

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

A. 510(k) Number:

K052591

B. Purpose for Submission:

New submission

C. Measurand:

C-Reactive Protein

D. Type of Test:

Quantitative latex agglutination immunoassay

E. Applicant:

CLINICAL DATA, INC.

F. Proprietary and Established Names:

NANOPIA Wide Range C-Reactive Protein (CRP) REAGENT KIT

G. Regulatory Information:

1. Regulation section:

21CFR §866.5270-C-reactive protein immunological test system.

21CFR §862.1150-Calibrator.

2. Classification:

2

3. Product code:

DCK - C-REACTIVE PROTEIN, ANTIGEN, ANTISERUM, AND CONTROL
JIS- CALIBRATOR, PRIMARY

4. Panel:

Immunology (82) Chemistry (75)

H. Intended Use:

1. Intended use(s):

The intended use of the Nanopia Wide Range CRP Reagent is for the in vitro quantitative determination of C-Reactive Protein in human serum and plasma. The assay is intended for use in the evaluation of infection, tissue injury and inflammatory disorders in combination with a complete clinical evaluation.

2. Indication(s) for use:

The intended use of the Nanopia Wide Range CRP Reagent is for the in vitro quantitative determination of C-Reactive Protein in human serum and plasma. The assay is intended for use in the evaluation of infection, tissue injury and inflammatory disorders in combination with a complete clinical evaluation.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Roche Hitachi 917

I. Device Description:

Reagent 1 is a solution of Tris (hydroxymethyl) aminomethane buffer (pH 8.5).

Reagent 2 is the latex reagent containing anti-human CRP (mouse) monoclonal antibody-coated latex particles (2 mg/mL). Both reagents contain Proclin 300 as a preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):
N-Geneous Wide Range CRP Reagent
2. Predicate 510(k) number(s):
K040241
3. Comparison with predicate:

The predicate device and the Nanopia Wide Range CRP assay are essentially the same product both produced by Daiichi Pure Chemicals Co. Ltd. for distribution by the respective companies.

Similarities		
Item	Device	Predicate
Intended use	Quantitative measurement of CRP in serum or plasma	Same
Sample Matrix	Serum or plasma	Same
Antibody	Mouse monoclonal anti-human CRP	Same
Assay Range	0.1 – 400 mg/L	0.04 – 320 mg/L
Antibody substrate	Latex	Same
Number of calibrators	5	Same

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

CLSI EP5-A – Evaluation of Precision Performance of Clinical Chemistry Devices

CLSI EP6-A – Evaluation of the Linearity of Quantitative Analytical Methods

CLSI EP7-A – Interference Testing in Clinical Chemistry

CLSI EP9-A – Method Comparison and Bias Estimation Using Patient Samples

CLSI EP17-A – Protocols for Determination of Limits of Detection and Limits of Quantitation

L. Test Principle:

CRP present in serum reacts with anti-human CRP (mouse) monoclonal antibody-coated latex particles. The antigen-antibody reaction results in agglutination of the latex particles and is detected as an absorbance change at 578 nm. The change in absorbance is proportional to the concentration of CRP in the sample when compared to a standard curve generated by the analysis of known CRP standards.

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

Serum pools were prepared and run in triplicate over 20 days to determine within run and run-to run precision using CLSI/NCCLS EP5-A protocol

Sample	N	Within Run			Run-to-Run	
		Mean (mg/L)	1 Std. Dev.	%CV	1 Std. Dev.	%CV
1	60	0.886	0.16	1.83	0.022	2.46
2	60	6.71	0.05	0.76	0.089	1.31
3	60	38.88	0.24	0.61	0.430	1.11

b. *Linearity/assay reportable range:*

The usable range of this reagent is from 0.1 to 400 mg/L. Samples that exceed 400 mg/L should be diluted with saline and the analysis repeated with correction of the results for the dilution factor.

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

Calibrator value assignment to IFCC CRM470 and stability testing is described. Calibrators are of human source material, tested and found to be negative for Hepatitis B surface antigens, anti-Hepatitis C virus antibodies, and anti-human immunodeficiency virus antibodies with FDA approved assays.

d. *Detection limit:*

Limit of blank, limit of detection, and limit of quantitation was determined using CLSI/NCCLS EP-174. The limit of quantitation was 0.024 mg/L. The limit of blank and limit of detection were found to be 0.015 and 0.030 mg/L, respectively.

e. *Analytical specificity:*

Serum pools spiked with Bilirubin up to 50 mg/dL, hemoglobin up to 1000 mg/dL, lipid up to 2000 formazin turbidity units, ascorbic acid up to 100 mg/dL, and rheumatoid factor up to 500 IU/mL do not change from the unspiked serum by more than 3%. No hook effect was observed with concentrations up to 500 mg/L. Human anti-mouse antibody testing (HAMA) was not performed.

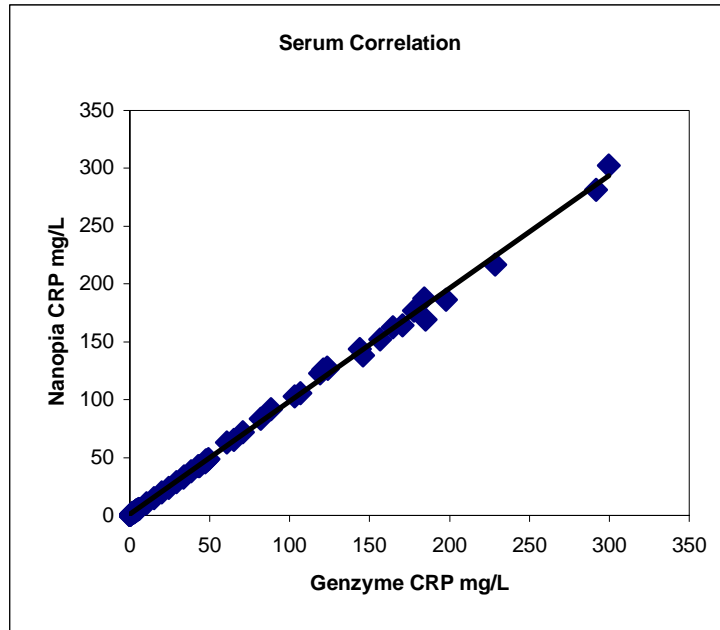
f. *Assay cut-off:*

Not Applicable

2. Comparison studies:**a. *Method comparison with predicate device:***

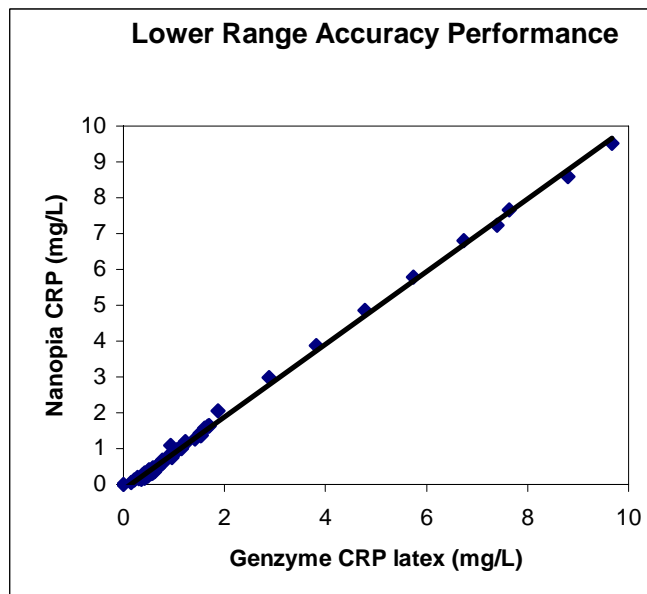
Wide Range Correlation

Comparison of 98 serum samples analyzed using the Nanopia CRP on the Hitachi 917 with a commercially available assay using least squares regression analysis. These studies showed a full range (0 – 320 mg/L) correlation coefficient (R²) of 0.9992 with a regression equation $y = 1.015x - 0.035$ where x was the predicate method and y was the Nanopia CRP.



Low Range Correlation

Additional correlation with patient samples with CRP concentrations below 10 mg/L was compiled from 71 paired samples. At this low range recovery of the Nanopia CRP compared to the predicate demonstrated a correlation coefficient (R²) of 0.9981 and a regression equation of $y = 1.015x - 0.14$ where x was the predicate method and y was the Nanopia CRP.



- b. Matrix comparison:
EDTA plasma to serum yielded method comparison regression of
 $Y = 0.994x + 0.03$ $R = 0.999$ $N = 50$
Comparison to serum samples (0.10, 5.30, 15.90 mg/L) from 4 blood plasma
treated by citrate-Na, oxalate-Na, EDTA-2Na and heparin-Na yield recover from
96.4 to 105.7%.
 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:
Expected results for CRP in human serum referenced to CRM470 is less than 5 mg/L.
Burtis CA and Ashwood ER, Teitz Fundamentals of Clinical Chemistry, 5th ed.
Philadelphia: WB Saunders, 2001, pg. 329.
- N. Proposed Labeling:**
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.
- O. Conclusion:**