

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

A. 510(k) Number:

k060645

B. Purpose for Submission:

New document

C. Measurand:

The Roche Preciset DAT Plus I and Roche Cfas DAT Qualitative Plus - calibrators for amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, Methaqualone, opiates, phencyclidine and propoxyphene.

The Roche Preciset DAT Plus II - calibrator for amphetamines, benzodiazepines, cannabinoids and opiates.

D. Type of Test:

Not Applicable

E. Applicant:

Roche Diagnostics Corp.

F. Proprietary and Established Names:

Preciset DAT Plus I, Preciset DAT Plus II, and CFAS DAT Qualitative Plus Calibrators

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):

See below indication(s) for use.

2. Indication(s) for use:

The Preciset DAT Plus I calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

The Preciset DAT Plus II calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

The Cfas DAT Qualitative Plus calibrator is designed for the qualitative calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

3. Special conditions for use statement(s):

Prescription use.

4. Special instrument requirements:

Roche/Hitachi 911/912/917/MODULAR P analyzers

COBAS Integra 400/400plus/700/800

I. Device Description:

Roche Preciset DAT Plus I calibrators contain a mixture of 10 different drugs, prepared by quantitative addition of drug or drug metabolite to drug-free human urine. Drugs included are amphetamines, barbiturates, benzodiazepines, cannabinoids, methadone, methaqualone, opiates, phencyclidine, and propoxyphene. The calibrator set contains up to six levels for each drug contained in bottles 1-6. Bottle 1 is negative (drug free) human urine, followed by bottles 2-6 containing increasing amounts of each drug in a multi-analyte mixture. Drug or drug metabolite and their respective target levels are as follows:

Amphetamines: 0, 250, 500, 1000, 3000, 5000 (ng/mL)
Barbiturates: 0, 100, 200, 400 (ng/mL) [no 5th and 6th level]
Benzodiazepines: 0, 150, 300, 600, 1000, 3000 (ng/mL)
Cannabinoids: 0, 20, 50, 100, 200, 300 (ng/mL)
Cocaine: 0, 75, 150, 300, 1000, 5000 (ng/mL)
Methadone: 0, 150, 300, 600, 2000 (ng/mL) [no 6th level]
Methaqualone: 0, 150, 300, 600 (ng/mL) [no 5th and 6th level]
Opiates: 0, 600, 1000, 2000, 4000, 8000 (ng/mL)
PCP: 0, 12.5, 25.0, 50.0 (ng/mL) [no 5th and 6th level]

Propoxyphene: 0, 150, 300, 600 (ng/mL) [no 5th and 6th level]

Roche Preciset DAT Plus II calibrators contain a mixture of 4 different drugs, prepared by quantitative addition of drug or drug metabolite to drug-free human urine. Drugs included are amphetamines, benzodiazepines, cannabinoids, and opiates. The calibrator set contains up to six levels for each drug contained in bottles 1-6. Bottle 1 is negative (drug free) human urine, followed by bottles 2-6 containing increasing amounts of each drug in a multi-analyte mixture. Drug or drug metabolite and their respective target levels are as follows:

Amphetamines: 0, 150, 300, 600, 1000, 2000 (ng/mL)

Benzodiazepines: 0, 50, 100, 200, 400, 1000 (ng/mL)

Cannabinoids: 0, 10, 20, 40, 100 (ng/mL) [no 6th level]

Opiates: 0, 150, 300, 600, 1000, 2000 (ng/mL)

Roche Cfas DAT Qualitative Plus calibrator contains a mixture of 10 different drugs, prepared by quantitative addition of drug or drug metabolite to drug-free human urine. Drugs included are amphetamines, barbiturates, benzodiazepines, cannabinoids, methadone, Methaqualone, opiates phencyclidine and propoxyphene. The calibrator set contains a single level for each drug in a drug mixture. Drugs or drug metabolites and their respective target levels are as follows:

Amphetamines: 500 (ng/mL)

Barbiturates: 200 (ng/mL)

Benzodiazepines: 300 (ng/mL)

Cannabinoids: 50 (ng/mL)

Cocaine: 150 (ng/mL)

Methadone: 300 (ng/mL)

Methaqualone: 50 (ng/mL)

Opiates: 2000 (ng/mL)

Phencyclidine: 25 (ng/mL)

Propoxyphene: 300 (ng/mL)

J. Substantial Equivalence Information:

Predicate	k031775 - Preciset DAT Plus I k033306: Preciset DAT Plus II and Cfas DAT Qualitative Plus
Describe the item being compared	
The Roche Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus multianalyte calibrators are substantially equivalent to the currently marketed Roche Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus multianalyte calibrators, manufactured for Roche Diagnostics and cleared in the following 510(k) submissions: K031775: Preciset DAT Plus I K033306: Preciset DAT Plus II and Cfas DAT Qualitative Plus. The Preciset DAT Plus I and Preciset DAT Plus II calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers. The Cfas DAT Qualitative Plus calibrator is designed for the qualitative calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.	

Similarities		
Feature	Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrators (Predicate Device)	Roche Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrator
Indications for Use	<p>Preciset DAT Plus I</p> <p>The Preciset DAT Plus I calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.</p> <p>Preciset DAT Plus II</p> <p>The Preciset DAT Plus II calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.</p> <p>Cfas DAT Qualitative Plus</p> <p>The Cfas DAT Qualitative Plus calibrator is designed for the qualitative calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.</p>	<p>Preciset DAT Plus I</p> <p>The Preciset DAT Plus I calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.</p> <p>Preciset DAT Plus II</p> <p>The Preciset DAT Plus II calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.</p> <p>Cfas DAT Qualitative Plus</p> <p>The Cfas DAT Qualitative Plus calibrator is designed for the qualitative calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.</p>
Type of Material	<p>Preciset DAT Plus I</p> <p>Liquid, ready to use calibrators, consists of 6 levels, Calibrators 1-6.</p> <p>Cfas DAT Qualitative Plus</p> <p>Liquid, ready to use calibrator, consists of a single level.</p>	<p>Preciset DAT Plus I</p> <p>Liquid, ready to use calibrators, consists of 6 levels, Calibrators 1-6.</p> <p>Cfas DAT Qualitative Plus</p> <p>Liquid, ready to use calibrator, consists of a single level.</p>
Matrix	Human urine with stabilizers and preservatives.	Human urine with stabilizers and preservatives.
Packaging	<p>Preciset DAT Plus I Calibrators 1-6: 5 ml each level</p> <p>Preciset DAT Plus II Calibrators 1-6: 5 ml each level</p>	<p>Preciset DAT Plus I Calibrators 1-6: 5 ml each level</p> <p>Preciset DAT Plus II Calibrators 1-6: 5 ml each level</p>

	Cfas DAT Qualitative Plus Calibrator: 6 x 5 ml	Cfas DAT Qualitative Plus Calibrator: 6 x 5 ml
Differences		
Feature	Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrators (Predicate Device)	Roche Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrators
Calibrator Level	Preciset DAT Plus I	Preciset DAT Plus I
	Amphetamines (d-methamphetamine): 0, 250, 500, 1000, 3000, 5000 (ng/mL)	Amphetamines (d-methamphetamine): 0, 250, 500, 1000, 3000, 5000 (ng/mL)
	Barbiturates (Secobarbital): 0, 100, 200, 400 (ng/mL)	Barbiturates (Secobarbital): 0, 100, 200, 400 (ng/mL)
	Benzodiazepines (nordiazepam): 0, 150, 300, 600 (ng/mL)	Benzodiazepines (nordiazepam): 0, 150, 300, 600, 1000, 3000 (ng/mL)
	Cannabinoids (.9 TCH-COOH): 0, 20, 50, 100, 200, 300 (ng/mL)	Cannabinoids (.9 TCH-COOH): 0, 20, 50, 100, 200, 300 (ng/mL)
	Cocaine (benzoylecgonine): 0, 75, 150, 300, 1000, 5000 (ng/mL)	Cocaine (benzoylecgonine): 0, 75, 150, 300, 1000, 5000 (ng/mL)
	Methadone (dl-methadone): 0, 150, 300, 600, 2000 (ng/mL)	Methadone (dl-methadone): 0, 150, 300, 600, 2000 (ng/mL)
	Opiates (d-morphine): 0, 600, 1000, 2000, 4000, 8000 (ng/mL)	Methaqualone (Methaqualone): 0, 150, 300, 600 (ng/mL)
	PCP (phencyclidine): 0, 12.5, 25.0, 50.0 (ng/mL)	Opiates (d-morphine): 0, 600, 1000, 2000, 4000, 8000 (ng/mL)
	Propoxyphene (propoxyphene): 0, 150, 300, 600 ng/mL)	PCP (phencyclidine): 0, 12.5, 25.0, 50.0 (ng/mL)
		Propoxyphene (propoxyphene): 0, 150, 300, 600 ng/mL)
	Preciset DAT Plus II	Preciset DAT Plus II
	Benzodiazepine: (nordiazepam): 0, 50, 100, 200, 400 ng/mL) no level 6	Amphetamines (d-methamphetamine): 0, 150, 300, 600, 1000, 2000 (ng/mL)

Opiates (d-morphine): 0, 150, 300, 600, 1000, 2000 (ng/mL)	Benzodiazepine: (nordiazepam): 0, 50, 100, 200, 400, 1000 ng/mL)
	Cannabinoids (.9 THC-COOH): 0, 10, 20, 40, 100 (ng/mL)
	Opiates (d-morphine): 0, 150, 300, 600, 1000, 2000 (ng/mL)
Cfas DAT Qualitative Plus	Cfas DAT Qualitative Plus
Barbiturates: 200 (ng/mL)	Amphetamines: 500 (ng/mL)
Benzodiazepines: 300 (ng/mL)	Barbiturates: 200 (ng/mL)
Cocaine: 150 (ng/mL)	Benzodiazepines: 300 (ng/mL)
Methadone: 300 (ng/mL)	Cannabinoids: 50 (ng/mL)
Opiates: 2000 (ng/mL)	Cocaine: 150 (ng/mL)
Phencyclidine: 25 (ng/mL)	Methadone: 300 (ng/mL)
Propoxyphene: 300 (ng/mL)	Methaqualone: 50 (ng/mL)
	Opiates: 2000 (ng/mL)
	Phencyclidine: 25 (ng/mL)
	Propoxyphene: 300 (ng/mL)

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

STANDARDS

Title and Reference Number

Medical devices - Application of risk management to medical devices (14971:2000)

GUIDANCE

Document Title	Office	Division	Web Page
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	OIVD		http://www.fda.gov/cdrh/ode/calibrator.html

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):

Analyte concentrations in the Preciset DAT Plus I, Preciset DAT plus II and Cfas DAT Qualitative Plus calibrator sets are traceable to and verified by a primary reference method, specifically GC-MS.

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):

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.