LZI Oral Fluid Ethyl Alcohol Calibrators





For Forensic Use Only

Lin-Zhi International, Inc.

REF	Description	Quantity
S0001	LZI Oral Fluid Negative Calibrator	1 x 5 mL
S0226	LZI Oral Fluid Ethyl Alcohol 25 mg/dL Calibrator/Control	1 x 5 mL
S0223	LZI Oral Fluid Ethyl Alcohol 50 mg/dL Calibrator	1 x 5 mL
S0227	LZI Oral Fluid Ethyl Alcohol 75 mg/dL Calibrator/Control	1 x 5 mL
S0228	LZI Oral Fluid Ethyl Alcohol 100 mg/dL Calibrator	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Ethyl Alcohol Calibrators are for use as calibrators in the quantitative calibration of the LZI Oral Fluid Ethyl Alcohol Enzymatic Assay (Ref# S0220/S0221) on a number of automated clinical chemistry analyzers (1). These calibrators are for Forensic Use Only and should not be repackaged for *in vitro* diagnostic use.

Description of the Calibrators:

The LZI Oral Fluid Ethyl Alcohol Calibrators are in a negative synthetic oral fluid matrix and ready-to-use. The LZI Oral Fluid Negative Calibrator is a drug-free synthetic oral fluid 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 LZI Oral Fluid Negative Calibrator.

Precautions and Warnings

- The LZI Oral Fluid Ethyl Alcohol Calibrators are for Forensic Use Only and should not be repackaged for in vitro diagnostic use.
- 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 (2).
- The calibrators are prepared from a non-sterile synthetic oral fluid matrix. Always apply good laboratory practices 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 and 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 the 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 Oral Fluid Ethyl Alcohol Enzymatic Assay (Ref# S0220/S0221) package insert (1).

Limitations

The LZI Oral Fluid Ethyl Alcohol Calibrators are for use with the LZI Oral Fluid Ethyl Alcohol Enzymatic Assay (Ref# S0220/S0221) to detect ethyl alcohol concentration in human oral fluid only.

Bibliography

- 1. LZI Oral Fluid Ethyl Alcohol Enzymatic Assay (Ref# S0220/S0221) package insert.
- 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

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.

Additions, deletions, or changes are indicated by a change bar in the margin.

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Manufacturer:

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