

# LZI Cotinine Calibrators



**| For Employment and Insurance Testing Use Only**

## ***Lin-Zhi International, Inc.***

<b>REF</b>	<b>Description</b>	<b>Quantity</b>
0001	Negative Calibrator	1 x 5 mL
0232	Cotinine 250 ng/mL Low Calibrator	1 x 5 mL
0233	Cotinine 500 ng/mL Cutoff Calibrator	1 x 5 mL
0234	Cotinine 1000 ng/mL Intermediate Calibrator	1 x 5 mL
0235	Cotinine 2000 ng/mL High Calibrator	1 x 5 mL

### **Intended Use**

The Lin-Zhi International (LZI) Cotinine Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Cotinine Enzyme Immunoassay (Ref# 0230/0231) on a number of automated clinical chemistry analyzers (1). These calibrators are for Employment and Insurance Testing Use Only and should not be repackaged for *in vitro* diagnostic use.

### **Description of the Calibrators:**

The LZI Cotinine Calibrators are human urine-based liquids 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**

- *This test does not include test systems intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.) The LZI Cotinine Calibrators 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 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 apply good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the calibrators beyond their expiration dates.*

### **Preparation and Storage**

The calibrators are provided 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 of the clinical analyzer should be discarded after use.

### **Procedure and Results**

For qualitative calibration, use the 500 ng/mL as your cutoff calibrator. For semi-quantitative calibration, use all five calibrators. Recalibration should be performed after reagent bottle change or there is a change in calibrators or reagent lot, and after instrument maintenance is performed. For interpretation of results, refer to the appropriate LZI Cotinine Enzyme Immunoassay (Ref# 0230/0231) package insert (1).

### **Limitations**

The LZI Cotinine Calibrators are for use with the LZI Cotinine Enzyme Immunoassay (Ref# 0230/0231) to detect Cotinine in human urine only.

### **Bibliography**

1. LZI Cotinine Enzyme Immunoassay (Ref# 0230/0231) 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.



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