

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

A. 510(k) Number:

k120936

B. Purpose for Submission:

New device

C. Measurand:

Calibrator materials

D. Type of Test:

Not applicable

E. Applicant:

Microgenics Corporation

F. Proprietary and Established Names:

Abbott TDM Multiconstituent Calibrator

Thermo Scientific QMS[®] TDM Multi-Constituent Calibrator

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.3200; Clinical Toxicology Calibrator
2. Classification:
Class II
3. Product code:
DKB
4. Panel:
Toxicology (91)

H. Intended Use:

1. Intended use(s):
See Indications for Use below.

2. Indication(s) for use:

Abbott TDM Multiconstituent Calibrator

For in vitro diagnostic use in the calibration of the Amikacin, Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Quinidine, Theophylline, Valproic Acid, and Vancomycin human serum and plasma assays on the ARCHITECT cSystems.

Lot-specific calibrator for the ARCHITECT cSystems are listed in the TDM

MCC value sheet, packaged with the calibrator.

Thermo Scientific QMS[®] Multi-Constituent Calibrator

For *in vitro* diagnostic use in the calibration of assays for the detection of Amikacin, Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Quinidine, Theophylline, Valproic Acid, and Vancomycin in human serum and plasma for use on clinical laboratory analyzers.

Lot-specific calibrator values with specific analyzers are provided in the value sheet packaged with the calibrator.

3. Special conditions for use statement(s):
For *in vitro* diagnostic use
For prescription use
4. Special instrument requirements:
For use with the Architect c16000 System

I. Device Description:

Both TDM Multi-Constituent Calibrator and QMS TDM Multi-Constituent Calibrator are identical calibrators and the only difference is the trade name. The calibrator set is sold separately and may be used with any reagent lot. The calibrators in this set are designed for use as a unit. Do not substitute or mix calibrators with those from other lots.

Each TDM and QMS Multiconstituent Calibrator set is packaged in a rectangular cardboard box with a 12-bottle divider, a product insert, and a value sheet. Kits are stored refrigerated at 2-8°C. TDM Multiconstituent Calibrator set is prepared from a bovine serum matrix and contains the following analytes (6 levels each): amikacin, carbamazepine, digoxin, gentamicin, phenobarbital, phenytoin, quinidine, theophylline, valproic acid, and vancomycin. Sodium azide at 0.09% and ProClin 300 at 0.1% are present as preservatives. TDM Multiconstituent Calibrator levels are provided in liquid ready to use form and can be stored at 2-8°C until the expiration date on the label. Once opened, the opened bottles are stable for 60 days when capped tightly and stored at 2-8°C.

J. Substantial Equivalence Information:

1. Predicate device name(s):
CEDIA TDM Core Multi-cals
2. Predicate k number(s):
k961659

3. Comparison with predicate:

Similarities and Differences

Item	Candidate Devices	Predicate Device (k961659)
Intended Use	For in vitro diagnostic use in the calibration of the Amikacin, Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Quinidine, Theophylline, Valproic Acid, and Vancomycin assays.	Same
Matrix	Bovine Serum	Same
Analytes	Amikacin Carbamazepine Digoxin Gentamicin Phenobarbital Phenytoin Quinidine Theophylline Valproic Acid Vancomycin	Carbamazepine Phenobarbital Phenytoin Theophylline Valproic Acid
Stability	24 months at 2-8°C. Open bottle stability of 60 days at 2-8°C and for 24 hours at 15-30°C	Closed vial up until expiration date; 30 days open vial stability

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):*

Traceability:

Both TDM Multi-Constituent Calibrator and QMS TDM Multi-Constituent Calibrator are traceable to USP standards. The Primary Reference Standards were prepared by gravimetric additions of the United States Pharmacopeia (USP) grade drugs into a drug-free human serum pool. These materials were aliquot in single-use cryo vials, and stored at -70°C.

Stability:

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Stability characteristics of the TDM and QMS TDM Multi-Constituent Calibrators were determined using accelerated (closed bottle) stability studies, real time (closed bottle) stability studies and real-time opened bottle stability studies. Based on the accelerated stress stability data, the shelf life claim is set for 24 months at 5°C. Real-time stability studies demonstrated a shelf life claim of 24 months at 2-8°C. Open bottle stability of 60 days was demonstrated at the recommended storage temperature (2-8°C) and for 24 hours at 15-30°C. Open vial and closed vial expiration dates are located in the package insert.

Value Assignment:

The values of the TDM Multi-Constituent Calibrators (TDM MCC) are assigned by generating calibration curve using internal Primary Reference Standards with their target values for each level of analyte. Assay controls were used to verify that control recoveries are within the published ranges to validate the calibration curve. Two lots of the TDM MCC were used and one lot of control were used in the value assignment procedure. TDM MCC Level 1 values are assigned to zero, since no drugs are present. The TDM MCC and the corresponding Primary Reference Standards were assayed on the Abbott

Architect c16000. TDM MCC values were determined by ratio calculations of the assay recovery values of the TDM MCC and assay recovery values of the Primary Reference Standards. Calibration curves are generated using the TDM MCC with the new assigned values (shown in the table below).

Analyte	TDM Multi-Constituent Target (µg/mL)					
	L1	L2	L3	L4	L5	L6
Amikacin	0.0	2.92	9.59	19.75	33.98	50.71
Carbamazepine	0.0	1.86	3.76	7.68	11.64	18.64
Digoxin	0.0	0.49	0.96	1.89	2.74	4.57
Gentamicin	0.0	0.49	1.50	3.18	6.64	10.71
Phenobarbital	0.0	4.78	10.28	19.97	41.90	85.01
Phenytoin	0.0	2.50	5.27	10.41	20.82	41.40
Quinidine	0.0	0.43	1.03	1.93	3.71	7.40
Theophylline	0.0	2.91	5.64	11.28	21.81	43.28
Valproic Acid	0.0	14.16	25.43	52.27	100.56	151.63
Vancomycin	0.0	4.83	9.89	24.86	48.39	97.90

- 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 values for each analyte are stated in the labeling.

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.