

K962276

510(k) Summary

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1. Submitter's Name/Contact Person

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2. Device Name

Trade Name: Hemagen ® DNA Kit (EIA method)
Common Name: Anti-DNA
Classification Name: Anti-DNA Antibody, Antigen and Control

3. Predicate Device

Hemagen VIRGO ® Anti-nDNA IgG IFA Kit
{Reference 510 (k) No. K 771376A}

3. Description of Device

An enzyme-linked immunosorbent assay (ELISA) designed for the detection and measurement of antibodies to native DNA in human serum.

The ELISA methodology is commonly used for serum antibody evaluations. Purified native DNA has been attached to the inner surfaces of the microwell plate. During the initial incubation step, antibodies in patient serum bind specifically to the immobilized antigen and remain in place after a wash step.

A second antibody which is conjugated to horseradish peroxidase (HRP) is used to recognize the "heavy + light" chain regions of the patient's DNA antibodies that remain after the wash step. In the wells where the second antibody remains bound, the conjugated HRP catalyzes a color change in the substrate. After the reaction is stopped, the color is read in an EIA Plate reader.

4. Intended Use of Device

An enzyme-linked immunosorbent assay (ELISA) designed for the detection and measurement of circulating antibodies to native DNA. These autoantibodies are often associated with systemic lupus erythematosus (SLE) and give positive results in screening tests for antinuclear antibodies.

5.(A) Technological Characteristics

Proposed Device

The **Hemagen dsDNA Kit** is an enzyme-linked immunosorbent assay. The device utilizes optical density as a measure of antibody presence, with an established cutoff point between a positive and a negative reaction.

Predicate Device

The Hemagen VIRGO Anti-DNA IgG {heavy + light} IFA Kit is an indirect fluorescent antibody assay. The device utilizes the indirect method of fluorescent antibody staining. The resultant level of observed fluorescence is used to determine the presence or absence of antibodies.

5.(B) Performance Data

I. Precision

To evaluate precision, inter-assay and intra-assay studies were conducted.

A. Inter-assay reproducibility {Between-run}

Eight different serum samples were assayed five times each, twice a day, on five different days (a total of 50 readings)

<u>Sample</u>	<u>Mean IU/mL</u>	<u>Std. Dev.</u>	<u>% CV</u>	<u>Mean O.D.</u>	<u>Std. Dev.</u>	<u>% CV</u>
1	102.1	11.3	11.1	0.617	0.05	8.3
2	102.4	6.4	6.2	0.620	0.05	7.4
3	90.1	6.5	7.2	0.553	0.04	7.7
4	55.3	5.2	9.4	0.356	0.04	9.9
5	< 50	N/A	N/A	0.213	0.03	12.4
6	< 50	N/A	N/A	0.264	0.03	9.8
7	122.7	13.8	11.3	0.731	0.09	12.3
8	142.6	9.2	6.4	0.840	0.07	8.3

B. Intra-assay reproducibility {Within-run}

Eight different samples were assayed 20 consecutive times in a single run:

<u>Sample</u>	<u>Mean IU/mL</u>	<u>Std. Dev.</u>	<u>% CV</u>	<u>Mean O.D.</u>	<u>Std. Dev.</u>	<u>% CV</u>
1	105.2	17.9	17.0	0.604	0.08	13.9
2	97.2	2.8	2.8	0.567	0.01	2.2
3	84.9	2.2	2.6	0.505	0.01	2.2
4	54.3	1.7	2.6	0.355	0.01	2.4
5	< 50	N/A	N/A	0.199	0.02	9.0
6	< 50	N/A	N/A	0.240	0.01	5.5
7	115.4	5.6	4.8	0.688	0.03	4.2
8	129.4	3.8	2.9	0.765	0.02	2.6

II. Verification of the DNA Calibrators

The kit calibrators have been compared to the World Health Organization Standard for Anti-Double Stranded DNA (ANTI-dsDNA) 1st International Standard, Code Wo / 80. A study was conducted to demonstrate the high degree of correlation that exists between the kit calibrators and the W.H.O. Standard.

III. Comparison Testing

The Hemagen dsDNA Kit and the Hemagen VIRGO Anti-nDNA IgG IFA Kit were used to assay 100 serum specimens from different patients with known or suspected autoimmune disease. Forty (40) specimens from apparently healthy blood donors were also assayed with the Hemagen dsDNA Kit and the Hemagen VIRGO Anti-nDNA IgG IFA Kit.

Summary Tables

Table A: Summary of disease state patients, N = 100 {Initial testing}

<u>Proposed Device</u>	<u>Predicate Device</u>		<u>TOTAL</u>
	<u>Positive</u>	<u>Negative</u>	
Positive	23	2 ¹	25
Negative	7 ¹	68	75
Totals	30	70	100

1. The nine discrepant samples were evaluated by hemagglutination for resolution

Table B: Summary of disease state patients, N = 100 {Final results}

<u>Proposed Device</u>	<u>Predicate Device</u>		<u>TOTAL</u>
	<u>Positive</u>	<u>Negative</u>	
Positive	23	2	25
Negative	0	75	75
Totals	23	77	100

The relative analytical sensitivity was found to be 100 % (23/23).
 The relative analytical specificity was found to be 97.4 % (75/77).

Table C: Normal blood donors, N = 40

<u>Proposed Device</u>	<u>Predicate Device</u>		<u>TOTAL</u>
	<u>Positive</u>	<u>Negative</u>	
Positive	0	0	0
Negative	0	40	40
Totals	0	40	40

IV. **Interfering Substances**

Lipemic, hemolytic, and icteric samples were evaluated with the assay in accordance with NCCLS Document EP7-P Proposed Guideline " Interference Testing in Clinical Chemistry." The results indicate that there is no significant effect (<15 % variation) on the assay for samples with:

Hemoglobin concentration:	≤ 500 mg/dL
Lipid concentration:	≤ 3000 mg/dL
Bilirubin concentration:	≤ 20 mg/dL

V. **Prozone**

The **Hemagen dsDNA Kit** was used to assay a high titered serum sample to determine if the kit would return unexpectedly low values. The results of this evaluation indicate that the kit gives appropriately high positive results with high titered sera.

6. **Conclusion**

The results of the comparative studies support the claim that the **Hemagen dsDNA Kit** is substantially equivalent to the predicate device.