LZI Oral Fluid Ethyl Alcohol Control

2°C 8°C

For Forensic Use Only

Lin-Zhi International, Inc.

REF		Description	Quantity
S0226	CONTROL -	LZI Oral Fluid Ethyl Alcohol 25 mg/dL Calibrator / Control	1 x 5 mL
S0227	CONTROL +	LZI Oral Fluid Ethyl Alcohol 75 mg/dL Calibrator / Control	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Ethyl Alcohol Controls are for use as assayed quality control materials to monitor the precision of the LZI Oral Fluid Ethyl Alcohol Enzymatic Assay (REF# S0220/S0221) on a number of automated clinical chemistry analyzers (1). These controls are for Forensic Use Only and should not be repackaged for *in vitro* diagnostic use.

Description of the Control:

The LZI Oral Fluid Ethyl Alcohol Controls are in a negative synthetic oral fluid matrix and ready-to-use. The constituent is a drug-free synthetic oral fluid matrix containing buffers, stabilizers, and less than 0.1 % of sodium azide. The control is prepared by spiking known concentrations of ethyl alcohol into the drug-free matrix.

Precautions and Warning

- *The LZI Oral Fluid Ethyl Alcohol Controls are for Forensic Use Only and should not be repackaged for in vitro diagnostic use.*
- *Harmful if swallowed.*
- *The control 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 (2).*
- *The control is prepared from a non-sterile synthetic oral fluid matrix. Always apply good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the control beyond its expiration dates.*

Preparation and Storage

The control is ready-to-use. No reconstitution is required. Label the cap before removal to identify it with the original bottle. The control should be stored refrigerated at 2-8ºC when not in use.

Stability

When stored refrigerated at 2-8ºC, the control is stable either opened-recapped, or unopened, until the expiration date printed on the vial label. Store control tightly capped when not in use. Control solution dispensed in the sample cups and left on board the clinical analyzer should be discarded after use.

Procedure and Results

The controls (25 mg/dL and 75 mg/dL) should be run daily to ensure proper assay performance. Additionally, run with each new calibration and after specific maintenance or troubleshooting procedures are 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 Control is for use with the LZI Oral Fluid Ethyl Alcohol Enzymatic Assay (Ref# S0220/S0221) to detect ethyl alcohol in human oral fluid only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Bibliography

1. LZI Oral Fluid Ethyl Alcohol Enzymatic Assay (REF# S0220/S0221) package insert.
2. 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.

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