

**For Export Only – Not For Sale in USA**

## ARK™ HS Benzodiazepine II Calibrator

This ARK Diagnostics, Inc. package insert for the ARK HS Benzodiazepine 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.

### Customer Service













**ARK Diagnostics, Inc.**  
 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



Emergo Europe  
 Prinsessegracht 20  
 2514 AP The Hague  
 The Netherlands

### Key to Symbols Used

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer
	Authorized Representative		CE Mark
	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  5073-0002-00

Negative Kit  5073-0002-01

Cutoff Kit  5073-0002-02; 5073-0002-03

# 1 Name

## **ARK<sup>TM</sup> HS Benzodiazepine II Calibrator**

# 2 Intended Use

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

# 3 Content

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

REF	Product Description	Quantity/Volume	
5073-0002-00	<b>ARK HS Benzodiazepine II Calibrator</b> Etizolam, 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>	1000 ng/mL	1 X 10 mL
	<b>E</b>	3000 ng/mL	1 X 10 mL

REF	Product Description	Quantity/Volume
5073-0002-01	<b>ARK HS Benzodiazepine II Calibrator A (Negative)</b> Human urine, stabilizer and sodium azide	Dropper Vials
	<b>Negative</b>	0 ng/mL

REF	Product Description	Quantity/Volume
5073-0002-02	<b>ARK HS Benzodiazepine II Calibrator B (Cutoff)</b> Etizolam, human urine, stabilizer and sodium azide	Dropper Vials
	<b>Cutoff</b>	100 ng/mL

REF	Product Description	Quantity/Volume
5073-0002-03	<b>ARK HS Benzodiazepine II Calibrator C (Cutoff)</b> Etizolam, human urine, stabilizer and sodium azide	Dropper Vials
	<b>Cutoff</b>	200 ng/mL

## 4 Standardization

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

Calibrators are made with non-sterile, processed human urine free of etizolam. 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 HS Benzodiazepine II Assay, refer to the package insert for the ARK HS Benzodiazepine II Assay.
- 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.
- Use prior to the expiration date.

## 7 Procedure

### Qualitative Results

Use the 100 ng/mL Calibrator B or the 200 ng/mL Calibrator C as a Cutoff Calibrator to distinguish negative and positive samples. Run the ARK HS Benzodiazepine II Low (75 ng/mL) and High (125 ng/mL) Controls with Cutoff Calibrator B or the ARK HS Benzodiazepine II Low (150 ng/mL) and High (250 ng/mL) Controls with Cutoff Calibrator C, as Negative and Positive respectively. Report test results less than the response value for the applicable Cutoff Calibrator as Negative. Report test results equal to or greater than the response value for the applicable Cutoff Calibrator as Positive.

### **Semiquantitative Results**

Perform a 5-point calibration procedure; test calibrators in duplicate. Verify the calibration curve with the ARK HS Benzodiazepine II Low and High quality controls according to the established laboratory quality assurance plan. Specimens with sample results above the highest ARK HS Benzodiazepine II Calibrator level (3000 ng/mL) may be diluted in ARK HS Benzodiazepine 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 15 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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