ARK Diagnostics, Inc.

For Export Only – Not For Sale in USA

ARK™ *Pregabalin II Calibrator*

This ARK Diagnostics, Inc. package insert for the ARK Pregabalin 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

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KEY TO SYMBOLS USED

LOT	Batch code	YYYY-MM-DD	Use by/Expiration date
REF	Catalog Number		Manufacturer
EC REP	Authorized Representative	CE	CE Mark
	Consult Instructions for Use	CALIBRATOR	Calibrator
	Temperature limitation	IVD	*In Vitro* Diagnostic Medical Device
Rx Only	For Prescription Use Only		

1 NAME

ARK™ *Pregabalin II Calibrator*

2 INTENDED USE

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

3 CONTENT

The ARK Pregabalin II Calibrator is composed of a non-sterile, processed human urine matrix with the following concentrations of pregabalin.

REF	Product Description		Quantity/Volume
5059-0002-00	**ARK Pregabalin II Calibrator** Pregabalin, human urine, stabilizer and sodium azide		Dropper Vials
	A	0 ng/mL	1 X 4 mL
	B	100 ng/mL	1 X 4 mL
	C	500 ng/mL	1 X 4 mL
	D	1000 ng/mL	1 X 4 mL
	E	2000 ng/mL	1 X 4 mL

4 STANDARDIZATION

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

Calibrators are made with non-sterile, processed human urine free of pregabalin. 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 Pregabalin II Assay, refer to the package insert for the ARK Pregabalin II 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 500 ng/mL Calibrator C as a Cutoff Calibrator to distinguish negative and positive samples. Run the ARK Pregabalin II Low (250 ng/mL) and High (750 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 Pregabalin II Low (250 ng/mL) and High (750 ng/mL) quality controls according to the established laboratory quality assurance plan. Specimens with sample results above the highest ARK Pregabalin II calibrator level (2000 ng/mL) may be diluted in ARK Pregabalin 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 6 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.

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9 TRADEMARKS

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