

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

A. 510(k) Number: K031775

B. Analyte: Preciset DAT Plus I Calibrators containing specific levels of drugs of abuse (amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, opiates, phencyclidine, and propoxyphene).

C. Type of Test: N/A

D. Applicant: Roche Diagnostics

E. Proprietary and Established Names: Preciset DAT Plus I Calibrators

F. Regulatory Information:

1. Regulation section: 21 CFR 862.3200
2. Classification: Class II
3. Product Code: DKB
4. Panel: 91

G. Intended Use:

1. 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 analyzers.
2. Special condition for use statement(s): none
3. Special instrument Requirements: none

H. Device Description: 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 analyzers. These calibrators are liquid ready to use calibrators consisting of 6 levels (Calibrators 1 – 6) and are comprised of human urine with preservatives and specific levels of drugs of abuse (amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, opiates, phencyclidine, and propoxyphene).

I. Substantial Equivalence Information:

1. Predicate device name(s): Abuscreen OnLine Preciset DAT I multianalyte calibrators which were later renamed Abuscreen Online Preciset DAT I without modification
2. Predicate K number(s): K951595
3. Comparison with predicate:

DEVICE		PREDICATE	
A. Similarities			
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 I calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers	
Liquid ready to use		Liquid ready to use	
Human urine with added preservatives		Human urine with added preservatives	
B. Differences			
Contains 6 levels of calibrators in the following concentrations – Amphetamines (0, 250, 500, 1000, 3000, 5000 ng/ml), Barbiturates (0, 100, 200, 400 ng/ml), Benzodiazepines (0, 150, 300, 600 ng/ml), Cannaboids (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), Opiates (0, 600, 1000, 2000, 4000, 8000 ng/ml), Phencyclidine (0, 12.5, 25.0, 50.0 ng/ml), Propoxyphene (0,150,300,600 ng/ml).		Contains 4 levels of calibrators in the following concentrations - Amphetamines (0, 500, 1000, 2000 ng/ml), Barbiturates (0, 100, 200, 400 ng/ml), Benzodiazepines (0, 50, 100, 200 ng/ml), Cocaine(0, 150, 300, 600 ng/ml), Methadone (0,150,300,600 ng/ml), Methaqualone (0, 150, 300, 600 ng/ml), Opiates (0, 150, 300, 600 ng/ml), Phencyclidine (0, 12.5, 25.0, 50.0 ng/ml), Propoxyphene (0,150,300,600 ng/ml).	

J. Standard/Guidance Document Referenced (if applicable) Guidance for Industry - Abbreviated 510(k) Submissions for InVitro Calibrators

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): Analyte concentrations in the Preciset DAT Plus I calibrator set are traceable to and verified by a primary reference method, specifically GC-MS (Gas chromatograph-mass spectrometry).

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/A

3. Clinical studies:

a. Clinical sensitivity: N/A

b. Clinical specificity: N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

M. Conclusion: Based upon the information provided, I recommend that the Roche Preciset DAT Plus I calibrators be found substantially equivalent with similar predicate devices as defined in 21 CFR 862.3200.