DRI® Multi-Drug Calibrators

thermo scientific

IVD **For In Vitro Diagnostic Use**

Rx Only

REF

1588 Calibrator 1 (10 mL)
1589 Calibrator 1 (25 mL)
1591 Calibrator 2 (10 mL)
1592 Calibrator 2 (25 mL)
1594 Calibrator 3 (10 mL)
1595 Calibrator 3 (25 mL)
1597 Calibrator 4 (10 mL)
1598 Calibrator 4 (25 mL)
1664 Negative Calibrator (10 mL)
1388 Negative Calibrator (25 mL)

Intended Use

The DRI® Multi-Drug Calibrators are intended for the calibration and validation of drugs of abuse enzyme immunoassays for the detection of amphetamines, barbiturates, benzodiazepines, cocaine metabolites, methadone, methaqualone, morphine, phencyclidine and propoxyphene in human urine.

Description of the Multi-Drug Calibrators

The DRI Multi-Drug Calibrators are human urine-based and ready-to-use. They are prepared by spiking negative urine with known quantities of d-methamphetamine, secobarbital, oxazepam, benzoylecgonine, methadone, methaqualone, morphine, phencyclidine and propoxyphene. Calibrator 2 is used as a qualitative cutoff reference for distinguishing from "positive" and "negative" samples. When a rough estimate of drug concentration is required, a calibration curve can be established with the Negative Calibrator and Calibrators 1-4. The concentrations for each drug in these calibrators are outlined in Table 1.

Table 1. Drug Concentrations in Calibrators

	Concentration (ng/mL)			
Drug Analyte	**Cal. 1**	**Cal. 2**	**Cal. 3**	**Cal. 4**
Methamphetamine	500	1,000	1,500	2,000
Secobarbital	100	200	500	1,000
Oxazepam	100	200	500	1,000
Benzoylecgonine	150	300	500	1,000
Methadone	150	300	500	1,000
Methaqualone	150	300	500	1,000
Morphine	1,000	2,000	4,000	6,000
Phencyclidine	12.5	25	50	100
Propoxyphene	150	300	500	1,000

⚠ Precautions and Warning

The Multi-Drug Calibrators are for in vitro diagnostic use only. They are harmful if swallowed.

DANGER: DRI Multi-Drug Calibrator 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 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 are prepared from non-sterile human urine. The human urine used in the preparation of calibrators were tested by an FDA approved method and found to be non-reactive for hepatitis B surface antigen and HIV antibody. **Because no test method can offer complete assurance that it will not transmit any infectious agents, it is recommended that the urine calibrators be handled as potentially infectious.**

Do not use the calibrators beyond their expiration dates.

Calibrator Preparation and Storage

The DRI Multi-Drug Calibrator are ready-to-use. Store refrigerated at 2-8°C.

Assay Procedure

Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Results

The Calibrator 2 is used as a reference for distinguishing "positive" from "negative" samples. A sample that gives a change in absorbance (ΔA) value equal to or greater than that obtained with the Calibrator 2 is considered positive. A sample that gives a change in absorbance (ΔA) value lower than that obtained with the Calibrator 2 is considered negative. Controls should be used in parallel to validate assay performance. The result of the controls should be within the range established by each laboratory.

When a rough estimate of the drug concentration is required, a calibration curve can be established with the Negative Calibrator and Calibrators 1-4. The drug concentration of unknown sample can be obtained by quantisation off the calibration curve. When the sample concentration is greater than the highest calibrator, it may be diluted and retested.

Quality Control

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

Limitations

The Multi-Drug Calibrators are designed for use in enzyme immunoassays for the detection of drugs of abuse in human urine only.

Glossary:

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

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Other countries:
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