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510(k) Summary K962836

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2. Device Name

Trade Name:	Hemagen® Rheumatoid Factor Kit
Common Name:	RF (Rheumatoid Factor)
Classification Name:	System, Test, Rheumatoid Factor

3. Predicate Device

Hemagen ® RF Kit {Reference 510 (k) No. **K 855221/A**}

3. Description of Device

An enzyme-linked immunosorbent assay (ELISA) designed for the detection and measurement of IgM rheumatoid factor in human serum and plasma.

The ELISA methodology is commonly used for antibody evaluations. Purified IgG has been attached to the inner surfaces of the microwell plate. During the initial incubation step, rheumatoid factor in patient serum or plasma binds specifically to the immobilized IgG and remains in place after a wash step.

A second antibody which is conjugated to horseradish peroxidase (HRP) is used to recognize the "μ" chain regions of the patient's IgM rheumatoid factor remaining 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 IgM rheumatoid factor. When used according to instructions, the kit is useful in establishing the presence of rheumatoid factor and as an aid in the diagnosis and management of rheumatic diseases.

5.(A) Technological Characteristics

Proposed Device

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

Predicate Device

The Hemagen RF(HA) Kit is a hemagglutination based assay. The device utilizes the method of agglutination of specifically sensitized human erythrocytes by patient serum containing rheumatoid factor. The resultant level of agglutination is used to determine the presence or absence of rheumatoid factor.

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)

Sample	Mean IU/mL	Std. Dev.	% CV	Mean O.D.	Std. Dev.	% CV
1	< 20	N/A	N/A	0.038	0.005	13.1
2	< 20	N/A	N/A	0.032	0.005	15.6
3	41.8	4.9	11.7	0.430	0.059	13.7
4	32.8	3.7	11.3	0.343	0.047	13.7
5	73.3	5.8	7.9	0.708	0.109	15.3
6	77.7	8.2	10.6	0.763	0.108	14.2
7	94.3	6.8	7.2	0.890	0.126	14.2
8	105.3	7.8	7.4	0.982	0.114	11.6

B. Intra-assay reproducibility {Within-run}

Eight different samples were assayed 10 consecutive times in a single run:

Sample	Mean IU/mL	Std. Dev.	% CV	Mean O.D.	Std. Dev.	% CV
1	< 20	N/A	N/A	0.038	0.002	5.3
2	< 20	N/A	N/A	0.026	0.001	3.8
3	37.8	3.0	7.9	0.442	0.029	6.6
4	31.5	3.4	10.8	0.383	0.032	8.4
5	74.8	3.7	4.9	0.794	0.035	4.4
6	71.4	4.7	6.6	0.761	0.045	5.9
7	89.1	2.3	2.6	0.929	0.021	2.3
8	100.8	4.2	4.2	1.041	0.040	3.8

II. Verification of the RF Calibrators

The kit calibrators have been compared to the World Health Organization International Reference Preparation of Rheumatoid Arthritis Serum. 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 Rheumatoid Factor Kit** and the **Hemagen RF Hemagglutination Kit** were used to assay serum specimens from rheumatoid arthritis patients and normal apparently healthy donors.

Table 1: RF panels , N =106

	Predicate Device		
Proposed Device	Positive	Negative	TOTAL
Positive	73	2	75
Negative	4	27	31
Totals	77	29	106

The relative analytical sensitivity is (73/77), 94.8 % {87.3 % to 97.9%} 0.95 exact confidence interval
The relative analytical specificity is (27/29), 93.1 % {78.0 % to 98.1 %} 0.95 exact confidence interval

Table 2: Normal blood donors, N = 82

	Predicate Device		
Proposed Device	Positive	Negative	TOTAL
Positive	4	0	4
Negative	0	78	78
Totals	4	78	82

IV. Assay performance with Serum and Plasma

Ninety two (92) matched serum and plasma samples were compared. Half of the volume of each sample was converted to serum by recalcification using a standard Ca^{2+}/thrombin methodology.

All of the plasma and converted serum samples were evaluated with the **Hemagen Rheumatoid Factor Kit**. The results of the evaluation with the proposed device indicate that it can provide accurate estimates of IgM rheumatoid factor in both human serum and plasma.

V. **Interfering Substances**

Lipemic, hemolytic, and icteric samples were evaluated with the assay. The results indicate that there is no significant effect (< 20 % variation) on the assay for samples with:

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

VI. **Prozone**

The **Hemagen Rheumatoid Factor 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 Rheumatoid Factor Kit** is substantially equivalent to the predicate device.