

For Export Only – Not For Sale in USA

ARK™ Fentanyl Control

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

 **ARK Diagnostics, Inc.**











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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™ Fentanyl Control

2 INTENDED USE

ARK Fentanyl Control is an assayed control material intended for use in quality control of the ARK Fentanyl Assay.

3 CONTENT

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

REF	Product Description	Quality Control
5031-0003-00	ARK Fentanyl Control (each 2 X 10 mL) Fentanyl, human urine, stabilizer and sodium azide	Expected Range (Mean ng/mL)
	LOW / Negative (0.5 ng/mL)	0.3 – 0.7
	HIGH / Positive (1.5 ng/mL)	1.2 – 1.8

Traceability and Value Assignment: A certified solution of fentanyl is traceable to HPLC. Testing is performed with the ARK Fentanyl Assay calibrated with the ARK Fentanyl Calibrator. Individual laboratory performance for semiquantitative determinations may vary. Mean values should fall within the expected range shown.

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 1.0 ng/mL Cutoff Calibrator.

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