DRI® Ethyl Glucuronide Calibrators and Controls

Intended Use
The DRI® Ethyl Glucuronide Calibrators are used to calibrate the DRI Ethyl Glucuronide Assay in human urine. The DRI Ethyl Glucuronide Controls are used to validate the DRI Ethyl Glucuronide Assay calibration.

Description of DRI Ethyl Glucuronide Calibrators and Controls
The DRI Ethyl Glucuronide Calibrators and Controls are liquid ready-to-use. They are prepared by spiking negative human urine matrix with known quantities of Ethyl Glucuronide. The DRI Ethyl Glucuronide 500 ng/mL and 1000 ng/mL Calibrators can be used as a qualitative cutoff references for distinguishing “positive” from “negative” samples. A rough estimate of drug concentration in the samples can be obtained by running a standard curve using all calibrators and by quantitating samples off the standard curve.

The controls are sold separately. Each laboratory should establish its own acceptable control ranges.

Storage
The calibrators and controls should be stored refrigerated at 2 to 8°C when not in use. They are stable until the expiration date indicated on the box label.

Intended Use
The DRI® Ethyl Glucuronide Assay is for in vitro diagnostic use only. They are intended for use in the detection of Ethyl Glucuronide in human urine. The DRI Ethyl Glucuronide Assay is a competitive immunoassay.

Calibrators and Controls Preparation
The DRI Ethyl Glucuronide Calibrators and Controls are liquid ready-to-use.

Assay Procedure
For instructions, refer to the instrument specific application sheets for the DRI Ethyl Glucuronide Immunoassay.

Results and Expected Values
Qualitative
The 500 ng/mL and 1000 ng/mL Calibrators can be used as a cutoff reference for distinguishing “positive” from “negative” samples. A sample that exhibits a change in absorbance value (ΔA) equal to or greater than that obtained with cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value (ΔA) lower than that obtained with the cutoff calibrator is considered negative. The controls should be used in parallel to validate the assay. The results of the controls should be within the range established by each laboratory.

Semi-quantitative
A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and by quantitating samples off the standard curve. When the sample concentration is greater than the highest calibrator, the sample can be diluted with the Negative Calibrator and retested.

Limitations
The DRI Ethyl Glucuronide Calibrators and Controls are designed for use with the DRI Ethyl Glucuronide Assay for the detection of Ethyl Glucuronide in human urine.

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

Bibliography
DRI Ethyl Glucuronide Assay Package Insert.

Microgenics Corporation
48500 Kato Road
Fremont, CA 94538 USA
US Customer and Technical Support:
1-800-232-3342

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

Other countries:
Please contact your Thermo Fisher Scientific representative.

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