

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k062924

B. Purpose for Submission:

New intended use for device.

C. Measurand:

C-Reactive Protein (CRP)

D. Type of Test:

Two-site sandwich immunoassay, quantitative

E. Applicant:

Dade Behring Inc.

F. Proprietary and Established Names:

Stratus® CS Acute Care™ CardioPhase® hsCRP TestPak

G. Regulatory Information:

1. Regulation section:

21 CFR 866.5270, C-reactive protein immunological test system

2. Classification:

Class II

3. Product code:

NQD - Cardiac c-reactive protein, antigen, antiserum, and control

4. Panel:

82 - Immunology

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Stratus CS Acute Care CardioPhase hsCRP assay is an in vitro diagnostic reagent for the quantitative determination of C-reactive protein (CRP) in lithium and sodium heparin plasma. This method is for use by trained health care professionals in the clinical laboratory and point of care (POC) settings.

In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, is observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. High sensitivity CRP (hsCRP) measurements may be used as an independent risk marker for the identification of individuals at risk for future cardiovascular disease. Measurements of hsCRP, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Dade Behring Stratus CS Analyzer

I. Device Description:

Each box of the test kit contains 60 TestPaks and each TestPak is comprised of individual wells containing the following reagents: alkaline phosphatase conjugated anti-CRP mouse monoclonal antibody, dendrimer linked anti-CRP mouse monoclonal antibody, 4-methylumbelliferyl phosphate in a diethanolamine buffer with preservative. The device is a two site sandwich assay based upon solid phase Radial Partition Immunoassay (RPIA) technology.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Stratus® CS Acute Care™ CardioPhase® hsCRP TestPak

2. Predicate 510(k) number(s):

k060369

3. Comparison with predicate:

The devices are identical. The only difference is an expanded indication for use to include point of care settings.

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP-15A User Demonstration of Performance for Precision and Accuracy;
Approved Guidelines

L. Test Principle:

The Stratus CS Acute Care CardioPhase hsCRP method is a two-site sandwich assay based upon solid phase Radial Partition Immunoassay (RPIA) technology. In this procedure, dendrimer linked monoclonal antibody is added to the center portion of a square piece of glass fiber paper in the CCRP TestPak. This antibody recognizes a distinct antigenic site on the CRP molecule. Sample is then added onto the paper where it reacts with the immobilized antibody. After a short incubation, a conjugate consisting of enzyme-labeled monoclonal antibody directed against the same antigenic site is pipetted onto the reaction zone of the paper. During this second incubation period, enzyme-labeled antibody reacts with the bound CRP, forming an antibody-antigen-labeled antibody sandwich. The unbound labeled antibody is later eluted from the field of view of the Stratus CS analyzer by applying a substrate wash solution to the center of the reaction zone. By including substrate for the enzyme within the wash solution, initiation of enzyme activity occurs simultaneously with the wash. The enzymatic rate of the bound fraction increases directly with the concentration of CRP in the sample. The reaction rate can then be measured by an optical system that monitors the reaction rate via front surface fluorescence. All data analysis functions are performed by the microprocessor within the analyzer.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision was previously established in k060369. In order to expand the intended use to include the point of care setting, an additional precision study was performed. In the additional study plasma pools were evaluated over a period of five days by lab, emergency department, and critical care unit personnel on the instruments located in their respective areas. The data was calculated according to CLSI EP15-A and had within run CVs ranging from 4.0% to 8.5% and total CVs ranging from 4.6% to 8.5%. The precision results were similar in all settings tested.

- b. *Linearity/assay reportable range:*
Previously established (k060369)
- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Previously established (k060369)
- d. *Detection limit:*
Previously established (k060369)
- e. *Analytical specificity:*
Previously established (k060369)
- f. *Assay cut-off:*
Not applicable

2. Comparison studies:

- a. *Method comparison with predicate device:*

A method comparison to a predicate device was previously performed in k060369. In order to expand the intended use to include the point of care setting, an additional method comparison was performed. In this study samples were evaluated by lab, emergency department (ED), and critical care unit (CCU) personnel on the instruments located in their respective areas. The results are summarized in the table below.

Location	Range of samples	Slope	Intercept	r	N
Lab v. ED	0 – 50 mg/L	1.05	-0.19	0.98	71
	0 – 10 mg/L	0.93	0.16	0.98	45
Lab v. CCU	0 – 50 mg/L	1.07	-0.07	0.99	73
	0 – 10 mg/L	1.01	.10	0.98	46

- b. *Matrix comparison:*
Previously established (k060369)

3. Clinical studies:

- a. *Clinical Sensitivity:*
Not applicable
- b. *Clinical specificity:*

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Relative risk categories and average hsCRP levels as recommended in the AHA/CDC Scientific Statement are found in the labeling:

Risk	hsCRP (mg/L)
Low	< 1.0
Average	1.0 - 3.0
High	> 3.0

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

