LZI Amphetamines Controls

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Lin-Zhi International, Inc.

Outside USA Only

REF		Description	Quantity
0047	CONTROL -	LZI Amphetamines Level 1 Control (750 ng/mL)	1 x 5 mL
0048	CONTROL +	LZI Amphetamines Level 2 Control (1250 ng/mL)	1 x 5 mL

Intended Use

The Lin–Zhi International, Inc. (LZI) Amphetamines Controls are for use as assayed quality control materials to monitor the precision of the LZI Amphetamines Enzyme Immunoassay (Ref# 0040/0041) on a number of automated clinical chemistry analyzers (1).

Description of the Controls

The LZI Amphetamines 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 d-methamphetamine 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 Amphetamines 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 of 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, hepatitis antigens, and/or anti-hepatitis antibodies. They should be handled as potentially infectious. Always apply good laboratory practices 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. See the expiration date on individual bottle labels.

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. Control 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 750 ng/mL and 1250 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 Amphetamines Enzyme Immunoassay (Ref# 0040/0041) package insert (4).

Limitations

The LZI Amphetamines Controls are for use with the LZI Amphetamines Enzyme Immunoassay (Ref# 0040/0041) to detect amphetamines in human urine only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Bibliography

1. Urine testing for Drug of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
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.
4. LZI Amphetamines Enzyme Immunoassay (Ref# 0040/0041) package insert.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

LZI uses the symbols and signs listed on the symbol glossary on the website. Visit www.lin-zhi.com/symbol-glossary for detailed information.

Additions, deletions, or changes are indicated by a change bar in the margin.
For technical assistance please call: (408) 970-8811

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

Authorized European Rep. within the EU:
AR Experts B.V.
Boeingavenue 209,
1119 PD, Schiphol-Rijk
The Netherlands

Importer within the EU:
MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 – Suite 123
2595 AM, The Hague
The Netherlands

UK Responsible Person within the UK:
UKCA Experts Ltd.
6th Floor City Gate East,
Tollhouse Hill
Nottingham
NG1 5FS
The United Kingdom (UK)

Importer within the UK:
MedEnvoy UK Limited
85 Great Portland Street,
First Floor, London
W1W 7LT
The United Kingdom (UK)