

For Export Only – Not For Sale in USA

ARK™ Pregabalin Urine Calibrator

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

	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

1 NAME

ARK™ Pregabalin Urine Calibrator

2 INTENDED USE

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

3 CONTENT

ARK Pregabalin Urine Calibrator is comprised of a non-sterile, processed human urine matrix with the following concentrations of pregabalin:

REF	Product Description	Quantity/Volume
5035-0002-00	ARK Pregabalin Urine Calibrators Pregabalin, human urine, stabilizer and sodium azide	Dropper vials
	A	0 ng/mL
	B	100 ng/mL
	C	500 ng/mL
	D	1000 ng/mL
E	2000 ng/mL	

4 STANDARDIZATION

There is no internationally recognized standard for pregabalin. ARK Pregabalin Calibrators are prepared by volumetric dilution of high purity pregabalin into 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 Diagnostics* Use. **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 Assay, refer to the package insert for the ARK Pregabalin Urine 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 Low and High Controls as Negative and Positive respectively. All qualitative testing results are expressed as enzymatic rate (mA/min). Report test results less than the rate for the Cutoff Calibrator as Negative. Report results equal to or greater than the rate for the Cutoff Calibrator as Positive.

Semi-Quantitative Results

To estimate the concentration of pregabalin, perform a 5-point calibration procedure; test calibrators in duplicate. Verify the calibration curve with ARK Low and High quality controls according to the established laboratory quality assurance plan.

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

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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