



# ARK™ Tramadol Calibrator

This ARK Diagnostics, Inc. package insert for the ARK Tramadol 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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## 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		Calibrator
	Temperature limitation		In Vitro Diagnostic Medical Device
<b>Rx Only</b>	For Prescription Use Only		

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Calibrator Kit 5040-0002-00

Negative Kit 5040-0002-01

Cutoff Kit 5040-0002-02

## 1 Name

### **ARK™ Tramadol Calibrator**

## 2 Intended Use

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

## 3 Content

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

REF	Product Description	Quantity/Volume	
5040-0002-00	<b>ARK Tramadol Calibrator</b> Tramadol, human urine, stabilizer and sodium azide	Dropper Vials	
	<b>A</b>	0 ng/mL	1 X 10 mL
	<b>B</b>	100 ng/mL	1 X 10 mL
	<b>C</b>	200 ng/mL	1 X 10 mL
	<b>D</b>	500 ng/mL	1 X 10 mL
	<b>E</b>	1000 ng/mL	1 X 10 mL

REF	Product Description	Quantity/Volume
5040-0002-01	<b>ARK Tramadol Calibrator A (Negative)</b> Human urine, stabilizer and sodium azide	Dropper Vials
	<b>Negative</b>	0 ng/mL

REF	Product Description	Quantity/Volume
5040-0002-02	<b>ARK Tramadol Calibrator B (Cutoff)</b> Tramadol, human urine, stabilizer and sodium azide	Dropper Vials
	<b>Cutoff</b>	100 ng/mL

## 4 Standardization

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

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

## 7 Procedure

### Qualitative Results

Use the 100 ng/mL Calibrator B as a Cutoff Calibrator to distinguish negative and positive samples. Run the ARK Tramadol 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; test calibrators in duplicate. Verify the calibration curve with the ARK Tramadol Low (75 ng/mL) and High (125 ng/mL) quality controls according to the established laboratory quality assurance plan. Specimens with sample results above the highest ARK Tramadol calibrator level (1000 ng/mL) may be diluted in ARK Tramadol 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 30 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**

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

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



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Revised July 2025  
1600-0682-00 Rev 04