

ARK™ Ketamine II Calibrator

This ARK Diagnostics, Inc. package insert for the ARK Ketamine II 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













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
	In Vitro Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use		Calibrator
Rx Only	For Prescription Use Only		

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Calibrator Kit  5083-0002-00

Negative Kit  5083-0002-01 Cutoff

50 ng/mL Kit  5083-0002-02

Cutoff 100 ng/mL Kit  5083-0002-03

1 Name
ARK™ Ketamine II Calibrator

2 Intended Use

The ARK Ketamine II Calibrator is intended for use in calibration of the ARK Ketamine II Assay.

3 Content

The ARK Ketamine II Calibrator is composed of a non-sterile, processed human urine matrix with the following concentrations of ketamine. Negative and Cutoff calibrators may be obtained separately for qualitative analysis.

REF	Product Description	Quantity/Volume
5083-0002-00	ARK Ketamine II Calibrator Ketamine, human urine, stabilizer and sodium azide	Dropper Vials
	A	0 ng/mL
	B	50 ng/mL
	C	100 ng/mL
	D	200 ng/mL
	E	500 ng/mL

REF	Product Description	Quantity/Volume
5083-0002-01	ARK Ketamine II Calibrator A (Negative) Human urine, stabilizer and sodium azide	Dropper Vials
	Negative	0 ng/mL

REF	Product Description	Quantity/Volume
5083-0002-02	ARK Ketamine II Calibrator B (50 ng/mL Cutoff) Ketamine, human urine, stabilizer and sodium azide	Dropper Vials
	Cutoff	50 ng/mL

REF	Product Description	Quantity/Volume
5083-0002-03	ARK Ketamine II Calibrator C (100 ng/mL Cutoff) Ketamine, human urine, stabilizer and sodium azide	Dropper Vials
	Cutoff	100 ng/mL

4 Standardization

There is no internationally recognized standard for ketamine. A certified solution of ketamine is traceable to HPLC. ARK Ketamine II Calibrators are prepared by volumetric dilution of high purity ketamine into non-sterile, processed human urine free of ketamine.

Calibrators 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.

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 Ketamine II Assay, refer to the package insert for the ARK Ketamine 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

For 50 ng/mL Cutoff, use the 50 ng/mL Calibrator B as a Cutoff Calibrator to distinguish negative and positive samples. Run the ARK Ketamine II Low (25 ng/mL) and High (75 ng/mL) Controls as Negative and Positive respectively. Report test results less than the response value for the Cutoff Calibrator as Negative. Report test results equal to or greater than the response value for the Cutoff Calibrator as Positive.

For 100 ng/mL Cutoff, use the 100 ng/mL Calibrator C as a Cutoff Calibrator to distinguish negative and positive samples. Run the ARK Ketamine II Low (75 ng/mL) and High (125 ng/mL) Controls as Negative and Positive respectively. Report test results less than the response value for the Cutoff

Calibrator as Negative. Report test results equal to or greater than the response value for the Cutoff Calibrator as Positive.

Semiquantitative Results

Perform a 5-point calibration procedure; run calibrators in duplicate. Verify the calibration curve with the ARK Ketamine II Low (25 ng/mL) and High (75 ng/mL) (for 50 ng/mL Cutoff), and the ARK Ketamine II Low (75 ng/mL) and High (125 ng/mL) (for 100 ng/mL Cutoff) quality controls according to the established laboratory quality assurance plan. Specimens with sample results above the highest ARK Ketamine II calibrator level (500 ng/mL) may be diluted in ARK Ketamine II Calibrator A (Negative urine) and retested.

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 9 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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ARK Diagnostics, Inc.
Fremont, CA 94538 USA

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