



05993571001V7.0

LSD Calibration/Control Pack

cobas®

Abuscreen OnLine Calibrator/Control

REF 20766356 122

1 × 5 mL Calibrator

2 × 4 mL Negative Control

2 × 4 mL Positive Control

English

System information

For use on Roche/Hitachi **cobas c** analyzers the calibrator code is 640.

For use on COBAS INTEGRA analyzers the system-ID for the calibrator is 07 3565 5. The system-ID is 07 6533 3 for the Negative Control and 07 6534 1 for the Positive Control.

Intended use

The Abuscreen OnLine LSD Calibration/Control Pack is designed for calibration and quality control of the Roche assays for LSD (lysergic acid diethylamide) in human urine on automated clinical chemistry analyzers.

Summary

The Abuscreen OnLine LSD Calibration/Control Pack consist of a ready-for-use calibrator and 2 ready-for-use controls prepared by the quantitative addition of drug to drug-free human urine.

The concentration of the calibrator component has 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 added LSD (as tartrate) as specified below.

Drug concentrations in Abuscreen OnLine LSD calibrator and controls were verified by Gas Chromatography or Liquid Chromatography coupled with Mass Spectrometry or Tandem Mass Spectrometry (GC/MS, GC/MS/MS, LC/MS, or LC/MS/MS)

Drug:	Negative Control (ng/mL)	Calibrator (ng/mL)	Positive Control (ng/mL)
LSD	0.25	0.5	1

Non-reactive components

Preservatives

Traceability information is given in the relevant Method Sheets for the system reagents.

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: For prescription use only.

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

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

The calibrator and controls are supplied in protective bottles to prevent photodegradation, since LSD is a light-sensitive substance. Assay performance is unaffected under standard lighting conditions.

Materials provided

See "Reagents – working solutions" section.

Materials required (but not provided)

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

Assay

Calibrator: Dispense the required volume into an instrument sample cup. Assay as directed in the appropriate assay Method Sheet.

Controls: Dispense the required volume of each level into a sample cup. Use the controls as specified in the appropriate assay Method Sheet. Control intervals must be adapted to individual laboratory's requirements.

Follow the applicable government regulations and local guidelines for quality control.

The calibrator/controls are supplied as a matched set and must not be interchanged with vials from different kit lots.

Results

Laboratory values obtained should fall within these established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

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.

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:

	Contents of kit
	Calibrator
	Volume after reconstitution or mixing
	Global Trade Item Number

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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