LZI Cotinine Controls

2°C 8°C

For Employment and Insurance Testing Use Only

Lin-Zhi International, Inc.

REF		Description	Quantity
0232	CONTROL -	Cotinine 250 ng/mL Level 1 Control	1 x 5 mL
0238	CONTROL +	Cotinine 750 ng/mL Level 2 Control	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Cotinine Controls are for use as assayed quality control materials to monitor the precision of the LZI Cotinine Enzyme Immunoassay (Ref# 0230/0231) on a number of automated clinical chemistry analyzers (1). These controls are for Employment and Insurance Testing Use Only and should not be repackaged for *in vitro* diagnostic use.

Description of the Controls:

The LZI Cotinine Controls are human urine-based liquids and ready-to-use. The constituent is a processed drug-free human urine matrix containing buffers, stabilizers, and less than 0.1 % of sodium azide. The controls are prepared by spiking known concentrations of cotinine into the drug-free matrix.

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 Controls should not be repackaged for in vitro diagnostic use.*
- *Harmful if swallowed.*
- *The controls 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 controls 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 controls beyond their expiration dates.*

Preparation and Storage

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

Stability

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

Procedure and Results

Both levels of controls (250 ng/mL and 750 ng/mL for the 500 ng/mL cutoff) should be run daily to ensure proper assay performance. Additionally, run the controls with each new calibration and after specific maintenance or troubleshooting procedures are performed. For interpretation of results, refer to the appropriate LZI Cotinine Enzyme Immunoassay (Ref# 0230/0231) package insert (1).

Limitations

The LZI Cotinine Controls are for use with the LZI Cotinine Enzyme Immunoassay (Ref# 0230/0231) to detect cotinine in human urine only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

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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