

For Export Only – Not For Sale in USA

ARK™ Fentanyl Calibrator

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

 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		Calibrator
	Temperature limitation		In Vitro Diagnostic Medical Device
Rx Only	For Prescription Use Only		

1 NAME

ARK™ Fentanyl Calibrator

2 INTENDED USE

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

3 CONTENT

ARK Fentanyl Calibrator is composed of a non-sterile, processed human urine matrix with the following concentrations of fentanyl. Negative and Cutoff calibrators may be obtained separately for qualitative analysis.

REF	Product Description	Quantity/Volume
5031-0002-00	ARK Fentanyl Calibrator Fentanyl, human urine, stabilizer and sodium azide	Dropper vials
	A	0 ng/mL
	B	1.0 ng/mL
	C	2.0 ng/mL
	D	4.0 ng/mL
E	10.0 ng/mL	

REF	Product Description	Quantity/Volume
5031-0002-01	ARK Fentanyl Calibrator A (Negative) Human urine, stabilizer and sodium azide	Dropper vials
	Negative	0 ng/mL

REF	Product Description	Quantity/Volume
5031-0002-02	ARK Fentanyl Calibrator B (Cutoff) Fentanyl, human urine, stabilizer and sodium azide	Dropper vials
	Cutoff	1.0 ng/mL

4 STANDARDIZATION

There is no internationally recognized standard for fentanyl. A certified solution of fentanyl is traceable to HPLC. ARK Fentanyl Calibrators are prepared by volumetric dilution of high purity fentanyl into non-sterile, processed human urine free of fentanyl.

Calibrators 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.

5 WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic 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 Fentanyl Assay, refer to the package insert for the ARK Fentanyl 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 1.0 ng/mL Calibrator B 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.

Semiquantitative Results

To estimate the concentration of fentanyl, 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. Specimens may be diluted in ARK Calibrator A (Negative urine), and the result should fall within 0.3 to 10.0 ng/mL.

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 15 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.

9 TRADEMARKS

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