

LZI Hydrocodone 300 Controls

For Beckman Coulter, Inc.



IVD For In Vitro Diagnostic Use Only



Lin-Zhi International, Inc.

REF	CONTROL	Description	Quantity
C68828	CONTROL -	LZI Hydrocodone 300 Level 1 Control HYD 300 Level 1 Control (225 ng/mL)	1 x 5 mL
C68829	CONTROL +	LZI Hydrocodone 300 Level 2 Control HYD 300 Level 2 Control (375 ng/mL)	1 x 5 mL

Intended Use

The LZI Hydrocodone 300 Level 1 Control and LZI Hydrocodone 300 Level 2 Control are for use as assayed quality control materials to monitor the precision of the LZI Hydrocodone Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68823) on a number of automated clinical chemistry analyzers (1).

Description of the Controls

The LZI Hydrocodone 300 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 hydrocodone into the drug-free matrix.

*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 Hydrocodone 300 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: Federal law restricts this device to sale by or on the order of a physician.

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 2-8°C when not in use.

Stability

When stored refrigerated at 2-8°C, 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 (225 ng/mL and 375 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 Hydrocodone Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68823) package insert (1).

Limitations

The LZI Hydrocodone 300 Controls are for use with the LZI Hydrocodone Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68823) to detect hydrocodone 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	COO	Country of Origin		Manufacturer	SDS	Safety Data Sheet
	Biological Risks		Date of Manufacture	Rx ONLY	Medical Prescription Only		Temperature Limits
CE	CE Mark	GTIN	Global Trade Item Number	CONTROL -	Negative Control	T.K.	Test Kit Number
	Consult Instructions for Use	IVD	In Vitro Diagnostic medical device	CONTROL +	Positive Control		Use-by Date
CONTENTS	Contents	LOT	Lot Number	REF	Reference Number		

Additional Information

Registered trademarks are the property of their respective owners.

Shipping Damage

Please notify your Beckman Coulter Clinical Support Center if this product is received damaged.

Bibliography

1. LZI Hydrocodone Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68823) 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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