

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

A. 510(k) Number:

k053075

B. Purpose for Submission:

Device modification. Addition of heparinized and EDTA plasmas as sample matrices for both human transferrin and haptoglobin (note: haptoglobin is Class II exempt)

C. Measurand:

Human transferrin and human haptoglobin

D. Type of Test:

Quantitative immunonephelometry

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

N Antisera to Human Transferrin, Transferrin immunological test system

N Antisera to Human Haptoglobin, Haptoglobin immunological test system

G. Regulatory Information:

1. Regulation section:

21 CFR 866.5880, Transferrin immunological test system

21 CFR 866.5460, Haptoglobin immunological test system

2. Classification:

Class II (Transferrin)

Class II (Haptoglobin)

3. Product code:

DDG, Transferrin, antigen, antiserum, control

DAD, Haptoglobin, antigen, antiserum, control

4. Panel:

Immunology 82

H. Intended Use:

1. Intended use(s):

In vitro diagnostic reagents for the quantitative determination of transferrin and haptoglobin in human serum, heparinized and EDTA plasma, as well as transferrin in human urine by means of immunonephelometry on the BN™ systems.

2. Indication(s) for use:

In vitro diagnostic reagents for the quantitative determination of transferrin in human serum, heparinized and EDTA plasma, as well as transferrin in human urine by means of immunonephelometry on the BN™ Systems. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

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 transferrin.

J. Substantial Equivalence Information:

1. Predicate device name(s):
N Antisera to Human Transferrin
2. Predicate 510(k) number(s):
k972840
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	<i>In vitro</i> diagnostic reagents for the quantitative determination of transferrin and haptoglobin in human serum, heparinized and EDTA plasma, as well as transferrin in human urine by means of immunonephelometry on the BN™ systems.	<i>In vitro</i> diagnostic reagents for the quantitative determination of transferrin and haptoglobin in human serum, as well as transferrin in human urine by means of immunonephelometry on the BN™ systems.
Antibody	Rabbit anti-Human transferrin (polyclonal)	Same
Instrumentation	BN™ Systems	Same
Assay Format	Quantitative nephelometry	Same

Differences		
Item	Device	Predicate
Sample	Serum, heparinized and EDTA plasma, urine	Serum and urine

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
Transferrin: Normal serum samples (2.14-3.17 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, 8.2 g/L triglycerides and 10 g/L hemoglobin. Normal serum samples (2.17-2.94 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 (-)1.06 to (+)0.528%.
Haptoglobin: No data was provided for interference from bilirubin, hemoglobin, or triglycerides. Normal serum samples (0.6-2.11 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 (-)1.59 to (+)0.403%.
- f. *Assay cut-off:*
No change.
2. Comparison studies:
- a. *Method comparison with predicate device:*
Not applicable.
- b. *Matrix comparison:*
Fresh and/or frozen serum and plasma samples, covering the reportable range (1:20 dilutions, Transferrin: 0.35-5.6 g/L; Haptoglobin: 0.26-8.3 g/L) were compared to determine if any significant bias existed 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)
Transferrin				
Heparin	99	$y = 0.9768x - 0.0204$	0.9851	0.9499, 1.003
EDTA	40	$y = 1.0067x - 0.0508$	0.9916	0.9767, 1.0425
Haptoglobin				
Heparin	79	$y = 0.9777x - 0.0095$	0.9932	0.9579, 1.0037
EDTA	47	$y = 0.9963x - 0.0208$	0.9936	0.9799, 1.0180

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.