

For Export Only – Not For Sale in USA

ARK™ Pregabalin II Control

This ARK Diagnostics, Inc. package insert for the ARK Pregabalin II Control 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		Quality Control
	Temperature limitation		<i>In Vitro</i> Diagnostic Medical Device
Rx Only	For Prescription Use Only		

1 NAME

ARK™ Pregabalin II Control

2 INTENDED USE

The ARK Pregabalin II Control is intended for use in quality control of the ARK Pregabalin II Assay.

3 CONTENT

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

REF	Product Description	Quantity/Volume
5059-0003-00	ARK Pregabalin II Control Pregabalin, human urine, stabilizer and sodium azide	Dropper Vials
	LOW / Negative (250 ng/mL)	3 X 4 mL
	HIGH / Positive (750 ng/mL)	3 X 4 mL

Traceability and Value Assignment: A certified solution of pregabalin is traceable to LC/MS. Testing is performed with the ARK Pregabalin II Assay calibrated with the ARK Pregabalin II Calibrator.

Each laboratory should establish its own ranges for each new lot of controls based on its own test system and criteria.

In Qualitative Mode, the Low Control should be Negative and the High Control should be Positive relative to the 500 ng/mL Cutoff Calibrator.

Controls 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.

4 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 controls 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.

5 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.
- Controls 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.

6 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.

7 TRADEMARKS

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