



ARK Diagnostics, Inc.

For Export Only – Not For Sale in USA

ARK™ Ethyl Glucuronide Control

This ARK Diagnostics, Inc. package insert for the ARK Ethyl Glucuronide 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.

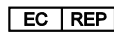
Customer Service



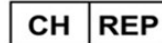
48089 Fremont Blvd
Fremont, CA 94538 USA
Tel: 1-877-869-2320
Fax: 1-510-270-6298
customersupport@ark-tdm.com
www.ark-tdm.com
SRN: US-MF-000023925



2797



Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

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		Quality Control
	Temperature Limitation		In Vitro Diagnostic Medical Device
Rx Only	For Prescription Use Only		

1 Name

ARK™ Ethyl Glucuronide Control

2 Intended Use

The ARK Ethyl Glucuronide Control is intended for use in quality control of the ARK Ethyl Glucuronide Assay and ARK Ethyl Glucuronide II Assay.

3 Content

ARK Ethyl Glucuronide Control is composed of a non-sterile, processed human urine matrix with the following target concentrations of ethyl glucuronide.

For use with Cutoff Calibrator C (500 ng/mL)

REF	Product Description	Quality Control
5036-0003-00	ARK Ethyl Glucuronide Control (375 ng/mL and 625 ng/mL) (each 2 X 10 mL) Ethyl glucuronide, human urine, stabilizer and sodium azide	Expected Range (Mean ng/mL)
	LOW / Negative (375 ng/mL)	300 – 450
	HIGH / Positive (625 ng/mL)	500 – 750

For use with Cutoff Calibrator D (1000 ng/mL)

REF	Product Description	Quality Control
5036-0003-01	ARK Ethyl Glucuronide Control (750 ng/mL and 1250 ng/mL) (each 2 X 10 mL) Ethyl glucuronide, human urine, stabilizer and sodium azide	Expected Range (Mean ng/mL)
	LOW / Negative (750 ng/mL)	600 – 900
	HIGH / Positive (1250 ng/mL)	1000 – 1500

Traceability and Value Assignment: A certified solution of ethyl glucuronide is traceable to LC/MS. Testing is performed with the ARK Ethyl Glucuronide Assay calibrated with the ARK Ethyl Glucuronide Calibrator. Individual laboratory performance for semiquantitative determinations may vary. Mean values should fall within the expected ranges shown in the tables above.

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 applicable 500 ng/mL and 1000 ng/mL Cutoff Calibrators.

Controls are made with non-sterile, processed human urine free of ethyl glucuronide. 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 ARK Ethyl Glucuronide Assay or ARK Ethyl Glucuronide II Assay, refer to the package insert for the ARK Ethyl Glucuronide Assay or ARK Ethyl Glucuronide II Assay.
- Controls are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume ($\sim 40\mu\text{L}/\text{drop}$) 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

ARKTM 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

Revised October 2025
1600-0611-00 Rev 05