LZI Norketamine Calibrators – EU Only

2-8°C

IVD For In Vitro Diagnostic Use Only

Lin-Zhi International, Inc.

REF	Description	Quantity
0001	Universal Negative Calibrator	1 x 5 mL
0662	LZI Norketamine Low Calibrator (25 ng/mL)	1 x 5 mL
0663	LZI Norketamine Cutoff #1 Calibrator (50 ng/mL)	1 x 5 mL
0664	LZI Norketamine Cutoff #2 Calibrator (100 ng/mL)	1 x 5 mL
0665	LZI Norketamine Intermediate #1 Calibrator (250 ng/mL)	1 x 5 mL
0666	LZI Norketamine High Calibrator (500 ng/mL)	1 x 5 mL

Intended Use

The LZI Norketamine Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Ketamine Enzyme Immunoassay (Ref# 0660/0661) on a number of automated clinical chemistry analyzers (1).

Description of the Calibrators

The LZI Norketamine 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 known concentrations of norketamine into the Negative Calibrator.

*****Actual concentrations of these calibrators are confirmed 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 (3).

Precautions and Warning

- *The LZI Norketamine 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 (4).*
- *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 use 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 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.

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 a clinical analyzer should be discarded after use.

Procedure and Results

For qualitative calibration, use Cutoff #1 Calibrator (50 ng/mL) as the 50 ng/mL cutoff calibrator and Cutoff #2 Calibrator (100 ng/mL) as the 100 ng/mL cutoff calibrator. For semi-quantitative calibration, use all six calibrators including the universal negative calibrator. 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 Ketamine Enzyme Immunoassay (Ref# 0660/0661) package insert (1).

Limitations

The LZI Norketamine Calibrators are for use with the LZI Ketamine Enzyme Immunoassay (Ref# 0660/0661) to detect norketamine in human urine only.

Symbols Used

EC REP	Authorized Representative	**COO**	Country of Origin	REF	Reference Number
	Biological Risks		Date of Manufacture	SDS	Safety Data Sheet
CALIBRATOR	Calibrator	GTIN	Global Trade Item Number		Temperature Limits
CE	CE Mark	IVD	In Vitro Diagnostic medical device		Use-by Date
	Consult Instructions for Use	LOT	Lot Number		
CONTENTS	Contents		Manufacturer		

Bibliography

1. LZI Ketamine Enzyme Immunoassay (Ref# 0660/0661) package insert.
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.
3. 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

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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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