

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

A. 510(k) Number:

k060140

B. Purpose for Submission:

New Submission

C. Measurand:

Calibrator materials for C-Reactive Protein

D. Type of Test:

Not applicable

E. Applicant:

Diagnostic Chemicals LTD.

F. Proprietary and Established Names:

CRP-ADVANCE MULTI CALIBRATOR SET, MODEL SE-250

G. Regulatory Information:

1. Regulation section:

21CFR Sec.- 862.1150-Calibrator

2. Classification:

Class 2

3. Product code:

JIT - Calibrator, Secondary

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

For the IN VITRO diagnostic use as calibrators for the DCL CRP-ADVANCE Assay for the quantitation of C-reactive protein in serum.

The CRP-ADVANCE Multi-Calibrator Set, Cat. No SE-250 are C-reactive protein standards containing known quantities of human c-reactive protein. These calibrators are to be used with the DCL CRP-ADVANCE Assay.

3. Special conditions for use statement(s):
For prescription use
4. Special instrument requirements:
The Hitachi 911 or any analyzer with assay compatible specifications

I. Device Description:

The calibrators included are C-reactive protein standards containing known quantities of human C-reactive protein. These calibrators are to be used with the DCL CRP-ADVANCE Assay. There are 5 levels of calibrators ranging from 3.0 mg/L to 362 mg/L. They are packaged ready to use in 2 mL vials.

Each serum donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HBsAg, HCV, and antibody to HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Equal Diagnostics', CRP Ultra Wide Range Calibrator Set B manufactured by Denka Seiken Co., Ltd.
2. Predicate 510(k) number(s):
k030546
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Intended to calibrate Quantitative C-Reactive Protein Assay	Intended to calibrate Quantitative C-Reactive Protein Assay
Sample	Serum	Serum
Matrix	Liquid ready to use	Liquid ready to use

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

CLSI - Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline - EP06
 CLSI - Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition - EP09

L. Test Principle:

Calibrator for Quantitative immuno-agglutination assay

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):*

The calibrator is traceable to European Reference Materials (ERM) 470 and the assigned values of 3.0, 6.1, 30.0, 181.0 and 362.0 mg/L have been validated by calibrator comparison studies on the Hitachi 911 yielding results of 2.98, 6.12, 30.18, 184.71 and 358.75 mg/L respectively.

Stability studies include accelerated and ongoing real time studies for unopened shelf life when stored at 2-8°C and real time studies for opened calibrators when stored at 2-8°C at 30 days.

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

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.