

For Criminal Justice and Forensic Use Only

ARK™ Meperidine Calibrator

This ARK Diagnostics, Inc. package insert for the ARK Meperidine 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 |  YYYY-MM-DD | Use by/Expiration date |
|  | Catalog Number |  | Manufacturer |
|  | Consult Instructions for Use |  | Calibrator |
|  | Temperature limitation | | |

1 NAME

ARK™ Meperidine Calibrator

2 INTENDED USE

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

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

3 CONTENT

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

| REF | Product Description | Quantity/Volume |
|--------------|--|-----------------|
| 5039-0005-00 | ARK Meperidine Calibrator Meperidine, human urine, stabilizer and sodium azide | Dropper Vials |
| | A | 0 ng/mL |
| | B | 100 ng/mL |
| | C | 200 ng/mL |
| | D | 500 ng/mL |
| | E | 1000 ng/mL |

| REF | Product Description | Quantity/Volume |
|--------------|---|-----------------|
| 5039-0005-01 | ARK Meperidine Calibrator A (Negative) Human urine, stabilizer and sodium azide | Dropper Vials |
| | Negative | 0 ng/mL |

| REF | Product Description | Quantity/Volume |
|--------------|---|-----------------|
| 5039-0005-02 | ARK Meperidine Calibrator B (Cutoff) Meperidine, human urine, stabilizer and sodium azide | Dropper Vials |
| | Cutoff | 100 ng/mL |

4 STANDARDIZATION

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

Calibrators are made with non-sterile, processed human urine free of meperidine. 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 ARK Meperidine Assay, refer to the package insert for the ARK Meperidine 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 100 ng/mL Calibrator B as a Cutoff Calibrator to distinguish negative and positive samples. Run the ARK Meperidine Low (75 ng/mL) and High (125 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.

Semiquantitative Results

Perform a 5-point calibration procedure; test calibrators in duplicate. Verify the calibration curve with the ARK Meperidine Low (75 ng/mL) and High (125 ng/mL) quality controls according to the established laboratory quality assurance plan. Specimens with sample results above the highest ARK Meperidine calibrator level (1000 ng/mL) may be diluted in ARK Meperidine Calibrator A (Negative urine) and retested.

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 32 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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