

ARK™ Zopiclone Control

This ARK Diagnostics, Inc. package insert for the ARK Zopiclone 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


ARK Diagnostics, Inc.

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













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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	 2797	CE Mark with notified body number
	Consult Instructions for Use	Rx Only	For Prescription Use Only
	Temperature limitation		Quality Control
	In Vitro Diagnostic Medical Device		

1 Name

ARK Zopiclone Control

2 Intended Use

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

3 Content

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

REF	Product Description	Quantity/Volume
5043-0003-00	ARK Zopiclone Control Zopiclone, human urine, stabilizer and sodium azide	Dropper Vials
	LOW / Negative (7.5 ng/mL)	2 X 10 mL
	HIGH / Positive (12.5 ng/mL)	2 X 10 mL

Traceability and Value Assignment: A certified solution of Zopiclone is traceable to HPLC. Testing is performed with the ARK Zopiclone Assay calibrated with the ARK Zopiclone 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 10 ng/mL Cutoff Calibrator.

Controls are made with non-sterile, processed human urine free of Zopiclone. 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 Zopiclone Assay, refer to the package insert for the ARK Zopiclone 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

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ARK Diagnostics, Inc.
Fremont, CA 94538 USA

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