

LZI Methadone Calibrators



IVD For In Vitro Diagnostic Use Only



Lin-Zhi International, Inc.

REF	Description	Quantity
0001	LZI Universal Negative Calibrator	1 x 5 mL
0112	LZI Methadone Low Calibrator (150 ng/mL)	1 x 5 mL
0113	LZI Methadone Cutoff Calibrator (300 ng/mL)	1 x 5 mL
0114	LZI Methadone Intermediate Calibrator (600 ng/mL)	1 x 5 mL
0115	LZI Methadone High Calibrator (1000 ng/mL)	1 x 5 mL

Intended Use


The LZI Methadone Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Methadone and LZI Methadone II Enzyme Immunoassay (Ref# 0110/0111 and Ref# 0630/0631) on a number of automated clinical chemistry analyzers. (1, 2)

Description of the Calibrators

The LZI Methadone Calibrators are human urine-based liquid and ready-to-use. The LZI Universal 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 methadone 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 Methadone 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 apply good laboratory practice to avoid any skin contact or ingestion.
- Do not use the calibrators beyond their expiration dates.
-  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 2-8°C when not in use.

Stability

When stored refrigerated at 2-8°C, 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.







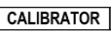







Procedure and Results

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 Methadone and LZI Methadone II Enzyme Immunoassay (Ref# 0110/0111 and Ref# 0630/0631) package inserts. (1, 2)

Limitations

The LZI Methadone Calibrators are for use with the LZI Methadone and LZI Methadone II Enzyme Immunoassay (Ref# 0110/0111 and Ref# 0630/0631) to detect methadone in human urine only. (1, 2)

Symbols Used

	Authorized Representative		Contents		Reference Number
	Biological Risks		Global Trade Item Number		Safety Data Sheet
	Calibrator		In Vitro Diagnostic medical device		Temperature Limits
	CE Mark		Lot Number	T.K.	Test Kit Number
	Consult Instructions for Use		Manufacturer		Use-by Date

Bibliography

1. LZI Methadone Enzyme Immunoassay (Ref# 0110/0111) package insert.
2. LZI Methadone II Enzyme Immunoassay (Ref# 0630/0631) 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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