

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

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

K033165

**B. Analyte:**

Amphetamines

**C. Type of Test:**

Calibrators

**D. Applicant:**

Roche Diagnostics

**E. Proprietary and Established Names:**

Preciset DAT Amphetamine Calibrators

Cfas DAT Qualitative Amphetamine Calibrator

**F. Regulatory Information:**

1. Regulation section:  
21 CFR § 862.3200, Clinical toxicology calibrator
2. Classification:  
Class II
3. Product Code:  
DLJ, Calibrators, Drug Specific
4. Panel:  
Toxicology (91)

**G. Intended Use:**

1. Intended use(s):  
Refer to Indications for use.
2. Indication(s) for use:

The Preciset DAT Amphetamine Calibrators are designed for the calibration of the Roche Abuscreen OnLine assay for Amphetamines and the cassette COBAS Integra Amphetamines (AMPS) for the determination of amphetamines in human urine on automated clinical chemistry analyzers.

The Cfas DAT Qualitative Amphetamine Calibrator is designed for the qualitative calibration of the Roche Abuscreen OnLine assay for Amphetamines and the cassette COBAS Integra Amphetamines (AMPS) for

the determination of amphetamines in human urine on automated clinical chemistry analyzers.

3. Special condition for use statement(s):  
The device is for in vitro diagnostic use.  
The device is for prescription use.
4. Special instrument Requirements:

Automated clinical chemistry analyzer

#### **H. Device Description:**

Roche Preciset DAT Amphetamine calibrators contain 6 levels of amphetamines, prepared by the quantitative addition of d-amphetamine to drug-free human urine. Drug concentrations are verified by GC/MS. The negative calibrator is drug-free human urine, followed by five calibrators containing increasing amounts of amphetamines (250, 500, 1000, 1500, and 2000 ng/mL).

Roche Cfas DAT Qualitative Amphetamine calibrators contain a single level of amphetamines (target concentration = 1000 ng/mL). The calibrator is prepared by the addition of d-amphetamine to drug-free human urine. Drug concentrations are verified by GC/MS. The set contains 3 bottles of calibrator at 5 mL each.

#### **I. Substantial Equivalence Information:**

1. Predicate device name(s):  
Roche Abuscreen OnLine Preciset DAT I Calibrators (formerly Abuscreen OnLine Calibration Pack)
2. Predicate K number(s):  
K951595
3. Comparison with predicate:

Both calibrators and their predicate share a similar intended use, matrix, and packaging. The devices differ in the number and concentrations of the calibrators (See traceability for calibrator description.) The predicate device contains a mixture of 9 drugs, while the current devices contain only the single drug (d-amphetamine).

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

How to Prepare an Abbreviated 510(k), 1998

Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators, 1999

ISO 14971:2000

#### **K. Test Principle:**

Not applicable. This submission is for calibrators.

**L. Performance Characteristics (if/when applicable):**1. Analytical performance:*a. Precision/Reproducibility:*

Not applicable. See below for calibrator traceability.

*b. Linearity/assay reportable range:*

Not applicable.

*c. Traceability (controls, calibrators, or method):*

The Preciset DAT Amphetamine calibrators contain 6 levels. They are made by the quantitative addition of d-amphetamine to drug-free human urine. Targeted concentrations are 0, 250, 500, 1000, 1500, and 2000 ng/mL d-amphetamine. Drug concentrations are verified by GC/MS analysis both at Roche and an independent, NIDA-certified, GC/MS laboratory.

The Cfas DAT Qualitative Amphetamine calibrator is made by the quantitative addition of d-amphetamine to drug-free human urine. Targeted concentration is 1000 ng/mL d-amphetamine. Drug concentration is verified by GC/MS analysis both at Roche and an independent, NIDA-certified, GC/MS laboratory.

Stability studies are summarized for the calibrators. The sponsor specifies the concentrations of materials evaluated in the studies, the frequency of testing, the method for testing the materials, environmental conditions of storage, and acceptance criteria for the study. Accelerated studies are being used by the sponsor to estimate the expiration date; however, on-going real time studies are being performed.

The new Amphetamine calibrators will be validated on existing Roche drugs of abuse assays by performing experiments assessing verification of calibration, control recovery and crossover (relative to assay cutoffs), commercial control recovery, and endogenous sample recovery. Protocols and acceptance criteria are summarized.

*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.

**M. Conclusion:**

I recommend that the Preciset DAT Amphetamine Calibrators and the Cfas DAT Qualitative Amphetamine Calibrator be found substantially equivalent to the predicate device.