

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: K041870

B. Purpose for Submission: This Premarket Notification provides information demonstrating that Dade Behring's N Apolipoprotein Standard Serum is substantially equivalent to products that were in commercial distribution prior to May 28, 1976 or since cleared through the 510(k) process.

C. Analyte: N Apolipoprotein Standard Serum

D. Type of Test: Calibrator, immunonephelometric assay

E. Applicant: Dade Behring Inc

F. Proprietary and Established Names:

Proprietary – N Apolipoprotein Standard Serum

Established Name - lipoprotein calibrator

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1150
2. Classification: Class II
3. Product Code: JIX
4. Panel: 75

H. Intended Use:

1. Intended use(s): Establishment of reference curves for the quantitative immunonephelometric determination of Apolipoprotein AI and Apolipoprotein B assays using BN Systems
2. Indication(s) for use: For Calibration of the Apolipoprotein A-I and B assays on BN Systems
3. Special condition for use statement(s): For prescription use only
4. Special instrument Requirements: This calibrator is for use on the Dade Behring BN Systems

I. Device Description: N Apolipoprotein Standard Serum is a lyophilized reagent prepared from human serum. The concentration of the Apolipoprotein AI and B were calibrated against the IRP SP1-01 and IRP SP3-07 and are lot dependent.

J. Substantial Equivalence Information:

1. Predicate device name(s): Randox Laboratories Apolipoprotein Calibrator
2. Predicate K number(s): K023158
3. Comparison with predicate:

Predicate Comparisons		
Item	Device	Predicate
Intended Use	For the calibration of Apolipoprotein A-I and Apolipoprotein B assays Dade Behring BN Systems.	Apolipoprotein Calibrator based on the lyophilized human serum for use in the calibration of Apolipoprotein A-I and Apolipoprotein B assays. The constituent concentrations of the Randox Laboratories Limited Apolipoprotein Calibrator are present at 1 level.
Matrix	Stabilized reagent prepared from pooled human serum.	Stabilized reagent prepared from pooled human serum.
Analytes	Apolipoprotein A-I, B	Apolipoprotein A-I, B
Form	Lyophilized	Lyophilized

K. Standard/Guidance Document Referenced (if applicable): ODE Guidance “Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)”, dated January 10, 1997..

L. Test Principle: Immunonephelometric

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility*: n/a
 - b. *Linearity/assay reportable range*: n/a

c. Traceability (controls, calibrators, or method): N Apolipoprotein Standard Serum is prepared from pooled human serum from selected healthy donors. N Apolipoprotein Standard Serum is calibrated against the international (WHO) reference preparation SP1-01 for Apolipoprotein A-I and SP3-07 for Apolipoprotein B. Stability was evaluated by testing N Apolipoprotein Standard Serum in duplicate at each time point for a total of three lots. The standard was evaluated at the recommended storage temperature of 2 to 8 °C. Stability testing supports no significant change in recovery for at least 36 months, and for 15 days, once reconstituted.

d. Detection limit: n/a

e. Analytical specificity: n/a

f. Assay cut-off: n/a

2. Comparison studies:

a. Method comparison with predicate device:

b. Matrix comparison: Stabilized reagent prepared from pooled human serum.

3. Clinical studies:

a. Clinical sensitivity: N/A

b. Clinical specificity: N/A

c. Other clinical supportive data (when a and b are not applicable):
N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.