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Summary of Safety and Effectiveness Information
Ribosomal P ELISA Test Kit

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II. Description of Device

The Ribosomal P ELISA test is an enzyme-linked immunosorbent assay (ELISA) for the detection and semi-quantitation of IgG antibodies to Ribosomal P in human sera. The assay is to be used to detect 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). FOR IN VITRO DIAGNOSTIC USE.

The Ribosomal P ELISA test is an enzyme linked immunosorbent assay to detect IgG, M, A, antibodies to Ribosomal P. Purified Ribosomal P antigen is 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 IgG, M, A 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.

III. Clinical Data

Clinical studies were conducted using 451 sera from a lupus cohort. Forty five were found to be positive for a prevalence rate of 9.98%. The data indicate that the prevalence of Ribosomal P antibody found in this cohort using the Ribosomal P device is similar to that found in the literature (12-20%).

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XI. Performance Characteristics

1. Relative sensitivity and specificity. The Ribosomal P ELISA test results were compared to results obtained by ouchterlony analysis of serum from clinically defined lupus (n=46) and normals (n=137). The results of the study are summarized in Table 1.

Table 1
Sensitivity and Specificity of the Ribosomal P Test Kit Relative toOuchterlony

		Immuno Probe, Inc.			
		Positive	Equivocal	Negative	Total
Ouchterlony	Positive	46	0	0	46
	Negative	1	0	136	137
	Total	47	0	136	183

Relative Sensitivity = 46/46 = 100% 95% Confidence Interval = 93.5%-100%
Relative Specificity = 136/137 = 99.3 % 95% Confidence Interval = 97.8%-100%
Relative Agreement = 182/183 = 99.5 % 95% Confidence Interval = 98.4%-100%

The 95% confidence interval for relative sensitivity was calculated assuming one false negative.

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2. Precision

The precision of the Ribosomal P kit was determined by testing seven different sera eight times each on three different assays. The data is summarized in Table 2. With proper technique the user should obtain C.V.'s of less than 15%.

Table 2
Ribosomal P Precision Data

	Assay 1 (n=8)			Assay 2 (n=8)			Assay 3 (n=8)			Inter Assay (n=24)		
Serum #	X	S.D.	C.V.	X	S.D.	C.V.	X	S.D.	C.V.	X	S.D	C.V.
1	1.57	0.117	7.4%	1.62	0.113	7.0%	1.50	0.134	8.9%	1.57	0.127	8.1%
2	1.68	0.176	10.5%	1.60	0.095	5.9%	1.66	0.148	8.9%	1.65	0.143	8.7%
3	2.98	0.113	3.8%	2.83	0.128	4.5%	2.74	0.127	4.6%	2.85	0.155	5.5%
4	2.89	0.115	4.09%	2.95	0.135	4.6%	2.94	0.068	2.3%	2.92	0.109	3.7%
5	0.29	0.027	9.29%	0.18	0.035	19.6%	0.20	0.039	19.6%	0.22	0.056	25.6%
6	0.09	0.042	46.3%	0.08	0.016	20.5%	0.08	0.037	46.5%	0.10	0.048	48.0%

X = Mean Ribosomal P Value
S.D. = Standard Deviation
C.V. = Coefficient of Variation

3. Linearity

The Ribosomal P index values were determined for serial twofold dilutions of five positive sera. The index values were compared to $\log_2$ of dilution by standard linear regression. The data in table # 3 indicates that the assay is semi-quantitative.

Table 3
Linearity

Index Serum #	Neat	1:2	1:4	1:8	1:16	1:32	1:64	1:128	r
1	2.70	2.52	2.24	1.93	1.57	1.33	0.98		0.997
2	2.53	2.29	1.99	1.57	1.20	0.86			0.997
3	2.89	2.71	2.47	2.23	1.93	1.57	1.20	0.90	0.994
4	3.68	3.18	2.59	1.94	1.59	1.00	0.68		0.997
5	2.09	1.38	0.94						0.991

Linear regression compared Ribosomal P Index Value to $\log_2$ of dilution

4. Cross Reactivity Data

Sera containing high levels of antibodies to potentially cross reactive antigens were assayed on the Ribosomal P ELISA kit. The data in Table 4 indicates that antibodies to alternate autoimmune antigens do not cross react with the Ribosomal P ELISA kit.

Table 4
Cross Reactivity

Serum #	Immunoprobe Index Value	Interpretation	Specificity
1	0.21	-	Ro
2	0.18	-	Ro
3	0.17	-	Ro
4	0.13	-	La
5	0.09	-	La
6	0.10	-	La
7	0.09	-	Scl-70
8	0.18	-	Scl-70
9	0.17	-	Scl-70
10	0.15	-	Jo-1
11	0.18	-	Jo-1
12	0.15	-	Jo-1
13	0.38	-	Sm
14	0.43	-	Sm
15	0.40	-	Sm
16	0.19	-	RNP
17	0.15	-	RNP
18	0.14	-	RNP
19	0.14	-	DNA

5. Prevalence. Clinical studies were conducted using 451 sera from a lupus cohort. Forty five were found to be positive for a prevalence rate of 9.98%. The data indicate that the prevalence of Ribosomal P antibody found in this cohort using the Ribosomal P device is similar to that found in the literature (12-20%).