Crohn's disease	30	1	3.3%
Cytomegalovirus	6	0	0.0%
Epstein Barr virus	5	0	0.0%
Granulomatosis w/polyangiitis	34	1	2.9%
Graves' disease	48	0	0.0%
Hashimoto's thyroiditis	33	1	3.0%
Hepatitis B	20	0	0.0%
Hepatitis C	21	0	0.0%
Idiopathic inflammatory myopathies	27	0	0.0%
Microscopic polyangiitis	31	1	3.2%
Primary biliary cholangitis	17	1	5.9%
Rheumatoid arthritis	54	0	0.0%
Ulcerative colitis	20	0	0.0%
Total controls	***501***	***9***	***1.8%***

IDS SS-B/La:

		Diagnosis			
		SLE	**SjS**	**Controls**	**Total**
IDS SS-B/La	**Positive**	44	40	7	91
	Negative	184	55	494	733
	Total	228	95	501	824

		Point Estimate	(95% CI)
Systemic lupus erythematosus (SLE)	Sensitivity	19.3%	14.7% to 24.9%
Sjögren's syndrome (SjS)	Sensitivity	42.1%	32.7% to 52.2%
Target Indications (SLE+SjS)	Sensitivity	26.0%	21.5% to 31.1%
Differential diagnosis controls	Specificity	98.6%	97.1% to 99.3%

IDS SS-B/La - **Distribution of the clinical study sample cohort and the antibody positive rate**			
Disease Category	***N***	**# of Positives**	**% Positive**
Target Diseases			
Systemic lupus erythematosus (SLE)	228	44	19.3%
Sjogren's syndrome (SjS)	95	40	42.1%
Control Diseases			
Systemic sclerosis (SSc)	86	3	3.5%
Antiphospholipid	22	1	4.5%
Atrophic gastritis	26	1	3.8%
Autoimmune liver disease	21	0	0.0%
Crohn's disease	30	0	0.0%
Cytomegalovirus	6	0	0.0%
Epstein Barr virus	5	0	0.0%
Granulomatosis w/polyangiitis	34	0	0.0%
Graves' disease	48	0	0.0%
Hashimoto's thyroiditis	33	0	0.0%
Hepatitis B	20	0	0.0%
Hepatitis C	21	0	0.0%
Idiopathic inflammatory myopathies	27	0	0.0%
Microscopic polyangiitis	31	0	0.0%
Primary biliary cholangitis	17	1	5.9%
Rheumatoid arthritis	54	1	1.9%
Ulcerative colitis	20	0	0.0%
Total controls	***501***	*7*	***1.4%***

D Expected Values/Reference Range:

A negative IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La test result is expected for apparently healthy individuals. To determine the reference interval for the three assays, IDS SS-A/Ro, IDS SS-A/Ro 60 kDa, and IDS SS-B/La, a panel of 112 or 115 (56 or 58 females and 56 or 57 males, ages 19 to 65 years, with mean of 44.1 or 44.4 and median of 46.0 or 47.0 years of age) apparently healthy blood donors were tested. The results are as follows:

Assay	N	# of Samples > LoQ	# of Positive (>10 AU/mL)	% of Positive (n/N)
IDS SS-A/Ro*	112	3	1	0.89% (1/112)
IDS SS-A/Ro 60 kDa	115	3	0	0.00% (0/115)
IDS SS-B/La	115	1	1	0.87% (1/115)

*Three samples were excluded from SS-A/Ro analysis due to insufficient sample volume.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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