LZI Multi-Analyte Set B Urine Drug of Abuse Calibrators

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Lin-Zhi International, Inc.

REF	Description	Quantity
0001	Negative Calibrator	1 x 5 mL
0832	Multi-Analyte Set B Urine Low Calibrator	1 x 15 mL
0833	Multi-Analyte Set B Urine Cutoff Calibrator	1 x 15 mL
0834	Multi-Analyte Set B Urine Intermediate Calibrator	1 x 15 mL
0835	Multi-Analyte Set B Urine High Calibrator	1 x 15 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Multi-Analyte Set B Urine Drug of Abuse Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of drugs of abuse enzyme immunoassays for the detection of ecstasy, morphine, oxazepam, and secobarbital in human urine on a number of automated clinical chemistry analyzers.

Description of the Calibrators:

The LZI Multi-Analyte Set B Urine Drug of Abuse Calibrators are human urine-based liquids, and ready to use. The Negative Calibrator is a processed drug-free human urine matrix containing buffers, stabilizers, and less than 0.1 % of sodium azide. The calibrators are prepared by spiking four stock solutions with known concentrations of analyte into the Negative Calibrator. Calibrators are made from NIST traceable standards. The calibrators contain targeted concentrations* of analyte as follows:

Drug Compound	Low Calibrator (ng/mL)	Cutoff Calibrator (ng/mL)	Intermediate Calibrator (ng/mL)	High Calibrator (ng/mL)
MDMA	250	500	750	1000
Morphine	1000	2000	4000	6000
Oxazepam	100	200	500	1000
Secobarbital	100	200	500	1000

*****Actual concentrations of these calibrators are within ±10 % of the target value as determined by GC/MS or LC/MS. Values are provided only as guidelines and laboratories should determine the ranges based on their own test system and tolerance (2).

Precautions and Warning

- *The LZI Multi Set B Urine Drug of Abuse Calibrators are for in vitro diagnostic use only. Harmful if swallowed.*
- *The calibrators contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azide. When disposing such liquids always flush with a large volume of water to prevent azide build-up.*
- *The calibrators are prepared from non-sterile human urine. They are not tested by licensed reagents for the presence of antibodies to human immunodeficiency viruses, the hepatitis antigens, and/or anti- hepatitis antibodies. They should be handled as potentially infectious. Always apply good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the calibrators beyond their expiration dates.*

Preparation and Storage

The calibrators are provided ready-to-use. No reconstitution is required. Label the cap before removal to identify it with the original bottle. The calibrators should be stored refrigerated at 2-8ºC when not in use. No performance study has been evaluated for storage conditions neither under freezing nor exposure to temperature above 32ºC (90ºF).

Stability

When stored refrigerated at 2-8ºC, the calibrators are stable either opened-recapped or unopened until the expiration date printed on the vial label. Store calibrators tightly capped when not in use. Calibrator solution dispensed in the sample cups and left on board of the clinical analyzer should be discarded after use.

Procedure

Always refer to the analyzer-specific application sheets before performing the assay. These sheets may contain additional instructions for use and assay specific parameters.

Results

A positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Each respective cutoff calibrator is used as a reference for distinguishing positive from negative samples.

Qualitative: A sample with a change in absorbance (ΔmA/min) equal to or greater than that obtained with the cutoff calibrator is considered positive. A sample with a change in absorbance (ΔmA/min) lower than that obtained with the cutoff calibrator is considered negative. Controls should be run to validate assay performance.

Semi-Quantitative: The semi-quantitative mode is for purposes of (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC/MS, LC/MS or (2) permitting laboratories to establish quality control procedures. When an approximation of concentration is required, a calibration curve can be established with 5 calibrators. The concentration of each respective analyte in the sample may then be estimated from the calibration curve.

Limitations

The LZI Multi-Analyte Set B Urine Drug of Abuse Calibrators are for use with Enzyme Immunoassays to detect drugs of abuse in human urine only.

Bibliography

1. Urine testing for Drug of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
2. Guidance for Industry, Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators. U.S. Department of Health and Human Services. FDA, Document issued on February 22, 1999.

Notice: Adulteration of reagents, use of instruments without appropriate capabilities, or other failure to follow instructions as set forth in this labeling can affect performance characteristics, and stated or implied label claims.

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