

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

A. 510(k) Number:

k053072

B. Purpose for Submission:

Modification to manufacturer's existing device - addition of heparinized and EDTA plasmas as sample matrices.

C. Measurand:

Human α_1 -Antitrypsin antibody

D. Type of Test:

Quantitative immunonephelometry

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

N Antisera to Human α_1 -Antitrypsin

G. Regulatory Information:

1. Regulation section:

21 CFR § 866.5130, Alpha-1-antitrypsin immunological test systems

2. Classification:

Class II

3. Product code:

DEM, Alpha-1-antitrypsin, Antigen, Antiserum, Control

4. Panel:

Immunology 82

H. Intended Use:

1. Intended use:

In vitro diagnostic reagent for the quantitative determination of α_1 - antitrypsin (α_1 - proteinase inhibitor) in human serum, heparinized and EDTA plasma by means of immunonephelometry on the BN™ systems.

2. Indication(s) for use:

In vitro diagnostic reagent for the quantitative determination of α_1 - antitrypsin in human serum, heparinized and EDTA plasma by means of immunonephelometry on the BN™ Systems. The measurements of α_1 - antitrypsin aids in the diagnosis of several conditions including adult cirrhosis of the liver. In addition, α_1 - antitrypsin deficiency has been associated with pulmonary emphysema in conjunction with other laboratory and clinical findings.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

Dade Behring BNII (k860894), BN 100 (k892223) and BN ProSpec® Nephelometer (k001647).

I. Device Description:

The device consists of one vial containing 5 mL or 2 mL of N antiserum to Human α_1 - antitrypsin.

J. Substantial Equivalence Information:

1. Predicate device name(s):
N Antisera to Human α_1 - Antitrypsin and α_2 - Macroglobulin.
2. Predicate 510(k) number(s):
k860894
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Antibody	Rabbit Anti-Human α_1 -antitrypsin (polyclonal)	Same
Technology	Quantitative Nephelometry	Same

Differences		
Item	Device	Predicate
Intended Use	<i>In vitro</i> diagnostic reagents for the quantitative determination of α_1 - antitrypsin in human serum, heparinized and EDTA plasma by means of immunonephelometry on the BN™ systems.	<i>In vitro</i> diagnostic reagents for the quantitative determination of α_1 - antitrypsin in human serum, using the BN™ systems.
Sample	Serum, heparinized and EDTA plasma	Serum
Instrumentation	BN™ Systems: BN II, BN 100, and BN ProSpec® Nephelometer	BN II Nephelometer

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

None.

L. Test Principle:

Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Four determinations per day over 10 days (n=40) were performed. The intra-assay CV on the five samples (three level controls and two level pooled sera) were 1.8 - 4.5% and the inter-assay CV were 1.1 – 2.5%.
 - b. *Linearity/assay reportable range:*
No change.
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
No change.

d. *Detection limit:*

No change.

e. *Analytical specificity:*

Interference Studies:

Known interfering substances: the table below lists substances that could commonly interfere with the assay. The package insert specifies that “lipemic or turbid samples which cannot be clarified (10 minutes at approximately 15,000 x g) must not be used”. No interferences were observed at the concentration levels tested as listed below.

Interferent	N	Level Tested up to	Results
Triglycerides	5	8.2 g/L	No interference
Hemoglobin	6	10.0 g/L	No interference
Bilirubin	6	0.6 g/L	No interference

Heparin salt interference: the table below lists the three heparin salts: lithium, sodium, ammonium that could potentially interfere with the assay. No interferences were observed at the concentration levels tested as listed below.

Heparin Salt	N	Level Tested up to	Results
Lithium	5	8.85 IU/mg	No interference
Sodium	5	9.05 IU/mg	No interference
Ammonium	5	8.45 IU/mg	No interference

f. *Assay cut-off:*

No change.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Sera and plasma samples, covering the assay measuring range (0.16 – 5.2 g/L) were compared to determine if any significant bias existed between matrices. The heparin samples in this study had unknown salt-heparin type. The correlation coefficients were acceptable and no bias was observed.

	N	Regression equation	r
Heparin	74	$y = 1.0186 x - 0.0186$	0.9916
EDTA	45	$y = 0.9913 x - 0.0183$	0.9948

3. Clinical studies:

a. *Clinical Sensitivity:*

No change.

b. *Clinical specificity:*

No change.

4. Clinical cut-off:

No change.

5. Expected values/Reference range:
No change.

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.