LZI Oral Fluid Benzodiazepine Calibrators

2°C 8°C

FOR RESEARCH & DEVELOPMENT USE ONLY

Lin-Zhi International, Inc.

REF	Description	Quantity
S0008	LZI Oral Fluid LIS Negative Calibrator	1 x 5 mL
S0137c	LZI Oral Fluid Benzodiazepine 10 ng/mL Low Calibrator / Level 1 Control	1 x 5 mL
S0133c	LZI Oral Fluid Benzodiazepine 20 ng/mL Cutoff Calibrator	1 x 5 mL
S0138c	LZI Oral Fluid Benzodiazepine 30 ng/mL Intermediate Calibrator / Level 2 Control	1 x 5 mL
S0135c	LZI Oral Fluid Benzodiazepine 50 ng/mL High Calibrator	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Benzodiazepine Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the Oral Fluid Benzodiazepine Enzyme Immunoassay (Ref# S0130c/S0131c) on a number of automated clinical chemistry analyzers.

Description of the Calibrators:

The LZI Oral Fluid Benzodiazepine Calibrators are in a negative synthetic oral fluid matrix, and ready to use. The LZI Oral Fluid LIS Negative Calibrator is a drug-free synthetic oral fluid matrix containing buffers, stabilizers, and 0.1 % of ProClin 300 as a preservative. The calibrators are prepared by spiking known concentrations of oxazepam into the LZI Oral Fluid LIS 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. Values are provided only as guidelines and laboratories should determine the ranges based on their own test system and tolerance (1).

Precautions and Warnings

- *The LZI Oral Fluid Benzodiazepine Calibrators are Non-FDA approved and are for Research & Development Use Only. The LZI Oral Fluid Benzodiazepine Calibrators should not be repackaged for in vitro diagnostic use.*
- *Harmful if swallowed.*
- *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 ºC when not in use.

Stability

When stored refrigerated at 2-8 ºC, 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

For qualitative calibration, use the 20 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 Oral Fluid Benzodiazepine Enzyme Immunoassay (Ref# S0130c/S0131c) package insert (2).

Limitations

The LZI Oral Fluid Benzodiazepine Calibrators are for use with the LZI Oral Fluid Benzodiazepine Enzyme Immunoassay (Ref# S0130c/S0131c) to detect benzodiazepines in human oral fluid only.

Bibliography

1. 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.
2. LZI Oral Fluid Benzodiazepine Enzyme Immunoassay (Ref# S0130c/S0131c) 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.

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