

## ARK™ Hydrocodone Calibrator

This ARK Diagnostics, Inc. package insert for the ARK Hydrocodone 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
	<i>In Vitro</i> Diagnostic Medical Device	<b>Rx Only</b>	For Prescription Use Only
	Consult Instructions for Use	<b>CALIBRATOR</b>	Calibrator
	Temperature limitation		

### 1 NAME

## ARK Hydrocodone Calibrator

### 2 INTENDED USE

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

### 3 CONTENT

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

REF	Product Description	Quantity/Volume
5076-0002-00	<b>ARK Hydrocodone Calibrator</b> Hydrocodone, human urine, stabilizer and sodium azide	Dropper Vials
	A	0 ng/mL
	B	50 ng/mL
	C	100 ng/mL
	D	300 ng/mL
	E	800 ng/mL

REF	Product Description	Quantity/Volume
5076-0002-01	<b>ARK Hydrocodone Calibrator A (Negative)</b> Human urine, stabilizer and sodium azide	Dropper Vials
	Negative	0 ng/mL

REF	Product Description	Quantity/Volume
5076-0002-02	<b>ARK Hydrocodone Calibrator D (Cutoff)</b> Hydrocodone, human urine, stabilizer and sodium azide	Dropper Vials
	Cutoff	300 ng/mL

### 4 STANDARDIZATION

There is no internationally recognized standard for hydrocodone. A certified solution of hydrocodone is traceable to HPLC. ARK Hydrocodone Calibrators are prepared by volumetric dilution of high purity hydrocodone into non-sterile, processed human urine free of hydrocodone. Calibrators are made with non-sterile, processed human urine free of hydrocodone. 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 ≤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 Hydrocodone Assay, refer to the package insert for the ARK Hydrocodone Assay.
- Calibrators 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 at 2-8°C. Use prior to the expiration date.

### 7 PROCEDURE

#### Qualitative Results

Use the 300 ng/mL Calibrator D as a Cutoff Calibrator to distinguish negative and positive samples. Run the ARK Hydrocodone Low (225 ng/mL) and High (375 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.

#### Semi-quantitative Results

Perform a 5-point calibration procedure, test calibrators in duplicate. Verify the calibration curve with the ARK Hydrocodone Low (225 ng/mL) and High (375 ng/mL) quality controls according to the established laboratory quality assurance plan. Specimens with sample results above the

Calibrator Kit  5076-0002-00

Negative Kit  5076-0002-01

Cutoff Kit  5076-0002-02

highest ARK Hydrocodone calibrator level (800 ng/mL) may be diluted in ARK Hydrocodone 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 14 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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