

ARK™ HS Benzodiazepine II Calibrator

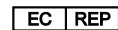
This ARK Diagnostics, Inc. package insert for the ARK HS Benzodiazepine II Calibrator must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Report any serious incident that has occurred in relation to the device to the manufacturer and the appropriate competent authority as applicable.

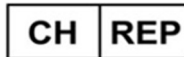
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


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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
Rx Only	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™ 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	ARK HS Benzodiazepine II Calibrator Etizolam, 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	200 ng/mL	1 X 10 mL
	D	1000 ng/mL	1 X 10 mL
	E	3000 ng/mL	1 X 10 mL

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

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

REF	Product Description	Quantity/Volume
5073-0002-03	ARK HS Benzodiazepine II Calibrator C (Cutoff) Etizolam, human urine, stabilizer and sodium azide	Dropper Vials
	Cutoff	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.
- This 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

- Refer to the package insert for the ARK HS Benzodiazepine II Assay for a complete summary and explanation of the 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.
- Store 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 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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