

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

A. 510(k) Number:

k053074

B. Purpose for Submission:

Device modification. Addition of heparinized plasma as sample matrix for both human ceruloplasmin and hemopexin (note: hemopexin is Class II exempt)

C. Measurand:

Human ceruloplasmin and human hemopexin

D. Type of Test:

Quantitative immunonephelometry

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

N Antisera to Human Ceruloplasmin, Ceruloplasmin immunological test system

N Antisera to Human Hemopexin, Hemopexin immunological test system

G. Regulatory Information:

1. Regulation section:

21 CFR 866.5210, Ceruloplasmin immunological test system

21 CFR 866.5490, Hemopexin immunological test system

2. Classification:

Class II (Ceruloplasmin)

Class II (Hemopexin)

3. Product code:

DDB, Ceruloplasmin, antigen, antiserum, control

CZX, Hemopexin, antigen, antiserum, control

4. Panel:

Immunology 82

H. Intended Use:

1. Intended use(s):

In vitro diagnostic reagents for the quantitative determination of ceruloplasmin and hemopexin 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 ceruloplasmin and hemopexin in human serum and heparinized plasma by means of immunonephelometry on the BN™ systems. Measurement of ceruloplasmin aids in the diagnosis of copper metabolism 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 containing 2 ml of N antiserum to human ceruloplasmin or hemopexin.

J. Substantial Equivalence Information:

1. Predicate device name(s):
N Antisera to Human Ceruloplasmin
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 ceruloplasmin and hemopexin in serum and heparinized plasma by means of immunonephelometry on the BN™ Systems.	<i>In Vitro</i> diagnostic reagents for the quantitative determination of ceruloplasmin in serum and heparinized plasma by means of immunonephelometry on the BN™ Systems.
Antibody	Rabbit anti-Human ceruloplasmin (polyclonal)	Same
Instrumentation	BN™ 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

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:*
No change.
 - 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 by endogenous substances:

Ceruloplasmin: Normal serum samples (0.175-0.43 g/L) were spiked with increasing concentrations of bilirubin, hemoglobin, and triglycerides. The percent recovery was determined for each sample relative to a reference sample ($\pm 20\%$). No interference was seen up to: 0.6 g/L bilirubin, 10 g/L hemoglobin, and 2.4 g/L triglycerides. Normal serum samples (0.258-0.466 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 ($\pm 7\%$) between the mean recoveries of the heparin types was (-)0.305 to (+)0.386%.

Hemopexin: No data was provided for interference from bilirubin, hemoglobin, or triglycerides. Normal serum samples (0.82-1.22 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 ($\pm 7\%$) between the mean recoveries of the heparin types was (-)2.301 to (-)0.907%.

f. *Assay cut-off:*

No change.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Matrix comparison: Fresh and frozen serum and heparinized plasma samples covering the reportable range (1:20 dilutions, Ceruloplasmin: 0.07-2.2 g/L; Hemopexin: 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 (see Interference studies above) was low, this was deemed acceptable.

	N (pooled)	Regression equation	R ²	95% Confidence intervals (slope)
Ceruloplasmin Heparin	111	$y = 1.0057x - 0.0043$	0.9971	0.9910, 1.0208
Hemopexin Heparin	84	$y = 0.9949x - 0.0140$	0.9944	0.9759, 1.0183

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.