

LZI Ethyl Alcohol Calibrators

IVD For In Vitro Diagnostic Use Only



Lin-Zhi International, Inc.

REF	Description	Quantity
0001	Universal Negative Calibrator	1 x 5 mL
0223	Ethyl Alcohol 100 mg/dL Calibrator	1 x 5 mL

Intended Use

The Lin-Zhi International (LZI) Ethyl Alcohol Calibrators are for use as calibrators in the quantitation of the LZI Ethyl Alcohol Enzymatic Assay (Ref# 0220/0221) on a number of automated clinical chemistry analyzers.

Description of the Calibrators:

The Ethyl Alcohol DAU 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 Alcohol into the Negative Calibrator. Calibrators are made from NIST traceable standards.

*Actual concentrations of these calibrators are within ± 10 % of the target value as 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 Alcohol 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.*
- *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.*

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. Do not freeze or expose the calibrators and controls to temperature above 32°C (90°F).

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

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 Ethyl Alcohol Enzymatic Assay (Ref# 0220/0221) package insert (3).

Limitations

The LZI Ethyl Alcohol Calibrators are for use with the Ethyl Alcohol Enzymatic Assay (Ref# 0220/0221) to detect ethyl alcohol concentration in human urine, serum, or plasma.

Bibliography

1. Urine testing for Drug of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
2. 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.
3. LZI Ethyl Alcohol Enzymatic Assay (Ref# 0220/0221) package insert.

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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