

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

A. 510(k) Number:

K033879

B. Analyte:

Acetaminophen, amikacin, carbamazepine, digoxin, gentamicin, lidocaine, phenobarbital, phenytoin, primidone, procainamide, quinidine, salicylate, theophylline, tobramycin, valproic acid, and vancomycin.

C. Type of Test:

Calibration.

D. Applicant:

Maine Standard Company

E. Proprietary and Established Names:

Validate® TDM Calibration Verification Test Set

F. Regulatory Information:

1. Regulation section:
CFR § 862. 3200, Clinical Toxicology Calibrator, Drug Mixture
2. Classification:
Class II
3. Product Code:
DKB
4. Panel:
Clinical Toxicology (91)

G. Intended Use:

1. Intended Use(s):
Refer to the Indications for Use.
2. Indication(s) for use:
The VALIDATE TDM Calibration Verification Test Set is used by trained laboratory professions for the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated, and manual clinical chemistry systems for the following analytes:
Acetaminophen, amikacin, carbamazepine, digoxin, gentamicin, lidocaine, phenobarbital, phenytoin, primidone, procainamide, quinidine, salicylate, theophylline, tobramycin, valproic acid, and vancomycin
3. Special condition for use statement(s):
Prescription Use Only

4. Special instrument Requirements:
Automated, semi-automated , and manual clinical chemistry systems

H. Device Description:

Validate TDM Calibration Verification Test Set contains purified chemicals in a human serum matrix. Multiple levels are provided to establish the relationship between theoretical operation and actual performance of each of the included analytes. Each set contains one bottle each of six (6) levels including zero. Each bottle contains 5 milliliters.

I. Substantial Equivalence Information:

1. Predicate device name(s):
TDM I CAL-VER
2. Predicate K number(s):
K913309
3. Comparison with predicate:

Similarities & Differences		
Item	Device	Predicate
Intended Use	For in vitro diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For in vitro diagnostic use in the quantitative determination of linearity on immunochemistry systems and clinical chemistry systems
Matrix	Human serum	Human serum
Number of levels	6 including zero	8
Analytes	Acetaminophen, amikacin, carbamazepine, digoxin, gentamicin, lidocaine, phenobarbital, phenytoin, primidone, procainamide, quinidine, salicylate, theophylline, tobramycin, valproic acid, and vancomycin	Acetaminophen, amikacin, carbamazepine, chloramphenicol, disopyramide, ethosuximide, digoxin, gentamicin, lidocaine, phenobarbital, phenytoin, primidone, procainamide, quinidine, theophylline, tobramycin, valproic acid, and vancomycin

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

N/A

K. Test Principle:

N/A

L. Performance Characteristics (if/when applicable):1. Analytical performance:*a. Precision/Reproducibility:* N/A*b. Linearity/assay reportable range:* N/A*c. Traceability (controls, calibrators, or method):*

Validate Calibration Verification Test Set Solutions are tested during manufacturing with standards traceable to National Institute for Standard and Technology (NIST) Standard Reference Materials, are available. For analytes where NIST materials are not available, primary analytical standards are used.

NIST SRM 900 and NIST 1599 are utilized for traceability testing for the VALIDATE TDM Calibration Verification Test Set during manufacture. NIST SRM 900, Antiepilepsy Drug Level Assay Standard, contains the therapeutic drugs Phenytoin, Ethosuximide, Phenobarbital, and Primidone at certified values. NIST SRM 1599, Anticonvulsant Drug Level Assay Standard, contains Valproic Acid and Carbamazepine at certified values.

d. Detection limit (functional sensitivity):

N/A

e. Analytical specificity:

N/A

f. Assay cut-off:

N/A

2. Comparison studies:*a. Method comparison with predicate device:* N/A*b. Matrix comparison:* N/A3. Clinical studies:*a. Clinical sensitivity:* N/A*b. Clinical specificity:* N/A4. Clinical cut-off: N/A5. Expected values/Reference range: N/A

M. Conclusion:

Based upon the information provided, I recommend that the Validate TDM Calibration Verification Test Set be found substantially equivalent with similar defined products based upon 21 CFR § 862.3200, Clinical Toxicology Calibrator, Drug Mixture