

LZI Ethyl Glucuronide Calibrators – EU Only

500 ng/mL Cutoff



IVD For In Vitro Diagnostic Use Only



Lin-Zhi International, Inc

REF	Description	Quantity
0001	Universal Negative Calibrator	1 x 5 mL
0542	LZI Ethyl Glucuronide 500 Low Calibrator (200 ng/mL)	1 x 5 mL
0543	LZI Ethyl Glucuronide 500 Cutoff Calibrator (500 ng/mL)	1 x 5 mL
0544	LZI Ethyl Glucuronide 500 Intermediate Calibrator (1000 ng/mL)	1 x 5 mL
0545	LZI Ethyl Glucuronide 500 High Calibrator (2000 ng/mL)	1 x 5 mL

Intended Use

The LZI Ethyl Glucuronide 500 Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Ethyl Glucuronide III Enzyme Immunoassay (Ref# 0530/0531) on a number of automated clinical chemistry analyzers (1).

Description of the Calibrators

The LZI Ethyl Glucuronide 500 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 Ethyl Glucuronide into the Negative Calibrator.

*Actual concentrations of these calibrators are determined 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 Ethyl Glucuronide 500 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 (3).
- 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.

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

For qualitative calibration, use the 500 ng/mL as the cutoff calibrator. For semi-quantitative calibration, use all five calibrators.

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 Ethyl Glucuronide III Enzyme Immunoassay (Ref# 0530/0531) package insert (1).

Limitations

The LZI Ethyl Glucuronide 500 Calibrators are for use with the LZI Ethyl Glucuronide III Enzyme Immunoassay (Ref# 0530/0531) to detect ethyl glucuronide in human urine only.

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

- LZI Ethyl Glucuronide III Enzyme Immunoassay (Ref# 0530/0531) package insert.
- 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.
- 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>

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

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.



Manufacturer:

Lin-Zhi International, Inc.
2945 Oakmead Village Court
Santa Clara, CA 95051
USA
Tel: (408) 970-8811
Fax: (408) 970-9030
www.lin-zhi.com



Authorized European Rep. within the EU:

CEpartner4U
Esdoornlaan 13
3951 DB Maarn
The Netherlands
www.cepartner4u.eu

© July 2021 Rev. 1

