

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

A. 510(k) Number:

k050713

B. Purpose for Submission:

New device

C. Analyte:

C-reactive protein

D. Type of Test:

Quantitative

E. Applicant:

Good Biotech Corp.

F. Proprietary and Established Names:

Duet hs-CRP LIT Assay

Duet hs-CRP Calibrator Set

G. Regulatory Information:

1. Regulation section:
21 CFR 866.5270 C-reactive protein
21 CFR 862.1150 Calibrator
2. Classification:
Class II
Class II
3. Product Code:
DCN
JIT
4. Panel:
82 Immunology
75 Chemistry

H. Intended Use:

1. Intended use(s):
See Indications for use below.
2. Indication(s) for use:

Good Biotech Corp. Duet hs-CRP LIT Assay is intended to be used as a high sensitive assay for the quantitative determination of C-reactive protein in serum by latex particle enhanced immunoturbidimetry (LIT). Highly sensitive measurement of C-reactive protein is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

Good Biotech Corp. Duet hs-CRP Calibrator Set is intended to be used with Duet hs-CRP LIT Assay for the quantitative determination of C-reactive protein in serum samples.

For *in vitro* diagnostic use only.

3. Special condition for use statement(s):
For prescription use only.
4. Special instrument Requirements:
Roche Diagnostic Hitachi 911 Analyzer

I. Device Description:

The Good Biotech Corp. Duet hs-CRP reagent consists of two wet reagents. Reagent 1 is a buffering solution and reagent 2 contains latex particles coated with anti-CRP duck monoclonal antibodies. Duck anti-CRP IgY is purified from duck yolk. The host ducks selected for immunization are domestic stock and have been inoculated to prevent avian-associated diseases.

The Good Biotech Duet hs-CRP is a six level calibrator kit that is composed of stabilized human serum to which human C-reactive protein, preservatives and stabilizers have been added. The calibrator sets are prepared from human sera which were tested by FDA acceptable methods and found to be negative for HBsAg, anti-HIV 1 and 2 antibodies, and anti-HCV antibody. The calibrator set is a combination of 2 previously cleared calibrator sets - k021882 and k021757. The controls used in this submission were previously cleared under k022725.

J. Substantial Equivalence Information:

1. Predicate device name(s):
K-Assay CRP (3) and K-Assay CRP Multi-Calibrator D
2. Predicate K number(s):
k023828

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Intended to be used as a high sensitive assay for the quantitative determination of C-reactive protein in serum by latex particle enhanced immunoturbidimetry (LIT). Highly sensitive measurement of C-reactive protein is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.	Intended to be used as a high-sensitive assay for the quantitative determination of CRP in serum and plasma by immunoturbidimetric assay. Measurement of C-Reactive Protein aids in the detection and evaluation of tissue injury, inflammatory disorders, and related diseases.
Methodology	Latex Particle Enhanced Immunoturbidimetry (LIT)	Latex Particle Enhanced Immunoturbidimetry (LIT)
Test	Quantitative	Quantitative
Wavelength	570 nm	570 nm
Differences		
Item	Device	Predicate
Antibody	Duck anti-CRP IgY	Rabbit anti-CRP antibodies
Range	0.3-200 mg/L	0.1-320 mg/L
Matrix	Serum	Serum and Plasma

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

None referenced

L. Test Principle:

When CRP in a sample encounters the latex microparticles sensitized with duck anti-CRP IgY, agglutination among the latex microparticles occurs based on the antigen-antibody reaction. Agglutination increases and is detected by the absorbance change at 570 nm. The absorbance change is proportional to the CRP concentration of the sample and is recorded by an autoanalyzer. The actual CRP concentration of the sample is determined by the interpolation of the calibration curve obtained by standard samples with known CRP concentrations.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Precision was conducted using three quality control materials (low, medium and high). Within-run precision was conducted by analyzing each of the three controls in replicates of 20. Day-to-day precision was conducted for each of the three controls in triplicate

for 10 days. The precision testing gave CV's within 10% and the results are shown in the chart below.

	Within-run Precision			Day-to-Day Precision		
	Control-L	Control-M	Control-H	Control-L	Control-M	Control-H
N	20	20	20	10	10	10
Mean (mg/L)	1.532	6.331	67.03	1.744	5.656	60.06
SD	0.106	0.169	0.497	0.041	0.110	0.927
CV%	6.93	2.67	0.74	2.36	1.95	1.54
Max	1.77	6.58	67.66	1.82	5.84	62.21
Min	1.38	5.88	65.74	1.69	5.45	59.03

b. Linearity/assay reportable range:

Linearity was conducted with dilutions of a CRP standard that ranged from 1 to 200 mg/L. The assays were run in triplicate. The sponsor's acceptance criteria is a R^2 value greater than 0.95. The results showed that the Duet hs-CRP LIT assay was linear from 0-200 mg/L and revealed an equation $Y = 200.47X + 1.2308$ with a $R^2 = 0.9997$.

The sponsor also conducted a prozone hook effect study with the Duet hs-CRP LIT assay using serum samples with CRP concentrations (dilutions of a CRP standard) that ranged from 0 to 838 mg/L. There was no prozone phenomenon observed up to 800 mg/L.

c. Traceability (controls, calibrators, or method):

The calibrators that are used with the Duet hs-CRP LIT assay and are included with this submission are a merge of 2 previously cleared calibrators, K021882 (CRPex HS CRP Calibrator Set) and K021757 (CRPex BR CRP Calibrator Set). The Duet hs-CRP calibrator set is a six-level liquid calibrator set. Levels 1, 2, 3, and 4 of the Duet hs-CRP Calibrator Set are actually 1, 4, 5 and 6 of the CRPex HS CRP calibrator set. Levels 5 and 6 of the Duet hs-CRP Calibrator Set are actually 4 and 5 of the CRPex BR CRP calibrator set.

d. Detection limit:

The detection limit was determined using the zero calibrator. The zero calibrator was run in replicates of 20 with the Duet hs-CRP LIT assay. The detection limit of 0.041 mg/L CRP was calculated as 2 standard deviations above the mean response of the zero calibrator.

Ten serum samples containing low concentrations of CRP ranging in concentration from 0.1 to 0.59 mg/L were tested in replicates of ten. The percent CV was plotted as a function of analyte concentration and the CRP concentration (0.3 mg/L) for which the CV was 20% was defined as the functional sensitivity.

e. *Analytical specificity:*
Hemoglobin (up to 805 mg/dL), bilirubin C and F (up to 45 mg/dL) and lipemia (up to 10 g/L Liposyn) were found not to interfere with the assay. Interference was defined by the sponsor as recovery of more than +/- 5% of the initial measured value.

f. *Assay cut-off:*
Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*
The sponsor conducted a method comparison study with the predicate device [(K-Assay CRP (3) assay)] with a total of 93 non traceable serum samples (64 of which fell in the high sensitivity range of 1 to 10 mg/L). The samples ranged from 1 to 200 mg/L. The following linear regressions were derived from the regression analysis:
Duet hs-CRP LIT Assay= $0.955X + 0.938$ with a correlation coefficient of 0.998, where X is the predicate device for the entire 93 samples of CRP concentration ranging from 1- 200 mg/L.
Duet hc-CRP LIT Assay= $1.08X + 0.226$ with a correlation coefficient of 0.996, where X is the predicate device for the 64 samples of CRP concentration ranging from 0-10 mg/L.

b. *Matrix comparison:*
Not applicable because this assay is to be used with serum samples only and should be collected in red top tubes without serum separator.

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)*

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

The sponsor uses the IFCC/BCR/CAP reference material CRM 470 that states the reference range for CRP in serum of less than 5 mg/L. The sponsor also states that the reference interval varies with populations studies and calibrators used and that individual laboratories should establish their own reference interval.

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.