biomedical diagnostics

Premarket Notification 510(k) Summary

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1. Submitted by :

Name:	Biomedical Diagnostics S.A (bmd)
Contact Person:	Christelle COURIVAUD Regulatory Affairs Manager
Address:	Actipole 25, 4-6 Bld de Beaubourg 77435 Marne-La-Vallée Cedex 2 FRANCE
Telephone:	33 (0)1 64 62 10 12
Fax:	33 (0)1 64 62 09 66
Establishment Registration Number:	3003935253

US Agent correspondent:

Hoppe Regulatory Consultants
Ms P. Ann HOPPE
2335 Massey Lane
Decatur GA 30033 USA
Phone: 404 248 0002
E-mail: Hoppe Regulatory@cs.com

2. Device Name

Trade/Proprietary Name :	**FIDIS™ CONNECTIVE 10* assay**
Common/Usual Name :	**MX006 - FIDIS™ CONNECTIVE 10***: Detection test of 10 autoantibody specificities: double stranded DNA (dsDNA), SSA 60kDa, SSA 52kDa, SSB, Sm, Sm/RNP, Scl70, Jo-1, Ribosome and Centromere.
Classification Name:	**Antinuclear antibody immunological test system**
Trade/Proprietary Name :	**FIDIS™ Analyzer**
Classification Name:	Instrumentation for Chemical Multiplex Systems
Trade/Proprietary Name :	**CARIS™ System**
Classification Name:	Device, Microtiter diluting/Dispensing

3. Intended use of the device

The **FIDIS™ CONNECTIVE 10*** kit is a semi-quantitative homogeneous fluorescent-based microparticles immunoassay using flow cytometry. The test system is used to simultaneously detect the presence of 10 autoantibody specificities: double stranded DNA (dsDNA), SSA (60 kDa and 52 kDa), SSB, Sm, Sm/RNP, Scl70, Jo1, ribosome and centromere.

*(*Antibodies to dsDNA, Sm, Sm/RNP, SSA, SSB, Scl-70, Jo-1, ribosome and centromere can be reported using this assay).*

Clinical utility:

The results of the **FIDIS™ CONNECTIVE 10*** are to be used in conjunction with the clinical findings and the other laboratory tests to aid in the diagnosis of connective diseases (systemic lupus erythematosus (SLE), Sjogren's syndrome, mixed connective tissue disease (MCTD), scleroderma, dermatomyositis and CREST syndrome).

FIDIS™ CONNECTIVE 10* kit uses serum only, and is to be run on the FIDIS™ Instrument and MLX-BOOSTER™ Software.

FIDIS™ CONNECTIVE 10* kit may be used with the **CARIS™ system** (diluting and dispensing device).

This test is for *in vitro* diagnostic use.

4. Materials supplied

1 x 96 wells microplate with filtering membrane and a lid.	1 plate
1 Vial **(A)** of 10 sets of color-coded microsphere beads coupled with dsDNA, SSA 60 kDa, SSA 52 kDa, SS-B, Sm, Sm/RNP, Scl-70, Jo-1, ribosomes, centromere antigen, plus 1 set of Internal standard beads. Lyophilized (to be diluted with the buffer named D)	Sufficient quantity to obtain 6mL after reconstitution
1 Vial **(B)** of sample dilution buffer (white vial) Ready to use	2 x 115mL
1 Vial of calibrator titered for the specificities to be mesured Ready to use ***Each titer is printed on the vial label***	1 x 1,5mL
1 Vial of positive control concentrate. This control has a standard reactivity, that provides evidence of the proper functioning of reagents and correct assay performance. To be diluted ***Expected values are printed on the vial label.***	1 x 250 µL
1 Vial of negative control* concentrate To be diluted	1 x 250µL

1 Vial of anti-human IgG coupled to phycoerythrin Ready to use	1 x 12mL
1 Vial **(C)** of washing buffer (black vial) Ready to use	1 x 100mL
1 Vial **(D)** of reconstitution buffer for the microsphere set Ready to use	1 x 6mL
Package insert	1
Microplate Assay Configuration Worksheet	1
Microplate sealing films	6

5. Predicate Device

510K Number	Device Classification Name	Manufacturer Name
K053653	**FIDIS™ CONNECTIVE 10***	bmd

6. Comparison with the predicate

		Predicate Device FIDIS™ CONNECTIVE 10* K053653*	Modified Device FIDIS™ CONNECTIVE 10*
Intended use		Individual determination in human serum of IgG antibodies against: dsDNA, SSA 60kDa, SSA 52kDa, SSB, Sm, Sm/RNP, Scl70, Jo-1, Ribosome and Centromere	Same (minor text changes)
CUT-OFF	**Negative**	<30 for the 10 specificities - In IU/mL for dsDNA - In AU/mL for the 9 other specificities	Same
	Equivocal	30-40 for the 10 specificities	Same
	Positive	>40 for the 10 specificities	Same
Material supplied		Microplate with caps	Microplate with sealing films
Beads		Vial of color-coded microsphere set ready to use (6mL)	Vial of color-coded microsphere set Lyophilized (sq 6mL)
Sample dilution		PBS-Tween concentrated	Sample dilution buffer ready to use
Washing buffer		PBS-Tween concentrated	Washing buffer ready to use
Internal standard beads		No	Yes

	Predicate Device FIDISTM CONNECTIVE 10 K053653	Modified Device FIDISTM CONNECTIVE 10
Assay configuration	1 "reagent-blank" well 1 "calibrator" well 1 "negative control" well 1 "positive control" well	1 "reagent-blank" well 1 "negative control" well 1 "positive control" well 2 "calibrator" wells
	Diluted sample wells	Same
	A second calibrator well every 48 well series	No
Incubation time	2 x 30mn RT	Same
Wash step	2 x 200µL	2 x 300µL
Assay protocol	Optional final wash step	Final wash step (not optional)
Software	Booster Version 1.35	Booster Version 2.2
Detection Method	Fluorescence (using Luminex 100)	Fluorescence (using Luminex 200)
Sample preparation	Manual preparation	Same
Automatic sample preparation (option)	CARIS™	Same

7. Performance Characteristics

1. Analytical performance

a. Precision

Precision of the assay was assessed in **53 samples**. Precision was determined by calculating the within-run (intra-assay) and the between run (inter-assay).

- For within run: 6 samples (except for Jo1 only 5 samples were tested) 10 times in a same run.
- For between run: 6 samples (except for Jo1 only 5 samples were tested) in 6 runs, 3 times per run.

Table 1: Summary of FIDIS™ CONNECTIVE 10* precision results

Sample range	Acceptance criteria for within-run and between-run	Within-run minimal CV% for the 10 parameters	Within-run maximal CV% for the 10 parameters	Between-run minimal CV% for the 10 parameters	Between-run maximal CV% for the 10 parameters
Less than 10 AU/mL or IU/mL	Not determined	5.9%	12.8%	7.4%	13.6%
10 to 29 AU/mL or IU/mL	CV≤20%	2.5%	11.8%	8.2%	17.3%
29 to 800 AU/mL or IU/mL	CV≤15%	2.1%	12.7%	4.5%	14.3%

b. Linearity/ assay reportable range

FIDIS™ CONNECTIVE 10* assay has been optimized to express the average binding capacity at the current dilution (1/200) by a flow cytometric reading resulting of the median fluorescence value obtained from 200 microspheres per parameter.
Further dilutions potentially give rise to inaccurate results because the reaction conditions and the equilibrium of the immunological reaction would be modified.

c. Interfering Substances

The study was conducted by testing 30 negative samples (for dsDNA, SSA 60kDa, SSA 52kDa, SSB, Sm, Sm/RNP, Scl70, Jo-1, Ribosome and Centromere) characterized as positive for various potential interferences obtained from routine laboratory (listed in following table).

Table 2: Potential interferences results

	Number of positive sample								
	dsDNA	SSA 60 kD	SSA 52kD	SSB	Sm	Sm/RNP	Scl70	Jo1	Ribo
Cryoglobulinemia N*=2	0	0	0	0	0	0	0	0	0
Complement N*=7	2	1	0	1	1	1	0	0	0
IgG monoclonal immunoglobulins N*=1	0	0	0	0	0	0	0	0	0
IgM monoclonal immunoglobulins N*=5	0	0	0	0	0	0	0	0	0
Rheumatoid factor N*=8	1	2	2	1	0	1	0	0	0
Plasma N*=3	0	0	0	0	0	0	0	0	0
Hemolyzed sera N*=3	0	0	0	0	0	0	0	0	0
Anti-smooth muscle antibodies N*=1	0	0	0	0	0	0	0	0	0

*N: number of samples tested

d. *Threshold values*

Threshold values were estimated from the 2 selected populations:

- 50 samples from blood donors
- 48 samples selected for their potential biological interferences

The negative thresholds (30AU/mL or 30IU/mL) correspond to the 97.9% for dsDNA, SSA, Sm/RNP; 99.0% for centromere and ribosome, and 100% for SSB, Sm, Scl70 and Jo1 for the populations studied.

e. *Stability of the assay results after final wash step*

This assay included 3 test series with:

- **5 positive samples** for SSA 52kDa, SSA 60kDa, SSB, Sm, Sm/RNP, Scl70, dsDNA and Centromere;
- **4 positive samples** for Jo1;
- **3 positive samples** for Ribosome.

Each series of tests was washed and read after different times:

- T= 0 hour: the first series of tests was read immediately after the final wash step.
- T= 4 hours: the second series of test was read after 4 hours of storage at room temperature away from direct sunlight.
- T=18 hours: the last series was read after 18 hours of storage at room temperature away from direct sunlight.

Table 4: Stability of the assay results after final wash step

%CV acceptance criteria	Parameter	Sample	Mean results Obtained after 18H (AU/mL)	%CV Obtained after 18H	Mean results Obtained after 4H (AU/mL	%CV Obtained after 4H
%CV ≤ 15%	SSA 52	Sample 1	169	9	Not calculated	Not calculated
		Sample 2	85	5		
		Sample 3	52	5		
		Sample 4	130	5		
		Sample 5	180	11		
	SSA 60	Sample 6	49	7	Not calculated	Not calculated
		Sample 7	94	11		
		Sample 8	68	4		
		Sample 9	85	7		
		Sample 10	95	13		

%CV acceptance criteria	Parameter	Sample	Mean results Obtained after 18H (AU/mL)	% CV Obtained after 18H	Mean results Obtained after 4H (AU/mL)	%CV Obtained after 4H
%CV ≤ 15%	SSB	Sample 11	167	6	Not calculated	Not calculated
		Sample 12	59	5		
		Sample 13	85	7		
		Sample 14	121	11		
		Sample 15	23	5		
	Sm	Sample 16	33	7	Not calculated	Not calculated
		Sample 17	309	10		
		Sample 18	50	7		
		Sample 19	103	13		
		Sample 20	147	3		
	Sm/RNP	Sample 21	202	7	Not calculated	Not calculated
		Sample 22	82	11		
		Sample 23	374	11		
		Sample 24	59	9		
		Sample 25	116	13		
	Scl70	Sample 26	57	4	Not calculated	Not calculated
		Sample 27	55	5		
		Sample 28	144	3		
		Sample 29	308	4		
		Sample 30	188	7		
	Jo1	Sample 31	79	13	Not calculated	Not calculated
		Sample 32	242	6		
		Sample 33	59	7		
		Sample 34	77	6		
	Centromere	Sample 35	91	16	81	7
		Sample 36	82	11	78	11
		Sample 37	81	7	78	6
		Sample 38	22	9	21	5
		Sample 39	19	5	20	0
	Ribosome	Sample 40	40	13	Not calculated	Not calculated
		Sample 41	141	7		
		Sample 42	71	6		
	dsDNA	Sample 43	49	11	Not calculated	Not calculated
		Sample 44	123	9		
		Sample 45	51	10		
		Sample 46	184	3		
		Sample 47	62	8		

Based on the common laboratories practices, the time range recommended is "one hour for a plate when stored at room temperature away from direct sunlight".

2. Comparison study with predicate

bmd has compared the results obtained with **modified FIDIS™ CONNECTIVE 10*** versus the results obtained with **predicate FIDIS™ CONNECTIVE 10* K053653** in manual use.

The study was performed on 264 samples characterized with the predicate test and the result repartition is described as below:

- **194 samples** were positive for one or more parameters (see table 5).
- **70 negative samples** including some samples **evaluated for their potential biological interferences**.

Table 5: Number of positive samples per parameter.

[redacted]	57
[redacted]	48
[redacted]	23
[redacted]	29
[redacted]	40
[redacted]	28
[redacted]	26
[redacted]	26
[redacted]	17
[redacted]	46

All equivocal samples with predicate and **modified FIDIS™ CONNECTIVE 10* assays** are considered negative for the comparison and the evaluation studies.

Tables 6: Specificity performances

dsDNA N=116		[redacted]		
		Pos	**Neg**	**Total**
[redacted]	**Pos**	45	1	46
	Neg	4	66	70
	Total	49	67	116

There were 3 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 91.84% (45/49)
Negative percent agreement: 98.51% (66/67)
Overall agreement: 95.69% (111/116)

SSA 60kDa N=118		[redacted]		
		Pos	**Neg**	**Total**
[redacted]	**Pos**	48	1	49
	Neg	0	69	69
	Total	48	70	118

There were 2 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (48/48)
Negative percent agreement: 98.57% (69/70)
Overall agreement: 99.15% (117/118)

SSA 52kDa N=127		Pos	Neg	Total
[illegible]	Pos	58	2	60
	Neg	3	64	67
	Total	61	66	127

There were 3 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 95.08% (58/61)
Negative percent agreement: 96.97% (64/66)
Overall agreement: 96.06% (122/127)

SS-B N=93		Pos	Neg	Total
[illegible]	Pos	23	2	25
	Neg	0	68	68
	Total	23	70	93

There were 1 equivocal result with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (23/23)
Negative percent agreement: 97.14% (68/70)
Overall agreement: 97.85% (91/93)

Sm N=99		Pos	Neg	Total
[illegible]	Pos	23	2	25
	Neg	1	73	74
	Total	24	75	99

There were 6 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 95.83% (23/24)
Negative percent agreement: 97.33% (73/75)
Overall agreement: 96.97% (96/99)

Sm/RNP N= 110		Pos	Neg	Total
[illegible]	Pos	31	2	33
	Neg	1	76	77
	Total	32	78	110

There were 7 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 96.88% (31/32)
Negative percent agreement: 97.44% (76/78)
Overall agreement: 97.27% (107/110)

Scl70 N=98		Pos	Neg	Total
[illegible]	Pos	27	2	29
	Neg	1	68	69
	Total	28	70	98

There is 1 equivocal result with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 96.43% (27/28)
Negative percent agreement: 97.14% (68/70)
Overall agreement: 96.94% (95/98)

Jo1 N=96		Pos	Neg	Total
[illegible]	Pos	26	0	26
	Neg	1	69	70
	Total	27	69	96

There is 0 equivocal result with the assay.

Positive percent agreement: 96.30% (26/27)
Negative percent agreement: 100% (69/69)
Overall agreement: 98.96% (95/96)

Centromere N=96		Pos	Neg	Total
	Pos	20	0	20
	Neg	4	72	76
	Total	24	72	96

There were 7 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 83.33% (20/24)
Negative percent agreement: 100% (72/72)
Overall agreement:95.83% (92/96)

Ribosome N=87		Pos	Neg	Total
	Pos	18	0	18
	Neg	0	69	69
	Total	18	69	87

There is 1 equivocal result with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (18/18)
Negative percent agreement: 100% (69/69)
Overall agreement: 100% (87/87)

Table 7: Summary of performance agreement results

Antigenic Specificity	Sample number	Positive percent agreement proportion	Negative percent agreement proportion	Overall agreement proportion
dsDNA	116	91.84%	98.51%	95.69%
SSA 60 kDa	118	100%	98.57%	99.15%
SSA 52 kDa	127	95.08%	96.97%	96.06%
SSB	93	100%	97.14%	97.85%
Sm	99	95.83%	97.33%	96.97%
Sm/RNP	110	96.88%	97.44%	97.27%
Scl70	98	96.43%	97.14%	96.94%
Jo1	96	96.3%	100%	98.96%
Centromere	96	83.33%	100%	95.83%
Ribosome	87	100%	100%	100%

In addition to the analysis above, the 95% one-sided lower confidence limit in percent of proportion agreement (95% LCL (%) was calculated using the Exact Binomial Test for proportions to determine how low this proportion could be with a 95% confidence.

Table 8: Summary of agreements results - 95% LCL (%)

Antigenic Specificity	Positive percent agreement				Negative percent agreement				Overall percent agreement			
	N_1	R_1	P_1 (%)	95% LCL (%)	N_2	R_2	P_2 (%)	95% LCL (%)	N	R	P (%)	95% LCL (%)
dsDNA	49	45	91.84	82.29	67	66	98.51	93.11	116	111	95.69	91.15
SSA 60 kDa	48	48	100	93.95	70	69	98.57	93.40	118	117	99.15	96.04
SSA 52 kDa	61	58	95.08	87.78	66	64	96.97	90.77	127	122	96.06	91.90
SSB	23	23	100	87.79	70	68	97.14	91.28	93	91	97.85	93.39
Sm	24	23	95.83	81.71	75	73	97.33	91.84	99	96	96.97	92.35
Sm/RNP	32	31	96.88	86.02	78	76	97.44	92.15	110	107	97.27	93.10
Scl70	28	27	96.43	84.15	70	68	97.14	91.28	98	95	96.94	92.28
Jo1	27	26	96.3	83.60	69	69	100	95.75	96	95	98.96	95.15
Centromere	24	20	83.33	65.82	72	72	100	95.92	96	92	95.83	90.72
Ribosome	18	18	100	84.67	69	69	100	95.75	87	87	100	96.62

N_1 = No. of positives; R_1 = No. of positive agreements; $P_1 = R_1/N_1$
N_2 = No. of negatives; R_2 = No. of negative agreements; $P_2 = R_2/N_2$
$N = N_1 + N_2$; $R = R_1 + R_2$; $P = R/N$

All of results show that **FIDIS™ CONNECTIVE 10* system** can be considered substantially equivalent to the predicate **K053653 FIDIS™ CONNECTIVE 10* system.**

3. **Comparison study with predicate**
   a. Precision

Precision of the assay was assessed in **36 samples**. Precision was determined by calculating the within-run (intra-assay) and the between run (inter-assay):

- For within run: 4 samples 10 times in a same run.
- For between run: 4 samples in 6 runs, 3 times per run.

Table 9: Summary of CARIS™ Precision results

Sample range	Acceptance criteria for within-run and between-run	Within-run minimal CV% for the 10 parameters	Within-run maximal CV% for the 10 parameters	Between-run minimal CV% for the 10 parameters	Between-run maximal CV% for the 10 parameters
Less than 10 AU/mL or IU/mL	Not determined	Not evaluated	Not evaluated	Not evaluated	Not evaluated
10 to 29 AU/mL or IU/mL	CV≤20%	3.8%	10.3%	7.3%	13.9%
29 to 800 AU/mL or IU/mL	CV≤15%	1.7%	10.8%	3.7%	12.5%

b. Comparison study (manual versus automated assay preparation steps)

bmd has compared the results obtained with the **modified FIDIS™ CONNECTIVE 10*** for the **manual or automated (with CARIS™)** assay preparation steps.

The study was performed on 264 samples characterized with the predicate test and the result repartition is described as below:

- **194 samples** were positive for one or more parameters (see Table 12)
- **70 negative samples** including some samples **evaluated for their potential biological interferences.**

Table 10: Number of the pathological population per parameter.

	Pathological sample number / parameter
SSA52	48
SSA60	40
SSB	22
Sm	26
Sm/RNP	33
Scl70	27
JO1	25
Centro	23
Ribo	6
dsDNA	42

All equivocal samples with **FIDIS™ CONNECTIVE 10* assays** are considered negative for the comparison and the evaluation studies.

Tables 11: Agreement performances

dsDNA N=112				
		Pos	Neg	Total
[illegible]	Pos	43	0	43
	Neg	0	69	69
	Total	43	69	112

There were 4 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (43/43)
Negative percent agreement: 100% (69/69)
Overall agreement: 100% (112/112)

SSA 60kDa N=110				
		Pos	Neg	Total
[illegible]	Pos	42	0	42
	Neg	0	68	68
	Total	42	68	110

There were 1 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (42/42)
Negative percent agreement: 100% (68/68)
Overall agreement: 100% (110/110)

Tables 11: Agreement performances

dsDNA

N=112

		MANUAL		
		Pos	**Neg**	**Total**
CARIS™	**Pos**	43	0	43
	Neg	0	69	69
	Total	43	69	112

There were 4 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (43/43)
Negative percent agreement: 100% (69/69)
Overall agreement: 100% (112/112)

SSA 60kDa

N=110

		MANUAL		
		Pos	**Neg**	**Total**
CARIS™	**Pos**	42	0	42
	Neg	0	68	68
	Total	42	68	110

There were 1 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (42/42)
Negative percent agreement: 100% (68/68)
Overall agreement: 100% (110/110)

SSA 52kDa

N=118

		MANUAL		
		Pos	**Neg**	**Total**
CARIS™	**Pos**	52	1	53
	Neg	0	65	65
	Total	52	66	118

There were 2 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (52/52)
Negative percent agreement: 98.48% (65/66)
Overall agreement: 99.15% (117/118)

SSB

N=92

		MANUAL		
		Pos	**Neg**	**Total**
CARIS™	**Pos**	25	0	25
	Neg	0	67	67
	Total	25	67	92

There is 1 equivocal result with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (25/25)
Negative percent agreement: 100% (67/67)
Overall agreement: 100% (92/92)

Sm

N=96

		MANUAL		
		Pos	**Neg**	**Tota l**
CARIS™	**Pos**	24	3	27
	Neg	0	69	69
	Total	24	72	96

There were 5 equivocal results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (24/24)
Negative percent agreement: 95.83% (69/72)
Overall agreement: 96.88% (93/96)

Sm/RNP

N= 103

		MANUAL		
		Pos	**Neg**	**Total**
CARIS™	**Pos**	32	3	35
	Neg	0	68	68
	Total	32	71	103

There were 6 borderline results with the assay. For purposes of calculation, these results were considered as negative.
Positive percent agreement: 100% (32/32)
Negative percent agreement: 95.77% (68/71)
Overall agreement: 97.09% (100/103)

Scl70

N=97

		MANUAL		
		Pos	**Neg**	**Total**
CARIS™	**Pos**	29	0	29
	Neg	0	68	68
	Total	29	68	97

There is 0 equivocal result with the assay.
Positive percent agreement: 100% (29/29)
Negative percent agreement: 100% (68/68)
Overall agreement: 100% (97/97)

Jo1

N=95

		MANUAL		
		Pos	**Neg**	**Total**
CARIS™	**Pos**	26	0	26
	Neg	0	69	69
	Total	26	69	95

There is 0 equivocal result with the assay.
Positive percent agreement: 100% (26/26)
Negative percent agreement: 100% (69/69)
Overall agreement: 100% (95/95)

Centromere N=93		[redacted] MANUAL		
		Pos	Neg	Total
[redacted]	Pos	20	4	24
	Neg	0	69	69
	Total	20	73	93

There were 6 equivocal results with the assay. For purpose of calculation, these results were considered as negative.
Positive percent agreement: 100% (20/20)
Negative percent agreement: 94.52% (69/73)
Overall agreement: 95.70% (89/93)

Ribosome N=76		[redacted] MANUAL		
		Pos	Neg	Total
[redacted]	Pos	8	0	8
	Neg	0	68	68
	Total	8	68	76

There is 0 equivocal result with the assay.

Positive percent agreement: 100% (8/8)
Negative percent agreement: 100% (68/68)
Overall agreement: 100% (76/76)

Table 12: Summary of performance agreement results

Antigenic Specificity	Sample number	Positive percent agreement	Negative percent agreement	Overall agreement
		proportion	proportion	proportion
dsDNA	112	100%	100%	100%
SSA 60 kDa	110	100%	100%	100%
SSA 52 kDa	118	100%	98.48%	98.48%
SSB	92	100%	100%	100%
Sm	96	100%	95.83%	95.83%
Sm/RNP	13	100%	95.77%	95.77%
Scl70	97	100%	100%	100%
Jo1	95	100%	100%	100%
Centromere	93	100%	94.52%	94.52%
Ribosome	76	100%	100%	100%

In addition to the analysis above, the 95% one-sided lower confidence limit in percent of proportion agreement (95% LCL (%) was calculated using the Exact Binomial Test for proportions to determine how low this proportion could be with a 95% confidence.

Table 13: Summary of performance agreements results - 95% LCL (%)

Antigenic Specificity	Positive percent agreement				Negative percent agreement				Overall percent agreement			
	N_1	R_1	P_1 (%)	95% LCL (%)	N_2	R_2	P_2 (%)	95% LCL (%)	N	R	P (%)	95% LCL (%)
dsDNA	43	43	100	93.27	69	69	100	95.75	112	112	100	97.36
SSA 60 kDa	42	42	100	93.12	68	68	100	95.69	110	110	100	97.31
SSA 52 kDa	52	52	100	94.40	66	65	98.48	93.01	118	117	99.15	96.04
SSB	25	25	100	88.71	67	67	100	95.63	92	92	100	96.80
Sm	24	24	100	88.27	72	69	95.83	89.58	96	93	96.88	92.12
Sm/RNP	32	32	100	91.06	71	68	95.77	89.44	103	100	97.09	92.64
Scl70	29	29	100	90.19	68	68	100	95.69	97	97	100	96.96
Jo1	26	26	100	89.12	69	69	100	95.75	95	95	100	96.90
Centromere	20	20	100	86.09	73	69	94.52	87.90	93	89	95.70	90.43
Ribosome	8	8	100	68.77	68	68	100	95.69	76	76	100	96.13

N_1 = No. of positives; R_1 = No. of positive agreements; $P_1 = R_1/N_1$
N_2 = No. of negatives; R_2 = No. of negative agreements; $P_2 = R_2/N_2$
$N = N_1 + N_2$; $R = R_1 + R_2$; $P = R/N$

All previous evaluation results indicate that manual and automated (with **CARIS™**) assay preparation steps are considered substantially equivalents.

8. Conclusions

In conclusion, all supporting data demonstrate that the **FIDIS™ CONNECTIVE 10*** system can be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 9 2007

Biomedical Diagnostics S.A. (BMD)
c/o Ms. Christelle Courivaud
Regulatory Affairs Manager
Actipole 25,
4-6 Bld de Beaubourg
77435 Marne La Vallée cedex 2
France

Re: k071210
Trade/Device Name: FIDIS™ CONNECTIVE 10* Assay
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LLL, LKS, LKO, LKP, LSW, LJM, MQA
Dated: December 5, 2007
Received: December 7, 2007

Dear Ms. Courivaud:

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 (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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to

begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K071210

Device Name: **FIDIS™ CONNECTIVE 10***

Indication For Use:

The **FIDIS™ CONNECTIVE 10*** kit is a semi-quantitative homogeneous fluorescent-based microparticles immunoassay using flow cytometry. The test system is used to simultaneously detect the presence of 10 autoantibody specificities: double stranded DNA (dsDNA), SSA (60 kDa and 52 kDa), SSB, Sm, Sm/RNP, Scl70, Jo1, ribosome and centromere.

*(*Antibodies to dsDNA, Sm, Sm/RNP, SSA, SSB, Scl-70, Jo-1, ribosome and centromere can be reported using this assay).*

Clinical utility:

The results of the **FIDIS™ CONNECTIVE 10*** are to be used in conjunction with the clinical findings and the other laboratory tests to aid in the diagnosis of connective diseases (systemic lupus erythematosus (SLE), Sjogren's syndrome, mixed connective tissue disease (MCTD), scleroderma, dermatomyositis and CREST syndrome).

FIDIS™ CONNECTIVE 10* kit uses serum only, and is to be run on the FIDIS™ Instrument and MLX-BOOSTER™ Software.

FIDIS™ CONNECTIVE 10* kit may be used with the **CARIS™ system** (diluting and dispensing device).

This test is for *in vitro* diagnostic use.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety