LZI Multi-Analyte Set D Urine Drug of Abuse Controls

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Lin-Zhi International, Inc.

REF		Description	Quantity
0877	CONTROL -	Multi-Analyte Set D Urine Level 1 Control	1 x 15 mL
0878	CONTROL +	Multi-Analyte Set D Urine Level 2 Control	1 x 15 mL

Intended Use

The Lin –Zhi International, Inc. (LZI) Multi-Analyte Set D Controls are for use as controls in the qualitative and semi-quantitative calibration of drugs of abuse enzyme immunoassays for the detection of cocaine metabolite, *d*-methamphetamine, morphine, oxazepam, and oxycodone in human urine on a number of automated clinical chemistry analyzers (1-5).

Description of the Controls

The LZI Multi-Analyte Urine Set D Controls are human urine-based liquids and ready-to-use. The constituent is a processed drug-free human urine matrix containing buffers, stabilizers, and less than 0.1 % of sodium azide. The controls are prepared by spiking five stock solutions with known concentrations of analyte into the drug-free matrix. The controls contain targeted concentrations* of analyte as follows:

Drug Compound	Level 1 Control (ng/mL)	Level 2 Control (ng/mL)
Benzoylecgonine	225	375
d-Methamphetamine	750	1250
Morphine	225	375
Oxazepam	150	250
Oxycodone	75	125

*****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 (6).

Precautions and Warning

- *The LZI Multi-Analyte Set D Controls are for in vitro diagnostic use only. Harmful if swallowed.*
- *The controls 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 (7).*
- *The controls 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 controls beyond their expiration dates.*
- Rx ONLY *For USA: Cautions: Federal law restricts this device to sale by or on the order of a physician.*

Preparation and Storage

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

Stability

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

Calibration and Quality Control

Both the LZI Multi-Analyte Set D Level 1 Control and Level 2 Control should be run daily to ensure proper assay performance**.** Additionally, run the controls with each new calibration and after specific maintenance or troubleshooting procedures are performed.

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 verification 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 five calibrators. The concentration of each respective analyte in the sample may then be estimated from the calibration curve.

Limitations

The LZI Multi-Analyte Set D Controls are for use with Enzyme Immunoassays to detect drugs of abuse in human urine only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Bibliography

1. LZI Amphetamines (AMP) Enzyme Immunoassay (Ref# 0040/0041) package insert.
2. LZI Benzodiazepines (BZO) Enzyme Immunoassay (Ref# 0130/0131) package insert.
3. LZI Cocaine Metabolite (COC) Enzyme Immunoassay (Ref# 0030/0031) package insert.
4. LZI Opiate (OPIb) Enzyme Immunoassay (Ref# 0020b/0021b) package insert.
5. LZI Oxycodone (OXYb) Enzyme Immunoassay (Ref# 0240b/0241b) package insert.
6. Guidance for Industry and FDA Staff, Assayed and Unassayed Quality Control Material. U.S. Department of Health and Human Services. FDA, Document issued on June 7, 2007.
7. Sodium Azide. National Institute for Occupational Safety (NIOSH) Pocket Guide to Chemical Hazards Third Printing, September 2007. Available online at: https://www.cdc.gov/niosh/npg/default.html

Additions, deletions, or changes are indicated by a change bar in the margin.

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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