LZI Opiate Calibrators

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Lin-Zhi International, Inc.

REF	Description	Quantity
0001	Negative Calibrator	1 x 5 mL
0022	Opiate 150 ng/mL Low Calibrator	1 x 5 mL
0023	Opiate 300 ng/mL Cutoff Calibrator	1 x 5 mL
0024	Opiate 600 ng/mL Intermediate Calibrator	1 x 5 mL
0025	Opiate 1000 ng/mL High Calibrator	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Opiate Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Opiate Enzyme Immunoassay (Ref# 0020b/0021b) on a number of automated clinical chemistry analyzers.

Description of the Calibrators:

The LZI Opiate 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 morphine 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 (2).

Precautions and Warning

- *The LZI Opiate 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 of such liquids always flush with a large volume of water to prevent azide build-up.*
- *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, hepatitis antigens, and/or anti-hepatitis antibodies. They should be handled as potentially infectious. Always apply good laboratory practices to avoid any skin contact or ingestion.*
- *Do not use the calibrators beyond their expiration dates.*

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.

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 onboard the clinical analyzer should be discarded after use.

Procedure and Results

For qualitative calibration, use the 300 ng/mL as your cutoff calibrator. For semi-quantitative calibration, use all five calibrators. Recalibration should be performed after reagent bottle change or there is a change in calibrators or reagent lot, and after instrument maintenance is performed. For interpretation of results, refer to the appropriate LZI Opiate Enzyme Immunoassay (Ref# 0020b/0021b) package insert (3).

Limitations

The LZI Opiate Calibrators are for use with the Opiate Enzyme Immunoassay (Ref# 0020b/0021b) to detect opiates in human urine only.

Symbols Used

EC REP	Authorized Representative	CONTENTS	Contents	REF	Reference Number
	Biological Risks	GTIN	Global Trade Item Number	SDS	Safety Data Sheet
CALIBRATOR	Calibrator	IVD	*In Vitro* Diagnostic medical device	2°C 8°C	Temperature Limits
CE	CE Mark	LOT	Lot Number	T.K.	Test Kit Number
	Consult Instructions for Use		Manufacturer		Use-by Date

Bibliography

1. Urine testing for Drug of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
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. LZI Opiate Enzyme Immunoassay (Ref# 0020b/0021b) package insert.

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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