LZI Norfentanyl Calibrators

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Lin-Zhi International, Inc.

REF	Description	Quantity
0313	LZI Norfentanyl Cutoff Calibrator (5 ng/mL)	1 x 5 mL

Intended Use

The LZI Norfentanyl Calibrator is for use as the calibrator in the qualitative calibration of the LZI Fentanyl and LZI Fentanyl II Enzyme Immunoassay (Ref# 0310/0311and Ref# 0570/0571) on a number of automated clinical chemistry analyzers (1, 2).

Description of the Calibrator

The LZI Norfentanyl Calibrator is a 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 calibrator is prepared by spiking a known concentration of norfentanyl 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 Norfentanyl Calibrator is for in vitro diagnostic use only. Harmful if swallowed.*
- *The calibrator contains 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 calibrator is 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 calibrator beyond their expiration dates.*
- Rx ONLY *For USA: Cautions: Federal law restricts this device to sale by or on the order of a physician.*

Preparation and Storage

The calibrator is ready-to-use. No reconstitution is required. Label the cap before removal to identify it with the original bottle. The calibrator should be stored refrigerated at 2-8ºC when not in use.

Stability

When stored refrigerated at 2-8ºC, the calibrator is stable either opened-recapped or unopened, until the expiration date printed on the vial label. Store calibrator 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 5 ng/mL as the cutoff calibrator. Recalibration should be performed after reagent bottle change, a change in calibrator or reagent lot, and after instrument maintenance is performed. For interpretation of results, refer to the appropriate LZI Fentanyl and LZI Fentanyl II Enzyme Immunoassay (Ref# 0310/0311 and Ref# 0570/0571) package insert. (1, 2)

Limitations

The LZI Norfentanyl Calibrator is for use with the LZI Fentanyl and LZI Fentanyl II Enzyme Immunoassay (Ref# 0310/0311 and Ref# 0570/0571) to detect norfentanyl in human urine only. (1, 2)

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. LZI Fentanyl Enzyme Immunoassay (Ref# 0310/0311) package insert.
2. LZI Fentanyl II Enzyme Immunoassay (Ref# 0570/0571) 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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