

DRI® Ecstasy Calibrators and Controls

Thermo
SCIENTIFIC

IVD For In Vitro Diagnostic Use

Rx Only

REF 1664 DRI Negative Calibrator (10 mL)
1388 DRI Negative Calibrator (25 mL)
100082 DRI Ecstasy 250 ng/mL Calibrator (10 mL)
100081 DRI Ecstasy 500 ng/mL Calibrator (10 mL)
100080 DRI Ecstasy 750 ng/mL Calibrator (10 mL)
100079 DRI Ecstasy 1000 ng/mL Calibrator (10 mL)
100202 MGC Select DAU Control Set

Intended Use

The DRI® Ecstasy Calibrators are intended for the calibration of the DRI Ecstasy Enzyme Immunoassay. The DRI Ecstasy Controls are unassayed controls intended for the validation of DRI Ecstasy Enzyme Immunoassay calibrations. These calibrators and controls are for in vitro diagnostic use only for the detection of Ecstasy drugs in human urine.

Description

The DRI Ecstasy Calibrators and Controls are human urine-based and ready-to-use. They are prepared by spiking negative urine matrix with known quantities of 3,4-methylenedioxymethamphetamine (MDMA). The DRI Ecstasy 500 ng/mL Calibrator is used as a qualitative cutoff. When a rough estimate of drug concentration is required, a calibration curve can be established with all calibrators (negative, 250 ng/mL, 500 ng/mL, 750 ng/mL and 1000 ng/mL).

Precautions and Warnings

The DRI Ecstasy Calibrators and Controls are for in vitro diagnostic use only. They are harmful if swallowed.

DANGER: DRI Ecstasy Calibrators and Controls contain ≤0.3% bovine serum albumin (BSA).

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

The calibrators and controls contain ≤0.09% sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.

The calibrators and controls are prepared from non-sterile human urine. **Handle the calibrators and controls as if they were potentially infectious.**

Do not use the calibrators or controls beyond their expiration dates.

Storage and Stability

Store calibrators and controls at 2-8°C when not in use.

Calibrators and Control Preparation

The DRI Ecstasy Urine Calibrators and Controls are ready-to-use.

Procedure

For procedural instructions, refer to the instrument-specific application sheet for the DRI Ecstasy Enzyme Immunoassay.

Results

The DRI Ecstasy 500 ng/mL Calibrator is used as a Cutoff reference for distinguishing “positive” from “negative” samples. A sample, which gives a change in absorbance (ΔA) value equal to greater than that obtained with the cutoff calibrator, is considered positive. A sample, which gives a change in absorbance (ΔA) value lower than that obtained with the cutoff calibrator, is considered negative. The controls should be within the range established by each laboratory.

Limitations

The DRI Ecstasy Calibrators and Controls are designed for use in the DRI Ecstasy Enzyme Immunoassay for the detection of Ecstasy drugs in human urine.

Quality Control

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Glossary:

<http://www.thermofisher.com/symbols-glossary>



Microgenics Corporation
46500 Kato Road
Fremont, CA 94538 USA
US Customer and
Technical Support:
1-800-232-3342



EC REP

B-R-A-H-M-S GmbH
Neuendorfstrasse 25
16761 Hennigsdorf, Germany



For insert updates go to:
www.thermoscientific.com/diagnostics

Other countries:
Please contact your local representative.

10006029-6-EN
2017 08