

JUL 29 1996

K 96 2407

Attachment 1

**510(k) Summary of Safety and Effectiveness for
N/T Protein Control PY**

1. Manufactures Name, Address, Telephone, and contact person, date of preparation:

Manufacturer Behringwerke AG
 Postfach 1140
 35001 Marburg
 Germany

Distributor Behring Diagnostics Inc.
 151 University Avenue
 Westwood, MA 02090
 617-320-3000
 Attn: Kathleen Dray-Lyons

Preparation date: June 20, 1996

2. Device Name/ Classification:

N/T Protein Control PY: Quality Control Material (assayed)

Classification Number: Class I (862.1660)

3. Identification of the legally marketed device:

Behring Diagnostic Inc., Control Plasma N

4. Proposed Device Description:

The N/T Protein Control PY is a lyophilized pool of citrate plasma consisting of one level containing the following proteins:

fibrinogen
antithrombin III
prothrombin
plasminogen
alpha₁-Antitrypsin
C1 Inhibitor

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5. Proposed Device Intended Use:

N/T Protein Control PY is used for control of accuracy and precision in the quantitative immunochemical determination of alpha₁-Antitrypsin, fibrinogen, antithrombin III, prothrombin, plasminogen, fibronectin*, C₁ Inhibitor with the Behring Nephelometer Systems and with the TurbiTimeSystem.

*not available in the U.S.

6. Medical device to which equivalence is claimed and comparison information:

The N/T Protein Control PY is substantially equivalent in intended use to the Control Plasma N. Both products are *in vitro* diagnostic reagents intended for use as a quality control material to monitor certain laboratory coagulation and protein procedures. The N/T Protein Control PY like the Control Plasma N is single level protein control from a human blood-based matrix (citrate plasma). Both controls are provided with a lot specific table of values. The N/T Protein Control PY like the Control Plasma N is used for the control of the following parameters; prothrombin, fibrinogen, plasminogen, C1 Inhibitor and antithrombin III. In addition, the N/T Protein Control PY contains alpha1-Antitrypsin. See Table I for comparative features and the attached N/T Protein Control PY draft package insert for specific product information.

The Behring Diagnostics N/T Protein Control PY differs from the Behring Control Plasma N in that the N/T Protein Control PY is a control for nephelometric coagulation and protein procedures while the Control Plasma N is a control for opto-mechanical and chromogenic coagulation procedures.

7. Proposed Device Performance Characteristics:

Precision and reproducibility:

Precision studies using multiple vials of the controls were run on the Behring Nephelometer. Ten vials of one lot were tested. Each of the parameters were determined in triplicate with each vial. The %CVs were calculated for each parameter. the %CVs ranged from 1.11 to 2.72%.

Stability:

Stability was run according to an in-house protocols and the control was found stable for at least 12 months lyophilized and 14 days once reconstituted.

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Table I

COMPARATIVE FEATURES

**N/T Protein Control PY vs
Control Plasma N**

Feature	Control Plasma N	N/T Protein Control PY
1. Human Blood-Based Matrix	Yes (citrate plasma)	Yes (citrate plasma)
2. Single Level Control	Yes	Yes
3. Multi-Constituent Control	Yes	Yes
4. Quality Control Product	Yes	Yes
5. Lyophilized	Yes	Yes
6. Table of Values Provided	Yes	Yes
7. Coagulation Control	Yes	Yes

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