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MAR 20 1996

**510(k) Summary of Safety and Effectiveness Information**  
**dsDNA EIA Test System K960182**

**This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and proposed 21 CFR Part 807.92.**

**Identification of predicate device:**

The dsDNA Immunoglobulin EIA test system is substantially equivalent to the Clark ELISA for dsDNA IgG, IgM antibodies.

**Description of New Device**

The dsDNA Immunoglobulin EIA test system is an enzyme-linked immunosorbent assay (EIA) for the detection and semi-quantitation of Immunoglobulin to dsDNA in human sera.

**Statement of the intended use:**

The assay is intended for use in detecting antibodies in a single serum specimen. The results of the assay are to be used as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE).

**Technological characteristics of the device:**

The dsDNA Immunoglobulin EIA test system is an enzyme linked immunosorbent assay to detect Immunoglobulin, to dsDNA. Purified dsDNA antigens are attached to a solid phase microtiter well. Diluted test sera is added to each well. If the antibodies are present that recognize the antigen, they will bind to the antigen in the well. After incubation the wells are washed to remove unbound antibody. An enzyme labeled anti-human Immunoglobulin is added to each well. If antibody is present it will bind to the antibody attached to the antigen on well. After incubation, the wells are washed to remove unbound conjugate. A substrate solution is added to each well. If enzyme is present, the substrate will undergo a color change. After an incubation period, the reaction is stopped and the color intensity is measured photometrically, producing an indirect measurement of specific antibody in the patient specimen.

**Description and conclusions of the clinical studies:**

The dsDNA Immunoglobulin EIA Test System is substantially equivalent to the Clark ELISA for dsDNA IgG, IgM antibodies. Equivalence is demonstrated by the following comparative results:

A total of 133 patient specimens were obtained. Eighty-eight of the specimens were from normal individuals. Forty-five specimens were thought to have autoimmune disease. The serum were evaluated relative to a commercially available dsDNA ELISA assay. The results were shown in Table 1.

**Table 1 Sensitivity and Specificity of the MarDx dsDNA EIA relative to Clark dsDNA test**

		MarDx dsDNA EIA			
		+	eq	-	Total
Alternate EIA	+	38	7	2*	47
	eq	0	0	2	2
	-	0	3	81	84
	Total	38	10	85	133

Sera falling in the equivocal range were not included in the following calculations.

These 2 sera were tested by *Crithidia* IFA and found to be negative.

Relative Sensitivity	= 38/40	= 95.0%
Relative Specificity	= 81/81	= 100%
Relative Accuracy	= 119/121	= 98.3%

The MarDx EIA was evaluated for precision by testing seven sera ten times each on three different days. The results are summarized in Table 2.

**Table 2 Precision of the MarDx EIA Test**

	Assay 1 (n=10)			Assay 2 (n=10)			Assay 3 (n=10)			Inter Assay (n=30)		
	<u>X</u>	<u>SD</u>	<u>CV</u>	<u>X</u>	<u>SD</u>	<u>CV</u>	<u>X</u>	<u>SD</u>	<u>CV</u>	<u>X</u>	<u>SD</u>	<u>CV</u>
1	7.78	0.252	3.24%	8.10	0.329	4.06%	7.31	0.237	3.24%	7.73	0.424	5.48%
2	8.07	0.188	2.32%	8.48	0.306	3.61%	7.77	0.222	2.88%	8.11	0.379	4.67%
3	4.78	0.324	6.78%	4.78	0.390	8.15%	4.37	0.272	6.22%	4.64	0.376	8.11%
4	3.77	0.260	6.90%	3.85	0.213	5.53%	3.81	0.213	5.59%	3.81	0.224	5.87%
5	4.42	0.295	6.67%	4.16	0.274	6.58%	3.91	0.254	6.50%	4.17	0.340	8.14%
6	0.78	0.122	15.70%	0.70	0.094	13.43%	0.62	0.101	16.29%	0.70	0.123	17.52%
7	0.54	0.073	13.50%	0.50	0.065	12.94%	0.39	0.037	9.49%	0.48	0.085	17.78%

**Table 3**  
**Linearity**

Serum	Neat	1:2	1:4	1:8	1:16	1:32	r
1	4.20	2.77	1.50	0.75			0.975
2	6.94	5.31	3.92	2.33	1.24	0.73	0.989
3	7.36	5.39	3.82	2.10	1.13	0.65	0.982
4	6.43	4.67	3.21	1.89	1.05	0.59	0.981
5	7.18	5.42	4.11	2.51	1.48	0.83	0.959

Linear regression compared dsDNA Index Value to log<sub>2</sub> of dilution.

**Table 4 Cross Reactivity**

Serum #	Index Value	Interpretation	Specificity
1.	0.28	-	Ro
2.	0.52	-	Ro
3.	0.74	-	Ro
4.	0.53	-	La
5.	0.28	-	La
6.	0.70	-	La
7.	0.64	-	SM
8.	0.90	equ	SM
9.	0.72	-	SM
10.	0.58	-	RNP
11.	0.40	-	RNP
12.	0.82	equ	RNP
13.	0.79	-	SCL-70
14.	0.70	-	SCL-70
15.	0.46	-	SCL-70
16.	0.25	-	Jo-1
17.	0.63	-	Jo-1
18.	0.76	-	Jo-1

**Table 5 International Unit Conversion**

<b>International Unit Standard Units / mL</b>	<b>Index Value</b>
200	4.20
100	2.37
50	1.50
25	0.75

Linear regression compared Index Value versus log International Units  
 $r = 0.975$     $a = 0.25$     $b = 1.28$     $Y = \log \text{I.U.}$     $X = \text{Index Value}$

Regression Equation Calculation

$$Y = Xa + b \quad \text{I.U.} = 10^Y$$