LZI Cannabinoids (cTHC) 100 Controls

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Lin-Zhi International, Inc.

REF		Description	Quantity
0076c	CONTROL -	Cannabinoids (cTHC) 75 ng/mL Control	1 x 5 mL
0009c	CONTROL +	Cannabinoids (cTHC) 125 ng/mL Control	1 x 5 mL

Intended Use

The Lin–Zhi International, Inc. (LZI) Cannabinoids (cTHC) Controls are for use as assayed quality control materials to monitor the precision of the LZI Cannabinoids (cTHC) Enzyme Immunoassay (Ref# 0070c/0071c) on a number of automated clinical chemistry analyzers.

Description of the Controls:

The LZI Cannabinoids (cTHC) Controls are human urine-based liquids, and ready to use. The constituent is a processed drug-free human urine matrix containing 11-nor-Δ^9-THC-9-COOH, buffers, stabilizers, and 0.09% of sodium azide. The controls are prepared by spiking known concentrations of 11-nor-Δ^9-THC-9-COOH into the drug-free matrix. Throughout this insert cTHC is referenced as an abbreviation for 11-nor-Δ^9-THC-9-COOH.

*****Actual concentrations of these calibrators 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 Cannabinoids (cTHC) 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.*
- *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.

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. Real-time open-recapped vial stability studies when stored refrigerated, indicate that expiration dates are at least 18 months from the production date. Real-time closed vial stability studies are currently at 60 days of storage and continue to be monitored. Accelerated studies for closed vial stability indicate that expiration dates should be at least 18 months from the production date. 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 (75 ng/mL and 125 ng/mL for the 100 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 Cannabinoids (cTHC) Enzyme Immunoassay (Ref# 0070c/0071c) package insert (3).

Limitations

The LZI Cannabinoids (cTHC) Controls are for use with the LZI Cannabinoids (cTHC) Enzyme Immunoassay (Ref# 0070c/0071c) to detect cannabinoids in human urine only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Symbols Used

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

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. LZI Cannabinoids (cTHC) Enzyme Immunoassay (Ref# 0070c/0071c) package insert.

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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