

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

A. 510(k) Number:

k042837

B. Purpose for Submission:

Premarket Notification 510(k) of intention to manufacture and market the Bio-Rad Laboratories, Liquichek Elevated C-Reactive Protein (CRP) Control

C. Measurand:

Quality Control Material (assayed) for C-Reactive Protein (CRP)

D. Type of Test:

Not applicable

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek™ Elevated CRP Control

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660; Quality Control Material (assayed and unassayed)

2. Classification:

Class I

3. Product code:

JJX; Single (specified) analyte controls (assayed and unassayed)

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

Liquichek Elevated CRP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for C-Reactive Protein (CRP).

2. Indication(s) for use:

Liquichek Elevated CRP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for C-Reactive Protein (CRP).

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Beckman Coulter Array
Beckman Coulter IMMAGE
Dade BEHRING BN Series
Dade BEHRING Dimension Series
Roche Cobas INTEGRA
Roche Hitachi

I. Device Description:

Liquichek™ Elevated CRP Control contains three levels of quality control material. The control materials are human serum-based and are provided ready-to-use. Value assignment and stability testing information are below.

Human source material was tested and found negative for HIV 1 and 2 , HBV and HCV using FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Liquichek™ Lipids Control

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

k012513

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Quality Control Material	Quality Control Material
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Differences		
Item	Device	Predicate
Storage (Unopened)	-10 to -70°C Until expiration date	-10 to -20°C Until expiration date
Open Vial Claim	30days at 2 to 8°C	14 days at 2 to 8°C
Analytes	C-Reactive Protein (CRP)	CRP, Apolipoprotein A-1, Apolipoprotein B, Cholesterol, Cholesterol HDL, Cholesterol LDL, Lipoprotein(a), triglycerides

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

None stated

L. Test Principle:

Not applicable. This submission is for clearance of control material.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

C-Reactive Protein (CRP) is a purchased product which is prepared into a stock solution. Several dilutions are made from the stock solution at specific concentrations within the CRP assay range. The dilutions are assayed using a commercially available assay and percent recovery is calculated for the stock solution, verifying the raw materials activity. CRP is then added to human serum based matrix at the appropriate target values. The material is analyzed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents. Refer to package insert for the assigned values and ranges.

Stability: Real time accelerated stability studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The stability is listed below:

Open vial stability is 30 days at 2 to 8°C

Closed vial stability is 3 years at -10 to -70°C

- d. *Detection limit:*

Not applicable

- e. *Analytical specificity:*

Not applicable

- f. *Assay cut-off:*

Not applicable

2. Comparison studies:

- a. *Method comparison with predicate device:*

Not applicable

- b. *Matrix comparison:*

Not applicable

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:

Not applicable

O. Conclusion:

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