LZI Oral Fluid LIS Negative Calibrator

IVD For In Vitro Diagnostic Use Only

2°C 8°C

FOR RESEARCH & DEVELOPMENT USE ONLY

Lin-Zhi International, Inc.

REF	Description	Quantity
S0008	Oral Fluid LIS Negative Calibrator	1 x 5 mL

Intended Use
The Lin-Zhi International (LZI) Oral Fluid LIS Negative Calibrator is for use as the negative calibrator in the qualitative and semi-quantitative calibration of a number of LZI Oral Fluid Enzyme Immunoassays on a number of automated clinical chemistry analyzers (1).

Description of the Calibrator:
The LZI Oral Fluid LIS Negative Calibrator is 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.

Precautions and Warning

- *The LZI Oral Fluid LIS Negative Calibrator is for in vitro diagnostic use only.*
- *Harmful if swallowed.*
- *The calibrators are prepared from a non-sterile synthetic oral fluid matrix. Always follow good laboratory practices to avoid any skin contact or ingestion.*
- *Do not use the calibrator beyond its expiration date.*

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

Stability
When stored refrigerated at 2-8ºC, the calibrator is stable either opened-recapped or unopened until the expiration date printed on the bottle label. Store calibrator 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 if there is a change in calibrator or reagent lot, and after instrument maintenance is performed. For interpretation of results, refer to the appropriate LZI Enzyme Immunoassay package insert.

Limitations
The LZI Oral Fluid LIS Negative Calibrator is for use with a number of LZI Oral Fluid Enzyme Immunoassays to detect a specific analyte 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.

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