

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

**A. 510(k) Number:**

k080085

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Quality control materials containing secobarbital, diazepam and nortriptyline

**D. Type of Test:**

N/A – quality control materials

**E. Applicant:**

ThermoFisher Scientific

**F. Proprietary and Established Names:**

MAS Tox Control

**G. Regulatory Information:**

1. Regulation section:  
21 CFR § 862. 3280 Clinical toxicology control material (assayed and unassayed)
2. Classification:  
Class I (reserved)
3. Product code:  
DIF, drug mixture control materials
4. Panel:  
Toxicology (91)

**H. Intended Use:**

1. Intended use(s):  
MAS Tox Control is intended for use as a consistent test sample of known concentration for monitoring assay conditions in the measurement of Benzodiazepines and Barbiturates in human serum and plasma and Tricyclic Antidepressants drugs (TCA) in human serum, plasma and urine. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.
2. Indication(s) for use:  
See intended use section above.
3. Special conditions for use statement(s):

For *in vitro* diagnostic use; for prescription use

4. Special instrument requirements:

The package insert includes ranges for the Advia 1200, Advia 1650 and Advia 2400

**I. Device Description:**

The **MAS Tox Control** is a liquid assayed control product suitable for monitoring conditions in specific toxicology determinations. The controls are prepared from a bovine plasma base and contain three (3) analytes (secobarbital, diazepam and nortriptyline). The analytes added to the bovine plasma base are from high purity ( $\geq 99\%$ ) chemical compounds with sodium azide added as a preservative. There are no human sourced components. The product will be marketed in both two- and three-level configurations consisting of six 5 mL vials per pack (kit). A lot-specific package insert (PI) indicating values for specific instrument use is provided.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

MAS PAR TDM Control

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

k032826

3. Comparison with predicate:

	<b>MAS Tox Control</b>	<b>PREDICATE MAS® PAR TDM Control</b>
Intended Use	For use as a consistent test sample of known concentration for monitoring assay conditions in the measurement of benzodiazepines and barbiturates in human serum and plasma and tricyclic antidepressant drugs (TCA) in human serum, plasma and urine. Assay values are provided for specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.	For use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include with patient serum specifications when assaying for any of the listed constituents. Assay values are provided for specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.
Analytes in bovine plasma base	Secobarbital, Diazepam, and Nortriptyline	Acetaminophen, Amikacin, Amitriptyline, Caffeine, Carbamazepine, Clonazepam, Cocaine Metabolite, Cyclosporine,

		Digoxin, Disopyramide, Estriol, Ethanol, Ethosuximide, Gentamicin, hCG, Lidocaine, Lithium, Methotrexate, NAPA, Netilmicin, Nortriptyline, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Thyroxine, Tobramycin, Thyroxine, TSH, Valproic Acid, Vancomycin
Product state at purchase	Liquid at 2-8°C	Liquid at 2-8°C

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

None were referenced.

**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):*

No traceability was provided.

Value assigned ranges are established at the wider of mean  $\pm$  20% or  $\pm$  3 SD. For each of the three control levels, a minimum of 20 data points are collected over five days for each instrument, samples run in duplicate, in two separate runs, (2 runs x 2 reps x 5 days = 20 data points).

The labeling recommends that the control ranges are provided as guidelines until the laboratory has established its own statistical limits. The printed values are based upon replicate assays of representative samples by participating laboratories in accordance with an established protocol and/or by direct correlation with another specific analytical system.

Real time and accelerated stability studies have been performed to determine the open vial stability and shelf life for the MAS Tox Control. Product claims are as follows: open vial: 20 days when stored tightly capped at 2-8°C; Stability (Closed vial): 2 years when stored at 2-8°C.

- 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:  
The lot specific target ranges for the product are provided in the package insert.

**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.