

For Criminal Justice and Forensic Use Only

## ARK™ Xylazine Calibrator

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

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### KEY TO SYMBOLS USED

|  |                              |   |                        |
|--|------------------------------|---|------------------------|
|  | Batch code                   | <br>YYYY-MM-DD | Use by/Expiration date |
|  | Catalog Number               |                | Manufacturer           |
|  | Consult Instructions for Use |                | Calibrator             |
|  | Temperature limitation       |   |                        |

### 1 NAME

## ARK™ Xylazine Calibrator

### 2 INTENDED USE

This product is intended for Criminal Justice and Forensic Use Only.

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

### 3 CONTENT

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

| REF          | Product Description  | Quantity/Volume        |
|--------------|--|------------------------|
| 5088-0002-00 | <b>ARK Xylazine Calibrator</b><br>Xylazine, human urine, stabilizer and sodium azide | Dropper Vials          |
|              | A  | 0 ng/mL<br>1 X 10 mL   |
|              | B  | 10 ng/mL<br>1 X 10 mL  |
|              | C  | 50 ng/mL<br>1 X 10 mL  |
|              | D  | 200 ng/mL<br>1 X 10 mL |
| E            | 500 ng/mL<br>1 X 10 mL   |                        |

| REF          | Product Description   | Quantity/Volume      |
|--------------|---|----------------------|
| 5088-0002-01 | <b>ARK Xylazine Calibrator A (Negative)</b><br>Human urine, stabilizer and sodium azide | Dropper Vials        |
|              | Negative  | 0 ng/mL<br>2 X 10 mL |

| REF          | Product Description   | Quantity/Volume       |
|--------------|---|-----------------------|
| 5088-0002-02 | <b>ARK Xylazine Calibrator B (Cutoff)</b><br>Xylazine, human urine, stabilizer and sodium azide | Dropper Vials         |
|              | Cutoff  | 10 ng/mL<br>2 X 10 mL |

### 4 STANDARDIZATION

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

Calibrators are made with non-sterile, processed human urine free of Xylazine. Donors were non-reactive in tests for HIV 1/2, HBsAg, HCV, HIV-1 (NAT), HCV (NAT) and RPR.

### 5 WARNINGS AND PRECAUTIONS

- Not 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 Xylazine Assay, refer to the package insert for the ARK Xylazine 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 10 ng/mL Calibrator B as a Cutoff Calibrator to distinguish negative and positive samples. Run the ARK Xylazine Low (5 ng/mL) and High (15 ng/mL) Controls as Negative and Positive respectively. Report test results less than the response value for the Cutoff Calibrator as Negative. Report test results equal to or greater than the response value for the Cutoff Calibrator as Positive.

#### Semi-quantitative Results

Perform a 5-point calibration procedure, test calibrators in duplicate. Verify the calibration curve with the ARK Xylazine Low (5 ng/mL) and High (15 ng/mL) quality controls according to the established laboratory quality assurance plan. Specimens with sample results above the highest ARK Xylazine Calibrator level (500 ng/mL) may be diluted in ARK Xylazine Calibrator A (Negative urine) and retested.

Calibrator Kit  5088-0002-00

Negative Kit  5088-0002-01

Cutoff Kit  5088-0002-02

**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 14 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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