DRI® Serum Tox Calibrators

thermo scientific

IVD **For in vitro diagnostic use**

Rx Only

REF 0962 Serum Tox Negative Calibrator (10 mL)
0963 Serum Tox Calibrator 1 (5 mL)
0965 Serum Tox Calibrator 2 (5 mL)
0967 Serum Tox Calibrator 3 (5 mL)
0976 Serum Tox Calibrator 4 (5 mL)

Intended Use
The DRI® Serum Tox Calibrators are intended for the qualitative or semiquantitative calibration of DRI Serum Tox Barbiturate, Benzodiazepine and Tricyclics Assays in human serum and plasma.

Description of the Calibrators
The DRI Serum Tox Calibrators are liquid and ready-to-use. They are prepared by spiking Tris buffer with known quantities of Secobarbital, Diazepem and Nortryptyline. The concentration of each analyte is determined by GC/MS or HPLC and further validated with an enzyme immunoassay against commercially available calibrators.

Drug Concentrations in the DRI Serum Tox Calibrators

Table 1. Drug Concentrations in Serum Tox Calibrators
Concentration (ng/mL)

	Secobarbital	Diazepam	Nortriptyline
Negative	0	0	0
Calibrator 1	500	25	150
Calibrator 2	1000	50	300
Calibrator 3	3000	100	500
Calibrator 4	6000	200	1000

⚠ Precautions and Warnings
The DRI Serum Tox Calibrators are harmful if swallowed.

DANGER: DRI Serum Tox Calibrators contain ≤0.1% 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 contain 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 beyond their expiration dates printed on their respective labels.

Preparation and Storage
The DRI Serum Tox Calibrators are ready-to-use. No further preparation is required. Calibrators, when stored refrigerated at 2-8° when not in use, are stable until the expiration date indicated on the label.

Assay Procedure
Refer to the individual instrument parameter sheets and package inserts for the respective DRI Serum Tox Assay.

Results and Expected Values
Qualitative Results
DRI Serum Tox Calibrators are designed for use with each respective Serum Tox Assay to detect the presence of a drug analyte. Calibrator 2 is intended to be used as a qualitative cutoff calibrator. A sample that exhibits a change of absorbance value (ΔA) equal to or greater than the rate obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value (ΔA) lower than the rate obtained with the cutoff calibrator is considered negative. The controls should be used in parallel to validate the assay. Commercial controls are available for use with these assays. The results of the controls should be within the ranges as established by each laboratory.

Semi-Quantitative Results
A rough estimate of drug concentration can be obtained by running a standard curve with all calibrators and estimating the concentration from the standard curve. When the sample concentration is greater than the highest calibrator, it may be diluted with Negative Calibrator and retested.

Limitations
The DRI Serum Tox Calibrators are designed for use in enzyme immunoassays for detection of barbiturates, benzodiazepines and tricyclic antidepressants in human serum and plasma only.

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

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For insert updates go to:
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Other countries:
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