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C.f.a.s. DAT Qual Plus Clinical

cobas®

C.f.a.s. DAT Qualitative Plus Clinical

REF **04590856** 190 3 x 5 mL Calibrator

English

System information

For use on Roche/Hitachi analyzers and **cobas c** analyzers the calibrator code is 699.

For use on COBAS INTEGRA analyzers the system ID is 07 6880 4.

Intended 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 as listed above in System information.

Summary

C.f.a.s. DAT Qualitative Plus Clinical calibrator is a ready-for-use calibrator 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.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

Reactive components:

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

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

Drug	Target Concentration (ng/mL)
Amphetamines (*d*-methamphetamine)	500
Barbiturates (secobarbital)	200
Benzodiazepines (nordiazepam)	100
Cannabinoids (Δ^9 THC-COOH)	50
Cocaine (benzoylecgonine)	300
Methadone (*d,l*-methadone)	300
Methaqualone (methaqualone)	300
Opiates (*d*-morphine)	300
PCP (phencyclidine)	25
PPX (propoxyphene)	300

Non-reactive components:

Preservative and stabilizer

C.f.a.s. DAT Qualitative Plus Clinical calibrator is 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.

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:	90 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 calibrator, avoid the use of plastic pipettes and/or tips.

Using a glass pipette, dispense at least 500 µL of C.f.a.s. DAT Qualitative Plus Clinical calibrator into an instrument sample cup. Assay as directed in the appropriate method sheet for the Roche assay for drugs of abuse.

References

1 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

2 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.

3 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.

CONTENT	Contents of kit
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing

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.

Significant additions or changes are indicated by a change bar in the margin.

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