

LZI Universal Negative Calibrator

For Beckman Coulter, Inc.



IVD For In Vitro Diagnostic Use Only



Lin-Zhi International, Inc.

REF	Description	Quantity
C68807	CALIBRATOR LZI Universal Negative Calibrator	1 x 5 mL

Intended Use

The LZI Universal Negative Calibrator is for use as the negative calibrator in the semi-quantitative calibration of a number of LZI Enzyme Immunoassays for Beckman Coulter, Inc. on a number of automated clinical chemistry analyzers.

Description of the Calibrators

The LZI Universal Negative 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.

Precautions and Warning

- The LZI Universal Negative Calibrator is 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 (1).
- 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 use good laboratory practice to avoid any skin contact or ingestion.
- Do not use the calibrators beyond their expiration dates.
- **Rx ONLY** For USA: Federal law restricts this device to sale by or on the order of a physician.

Preparation and Storage

The calibrators are 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 a clinical analyzer should be discarded after use.

Procedure and Results

Recalibration should be performed after reagent bottle change, a change in calibrators or reagent lot, and after instrument maintenance is performed. For interpretation of results, refer to the appropriate LZI Enzyme Immunoassay for Beckman Coulter, Inc. package insert.

Limitations

The LZI Universal Negative Calibrator is for use with a number of LZI Enzyme Immunoassays for Beckman Coulter, Inc.

Symbols Used

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

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. 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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