

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

A. 510(k) Number:

k053073

B. Purpose for Submission:

Device modification. Addition of heparinized plasma as sample matrix for human alpha 2-macroglobulin

C. Measurand:

Human alpha2-macroglobulin

D. Type of Test:

Quantitative immunonephelometry

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

N Antisera to Human α_2 -Macroglobulin test system

Alpha 2-Macroglobulin Immunological test system

G. Regulatory Information:

1. Regulation section:

21 CFR 866.5620, Alpha-2-Macroglobulin Immunological Test System

2. Classification:

Class II

3. Product code:

DEB, Alpha-2-Macroglobulin, Antigen, Antiserum, Control

4. Panel:

Immunology 82

H. Intended Use:

1. Intended use(s):

In vitro diagnostic reagents for the quantitative determination of α_2 -macroglobulin in human serum and heparinized plasma by means of immunonephelometry on the BN™ systems.

2. Indication(s) for use:

In vitro diagnostic reagents for the quantitative determination of α_2 -macroglobulin in human serum and heparinized plasma by means of immunonephelometry on the BN™ systems. Measurement of α_2 -macroglobulin may aid in the diagnosis of blood clotting or clot lysis disorders.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

For use on the Dade Behring BNII, BN 100, and BN Prospec analyzers, previously cleared under k860894.

I. Device Description:

The device consists of one vial of 2 ml or 5 ml of N antiserum to human α_2 -macroglobulin.

J. Substantial Equivalence Information:

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

Similarities		
Item	Device	Predicate
Intended Use	<i>In vitro</i> diagnostic reagents for the quantitative determination of α_2 -macroglobulin in serum and heparinized plasma by means of immunonephelometry on the BN TM Systems.	<i>In Vitro</i> diagnostic reagents for the quantitative determination of α_2 -macroglobulin in serum by means of immunonephelometry on the BN TM Systems.
Antibody	Rabbit anti-Human α_2 -macroglobulin (polyclonal)	Same
Instrumentation	BN TM Systems	Same
Assay Format	Quantitative nephelometry	Same

Differences		
Item	Device	Predicate
Sample	Serum and heparinized plasma	Serum

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

None provided.

L. Test Principle:

Proteins contained in human body fluids form 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:

Precision Study

The N Antisera to Human α_2 -Macroglobulin assay was used to measure α_2 -Macroglobulin concentrations ranging from 1.06 to 5.13 g/L in N/T Protein Control SL-L/M/H, a low serum pool, and a high serum pool. Four determinations per day over 10 days (n=40) were performed using a BNTM System. A summary of the precision data is presented in the Table below.

Precision Data Summary

	Mean value (g/L)	Run-to-Run (% CV)	Within Run (% CV)	Total (% CV)
N/T Protein Control SL - L	1.06	1.4	1.9	2.2

	Mean value (g/L)	Run-to-Run (% CV)	Within Run (% CV)	Total (% CV)
N/T Protein Control SL - M	1.77	1.3	1.6	1.9
N/T Protein Control SL - H	2.23	1.5	1.6	2.0
Serum Pool Low	3.26	1.7	2.3	2.7
Serum Pool High	5.13	1.1	2.9	2.8

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:*

Potentially interfering endogenous substances

Interference testing was performed to determine the effect of icterus, lipemia, and hemolysis, on the N Antisera to Human α_2 -Macroglobulin assay. Normal serum samples preparations (1.70-2.06 g/L) were spiked with increased concentrations of bilirubin, hemoglobin, and triglycerides. For each spiked sample, the % recovery was determined [% Recovery = (Test result/Baseline) x 100]. The acceptance criterion was ± 20 relative deviation from the base pool. No interference was seen up to: 0.6 g/L bilirubin, 10 g/L hemoglobin, and 5.7 g/L triglycerides.

Normal serum samples (1.41-2.21 g/L) were compared to sera spiked with 5% of lithium, sodium, or ammonium heparin to determine potential interference by heparin anticoagulants for plasma samples. No interference was seen.

Percent deviation between the mean recoveries of

Lithium/Sodium/Ammonium Heparin was $\pm 7\%$. (Lithium vs. Sodium: -2.81%, Lithium vs. Ammonium: -6.13% and Ammonium vs. Sodium: 4.21%)

f. *Assay cut-off:*

No change.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Fresh and frozen serum and heparinized plasma samples covering the reportable range (1:20 dilutions, α_2 -Macroglobulin: 0.2-6.4 g/L) were compared to determine if any significant bias between matrices. The heparin samples were a mixture of heparin types, however since the percent deviation between the heparin types was low, this was acceptable.

N	Regression equation	R ²	95% CI (slope)	95% CI (intercept)
82	y = 0.9836x - 0.0066	0.9929	0.9669, 0.9994	-0.0281, 0.00153

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.