LZI Multi-Analyte Set F Urine Drug of Abuse Calibrators

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Lin-Zhi International, Inc.

REF	Description	Quantity
0911	Multi-Analyte Set F Urine Negative Calibrator	1 x 15 mL
0912	Multi-Analyte Set F Urine Low Calibrator	1 x 15 mL
0913	Multi-Analyte Set F Urine Cutoff Calibrator	1 x 15 mL
0914	Multi-Analyte Set F Urine Intermediate Calibrator	1 x 15 mL
0915	Multi-Analyte Set F Urine High Calibrator	1 x 15 mL

Intended Use

The LZI Multi-Analyte Set F Calibrators are for use as calibrators 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 Calibrators

The LZI Multi-Analyte Set F Calibrators are human urine-based liquids and ready-to-use. The Multi-Analyte Set F 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 five stock solutions with known concentrations of analyte into the Multi-Analyte Set F Negative Calibrator. 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)
Benzoylecgonine	150	300	1000	3000
d-Methamphetamine	500	1000	1500	2000
Morphine	150	300	600	1000
Oxazepam	100	200	500	1000
Oxycodone	100	300	500	800

*****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 F 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 (7).*
- *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.*
- Rx ONLY *For USA: Cautions: Federal law restricts this device to sale by or on the order of a physician.*

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 32 ºC (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 and Results

Always refer to the analyzer-specific application sheets before performing the assay. These sheets may contain additional instructions for use and assay specific parameters. For qualitative calibration, use the Multi-Analyte Set F cutoff calibrator. For semi-quantitative calibration, use all five calibrators. Recalibration should be performed after reagent bottle change, a change in calibrators or reagent lot, and after instrument maintenance is performed. For interpretation of results, refer to the appropriate LZI Enzyme Immunoassay package insert (1-5).

Limitations

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

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, Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators. U.S. Department of Health and Human Services. FDA, Document issued on February 22, 1999.
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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