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Preciset DAT Plus I

cobas®

REF 03304671 190

6 × 5 mL Calibrator (Bottles 1-6)

English

System information

For use on Roche/Hitachi analyzers and **cobas c** analyzers the calibrator codes are 431-436 (1-6).

For use on COBAS INTEGRA analyzers, refer to the Calibration section of the appropriate method sheet.

Intended 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.

Summary

The Preciset DAT Plus I kit consists of 6 ready-for-use calibrators prepared by the quantitative addition of drug or drug metabolite to drug-free human urine.

The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

Reagents – working solutions

Reactive components:

Human urine with chemical additives (drugs or drug metabolites) as specified below.

Drug concentrations in Preciset DAT Plus I calibrators were verified by gas chromatography/mass spectrometry (GC/MS).

The target concentrations of the drugs or drug metabolites are as follows:

Drug	1 ng/mL	2 ng/mL	3 ng/mL	4 ng/mL	5 ng/mL	6 ng/mL
Amphetamines (<i>d</i> -methamphetamine)	0	250	500	1000	3000	5000
Barbiturates (secobarbital)	0	100	200	400	-	-
Benzodiazepines (nordiazepam)	0	150	300	600	1000	3000
Cannabinoids (Δ^9 THC-COOH)	0	20	50	100	200	300
Cocaine (benzoylecgonine)	0	75	150	300	1000	5000
Methadone (<i>d,l</i> -methadone)	0	150	300	600	2000	-
Methaqualone (methaqualone)	0	150	300	600	-	-
Opiates (<i>d</i> -morphine)	0	600	1000	2000	4000	8000
PCP (phencyclidine)	0	12.5	25.0	50.0	-	-
PPX (propoxyphene)	0	150	300	600	-	-

Non-reactive components:

Preservative and stabilizer

Preciset DAT Plus I calibrators are traceable to a primary reference method (GC/MS).

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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). Specimens containing human-sourced materials should be handled as if potentially infectious using safe laboratory procedures such as those outlined in Biosafety in Microbiological and Biomedical Laboratories (HHS Publication Number [CDC] 93-8395). In the event of exposure the directives of the responsible health authorities should be followed.^{1,2}

Handling

The product is ready-for-use. Prior to use swirl bottle carefully to obtain a homogenous solution. Record the date that the bottle was opened on the relevant bottle label.

Storage and stability

Store at 2-8 °C. **Do not freeze.**

Stability:

Unopened: Up to the stated expiration date at 2-8 °C.

After opening: 60 days or until the printed expiration date, whichever comes first, at 2-8 °C.

As the volume in each bottle nears depletion, the potential exists for a decrease in cannabinoids concentration.

If turbidity or precipitation develops, the product should be examined for microbial contamination. Discard the bottle if contaminated.

Materials provided

- See "Reagents – working solutions" section

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Cannabinoids and their derivatives may adsorb onto plastics.³ To minimize the potential for lowering the drug concentration of the calibrators, avoid the use of plastic pipettes and/or tips.

Using a glass pipette, dispense at least 500 µL of each level of Preciset DAT Plus I calibrators into an instrument sample cup. Assay as directed in the appropriate method sheet for the Roche assay for drugs of abuse.

Note: For **cobas c** 501/502 analyzers, an additional electronic method sheet may be available in some countries.

References

- Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.
- Decker WJ. Laboratory support of drug abuse control programs: An overview. Clinical Toxicology 1977; 10(1):28.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see <https://usdiagnostics.roche.com> for definition of symbols used):

CONTENT

Contents of kit

CALIBRATOR

Calibrator



Volume after reconstitution or mixing

GTIN

Global Trade Item Number



Preciset DAT Plus I

**FOR US CUSTOMERS ONLY: LIMITED WARRANTY**

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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