LZI Norketamine Calibrators

IVD For In Vitro Diagnostic Use Only

For Beckman Coulter, Inc.

2-8°C

Lin-Zhi International, Inc.

For Sales Outside USA (OUS) Only

REF		Description	Quantity
C68804	CALIBRATOR	**LZI Norketamine Qualitative Calibrator**	
		NKET Cutoff Calibrator (50 ng/mL)	1 x 5 mL
C68803	CALIBRATOR	**LZI Norketamine Semi-Quantitative Calibrator Set**	
		NKET Low Calibrator (25 ng/mL)	1 x 5 mL
		NKET Cutoff Calibrator (50 ng/mL)	1 x 5 mL
		NKET Intermediate #1 Calibrator (100 ng/mL)	1 x 5 mL
		NKET Intermediate #2 Calibrator (250 ng/mL)	1 x 5 mL
		NKET High Calibrator (500 ng/mL)	1 x 5 mL

Intended Use

The LZI Norketamine Qualitative Calibrator and LZI Norketamine Semi-Quantitative Calibrator Set are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Ketamine Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68802) 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 LZI Universal Negative Calibrator (2) 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 LZI Universal 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 the 50 ng/mL as the 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 for Beckman Coulter, Inc. (Ref# C68802) package insert (1).

Limitations

The LZI Norketamine Calibrators are for use with the LZI Ketamine Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68802) 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		

Additional Information
Registered trademarks are the property of their respective owners.

Shipping Damage
Please notify your Beckman Coulter Clinical Support Center if this product is received damaged.

Bibliography

1. LZI Ketamine Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68802) package insert.
2. LZI Universal Negative Calibrator for Beckman Coulter, Inc. (Ref# C68807) package insert.
3. 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.
4. 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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