



For Export Only – Not For Sale in USA

# ARK™ Ketamine Control

This ARK Diagnostics, Inc. package insert for the ARK Ketamine Control must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Report any serious incident that has occurred in relation to the device to the manufacturer and the appropriate competent authority as applicable

## Customer Service



48089 Fremont Blvd  
Fremont, CA 94538 USA  
Tel: 1-877-869-2320  
Fax: 1-510-270-6298  
customersupport@ark-tdm.com  
www.ark-tdm.com  
SRN: US-MF-000023925



EC REP

Emergo Europe  
Westervoortsedijk 60  
6827 AT Arnhem  
The Netherlands

## Key to Symbols Used

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer
	Authorized Representative		CE Mark with notified body number
	Consult Instructions for Use		Quality Control
	Temperature limitation		In Vitro Diagnostic Medical Device
<b>Rx Only</b>	For Prescription Use Only		

## 1 Name

### **ARK™ Ketamine Control**

## 2 Intended Use

The ARK Ketamine Control is intended for use in quality control of the ARK Ketamine Assay.

## 3 Content

The ARK Ketamine Control is composed of a non-sterile, processed human urine matrix with the following target concentrations of ketamine.

REF	Product Description	Quantity/Volume
5056-0003-00	<b>ARK Ketamine Control</b> Ketamine, human urine, stabilizer and sodium azide	Dropper Vials
	<b>LOW / Negative</b> (25 ng/mL)	2 X 10 mL
	<b>HIGH / Positive</b> (75 ng/mL)	2 X 10 mL

Traceability and Value Verification: A certified solution of ketamine is traceable to HPLC. Testing is performed with the ARK Ketamine Assay calibrated with the ARK Ketamine Calibrator.

Each laboratory should establish its own ranges for each new lot of controls based on its own test system and criteria.

In Qualitative Mode, the Low Control should be Negative and the High Control should be Positive relative to the 50 ng/mL Cutoff Calibrator.

Controls are made with non-sterile, processed human urine free of ketamine. Donors were non-reactive in tests for HIV 1/2, HBsAg, HCV, HIV-1 (NAT), HCV (NAT) and RPR.

## 4 Warnings and Precautions

- For *In Vitro* Diagnostic Use. For prescription use only.
- Harmful if swallowed.
- Contains human urine. Handle as potentially infectious.
- Do not mix controls from different lot numbers.
- Use each lot as a set.
- Product contains  $\leq 0.09\%$  sodium azide. As a precaution, affected plumbing including instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides.

## 5 Instructions For Use

- For a complete summary and explanation of the Ketamine Assay, refer to the package insert for the ARK Ketamine Assay.
- Controls are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume (~40µL/drop) into individual sample cups for each level. Consult instrument-specific sample volume requirements. Return caps to their original containers and keep tight.
- Store vials at 2-8°C. Once opened, use within 12 months and prior to the expiration date.

## 6 Limitations of Procedure

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, calibrators, controls, storage of product as directed, and good laboratory technique.

## 7 Trademarks

**ARK<sup>TM</sup>** is a trademark of ARK Diagnostics, Inc.

Other brand or product names are trademarks of their respective holders.



ARK Diagnostics, Inc.  
Fremont, CA 94538 USA

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