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510(k) Summary

1. Submitter's Name/Contact Person

Joseph M. Califano Manager, Regulatory Affairs

Address

Hemagen Diagnostics, Inc.
34-40 Bear Hill Road
Waltham, MA, 02154

Phone: (617) 890-3766
Fax: (617) 890-3748

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2. Device Name

Trade Name:	Rheumatoid Factor SPIA ™
Common Name:	RF (Rheumatoid Factor)
Classification Name:	System, Test, Rheumatoid Factor

3. Predicate Device

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

3a. Methods

I. Manual: *Described in Laboratory Diagnostic Procedures in the Rheumatic Diseases, 3rd Ed. (1985)* Chap. 4 Rheumatoid Factors,Techniques of Analysis by McDuffie, F.C.

II. Automated System: COBAS-MIRA Analyzer. **{510 (k) Docket No. k 851172}**

III. Third Party Test: Hemagen ® RF Kit (EIA method) **{510 (k) Docket No. K 962386}**

4. Description of Device

Raichem's Rheumatoid Factor SPIA ™ latex agglutination assay is a quantitative turbidimetric assay for the detection of Rheumatoid Factor IgM antibodies in human serum and plasma.

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Ralchem's Rheumatoid Factor SPIA ™ latex agglutination assay is a quantitative turbidimetric assay for the detection of Rheumatoid Factor IgM antibodies in human serum and plasma.

In this assay, latex microspheres coated with human and rabbit IgG are diluted in a reaction buffer designed to allow aggregation without rapid settling of Rheumatoid Factor complexed microparticles. As aggregates form, the suspension becomes less cloudy, resulting in less light being absorbed. The change in optical density is proportional to the amount of RF present in the suspension.

A quantitative determination of the amount of RF present in a serum/plasma sample is made by comparison to a standard curve.

5. Intended Use of Device

A latex agglutination assay intended for the quantitative turbidimetric detection of Rheumatoid IgM antibodies in human serum and plasma. When used according to instructions, the assay is useful in establishing the presence of rheumatoid factor and as an aid in the diagnosis and management of rheumatoid arthritis.

6.(A) Technological Characteristics

Proposed Device

Ralchem's Rheumatoid Factor SPIA ™ latex agglutination assay is a quantitative turbidimetric assay. The amount of RF present is proportional to the change in optical density in the suspension. The RF IgM antibody concentration is quantified by comparison to a standard curve. This assay is performed manually following clinically accepted methodologies. The assay is designed to enable users to readily adapt it for use with automated systems such as the Roche COBAS MIRA Analyzer.

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.

6.(B) Performance Data

I. Precision

To evaluate precision, inter-assay and intra-assay studies were conducted with the **Raichem Rheumatoid Factor SPIA ™** on an automated system {COBAS-MIRA}

A. Inter-assay reproducibility

Six different serum samples were assayed twice a day on four different days.

SAMPLE	Mean IU/mL	Std. Dev	% CV	Mean Delta	Std. Dev	% CV
1	95.4	5.0	5.3	0.111	0.007	6.4
2	80.3	5.3	6.6	0.097	0.007	7.7
3	67.9	9.9	14.6	0.087	0.010	11.8
4	45.9	9.5	20.7	0.071	0.010	13.8
5	< 20	N/A	N/A	0.037	0.003	9.4
6	< 20	N/A	N/A	0.036	0.005	15.0

B. Intra-assay reproducibility

Six different serum samples were assayed 20 consecutive times in a single run.

SAMPLE	Mean IU/mL	Std. Dev	% CV	Mean Delta	Std. Dev	% CV
1	56	3.7	6.7	0.080	0.004	5.4
2	48	3.2	6.6	0.070	0.004	5.3
3	28	2.8	10.0	0.047	0.003	7.1
4	23	2.7	11.5	0.041	0.004	9.6
5	< 20	N/A	N/A	0.015	0.005	31.4
6	< 20	N/A	N/A	0.011	0.003	31.5

II. Verification of the RF Calibrator

The RF Calibrator{120 IU/mL} supplied with the assay is the same as the High Calibrator supplied with the **Hemagen ® Rheumatoid Factor Kit** (EIA method) (Refer to 510 (k) **Docket No. 962386**). The kit calibrators were compared to the World Health Organization International Reference Preparation of Rheumatoid Arthritis Serum. It was demonstrated that there is a high degree of correlation that exists between the kit calibrators and the W.H.O. Standard.

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III. Comparison Testing

The **Raichem Rheumatoid Factor SPIA ™** and the **Hemagen® RF Hemagglutination Kit** were used to assay serum specimens from rheumatoid arthritis patients, patients with autoimmune diseases, and normal apparently healthy donors.

A. *Comparison with an automated method {COBAS-MIRA}*

Table 1.1 Disease State Specimens {combined} n =335

	Predicate Device			
	Positive	Negative	Equivocal	Total
Proposed Device				
Positive	141	3[1]	0	144
Negative	9[1] *	180	2[1] *	191
Total	150	183	2	335

1. The discrepant and equivocal samples were evaluated by a third party EIA method

	EIA	
	Positive	**Negative**
Proposed Device		
Positive	3	0
Negative	7	4

Table 1.2 Disease State Specimens {combined}, n =335

	Predicate Device		
	Positive	Negative	Total
Proposed Device			
Positive	144	0	144
Negative	7	184	191
Total	151	184	335

Relative analytical sensitivity = 95.4 % {144/151}, 0.95 $_{INTERVAL}$ = 90.8 % to 97.8 %
Relative analytical specificity = 100 % {184/184}, 0.95 $_{INTERVAL}$ = 98.0 % to 100 %