ARK Diagnostics, Inc.

ARK™ *Hydrocodone Control*

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

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

CUSTOMER SERVICE

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KEY TO SYMBOLS USED

LOT	Batch code	YYYY-MM-DD	Use by/Expiration date
REF	Catalog Number		Manufacturer
IVD	*In Vitro* Diagnostic Medical Device	**Rx Only**	For Prescription Use Only
	Consult Instructions for Use	CONTROL	Quality Control
	Temperature limitation		

1 NAME

ARK *Hydrocodone Control*

2 INTENDED USE

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

3 CONTENT

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

REF	Product Description	Quantity/Volume
5076-0003-00	**ARK Hydrocodone Control** Hydrocodone, human urine, stabilizer and sodium azide	Dropper Vials
	LOW / Negative (225 ng/mL)	2 X 10 mL
	HIGH / Positive (375 ng/mL)	2 X 10 mL

Traceability and Value Assignment: A certified solution of hydrocodone is traceable to HPLC. Testing is performed with the ARK Hydrocodone Assay calibrated with the ARK Hydrocodone 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 300 ng/mL Cutoff Calibrator.

Controls are made with non-sterile, processed human urine free of hydrocodone. 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 Hydrocodone Assay, refer to the package insert for the ARK Hydrocodone 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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