

LZI Cotinine II Calibrators

IVD For In Vitro Diagnostic Use Only



Lin-Zhi International, Inc.

REF	Description	Quantity
0001	Universal Negative Calibrator	1 x 5 mL
0522	Cotinine II 100 ng/mL Low Calibrator	1 x 5 mL
0523	Cotinine II 200 ng/mL Cutoff Calibrator	1 x 5 mL
0524	Cotinine II 400 ng/mL Intermediate Calibrator	1 x 5 mL
0525	Cotinine II 1000 ng/mL High Calibrator	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Cotinine II Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Cotinine II Enzyme Immunoassay (Ref# 0520/0521) on a number of automated clinical chemistry analyzers (1).

Description of the Calibrators

The LZI Cotinine II Calibrators are human urine-based liquid 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 cotinine into the Negative Calibrator.

Precautions and Warning

- The LZI Cotinine II 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 (2).
- 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 use good laboratory practice to avoid any skin contact or ingestion.
- Do not use the calibrators beyond their expiration dates.
- For USA: Cautions: Federal law restricts this device to sale by or on the order of a physician.

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-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 a clinical analyzer should be discarded after use.

Procedure and Results

For qualitative calibration, use the 200 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 Cotinine II Enzyme Immunoassay (Ref# 0520/0521) package insert (1).

Limitations

The LZI Cotinine II Calibrators are for use with the LZI Cotinine II Enzyme Immunoassay (Ref# 0520/0521) to detect cotinine in human urine only.

Bibliography

1. LZI Cotinine II Enzyme Immunoassay (Ref# 0520/0521) 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

Authorized European Rep. within the EU:
CEpartner4U
Esdoornlaan 13
3951 DB Maarn
The Netherlands
www.cepartner4u.eu

