August 21, 2026

Immunodiagnostics Systems Limited
Mohammed Adil Shaik Hussain
RA Manager (Specialist)
10 Didcot Way, Boldon Business Park
Boldon, Tyne and Wear NE35 9PD
United Kingdom

Re: K253817
Trade/Device Name: IDS SS-A/Ro
IDS SS-A/Ro 60 kDa
IDS SS-B/La
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LLL, OBE, PET
Dated: July 10, 2026
Received: July 10, 2026

Dear Mohammed Adil Shaik Hussain:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn

(https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and
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OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253817

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

Indications for Use *(Describe)*
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 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 antibodies 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).

The IDS SS-B/La test is an automated in vitro diagnostic device intended for the semi-quantitative determination of the 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 in the diagnosis of Systemic Lupus Erythematosus (SLE), and Sjögren's Syndrome (SjS).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

510k Number K253817

Introduction According to the requirements of 21CFR807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter

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Date prepared: 21 August 2026

Device Name

Proprietary names:
IDS SS-A/Ro
IDS SS-A/Ro 60 kDa
IDS SS-B/La

Common names:
IDS Ro
IDS Ro60
IDS SS-B

Classification:
21 CFR 866.5100 – Antinuclear antibody immunological test system
Class 2

Product Code/s:
LLL - IDS SS-A/Ro
LLL - IDS SS-A/Ro 60 kDa
LLL - IDS SS-B/La

Predicate Device ORGENTEC ANTI-SS-A(RO) ELISA (K962054)

Device Name IDS SS-A/Ro

Device Description
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**: 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. 1 bottle, 2.5 mL.
- **CONJ**: 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. 1 bottle, 15 mL.
- **DIL**: Sample Dilution Solution: phosphate buffer containing bovine serum albumin, detergent, inert blue dye, and Pro-Clin 300 and Gentamicin SO_4 as preservatives. 1 bottle, 25 mL.

Two kit lot specific calibrators (CAL A and CAL B, 1 vial per level) are included with the kit. 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.

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).

Conditions for use For in vitro diagnostic use only.
Rx Only

Special instrument Requirements:
IDS-iSYS Multi-Discipline Automated System (k091849)

Comparison Tables

Similarities compared to the chosen (FDA cleared; marketed) predicate device (K962054)

Parameter	**Predicate Device ORGENTEC ANTI-SS-A(RO) ELISA (K962054)**	**Candidate Device IDS SS-A/Ro**
Analyte	SS-A/Ro (60 and 52 kDa) autoantibodies	Same
Shelf Life	12 months	Same
Storage	2 - 8°C	Same

Differences compared to the chosen (FDA cleared; marketed) predicate device (K962054)

Parameter	**Predicate Device ORGENTEC ANTI-SS-A(RO) ELISA (K962054)**	**Candidate Device IDS SS-A/Ro**
Intended use	Quantitative determination of SS-A/Ro (52 and 60 kDa) autoantibodies in human serum and plasma.	Semi-quantitative determination of SS-A/Ro (52 and 60 kDa) IgG autoantibodies in human serum.
Indications for Use	Systemic rheumatic inflammatory autoimmune diseases, Sjögren's Syndrome (SS).	Systemic Lupus Erythematosus (SLE), Sjögren's Syndrome (SjS), and Systemic Sclerosis (SSc)
Detection/Operating principle	Enzyme-linked immunosorbent assay	Chemiluminescent immunoassay
Assay format	Manual	Automated
Solid phase	96-well plate	Paramagnetic microparticles (beads)
Conjugate	Anti-human IgG HRP labelled	Mouse monoclonal anti-human IgG antibody labelled with an acridinium ester derivative
Calibration	Lot specific 6 levels Calibrators, included in the kit	Lot specific Master Curve and two Calibrators, included in the kit
Antigen	Purified SS-A/Ro (52 and 60 kDa)	Purified recombinant SS-A/Ro (52 and 60 kDa)
Cut-off	Negative: < 15 U/mL Borderline: 15 to 25 U/mL Positive: > 25 U/mL	Negative: < 10.0 AU/mL Positive: ≥ 10.0 AU/mL
Assay Measuring Range (AMR)	0 – 200 U/mL	5.3 – 640.0 AU/mL
Unit	U/mL (arbitrary units)	AU (arbitrary units)

Performance Characteristics

Analytical Limits at Low levels

The limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) were determined with guidance from CLSI EP17-A, "*Protocols for Determination of Limits of Detection and Limits of Quantitation*" with two IDS SS-A/Ro kit lots. The LoB was determined with 80 replicates of four undetectable single donor serum samples per reagent lot. The LoD and LoQ were determined with 160 replicates of four undetectable single donor serum samples and four serum samples with low antibodies level per reagent lot.

Sensitivity	Index (AU/mL)
Limit of Blank (LoB)	0.0
Limit of Detection (LoD)	1.2
Limit of Quantitation (LoQ)	5.3

Precision

Precision studies were performed with guidance from CLSI EP05 A3 "*Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline*".

Single-Site Precision

A total of 7 serum samples were measured using 1 reagent lot, in duplicate, twice a day for 20 days on 1 IDS system for a total of 80 replicates per sample to assess the repeatability.

Sample		Mean	Repeatability		Between Run		Between Day		Reproducibility	
ID	N	(AU/mL)	SD	CV%	SD	CV%	SD	CV%	SD	CV%
RIP1	80	8.0	0.5	6.5%	0.1	1.7%	0.6	7.6%	0.8	10.2%
RIP7	80	10.5	0.4	3.7%	0.4	3.5%	0.6	6.1%	0.8	8.0%
RIP2	80	16.0	0.9	5.9%	0.7	4.4%	0.8	5.1%	1.4	9.0%
RIP3	80	79.9	1.6	2.0%	1.4	1.7%	2.6	3.2%	3.3	4.2%
RIP4	80	140.3	3.1	2.2%	3.4	2.4%	3.2	2.3%	5.6	4.0%
RIP5	80	306.4	5.7	1.9%	4.5	1.5%	6.2	2.0%	9.6	3.1%
RIP6	80	509.7	12.7	2.5%	6.9	1.4%	14.9	2.9%	20.8	4.1%

Multi-Lot Precision

A total of 7 serum samples were tested using 3 reagents lots in 5 replicates, once a day for 5 days on 1 IDS system by 1 operator per system for a total of 75 replicates per sample to determine the reproducibility.

Sample		Mean	Repeatability		Between Day		Between Lot		Reproducibility	
ID	N	(AU/mL)	SD	CV%	SD	CV%	SD	CV%	SD	CV%
RIP1	75	8.2	0.6	7.2%	0.2	1.9%	0.3	3.2%	0.7	8.2%
RIP7	75	9.9	0.8	7.9%	0.0	0.0%	0.2	2.0%	0.8	8.1%
RIP2	75	13.8	0.8	5.9%	0.9	6.4%	0.2	1.6%	1.2	8.9%
RIP3	75	88.8	2.6	2.9%	1.8	2.1%	7.5	8.4%	8.1	9.1%
RIP4	75	159.5	3.3	2.1%	4.8	3.0%	12.7	7.9%	14.0	8.8%
RIP5	75	343.0	6.4	1.9%	7.3	2.1%	29.9	8.7%	31.4	9.2%
RIP6	75	563.5	14.9	2.6%	29.3	5.2%	14.5	2.6%	35.9	6.4%

Multi-Instrument Precision

A total of 7 serum samples were measured using 1 reagent lot in 5 replicates, once a day for 5 days on 3 IDS systems by 1 operator per system for a total of 75 replicates per sample to determine the reproducibility.

Sample ID	N	Mean (AU/mL)	Repeatability SD	Repeatability CV%	Between Day SD	Between Day CV%	Between Instrument SD	Between Instrument CV%	Reproducibility SD	Reproducibility CV%
RIP1	75	8.1	0.8	9.8%	0.3	3.9%	0.5	6.2%	1.0	12.3%
RIP7	75	10.1	0.8	8.2%	0.3	3.1%	0.2	2.1%	0.9	9.0%
RIP2	75	15.6	0.8	5.4%	1.4	9.0%	0.5	3.1%	1.7	10.9%
RIP3	75	97.3	3.3	3.4%	4.0	4.1%	2.5	2.6%	5.8	5.9%
RIP4	75	173.6	3.8	2.2%	9.7	5.6%	4.2	2.4%	11.2	6.5%
RIP5	75	400.4	16.0	4.0%	10.9	2.7%	20.6	5.1%	28.3	7.1%
RIP6	75	572.8	28.3	4.9%	11.4	2.0%	0.0	0.0%	30.5	5.3%

Linearity

Linearity was evaluated following the guidance of CLSI EP06 ED2, "*Evaluation of Linearity of Quantitative Measurement Procedures*". For antibodies index by IDS SS-A/Ro, the measurement procedure shows linearity from 3.2 to 749.6 AU/mL within the allowable deviation of linearity (ADL) of ≤ ±15% or ≤ ± 3.0 AU/mL for index ≤ 10.0 AU/mL.

Analytical Measurement Range

The analytical measuring range (AMR) is determined based on the Limit of Quantitation, Linearity, and Precision results.

The measurement range of the IDS SS-A/Ro assay is 5.3 to 640.0 AU/mL.

- Results lower than 5.3 AU/mL will be shown as '<5.3 AU/mL'.
- Results greater than 640 AU/mL will be shown as '>640.0 AU/mL'.

Cut-off

AU/mL	Interpretation
< 10.0	The sample should be considered Negative for the presence of anti-SS-A/Ro IgG
≥ 10.0	The sample should be considered Positive for the presence of anti-SS-A/Ro IgG

It is recommended that each laboratory confirm the cut-off supplied by the manufacturer and determine its own cut-off and interpretation range using its own controls and patient population in accordance with its own established protocols.

Analytical Specificity

The interference testing of IDS SS-A/Ro was evaluated following the CLSI EP07-Ed3, "*Interference Testing in Clinical Chemistry*". The study was performed using three human serum specimens, one positive, one near the cutoff (borderline), and one negative sample. No significant interference (≤15%) was observed when the interfering substances were tested at the following threshold concentration:

Endogenous 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 Substance	Tested Concentration
Acetaminophen	15.6 mg/dL
Acetylsalicylic Acid	3.0 mg/dL
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 kit to demonstrate the specificity of the assay. The table below outlines the obtained results:

Sample ID	Catalog No.	CDC Description	AU/mL	Interpretation
ANA-01	IS2072	ANA Homogeneous Positive; Anti-native DNA Positive	5.4	Negative
ANA-02	IS2073	ANA Speckled Positive; Anti-SSB Positive	306.1	Positive
ANA-03	IS2074	ANA Speckled Positive	138.7	Positive
ANA-04	IS2075	ANA-U1 RNP Positive	9.3	Negative
ANA-05	IS2076	Anti-Sm Positive	<5.3	Negative
ANA-07	IS2105	Anti-SS-A Positive	552.6	Positive
ANA-08	IS2134	ANA Centromere Positive	<5.3	Negative
ANA-09	IS2135	Anti-Scl 70 Positive	<5.3	Negative
ANA-10	IS2187	Anti-Jo 1 Positive	232.0[±]	Positive
ANA-12	IS2706	Anti-Ribosomal P Positive	6.5	Negative

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

Method Comparison

The IDS SS-A/Ro was compared against a commercially available SS-A/Ro ELISA. A total of 246 single donor serum samples were measured by each method. Of the total tested samples, 132 samples were within the analytical measuring range of both assays. The comparator has an equivocal region; the data were analyzed with the equivocal results as either negative or positive. The results of samples within the analytical measuring range of both methods are presented in the following table:

		Comparator SSA/Ro ELISA			
		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
Positive Agreement (PPA): 90.9% (80.4% to 96.1%)
Negative Agreement (NPA): 100.0% (95.2% to 100.0%)
Total Percent Agreement (TPA): 96.2% (91.4% to 98.4%)

Equivocal as negative
Positive Agreement (PPA): 100.0% (91.6% to 100.0%)
Negative Agreement (NPA): 91.1% (83.4% to 95.4%)
Total Percent Agreement (TPA): 93.9% (88.5% to 96.9%)

Matrix comparison
Not Applicable. The test is performed only in serum.

Expected Values
The expected value in the normal population is “negative”.

The IDS SS-A/Ro was used to assess SS-A/Ro autoantibodies levels in a group of 112 apparently healthy blood donors (56 females and 56 males, ages 19 to 65 years, mean 44.4 and median 47.0 years of age). Three samples were within the analytical measurement range, ranging from 6.2 to 11.1 AU/mL (mean: 8.6 AU/mL). One sample (0.9%) tested positive for the IDS SS-A/Ro, with the cut-off at <10.0 AU/mL.

Clinical Sensitivity and Specificity
To validate the clinical performance of the IDS SS-A/Ro, a total of 824 characterized samples were used. The study comprised 409 samples from the diagnostic cohort with the diagnosis of systemic lupus erythematosus (SLE, n = 228), Sjögren's syndrome (SjS, n = 95), and systemic sclerosis (SSc, n = 86). The control group included 415 samples diagnosed with various autoimmune and infectious diseases. The results were analyzed to assess the sensitivity for each diagnostic disease independently.

IDS SS/A Ro Clinical Sensitivity and Specificity:

		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

Systemic Lupus Erythematosus (SLE): Sensitivity (95% CI): 46.9% (40.6% to 53.4%)
Sjögren’s syndrome (SjS): Sensitivity (95% CI): 80.0% (70.9% to 86.8%)
Systemic Sclerosis (SSc): Sensitivity (95% CI): 17.4% (10.9% to 26.8%)
Specificity (95% CI): 96.4% (94.1% to 97.8%)

The table below shows the distribution of the cohort and the SS-A/Ro positive rate:

Diagnosis Group	Total N	SSA/Ro Positive n	SSA/Ro Positive %
Target conditions			
Systemic Lupus Erythematosus (SLE)	228	107	46.9%
Sjögren's syndrome (SjS)	95	76	80.0%
Systemic sclerosis (SSc)	86	15	17.4%
Control conditions			
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%***

Conclusion

The IDS SS-A/Ro data presented and provided is complete and supports the basis for substantial equivalence to the predicate devices.

Predicate Device QUANTA Flash® Ro60 (K141328)

Device Name IDS SS-A/Ro 60 kDa

Device Description
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**: Magnetic particles coated with the SS-A/Ro 60 kDa antigen, in phosphate buffer containing stabilizing proteins and Pro-Clin 300 and sodium azide (< 0.1%) as preservatives. 1 bottle, 2.5 mL.
- **CONJ**: 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. 1 bottle, 15 mL.
- **DIL**: Sample Dilution Solution: phosphate buffer containing bovine serum albumin, detergent, inert blue dye, and Pro-Clin 300 and Gentamicin SO_4 as preservatives. 1 bottle, 25 mL.

Two kit lot specific calibrators (CAL A and CAL B, 1 vial per level) are included with the kit. 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.

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).

Conditions for use For in vitro diagnostic use only.
Rx Only

Special instrument Requirements:
IDS-iSYS Multi-Discipline Automated System (k091849)

Comparison Tables

Similarities compared to the chosen (FDA cleared; marketed) predicate device (k141328)

Parameter	Predicate Device QUANTA Flash® Ro60 (k141328)	Candidate Device IDS SS-A/Ro60 kDa
Intended use	Semi-quantitative determination of anti-Ro60 IgG autoantibodies in human serum	Same
Assay Methodology	Solid phase (heterogeneous) immunoassay	Same
Detection/ Operating principle	Chemiluminescent immunoassay	Same
Traceability	International Reference preparation is not available; results are traceable to inhouse standard	Same
Sample Type	Serum	Same
Antigen	Purified recombinant Ro60 antigen	Same
Shelf Life	12 months	Same
Indications for Use	Systemic Lupus Erythematosus (SLE) and Sjögren's Syndrome (SS)	Same
Assay Format	Automatic	Same
Solid Phase	Paramagnetic microparticles (beads)	Same

Differences compared to the chosen (FDA cleared; marketed) predicate device (k141328)

Parameters	Predicate Device QUANTA Flash® Ro60 (k141328)	Candidate Device IDS SS-A/Ro 60 kDa
Conjugate	Isoluminol conjugated anti-human IgG	Monoclonal mouse anti-human IgG antibody marked with an acridinium ester derivative.
Calibration	Lot specific Master Curve and two Calibrators (Sold separately)	Lot specific Master Curve and two Calibrators (Included in the kit)
Cut-off	Negative: < 20 CU Positive: ≥ 20 CU	Negative: < 10.0 AU/mL Positive: ≥ 10.0 AU/mL
Assay Measuring Range (AMR)	4.9 - 1374.8 CU	2.9 – 640.0 AU/mL
Unit	CU (Chemiluminescent units) (arbitrary)	AU (arbitrary units)

Performance Characteristics

Analytical Limits at Low levels

The limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) were determined with guidance from CLSI EP17-A, "*Protocols for Determination of Limits of Detection and Limits of Quantitation*" with two IDS SS-A/Ro 60 kDa kit lots. The LoB was determined with 80 replicates of four undetectable single donor serum samples per reagent lot. The LoD and LoQ were determined with 160 replicates of four undetectable single donor serum samples and four serum samples with low antibody level per reagent lot.

Sensitivity	Index (AU/mL)
Limit of Blank (LoB)	0.0
Limit of Detection (LoD)	1.3
Limit of Quantitation (LoQ)	2.9

Precision

Precision studies were performed with guidance from CLSI EP05 A3 "*Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline*".

Single-Site Precision

A total of 7 serum samples were measured using 1 reagent lot, in duplicate, twice a day for 20 days on 1 IDS system for a total of 80 replicates per sample to assess the repeatability.

Sample		Mean	Repeatability		Between Run		Between Day		Reproducibility	
ID	N	(AU/mL)	SD	CV%	SD	CV%	SD	CV%	SD	CV%
RIP1	80	8.3	0.5	6.6%	0.5	5.7%	0.1	1.4%	0.7	8.8%
RIP7	80	10.5	0.5	4.4%	0.5	4.7%	0.7	6.8%	1.0	9.4%
RIP2	80	15.2	0.6	4.2%	1.1	7.5%	0.6	4.1%	1.4	9.5%
RIP3	80	66.3	1.7	2.5%	2.9	4.4%	2.4	3.7%	4.2	6.3%
RIP4	80	169.8	3.1	1.8%	4.4	2.6%	5.5	3.2%	7.6	4.5%
RIP5	80	338.2	8.0	2.4%	10.2	3.0%	8.7	2.6%	15.6	4.6%
RIP6	80	544.7	17.6	3.2%	20.5	3.8%	12.5	2.3%	29.8	5.5%

Multi-Lot Precision

A total of 7 serum samples were tested using 3 reagent lots in 5 replicates, once a day for 5 days on 1 IDS system by 1 operator per system for a total of 75 replicates per sample to determine the reproducibility.

Sample		Mean	Repeatability		Between Day		Between Lot		Reproducibility	
ID	N	(AU/mL)	SD	CV%	SD	CV%	SD	CV%	SD	CV%
RIP1	75	8.3	0.5	5.7%	0.4	5.1%	0.3	3.1%	0.7	8.2%
RIP7	75	10.4	0.3	3.0%	0.3	2.8%	0.1	1.0%	0.4	4.2%
RIP2	75	14.6	0.6	4.4%	0.3	2.4%	0.5	3.3%	0.9	6.0%
RIP3	75	65.9	1.5	2.2%	2.0	3.1%	1.0	1.6%	2.7	4.1%
RIP4	75	164.1	3.7	2.3%	1.2	0.7%	6.3	3.8%	7.4	4.5%
RIP5	75	326.7	5.6	1.7%	8.7	2.7%	13.2	4.0%	16.8	5.1%
RIP6	75	535.5	19.4	3.6%	14.7	2.7%	24.2	4.5%	34.3	6.4%

Multi-Instrument Precision

A total of 7 serum samples were measured using one reagent lot in 5 replicates, once a day for 5 days on 3 IDS systems by 1 operator per system for a total of 75 replicates per sample to determine the reproducibility.

Sample ID	N	Mean (AU/mL)	Repeatability SD	Repeatability CV%	Between Day SD	Between Day CV%	Between Instrument SD	Between Instrument CV%	Reproducibility SD	Reproducibility CV%
RIP1	75	7.6	0.5	7.0%	0.5	6.6%	0.2	2.7%	0.8	10.0%
RIP7	75	10.3	0.7	7.2%	0.3	3.3%	0.2	1.5%	0.8	8.0%
RIP2	75	14.6	0.8	5.2%	0.9	6.4%	0.0	0.0%	1.2	8.2%
RIP3	75	60.5	1.4	2.3%	2.5	4.1%	3.4	5.7%	4.5	7.4%
RIP4	75	151.3	3.4	2.2%	4.0	2.6%	5.3	3.5%	7.5	4.9%
RIP5	75	298.4	6.4	2.1%	8.4	2.8%	11.1	3.7%	15.3	5.1%
RIP6	75	496.5	11.6	2.3%	8.0	1.6%	9.3	1.9%	16.8	3.4%

Linearity

Linearity was evaluated based on the guidance of CLSI EP06 Ed2, "*Evaluation of Linearity of Quantitative Measurement Procedures*". For antibodies levels by IDS SS-A/Ro 60 kDa, the measurement procedure shows linearity from 2.8 to 709.2 AU/mL within the allowable deviation of linearity (ADL) of ≤ ±15% or ≤ ± 3.0 AU/mL for index ≤ 10.0 AU/mL.

Analytical Measurement Range

The analytical measuring range (AMR) is determined based on the Limit of Quantitation, Linearity, and Precision results.

The measurement range of the IDS SS-A/Ro 60 kDa assay is 2.9 to 640.0 AU/mL.

- Results lower than 2.9 AU/mL will be shown as '<2.9 AU/mL'.
- Results greater than 640.0 AU/mL will be shown as '>640.0 AU/mL'.

Cut-off

AU/mL	Interpretation
< 10.0	The sample should be considered Negative for the presence of anti-SS-A/Ro 60 kDa IgG
≥ 10.0	The sample should be considered Positive for the presence of anti-SS-A/Ro 60 kDa IgG

It is recommended that each laboratory confirm the cut-off supplied by the manufacturer and determine its own cut-off and interpretation range using its own controls and patient population in accordance with its own established protocols.

Analytical Specificity

The interference testing of IDS SS-A/Ro 60 kDa was evaluated following the CLSI EP07-Ed3, "*Interference Testing in Clinical Chemistry*". The study was performed using three human serum specimens, one positive, one near the cutoff (borderline), and one negative sample. No significant interference (≤15%) was observed when the interfering substances were tested at the following threshold concentration:

Endogenous 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 Substance	Tested Concentration
Acetaminophen	15.6 mg/dL
Acetylsalicylic Acid	3.0 mg/dL
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 (Center for Disease Controls and Prevention) ANA human reference sera panel samples were tested using the IDS SS-A/Ro 60 kDa kit to demonstrate the specificity of the assay. The table below outlines the obtained results:

Sample ID	Catalog No.	CDC Description	AU/mL	Interpretation
ANA-01	IS2072	ANA Homogeneous Positive; Anti-native DNA Positive	<2.9	Negative
ANA-02	IS2073	ANA Speckled Positive; Anti-SSB Positive	292.8	Positive
ANA-03	IS2074	ANA Speckled Positive	198.3	Positive
ANA-04	IS2075	ANA-U1 RNP Positive	5.7	Negative
ANA-05	IS2076	Anti-Sm Positive	<2.9	Negative
ANA-07	IS2105	Anti-SS-A Positive	>640.0	Positive
ANA-08	IS2134	ANA Centromere Positive	<2.9	Negative
ANA-09	IS2135	Anti-Scl 70 Positive	8.6	Negative
ANA-10	IS2187	Anti-Jo 1 Positive	<2.9	Negative
ANA-12	IS2706	Anti-Ribosomal P Positive	<2.9	Negative

Method Comparison

The IDS SS-A/Ro 60 kDa was compared against a commercially available chemiluminescent semi-quantitative SSA Ro 60. A total of 254 single donor serum samples were measured by each method. Of the total tested samples, 148 samples were within the analytical measuring range of both assays. The data of samples within the analytical measuring range of both assays are presented in the following table:

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

Positive Agreement (PPA): 89.9% (80.5% to 95.0%)
Negative Agreement (NPA): 97.5% (91.2% to 99.3%)
Total Percent Agreement (TPA): 93.9% (88.8% to 96.8%)

Matrix comparison

Not Applicable. The test is performed only in serum.

Expected Values

The expected value in the normal population is “negative”.

The IDS SS-A/Ro 60 kDa was used to assess Ro60 autoantibodies levels in a group of 115 apparently healthy blood donors (58 females and 57 males, ages 19 to 65 years, mean 44.1 and median 46.0 years of age). Three samples were within the analytical measurement range, ranging from 4.2 to 8.4 AU/mL (mean: 6.3 AU/mL). None of the samples tested positive for SS-A/Ro 60 kDa, with the cut-off at <10.0 AU/mL.

Clinical Sensitivity and Specificity

To validate the clinical performance of the IDS SS-A/Ro 60 kDa, a total of 824 characterized samples were used. The study comprised 323 samples from the diagnostic cohort with the diagnosis of systemic lupus erythematosus (SLE, n = 228) and Sjögren's syndrome (SjS, n = 95). The control group included 501 samples diagnosed with systemic sclerosis (SSc, n = 86), various autoimmune and infectious diseases. The results were analyzed to assess the sensitivity for each diagnostic disease independently.

IDS SS/A Ro 60 kDa Clinical Sensitivity and Specificity:

		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

Systemic Lupus Erythematosus (SLE): Sensitivity (95% CI): 46.1% (39.7% to 52.5%)
Sjögren's syndrome (SjS): Sensitivity (95% CI): 74.7% (65.2% to 82.4%)
Specificity (95% CI): 98.2% (96.6% to 99.1%)

The table below shows the distribution of the cohort and the SS-A/Ro 60 kDa positive rate:

Diagnosis Group	Total N	Ro 60 kDa Positive n	Ro 60 kDa Positive %
Target conditions			
Systemic Lupus Erythematosus (SLE)	228	105	46.1%
Sjögren's syndrome (SjS)	95	71	74.7%
Control conditions			
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%***

Conclusion

The IDS SS-A/Ro 60 kDa data presented and provided is complete and supports the basis for substantial equivalence to the predicate device.

Predicate Device QUANTA Flash® SS-B (k141210)

Device Name IDS SS-B/La

Device Description
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**: 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. 1 bottle, 2.5 mL.
- **CONJ**: 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. 1 bottle, 15 mL.
- **DIL**: Sample Dilution Solution: phosphate buffer containing bovine serum albumin, detergent, inert blue dye, and Pro-Clin 300 and Gentamicin SO_4 as preservatives. 1 bottle, 25 mL.

Two kit lot specific calibrators (CAL A and CAL B, 1 vial per level) are included with the kit. 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 SO_4 as preservatives.

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).

Conditions for use For in vitro diagnostic use only.
Rx Only

Special instrument Requirements:
IDS-iSYS Multi-Discipline Automated System (k091849)

Comparison Tables

Similarities compared to the chosen (FDA cleared; marketed) predicate device (K141210)

Parameter	**Predicate Device QUANTA Flash® SS-B (K141210)**	**Candidate Device IDS SS-B/La**
Intended use	Semi-quantitative determination of anti-SS-B antibodies in human serum	Same
Assay Methodology	Solid phase (heterogeneous) immunoassay	Same
Detection/ Operating principle	Chemiluminescent immunoassay	Same
Traceability	International Reference preparation is not available; results are traceable to inhouse standard	Same
Sample Type	Serum	Same
Antigen	Purified recombinant SS-B antigen	Same
Shelf Life	12 months	Same
Indications for Use	Includes Sjögren's Syndrome and Systemic Lupus Erythematosus.	Same
Assay Format	Automatic	Same
Solid Phase	Paramagnetic microparticles (beads)	Same

Differences compared to the chosen (FDA cleared; marketed) predicate device (K141210)

Parameters	**Predicate Device QUANTA Flash® SS-B (K141210)**	**Candidate Device IDS SS-B/La**
Conjugate	Isoluminol conjugated anti-human IgG	Mouse monoclonal anti-human IgG antibody labelled with an acridinium ester derivative
Calibration	Lot specific Master Curve and two calibrators (Sold separately)	Lot specific Master Curve and two Calibrators (included in the kit)
Cut-off	Negative: < 20 CU Positive: ≥ 20 CU	Negative: < 10.0 AU/mL Positive: ≥ 10.0 AU/mL
Assay Measuring Range	3.3 – 1550 CU	4.6 – 640.0 AU/mL
Unit	CU (Chemiluminescent units) (arbitrary)	AU (arbitrary units)

Performance Characteristics

Analytical Limits at Low levels

The limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) were determined with guidance from CLSI EP17-A, "*Protocols for Determination of Limits of Detection and Limits of Quantitation*" with two IDS SS-B/La kit lots. The LoB was determined with 80 replicates of four undetectable single donor serum samples per reagent lot. The LoD and LoQ were determined with 160 replicates of four undetectable single donor serum samples and four serum samples with low antibodies level per reagent lot.

Sensitivity	Index (AU/mL)
Limit of Blank (LoB)	0.0
Limit of Detection (LoD)	1.1
Limit of Quantitation (LoQ)	4.6

Precision

Precision studies were performed with guidance from CLSI EP05 A3 *"Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline*".

Single-Site Precision

A total of 7 serum samples were measured using 1 reagent lot, in duplicate, twice a day for 20 days on 1 IDS system for a total of 80 replicates per sample to assess the repeatability.

Sample		Mean	Repeatability		Between Run		Between Day		Reproducibility	
ID	N	(AU/mL)	SD	CV%	SD	CV%	SD	CV%	SD	CV%
RIP1	80	7.1	0.6	9.2%	0.2	3.1%	0.4	6.3%	0.8	11.6%
RIP7	80	10.3	0.6	6.3%	0.6	6.1%	0.5	4.6%	1.0	9.9%
RIP2	80	13.7	0.7	4.8%	0.6	4.1%	0.7	5.2%	1.1	8.2%
RIP3	80	76.5	5.3	6.9%	0.0	0.0%	4.1	5.4%	6.7	8.7%
RIP4	80	135.7	9.5	7.0%	4.1	3.0%	3.3	2.5%	10.9	8.0%
RIP5	80	335.0	21.4	6.4%	11.9	3.5%	0.0	0.0%	24.5	7.3%
RIP6	80	497.6	42.8	8.6%	0.0	0.0%	15.6	3.1%	45.5	9.1%

Multi-Lot Precision

A total of 7 serum samples were tested using 3 reagent lots in 5 replicates, once a day for 5 days on 1 IDS system by 1 operator per system for a total of 75 replicates per sample to determine the reproducibility.

Sample		Mean	Repeatability		Between Day		Between Lot		Reproducibility	
ID	N	(AU/mL)	SD	CV%	SD	CV%	SD	CV%	SD	CV%
RIP1	75	7.6	0.7	9.1%	0.5	6.9%	0.1	1.6%	0.9	11.5%
RIP7	75	10.9	0.8	7.1%	0.4	3.4%	0.7	6.2%	1.1	10.0%
RIP2	75	16.5	1.5	9.2%	0.1	1.8%	0.8	3.3%	4.7	10.4%
RIP3	75	76.5	4.8	6.2%	3.6	4.7%	5.3	6.9%	8.0	10.4%
RIP4	75	137.8	9.6	7.0%	4.4	3.2%	7.3	5.3%	12.8	9.3%
RIP5	75	335.9	24.3	7.2%	18.1	5.4%	11.4	3.4%	32.4	9.6%
RIP6	75	513.5	36.3	7.1%	12.0	2.6%	8.6	1.7%	39.2	7.6%

Multi-Instrument Precision

A total of 7 serum samples were measured using one reagent lot in 5 replicates, once a day for 5 days on 3 IDS systems by 1 operator per system for a total of 75 replicates per sample to determine the reproducibility.

Sample ID	N	Mean (AU/mL)	Repeatability SD	Repeatability CV%	Between Day SD	Between Day CV%	Between Instrument SD	Between Instrument CV%	Reproducibility SD	Reproducibility CV%
RIP1	75	7.3	0.5	6.7%	0.3	4.5%	0.3	4.1%	0.7	9.1%
RIP7	75	10.8	0.6	5.8%	0.4	3.9%	0.2	2.2%	0.8	7.3%
RIP2	75	17.7	1.3	7.6%	0.5	3.0%	0.0	0.0%	1.5	8.2%
RIP3	75	77.0	3.1	4.0%	3.4	4.5%	1.0	1.3%	4.8	6.2%
RIP4	75	141.6	6.2	4.4%	5.9	4.1%	2.1	1.5%	8.8	6.2%
RIP5	75	338.5	13.4	4.0%	14.7	4.3%	6.2	1.8%	20.8	6.2%
RIP6	75	509.2	27.1	5.3%	5.4	1.1%	10.6	2.1%	29.6	5.8%

Linearity

Linearity was evaluated based on CLSI EP06 ED2, "*Evaluation of Linearity of Quantitative Measurement Procedures*". For antibodies levels by IDS SS-B/La, the measurement procedure shows linearity from 4.3 to 751.1 AU/mL within the allowable deviation of linearity (ADL) of ≤ ±15% or ≤ ± 3.0 AU/mL for index ≤ 10.0 AU/mL.

Analytical Measurement Range

The analytical measuring range (AMR) is determined based on the Limit of Quantitation, Linearity, and Precision results.

The measurement range of the IDS SS-B/La assay is 4.6 to 640.0 AU/mL.

- Results lower than 4.6 AU/mL will be shown as '<4.6 AU/mL'.
- Results greater than 640.0 AU/mL will be shown as '>640.0 AU/mL'.

Cut-off

AU/mL	Interpretation
< 10.0	The sample should be considered Negative for the presence of anti-SS-B/La IgG
≥ 10.0	The sample should be considered Positive for the presence of anti-SS-B/La IgG

It is recommended that each laboratory confirm the cut-off supplied by the manufacturer and determine its own cut-off and interpretation range using its own controls and patient population in accordance with its own established protocols.

Analytical Specificity

The interference testing of IDS SS-A/Ro 60 kDa was evaluated following the CLSI EP07-Ed3, "*Interference Testing in Clinical Chemistry*". The study was performed using three human serum specimens, one positive, one near the cutoff (borderline), and one negative sample. No significant interference (≤15%) was observed when the interfering substances were tested at the following threshold concentration:

Endogenous 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 Substance	Tested Concentration
Acetaminophen	15.6 mg/dL
Acetylsalicylic Acid	3.0 mg/dL
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 (Center for Disease Controls and Prevention) ANA human reference sera panel samples were tested using one lot of the IDS SS-B/La kit to demonstrate the specificity of the assay. The table below outlines the obtained results:

Sample ID	Catalog No.	CDC Description	AU/mL	Interpretation
ANA-01	IS2072	ANA Homogeneous Positive; Anti-native DNA Positive	<4.6	Negative
ANA-02	IS2073	ANA Speckled Positive; Anti-SSB Positive	>640.0	Positive
ANA-03	IS2074	ANA Speckled Positive	83.8	Positive
ANA-04	IS2075	ANA-U1 RNP Positive	<4.6	Negative
ANA-05	IS2076	Anti-Sm Positive	<4.6	Negative
ANA-07	IS2105	Anti-SS-A Positive	<4.6	Negative
ANA-08	IS2134	ANA Centromere Positive	<4.6	Negative
ANA-09	IS2135	Anti-Scl 70 Positive	<4.6	Negative
ANA-10	IS2187	Anti-Jo 1 Positive	<4.6	Negative
ANA-12	IS2706	Anti-Ribosomal P Positive	<4.6	Negative

Method Comparison

The IDS SS-B/La was compared against a commercially available semi-quantitative chemiluminescent SS-B. A total of 239 single donor serum samples were measured by each method. Of the 239 tested samples, 136 samples were within the analytical measuring range of both assays. The data of samples within both methods' analytical measuring ranges are presented in the following table.

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

Positive Agreement (PPA): 100.0% (95.1% to 100.0%)
Negative Agreement (NPA): 98.4% (91.3% to 99.7%)
Total Percent Agreement (TPA): 99.3% (96.0% to 99.9%)

Matrix comparison

Not Applicable. The test is performed only in serum.

Expected Values

The expected value in the normal population is "negative".

The IDS SS-B/La was used to assess SS-B autoantibodies levels in a group of 115 apparently healthy blood donors (58 females and 57 males, ages 19 to 65 years, mean 44.1 and median 46.0 years of age). One sample was within the analytical measurement range (14.5 AU/mL). One sample (0.9%) tested positive for SS-B, with the cut-off at <10.0 AU/mL.

Clinical Sensitivity and Specificity

To validate the clinical performance of the IDS SS-B/La, a total of 824 characterized samples were used. The study comprised 323 samples from the diagnostic cohort with the diagnosis of systemic lupus erythematosus (SLE, n = 228) and Sjögren's syndrome (SjS, n = 95). The control group included 501 samples diagnosed with systemic sclerosis (SSc, n = 86), various autoimmune and infectious diseases. The results were analyzed to assess the sensitivity for each diagnostic disease independently.

IDS SS/B La Clinical Sensitivity and Specificity:

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

Systemic Lupus Erythematosus (SLE): Sensitivity (95% CI): 19.3% (14.7% to 24.9%)
Sjögren's syndrome (SjS): Sensitivity (95% CI): 42.1% (32.7% to 52.2%)
Specificity (95% CI): 98.6% (97.1% to 99.3%)

The table below shows the distribution of the cohort and the SS-B/La positive rate:

Diagnosis Group	Total N	SS-B Positive n	SS-B Positive %
Target conditions			
Systemic Lupus Erythematosus (SLE)	228	44	19.3%
Sjögren's syndrome (SjS)	95	40	42.1%
Control conditions			
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%***

Conclusion

The IDS SS-B/La data presented and provided is complete and supports the basis for substantial equivalence to the predicate device.