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510(k) Summary Hemagen ® CRP 150 Kit

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 Names***

Trade Name:	Hemagen ® CRP 150 Kit
Common Name:	C-Reactive Protein Assay (EIA method)
Classification Name:	C-reactive protein immunological test system (per 21 CFR 866.5270)

3 ***Predicate Device***

Hemagen ® C-Reactive Protein Kit (EIA method)
Reference Docket No: **K 944288**

4 ***Description of Device***

An enzyme-linked immunosorbent assay (ELISA) designed for the semi-quantitative detection of C-Reactive Protein (CRP) in human serum and plasma.

The ELISA methodology is commonly used for serological evaluations. Antibodies to CRP have been attached to the inner surfaces of the microwell plate. During the initial incubation step, CRP in patient serum binds specifically to the immobilized antibody and remains in place after a wash step.

A second antibody, which is conjugated to the enzyme horseradish peroxidase, reacts with CRP bound in the first step. In the wells where the second antibody remains bound, the enzyme catalyzes a color change in the substrate, tetramethylbenzidine (TMB). After the reaction is stopped, the color is read in an EIA plate reader.

5 ***Intended Use of Device***

This kit has been designed for the measurement of C-reactive protein in human serum and plasma. When used according to instructions, the kit is useful in measuring the acute phase responses in humans to infection, tissue damage and various inflammatory conditions.

6.***(A) Technological Characteristics***

The Hemagen CRP 150 Kit is an enzyme-linked immunosorbent assay with the following features:

i. The assay's detection range is 1ug/mL to 50 ug/mL of CRP.
ii. A positive control.
iii. A set of CRP standards.
iv. The HRP conjugate is supplied as a liquid.

The predicate device is also an enzyme-linked immunosorbent assay.

6.***(B) Performance Data***

I. Verification of CRP Standards

The CRP Standards have been compared to the W.H.O International Standard for Human C-Reactive Protein (1st International Standard, Code 85/506). A study was conducted to demonstrate the high degree of correlation that exists between the Kit standards and the W.H.O. Standard.

II. Comparison Testing

Eighteen human serum* samples with CRP concentrations ranging from 1 to 100 ug/mL were evaluated concurrently with both the proposed device and the predicate device to demonstrate the equivalence of the CRP concentrations estimated with each of the kits in accordance with the instructions in their respective package inserts.

*{*In the submission for the predicate device, the EIA methodology was shown to be substantially equivalent to a latex aggluntination method by concurrent comparison with 166 human serum samples.}*

Analysis of the results of this study indicated that a linear relationship with a high degree of correlation exists between the estimated CRP concentrations for assayed serum samples as evidenced by an estimated regression slope of +1.0 and a correlation coefficient of > 0.90.

III. Assay performance with Serum and Plasma

Two sets of plasma samples of 41 samples each from apparently healthy donors were selected. 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 assayed for CRP concentrations with the **Hemagen CRP 150 Kit** in accordance with the Draft package insert.

The results of the evaluation with proposed device indicate that it can provide accurate estimates of CRP concentrations in both human serum and plasma.

IV. Interfering Substances

Lipemic, hemolytic, and iteric samples were evaluated with the **Hemagen CRP 150 Kit** following NCCLS Proposed Guideline, "Interference Testing in Clinical Chemistry" Document EP7-P ISSN 0273-3099. Samples with hemoglobin concentrations of ≤ 500 mg/dL, lipid concentrations of ≤ 3,000 mg/dL, and bilirubin concentrations of 20 mg/dL did not significantly affect the assay results.

V. Precision Studies

Between-run reproducibility {Inter Assay}

Eight serum samples were assayed five times each, twice a day, on five different days (a total of 50 readings per sample). The results are as follows:

Sample	Mean µg/mL	Std. Deviation	C.V.
1	1.4	0.2	12
2	1.7	0.2	11
3	4.0	0.3	7
4	10.0	0.8	8
5	23.6	1.9	8
6	24.9	1.9	8
7	32.5	2.2	7
8	30.2	1.6	5

Within-run reproducibility {Intra Assay}

Eight serum samples were assayed 19 consecutive times in single runs. The results are as follows:

Sample	Mean µg/mL	Std. Deviation	C.V.
1	1.0	0.2	17
2	1.1	0.3	25
3	4.0	0.7	17
4	10.6	1.6	15
5	22.8	1.1	5
6	25.9	1.5	6
7	31.9	1.9	6
8	28.1	3.2	11

7 *Conclusions*

The results of the comparative studies support the claim that the Hemagen kit is a safe and effective *in vitro* diagnostic test and is substantially equivalent to the predicate device.