

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

A. 510(k) Number:

k062162

B. Purpose for Submission:

New device

C. Measurand:

Amphetamines/ Methamphetamines, Barbiturates, Benzodiazepines, Cocaine metabolite, Methadone, Methaqualone, Opiates, Phencyclidine, Propoxyphene, and Cannabinoids

D. Type of Test:

Calibrator Materials

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista System Drugs of Abuse Calibrator (UDAT CAL - KC510)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
Calibrators, Drug Mixture (DKB)	Class II	21 CFR 862.3200, Clinical toxicology calibrator.	91 CLINICAL TOXICOLOGY (TX)

H. Intended Use:

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

The UDAT CAL is an in vitro diagnostic product for the calibration of Amphetamines/Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Methaqualone (MTQ), Opiates (OPI), Phencyclidine (PCP), Propoxyphene (PRX), and Cannabinoids (THC) methods on the Dimension Vista™ System.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Dade Behring Dimension Vista System

I. Device Description:

The UDAT CAL is a liquid, multi-analyte, drug free human urine based calibrator consisting of 6 vials (three of calibrator A and three of calibrator B). Calibrator A vials contain 2.5 mL and Calibrator B vials contain 2.6 mL. The component, constituent, and assigned values are listed in the table below. Intermediate levels are prepared and corresponding values calculated by the instrument.

Component	Source	Level A (ng/mL)	Level B (ng/mL)
Amphetamines 300	d-methamphetamine	0	1000
Amphetamines 500	d-methamphetamine	0	1000
Amphetamines 1000	d-methamphetamine	0	2000
BARB	Secobarbital	0	800
BENZ	Lormetazepam	0	1000
COC 150	Benzoylecgonine	0	1000
COC 300	Benzoylecgonine	0	1000
METH	Methadone	0	1000
MTQ	Methaqualone	0	1000
OPI 300	Morphine	0	2000
OPI 2000	Morphine	0	4000
PCP	Phencyclidine	0	75
PRX	Propoxyphene	0	500
THC	11-nor-delta 9-THC-9-COOH	0	100

J. Substantial Equivalence Information:

The predicate for the UDAT CAL is the Syva EMIT Calibrators/controls (k993755). The UDAT CAL has the same intended use, analytes, form, matrix and traceability.

The only noted difference is that the UDAT CAL has two levels whereas the predicate has six levels.

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

STANDARDS	
Title and Reference Number	
1) CEN 13540 Stability testing of In-Vitro Diagnostic Devices	
2) ISO 14971: 2000 Medical devices-Application of risk management to medical devices.	
Other Standards	

GUIDANCE			
Document Title	Office	Division	Web Page
Abbreviated 510k Submissions for In Vitro Diagnostic Calibrators	OIVD	----	http://www.fda.gov/cdrh/ode/calibrator.html
Guidance for Industry and FDA Staff; Use of Symbols on Labels and in Labeling of In Vitro Diagnostics Devices Intended for Professional Use.	CDRH CBER		http://www.fda.gov/cdrh/ocd/guidance/4444.html

L. Test Principle:

Not applicable (N/A)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

N/A

b. Linearity/assay reportable range:

N/A

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

Traceability

All analytes used in the UDAT CAL are traceable to commercially available USP reference material and/or Cerilliant reference material.

Stability

The sponsor conducted real-time stability studies with the multi-drug calibrator. When punctured (open vial) by the instrument, the vial is stable on board for 24 hours. A non-punctured (open) vial is stable in the refrigerator for 31 days. The closed stability for the UDAT CAL is 9 months.

Value assignment

The new calibrator master lot is made by gravimetrically adding quantities of the reference material into drug free normal human urine. The master lot (5 levels) are stored at -70°C and verified by recovery and GC/MS testing. The commercial lot stock solution is prepared by gravimetrically adding the analytes to form the target concentration. The commercial stock solution concentration is verified by comparing the master lot assigned values. The commercial lot is prepared by adding calculated quantities of the commercial stock solution to drug free normal human urine to the two level target concentrations. The concentration of the commercial lot is verified to be within acceptable ranges using an instrument calibrated with the master lot and GC/MS testing.

d. Detection limit:

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/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

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.