

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

A. 510(k) Number:

k052056

B. Purpose for Submission:

Clearance of a laboratory control

C. Measurand:

Control material for Acid Phosphatase, Alanine Aminotransferase, Albumin, Alkaline Phosphatase, Amylase, Aspartate Aminotransferase, Bicarbonate, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Cholesterol, Cholinesterase, Copper, Creatine Kinase, Creatinine, Glucose, Gamma Glutamyl Transpeptidase, HDL Cholesterol, Iron, Lactate Dehydrogenase, Lipase, Lithium, Magnesium, Inorganic Phosphorus, Potassium, Sodium, Total Protein, Triglycerides, UIBC, Urea Nitrogen, and Uric Acid

D. Type of Test

Quality control material

E. Applicant:

Thermo Electron Corporation

F. Proprietary and Established Names:

Thermo Data-Trol Normal Control Serum
Thermo Data-Trol A Abnormal Control Serum

G. Regulatory Information:

1. Regulation section:

21CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJY, multi-analyte controls, all kinds (assayed and unassayed)

4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use:

See indications for use below.

2. Indications for use:

Data-Trol N Normal Control Serum is intended for monitoring the accuracy and precision of clinical chemistry test procedures. It is for *in vitro* diagnostic use only.

Data-Trol A Abnormal Control Serum is intended for monitoring the accuracy and precision of clinical chemistry test procedures. It is for *in vitro* diagnostic use only.

3. Special conditions for use statement(s):

For Prescription Use Only

3. Special instrument requirements:

Not applicable

I. Device Description:

Data-Trol N Normal Control Serum and Data-Trol A Abnormal Control Serum are lyophilized products that are prepared from human sera to which human and nonhuman enzymes, non-protein constituents and bacteriostatic agents have been added. During manufacture of the product, the analytes are spiked into the matrix at the desired concentrations.

Human source material from which this product was derived has been tested at the donor level for Human Immunodeficient Virus (HIV1, HIV2) antibody, Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus (HCV) antibody and found to be non-reactive.

J. Substantial Equivalence Information:

1. Predicate device name:

Randox Laboratories Precision Multi Sera Human, Normal and Elevated

2. Predicate 510(k) number(s):

k942458

3. Comparison with predicate:

Similarities		
Characteristics	New Product	Predicate device
Intended Use	Control sera intended for monitoring the accuracy and precision of clinical chemistry test procedures. It is for <i>in vitro</i> diagnostic use only.	Human-Sera are lyophilized human based control sera for use in the quality control of diagnostic assays.
Components	Prepared from human serum to which human and nonhuman enzymes, non-protein constituents and bacteriostatic agents have been added.	Human based control sera.
Handling	Use exactly 5.0 mL distilled or deionized water that is at room temperature (18-25°C) and allow to stand closed for 30 minutes to reconstitute, and then mix gently.	Reconstitute in the appropriate accurately measured volume of distilled water at +20 to +25°C. Allow to stand closed for 30 minutes to reconstitute, and then mix gently.

K. Standard/Guidance Document Referenced (if applicable):

None were referenced in the submission.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The products are prepared from human serum to which human and nonhuman enzymes, non-protein constituents, and bacteriostatic agents have been added.

The concentrations of the added chemicals or biologicals are measured on various clinical chemistry analyzers using current lots of Thermo Electron reagents. Ten vials of each level are run in duplicate using two instruments and two different reagent lots. The grand mean value is calculated for each analyte. The sponsor determines that the data is acceptable when the calibration, control sera recoveries and/or reference material falls within expected ranges.

The target values are traceable to the test procedures listed in the assay data section of the package insert.

The tests listed in the labeling were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents.

Studies are performed to support the reconstituted stability claims for the product. The product is stored at the temperature indicated in the package insert (e.g., Acid phosphatase is stable 2 days at 2-8°C and 30 days at -20°C; and Albumin is stable 7 days at 2-8°C and 30 days at -20°C). This product is measured in replicates and the mean value is determined. In addition, freshly reconstituted controls are measured in replicates and the mean value is determined. The acceptance criterion is defined as the percent difference between the mean value of the product stored at the reconstituted stability temperature (A) minus the mean value of the freshly reconstituted control sera (B): $A - B = \text{difference} / B \times 100$. The sponsor has determined that data is acceptable for some analytes (e.g. albumin) when the % difference is $\pm 10\%$ or for some analytes (e.g. alkaline phosphatase) when the % difference is $\pm 15\%$.

d. *Detection limit:*

Not Applicable

e. *Analytical specificity:*

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

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

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

Not Applicable

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.