

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.

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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

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

3 CONTENT

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

| REF | Product Description | Quantity/Volume |
|--------------|---|-----------------|
| 5031-0003-00 | ARK Fentanyl Control Fentanyl, human urine, stabilizer and sodium azide | Dropper Vials |
| | LOW / Negative (0.5 ng/mL) | 2 X 10 mL |
| | HIGH / Positive (1.5 ng/mL) | 2 X 10 mL |

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.

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

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, or to the package insert for the ARK Fentanyl 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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