LZI Norfentanyl Calibrator

IVD For In Vitro Diagnostic Use Only

For Beckman Coulter, Inc.

2-8°C

Lin-Zhi International, Inc.

REF		Description	Quantity
C68815	CALIBRATOR	**LZI Norfentanyl (Q) Qualitative Calibrator**	
		NFEN Cutoff Calibrator (5 ng/mL)	1 x 5 mL

Intended Use

The LZI Norfentanyl (Q) Qualitative Calibrator is for use as the calibrator in the qualitative calibration of the LZI Fentanyl (Q) Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68808) on a number of automated clinical chemistry analyzers (1).

Description of the Calibrator

The LZI Norfentanyl (Q) Qualitative Calibrator is a human urine-based liquid 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 calibrator is prepared by spiking a known concentration of norfentanyl 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 Norfentanyl (Q) Qualitative 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 (Q) Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68808) package insert (1).

Limitations

The LZI Norfentanyl (Q) Qualitative Calibrator is for use with the LZI Fentanyl (Q) Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68808) to detect norfentanyl in human urine only.

Symbols Used

	Biological Risks		Date of Manufacture	Rx ONLY	Medical Prescription Only
CALIBRATOR	Calibrator	GTIN	Global Trade Item Number	REF	Reference Number
	Consult Instructions for Use	IVD	*In Vitro* Diagnostic medical device	SDS	Safety Data Sheet
CONTENTS	Contents	LOT	Lot Number		Temperature Limits
COO	Country of Origin		Manufacturer		Use-by Date

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 Fentanyl (Q) Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68808) 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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