LZI Norketamine (100) Controls – EU Only

IVD For In Vitro Diagnostic Use Only

2-8°C

Lin-Zhi International, Inc.

REF		Description	Quantity
0677	CONTROL –	LZI Norketamine (100) Level 1 Control (75 ng/mL)	1 x 5 mL
0678	CONTROL +	LZI Norketamine (100) Level 2 Control (125 ng/mL)	1 x 5 mL

Intended Use

The LZI Norketamine (100) Controls are for use as assayed quality control materials to monitor the precision of the LZI Ketamine Enzyme Immunoassay (Ref# 0660/0661) at the 100 ng/mL cutoff on a number of automated clinical chemistry analyzers (1).

Description of the Controls

The LZI Norketamine (100) Controls 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 controls are prepared by spiking known concentrations of norketamine into the Negative Calibrator.

*****Actual concentrations of these controls 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 (2).

Precautions and Warning

- *The LZI Norketamine (100) 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 (3).*
- *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 use good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the controls beyond their expiration dates.*

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.

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. Controls solution dispensed in sample cups and left onboard a clinical analyzer should be discarded after use.

Procedure and Results

Both levels of controls (75 ng/mL and 125 ng/mL) 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. For interpretation of results, refer to the appropriate LZI Ketamine Enzyme Immunoassay (Ref# 0660/0661) package insert (1).

Limitations

The LZI Norketamine (100) Controls are for use with the LZI Ketamine Enzyme Immunoassay (Ref# 0660/0661) to detect norketamine in human urine only at the 100 ng/mL cutoff. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Symbols Used

EC REP	Authorized Representative	IVD	*In Vitro* Diagnostic medical device	SDS	Safety Data Sheet
	Biological Risks	LOT	Lot Number		Temperature Limits
CE	CE Mark		Manufacturer		Use-by Date
	Consult Instructions for Use	CONTROL –	Negative Control	REF	Reference Number
CONTENTS	Contents	CONTROL +	Positive Control		

Bibliography

1. LZI Ketamine (100) Enzyme Immunoassay (Ref# 0660/0661) package insert.
2. 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.
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.

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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