



ARK Diagnostics, Inc.

For Export Only – Not For Sale in USA

ARK™ Ethyl Glucuronide Calibrator

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



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EC REP

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6827 AT Arnhem
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CH REP

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

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Calibrator Kit 5036-0002-00

Negative Kit 5036-0002-01

Cutoff Kit 5036-0002-02; 5036-0002-03

1 Name

ARK™ Ethyl Glucuronide Calibrator

2 Intended Use

The ARK Ethyl Glucuronide Calibrator is intended for use in calibration of the ARK Ethyl Glucuronide Assay and ARK Ethyl Glucuronide II Assay.

3 Content

ARK Ethyl Glucuronide Calibrator is composed of a non-sterile, processed human urine matrix with the following concentrations of ethyl glucuronide. Negative and Cutoff Calibrators may be obtained separately for qualitative analysis.

REF	Product Description	Quantity/Volume	
5036-0002-00	ARK Ethyl Glucuronide Calibrator Ethyl glucuronide, human urine, stabilizer and sodium azide	Dropper vials	
	A	0 ng/mL	1 X 10 mL
	B	100 ng/mL	1 X 10 mL
	C	500 ng/mL	1 X 10 mL
	D	1000 ng/mL	1 X 10 mL
	E	2000 ng/mL	1 X 10 mL

REF	Product Description	Quantity/Volume
5036-0002-01	ARK Ethyl Glucuronide Calibrator A (Negative) Human urine, stabilizer and sodium azide	Dropper vials
	Negative	0 ng/mL

REF	Product Description	Quantity/Volume
5036-0002-02	ARK Ethyl Glucuronide Calibrator C (500 ng/mL Cutoff) Ethyl glucuronide, human urine, stabilizer and sodium azide	Dropper vials
	Cutoff	500 ng/mL

REF	Product Description	Quantity/Volume
5036-0002-03	ARK Ethyl Glucuronide Calibrator D (1000 ng/mL Cutoff) Ethyl glucuronide, human urine, stabilizer and sodium azide	Dropper vials
	Cutoff	1000 ng/mL

4 Standardization

There is no internationally recognized standard for ethyl glucuronide. A certified solution of ethyl glucuronide is traceable to LC/MS. ARK Ethyl Glucuronide Calibrators are prepared by volumetric dilution of high purity ethyl glucuronide into non-sterile, processed human urine free of ethyl glucuronide.

Calibrators 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.

5 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 calibrators 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.

6 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.
- Calibrators are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume ($\sim 40\mu\text{L}$ /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.

7 Procedure

Qualitative Results

The 500 ng/mL Calibrator C or the 1000 ng/mL Calibrator D can be used as Cutoff Calibrators to distinguish negative and positive samples depending on laboratory specific criteria. Quality Controls are available for each cutoff level. Run the Low (375 ng/mL) and High (625 ng/mL) Controls with Cutoff Calibrator C, and run the Low (750 ng/mL) and High (1250 ng/mL) Controls with Cutoff Calibrator D as Negative and Positive respectively. All qualitative testing results are expressed as enzymatic rate (mA/min). Report test results less than the rate for the applicable Cutoff Calibrator as Negative.

Report results equal to or greater than the rate for the applicable Cutoff Calibrator as Positive.

Semiquantitative Results

To estimate the concentration of ethyl glucuronide, perform a 5-point calibration procedure; run calibrators in duplicate. Verify the calibration curve with ARK Low and High quality controls according to the established laboratory quality assurance plan. The semiquantitative measurement range is 100 ng/mL to 2000 ng/mL. Specimens having concentrations of ethyl glucuronide exceeding 2000 ng/mL may be diluted in ARK Calibrator A (Negative urine), and the result should fall within the semiquantitative measurement range.

When to Re-Calibrate

- Whenever a new lot number of reagents is used
- Whenever indicated by quality control results
- Whenever required by standard laboratory protocols

A stored calibration curve was effective up to at least 28 days based on supporting data.

8 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.

9 Trademarks

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