

## **510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY**

**A. 510(k) Number:**

K050665

**B. Purpose for Submission:**

Modification to current N antisera to Human Complements (C3c and C4) assays to add heparinized and EDTA plasma to the specimen type.

**C. Measurand:**

Complement C3 and Complement C4

**D. Type of Test:**

Quantitative, immunonephelometry

**E. Applicant:**

Dade Behring Inc.

**F. Proprietary and Established Names:**

N Antisera to Human Complement Factors (C3c, C4)

**G. Regulatory Information:**

1. Regulation section:  
21 CFR 866.5240, Complement components immunological test system
2. Classification:  
Class II
3. Product Code:  
CZW, Complement C3, antigen, antiserum, control  
DBI, Complement C4, antigen, antiserum, control
4. Panel:  
Immunology (82)

**H. Intended Use:**

1. Intended use(s):  
In vitro diagnostic reagents for the quantitative determination of complement factors (C3/3c and C4/C4c) in human serum or heparinized or EDTA plasma by means of immunonephelometry on the BN™ Systems as an aid in the diagnosis of immunological disorders associated with complement C3 or C4 protein.
2. Indication(s) for use:  
To aid in the diagnosis of immunological disorders associated with complement C3 or C4 protein.
3. Special condition for use statement(s):  
The device is for prescription use only.
4. Special instrument Requirements:  
Use with Dade Behring BN™ 100 (K892223), BN™ II (K943997) and BN ProSpec® Systems (K001647). These systems were 510(k) cleared and belong to the same instrument family with the same intended use and measuring method. Physical characteristics and operating features are also similar.

**I. Device Description:**

The N Antisera to Human Complement Factors (C3c, C4) kit consists of one vial each (5 mL or 2 mL) of rabbit anti-human C3c and anti-human C4. The antisera

contain sodium azide and are supplied as ready-for-use. The assay kit has to be used with the BN™ Systems. N Protein Standard SL (human) and N/T Protein Control SL (L, M and H) (human), N Reaction Buffer and N Diluent are required but not part of the kit.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
N Antisera to Human Complement Factors (C3, C4)
2. Predicate K number(s):  
K860894
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	For the quantitative determination of C3 and C4 by means of immunonephelometry on the BN™ Systems	Same
Indications for Use	Use as an aid in the diagnosis of immunologic disorders associated with complement C3 or C4 protein	Same
Methodology	Immunonephelometry	Same
Antibody	Rabbit polyclonal to human C3 or C4	Same
Instrumentation	BN™ Systems	Same

Differences		
Item	Device	Predicate
Sample matrix	Serum and plasma (EDTA and heparin)	Serum

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

None referenced.

**L. Test Principle:**

The N Antisera to Human Complement Factors (C3c, C4) uses immunonephelometry to measure C3 and C4 in human serum or plasma. C3 or C4 in the sample combines with specific antibodies to C3 or C4 to form immune complexes. These complexes scatter a beam of light passes through the sample. The intensity of the scattered light is proportional to the concentration of the respective analyte in the sample. C3 or C4 concentrations are automatically calculated from multi-point calibration curves.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:
  - a. *Precision/Reproducibility:*

Within-run, run-to-run and total precision studies were performed according to NCCLS Guideline EP5-A. N/T protein controls (low, medium and high) and two serum pools (low and high) were assayed in quadruplicate, two runs per day for 4 days. Results are summarized in the table below.

C3/C3c	Mean	Run-to-run	Within-run	Total
	(g/L)	CV (%)	CV (%)	CV (%)
N/T Protein Control, Level L	0.84	2.0	2.4	2.9
N/T Protein control, Level M	1.17	2.6	4.2	4.5
N/T Protein control, Level H	1.65	2.8	2.8	3.8
Serum Pool (low)	1.21	2.1	3.2	3.5
Serum Pool (high)	1.71	2.0	2.0	2.7
C4/C4c	Mean	Run-to-run	Within-run	Total
	(g/L)	CV (%)	CV (%)	CV (%)
N/T Protein Control, Level L	0.132	1.3	1.9	2.2
N/T Protein Control, Level M	0.197	1.9	1.9	2.6
N/T Protein Control, Level H	0.317	1.6	1.8	2.3
Serum Pool (low)	0.338	2.8	1.7	3.2
Serum Pool (high)	0.462	1.6	2.3	2.6

*b. Linearity/assay reportable range:*

Not applicable for this modification.

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

Traceable to IFCC/BCR/CAP Reference Material (CRM 470)

*d. Detection limit (functional sensitivity):*

Not applicable for this modification.

*e. Analytical specificity:*

Not applicable for this modification.

*f. Assay cut-off:*

Not applicable.

**2. Comparison studies:**

*a. Method comparison with predicate device:*

Serum samples covering the assay range were tested by the new device and the Dade Behring Dimension C3 and C4 Flex Reagent Cartridge (k994296 and k994293 respectively). The Dimension assays are immunoturbidimetric assays run on the Dimension RxL Instrument. Results were analyzed by regression analysis and summarized below.

Device	Concentration Range (g/L)	N	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient (r)
C3	0.625-2.655	146	0.8935 (0.8414, 0.9529)	-0.0671 (-0.1514, 0.0008)	0.9327
C4	5 – 120	129	1.0242 (0.9815, 1.0733)	-0.0403 (-0.0547, -0.0270)	0.945

*b. Matrix comparison:*

Anti-coagulant effects were evaluated by comparing EDTA and heparin plasma samples with serum samples. Twenty paired EDTA plasma/serum samples and 49 paired heparin plasma/serum samples were analyzed for 3 runs using the C3 or C4 reagent on the BN II System. Passing-Bablok regression analysis was used to evaluate the results which are summarized below.

Analyte	Anticoagulant	Passing-Bablok Regression Analysis		
		Slope (95% CI)	Intercept (95%CI)	Correlation Coefficient (r)
C3	Heparin	0.93 (0.86, 0.99)	0.02 (-0.04, 0.11)	0.98
	EDTA	0.89 (0.77, 0.97)	0.04 (-0.03, 0.21)	0.98
C4	Heparin	1.00 (0.93, 1.06)	-0.006 (-0.021, 0.011)	0.98
	EDTA	0.92 (0.84, 1.01)	0.01 (-0.007, 0.035)	0.98

3. Clinical studies:

*a. Clinical sensitivity:*

Not applicable for this modification.

*b. Clinical specificity:*

Not applicable for this application.

*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 for this modification.

**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.