LZI Cotinine II Controls

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Lin-Zhi International, Inc.

REF		Description	Quantity
0527	CONTROL –	LZI Cotinine II Level 1 Control (150 ng/mL)	1 x 5 mL
0528	CONTROL +	LZI Cotinine II Level 2 Control (250 ng/mL)	1 x 5 mL

Intended Use

The LZI Cotinine II Controls are for use as assayed quality control materials to monitor the precision of the LZI Cotinine II Enzyme Immunoassay (Ref# 0520/0521) on a number of automated clinical chemistry analyzers. (1)

Description of the Controls

The LZI Cotinine II Controls are human urine-based liquid 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.

*****Actual concentrations of these controls are confirmed by GC/MS or LC/MS. Values are provided only as guidelines and laboratories should determine the ranges based on their own test system and tolerance (2).

Precautions and Warning

- *The LZI Cotinine II Controls are for in vitro diagnostic use only. 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 (3).*
- *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 use good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the controls beyond their expiration dates.*
- Rx ONLY *For USA: Cautions: Federal law restricts this device to sale by or on the order of a physician.*

Preparation and Storage

The controls are 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 a clinical analyzer should be discarded after use.

Procedure and Results

Both levels of controls (150 ng/mL and 250 ng/mL) 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 II Enzyme Immunoassay (Ref# 0520/0521) package insert. (1)

Limitations

The LZI Cotinine II Controls are for use with the LZI Cotinine II Enzyme Immunoassay (Ref# 0520/0521) 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. (1)

Symbols Used

EC REP	Authorized Representative	IVD	*In Vitro* Diagnostic medical device	SDS	Safety Data Sheet
	Biological Risks	LOT	Lot Number	2°C 8°C	Temperature Limits
CE	CE Mark		Manufacturer	T.K.	Test Kit Number
	Consult Instructions for Use	CONTROL –	Negative Control		Use-by Date
CONTENTS	Contents	CONTROL +	Positive Control		
GTIN	Global Trade Item Number	REF	Reference Number		

Bibliography

1. LZI Cotinine II Enzyme Immunoassay (Ref# 0520/0521) package insert.
2. Guidance for Industry and FDA Staff, Assayed and Unassayed Quality Control Material. U.S. Department of Health and Human Services. FDA, Document issued on June 7, 2007.
3. 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

Additions, deletions, or changes are indicated by a change bar in the margin.

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.

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