

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

A. 510(k) Number:

K040351

B. Analyte:

C-Reactive Protein (CRP)

C. Type of Test:

Calibration Verification Material

D. Applicant:

Randox Laboratories Ltd.

E. Proprietary and Established Names:

Randox Liquid CRP Controls

F. Regulatory Information:

1. Regulation section:
21 CFR §862.1160 Single (Specified) Analyte Control (Assayed or Unassayed)
2. Classification:
Class I
3. Product Code:
JJX
4. Panel:
Clinical Chemistry (75)

G. Intended Use:

1. Intended use(s):
“The Randox Laboratories Ltd. CRP Controls are liquid controls containing human recombinant CRP in a stabilized protein matrix. They have been developed for use in the control of both accuracy and precision in CRP assays. The Randox Liquid C-Reactive Protein Controls should only be used by suitably qualified laboratory personnel under appropriate laboratory conditions.”
2. Special condition for use statement(s):
none
3. Special instrument Requirements:
The sponsor states this product is intended for use on any clinical chemistry analyzer using a immunotubidimetric CRP assay which is standardized to the international reference preparation CRM470.

H. Device Description:

This is a liquid product containing recombinant human CRP spiked into a stabilized protein matrix at the desired concentration (Level II ~ 20 mg/L, Level III ~150 mg/L).

I. Substantial Equivalence Information:

1. Predicate device name(s):
Bio-Rad Liquichek Immunology Control Levels 1, 2 and 3
2. Predicate K number(s):
K011494
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Assayed quality control material is intended to monitor laboratory testing procedures	Same
Form	Liquid	Same
Storage	2 – 8 °C	Same
Matrix	Human serum based with stabilizers and preservatives	Same
Analyte	Single – CRP	Multiple, including CRP
Differences		
Item	Device	Predicate
Levels	2 levels	3 levels
Stability-unopened	2 -8 °C for 18 months	2 -8 °C for 90 days
Stability-opened	2 – 8 °C for 18 months	2 – 8 °C for 30 days

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

None referenced.

K. Test Principle:

N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
N/A
 - b. *Linearity/assay reportable range:*
N/A
 - c. *Traceability (controls, calibrators, or method):*
The sponsor states traceability to CRM 407.

Assignment of values follows an internal QC procedure. A test lot is compared to a master lot stored at -80 °C. Ten replicates of test lot and master lot are run and then calculation of value is based on results obtained. The value must be within the manufacturing range specified for the product.

Real-time stability studies were performed and support a stability claim of 18 months when stored at 2-8 °C.

d. Detection limit:

N/A

e. Analytical specificity:

N/A

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

N/A

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical sensitivity:

N/A

b. Clinical specificity:

N/A

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Representative Assigned Values for Levels II and III

Level	Lot #	Assigned Value (mg/L)	Acceptable Range (mg/L)
II	1199CP	21.3	17.0 – 25.6
III	1189CP	150	120 - 180

M. Conclusion:

I recommend that Randox Liquid CRP Controls be found to be substantially equivalent to the predicate.