

DRI® Ethyl Glucuronide Calibrators and Controls

Thermo
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IVD For In Vitro Diagnostic Use

REF 10011207 DRI Ethyl Glucuronide Negative Calibrator (25 mL)
10011208 DRI Ethyl Glucuronide Calibrator 100 ng/mL (10 mL)
10011210 DRI Ethyl Glucuronide Calibrator 500 ng/mL (10 mL)
10011212 DRI Ethyl Glucuronide Calibrator 1000 ng/mL (10 mL)
10011213 DRI Ethyl Glucuronide Calibrator 2000 ng/mL (10 mL)

10012135 DRI Ethyl Glucuronide 375 ng/mL Control (25 mL)
10012136 DRI Ethyl Glucuronide 625 ng/mL Control (25 mL)
10012137 DRI Ethyl Glucuronide 750 ng/mL Control (25 mL)
10012138 DRI Ethyl Glucuronide 1250 ng/mL Control (25 mL)

**CAUTION: FOR EXPORT USE ONLY.
NOT FOR SALE IN THE UNITED STATES.**

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 and 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.

Precautions and Warning

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

DANGER: DRI Ethyl Glucuronide contains ≤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 printed on their respective labels.

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.

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
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