

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

- A. 510 (k) Number: K032237
- B. Analyte: N/T Protein Control LC
- C. Type of Test: Assayed Quality Control Material
- D. Applicant: Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714
- E. Proprietary and Established Names: N/T Protein Control LC

F. Regulatory Information:

1. Regulation section: 862.1660
2. Classification: Class I
3. Product Code: JJY
4. Panel Chemistry (75)

G. Intended Use:

1. Indication for use: N/T Protein Control LC is intended for use as an assayed Accuracy and Precision Control for immunochemical determination of IgA, IgG and IgM in CSF, transferrin and Alpha -1-microglobulin in urine, albumin and total protein in urine and CSF using the BN™ Systems and also for IgG in CSF and albumin in urine and CSF, using TurbiTime System.
2. Special conditions for use: NA
3. Special Instrument Requirements: For use by nephelometry with BN™ Systems and turbidimetry with Turbi Time System.

H. Device description:

N/T Protein is a lyophilized, multi-analyte control with known concentrations of specific proteins prepared from human urine with polygeline, rabbit albumin and preservative. It is intended to be used as an assayed accuracy and precision control for immunochemical determination of human proteins in urine and CSF by immunonephelometry with BN Systems and Immunturbidimetry with the Turbi Time System.

I. Substantial Equivalence Information

1. Predicate Device Name (s): N/T Protein Control LC

2. Predicate K number: K991704

3. Comparison with Predicate:

Similarities		
Item	Device	Predicate
Intended use:	Same as the predicate	
Matrix:	Same as the predicate	Urine and serum proteins of human origin with Polygeline, rabbit albumin and preservative
Analytes	Alpha -1- Microglobulin, transferrin, albumin, total protein CSF: IgA, IgG, IgM, Albumin	Alpha -1- Microglobulin, transferrin, albumin, total protein CSF: IgA, IgG, Albumin
Form:	Lyophilized	Lyophilized
Instruments used:	BN System and TurbiTime System	BN System and TurbiTime System
Differences		
Item	Device	Predicate
analytes	IgM in CSF	

J. Standards used: Commercially available standard preparation RPPHS lot 5 (CRM 470) for IgG, IgA, IgM, Albumin, Transferrin are used for calibration.

Guidance Document Referenced: None

K. Test Principle: Assayed Control

L. 1. Performance Characteristics: Not applicable

2. Comparison studies: Not applicable

3. Clinical studies: Not applicable

4. Clinical cut-off - not applicable

5. Expected values –not applicable

Assigned values are given in a table for one lot for BN system

M. Conclusion:

Dade Behring's N/T Protein Control LC, assayed quality control material (K032237), is substantially equivalent to Dade Behring's N/T Protein control, assayed quality control material which was previously cleared (K991704) by FDA . The only difference is the current N/T Protein control includes a new analyte-IgM in addition to IgG and IgA.