

# DRI® Ethyl Alcohol Calibrators and Controls

**Thermo**  
SCIENTIFIC

**IVD** For In Vitro Diagnostic Use

## Rx Only

<b>REF</b>	0311 Ethyl Alcohol Negative Calibrator (1 x 5 mL)
	1405 Ethyl Alcohol Negative Calibrator (1 x 25 mL)
	0241 Ethyl Alcohol 100 mg/dL Calibrator (1 x 5 mL)
	1406 Ethyl Alcohol 100 mg/dL Calibrator (1 x 25 mL)
	0239 Ethyl Alcohol 50 mg/dL Control (1 x 5 mL)
	0243 Ethyl Alcohol 300 mg/dL Control (1 x 5 mL)

## Intended Use

The DRI® Ethyl Alcohol Calibrators and Controls are intended for in-vitro diagnostic use for the calibration and validation of the Ethyl Alcohol Assay, which is used for the quantitative determination of ethyl alcohol in human urine, serum or plasma.

## Description of the DRI Ethyl Alcohol Calibrators and Controls

The alcohol calibrators and controls are ready-to-use solutions. The alcohol negative calibrator consists of Tris buffer with sodium azide as a preservative. The 50 mg/dL, 100 mg/dL and 300 mg/dL calibrators and/or controls are prepared by spiking the alcohol negative calibrator with a known quantity of ethyl alcohol. The negative and 100 mg/dL calibrators are used to calibrate the assay. The 50 mg/dL and 300 mg/dL alcohol controls are used to validate the assay performance. The negative calibrator can also be used for dilution of samples with alcohol concentrations greater than 600 mg/dL.

## Precautions and Warnings

**WARNING:** Reagents used in the assay components 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.

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

The bottles containing the calibrators and controls should be tightly capped and refrigerated when not in use to prevent evaporation.

## Calibrators and Controls Preparation and Storage

The Calibrators and Controls are ready to use. No further preparation is required. The calibrators and controls should be stored tightly capped and refrigerated at 2-8°C when not in use.

## Assay Procedure

For details on procedures, refer to the DRI Ethyl Alcohol Assay package insert and respective instrument parameters.

## Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Each laboratory must establish its own acceptable ranges. If results fall outside of the established range, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

## Results and Expected Values

Both the negative and 100 mg/dL calibrators are used for assay calibration.

The alcohol concentration of the sample can be determined using a two point linear calibration curve established with the negative and 100 mg/dL calibrators.

## Limitations

These Calibrators and Controls are designed for use with the DRI Ethyl Alcohol Assay for the quantitation of ethyl alcohol in human urine, serum and plasma only.

## 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](http://www.thermoscientific.com/diagnostics)

## Other countries:

Please contact your local representative.

0320-11-EN  
2017 08