

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

A. 510(k) Number:

k090939

B. Purpose for Submission:

New device

C. Measurand:

Calibrator and control for Roche/Hitachi analyzers and cobas c analyzers test system
Multiple constituents listed in the package insert

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

C.f.a.s. DAT Qualitative Plus Clinical calibrator
Control Set DAT Clinical

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.3280, Clinical toxicology calibrator
21 CFR § 862.3200, Clinical toxicology control material
2. Classification:
Class II
Class I - reserved
3. Product code:
DKB; DIF
4. Panel:
Toxicology (91)

H. Intended Use:

1. Intended use:

See indications for use below.

2. Indications for use:

The C.f.a.s. DAT Qualitative Plus Clinical_calibrator is designed for the qualitative calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

The Control Set DAT Clinical is for use as an assayed control in the Roche test system for qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

For use on Roche/Hitachi analyzers and **cobas c** analyzers

I. Device Description:

C.f.a.s. DAT Qualitative Plus Clinical_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, barbituates, benzodiazepines, cannabinoids, cocaine, methadone, methaqualone, opiates, phencyclidine, and propoxyphene. The calibrator set contains a single level for each drug in a drug mixture. Drug concentrations are verified by gas chromatography/mass spectrometry (GC/MS). Drugs or drug metabolites and their respective levels included are as follows:

Amphetamines: 500 ng/mL
Barbituates: 200 ng/mL
Benzodiazepines: 100 ng/mL
Cannabinoids: 50 ng/mL
Cocaine: 300 ng/mL
Methadone: 300 ng/mL
Methaqualone: 300 ng/mL
Opiates: 300 ng/mL
Phencyclidine: 25 ng/mL
Propoxyphene: 300 ng/mL

Control Set DAT Clinical controls 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, barbituates, benzodiazepines, cannabinoids, cocaine, methadone, methaqualone, opiates, phencyclidine, and propoxyphene. Drug concentrations are verified by gas chromatography/mass spectrometry (GC/MS). Target concentrations are established at $\pm 25\%$ of the assay cutoff.

Donors for the pools of human urine used in the preparation of this product all screened negative in annual serum testing for hepatitis B surface antigen (HBsAg), and for antibodies to HIV type 1, HIV type 2, and hepatitis C (anti-HCV), using FDA accepted test methods.

J. Substantial Equivalence Information:

1. Predicate device name:
 Preciset DAT Plus I Calibrators
 Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrators
 Control Set DAT I, Control Set DAT II, Control Set DAT III
2. Predicate 510(k) number(s):
 k031775; k033306; k080183
3. Comparison with predicate:

| New Device (Calibrator) | | Predicate Device | | |
|-------------------------|--|--|---|---|
| Item | C.f.a.s. DAT Qualitative Plus Clinical calibrator | Preciset DAT Plus I Calibrators | Preciset DAT Plus II | C.f.a.s DAT Qualitative Plus Calibrators |
| Intended Use | Same | Intended for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers. | Intended for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers. | Designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers. |
| Analytes | Amphetamines Barbituates Benzodiazepines Cannabinoids Cocaine Methadone Methaqualone Opiates Phencyclidine Propoxyphene | Amphetamines Barbituates Benzodiazepines Cannabinoids Cocaine Methadone Opiates Phencyclidine Propoxyphene | Benzodiazepines Opiates | Barbituates Benzodiazepines Cocaine Methadone Opiates Phencyclidine Propoxyphene |
| Form | Same | Liquid | Liquid | Liquid |
| Traceability | Same | GC/MS | GC/MS | GC/MS |

| | | | | |
|------------------|------|-------------------|-------------------|-------------------|
| Matrix | Same | Human urine based | Human urine based | Human urine based |
| Number of Levels | 1 | Up to 6 | Up to 6 | 1 |

| New Device (Control) | | Predicate Device |
|----------------------|--------------------------|---|
| Item | Control Set DAT Clinical | Control Set DAT I, Control Set DAT II, Control Set DAT III |
| Intended Use | Same | For use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers. |
| Analytes | Same | Amphetamines (<i>d</i> -methamphetamine) Barbituates (secobarbital) Benzodiazepines (nordiazepam) Cannabinoids (Δ^9 THC-COOH) Cocaine (benzoylecgonine) Methadone (<i>dl</i> -methadone) Methaqualone (methaqualone) Opiates (<i>d</i> -morphine) PCP (phencyclidine) Propoxyphene (propoxyphene) |
| Form | Same | Liquid |
| Traceability | Same | GC/MS |
| Matrix | Same | Human urine based |
| Number of Levels | 1 | 2 |

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

Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission

Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material

Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic

Calibrators; Final

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):

Drug concentrations in C.f.a.s. DAT Qualitative Plus Clinical calibrator were verified by gas chromatography/mass spectrometry (GC/MS).

C.f.a.s. DAT Qualitative Plus Clinical calibrator is traceable to a primary reference method (GC/MS).

Drug concentrations in Control Set DAT Clinical were verified by gas chromatography/mass spectrometry (GC/MS). Target concentrations are established at $\pm 25\%$ of the assay cutoff.

Control Set DAT Clinical controls is traceable to a primary reference method (GC/MS).

The protocols for establishing shelf-life and open-vial stability were reviewed and adequate.

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):*
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.