

For Criminal Justice and Forensic Use Only

ARK™ Ethyl Glucuronide Control

This ARK Diagnostics, Inc. package insert for the ARK Ethyl Glucuronide 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.**

48089 Fremont Blvd

Fremont, CA 94538 USA








Tel: 1-877-869-2320

Fax: 1-510-270-6298

customersupport@ark-tdm.com

www.ark-tdm.com

KEY TO SYMBOLS USED

| | | | |
|--|------------------------------|---|------------------------|
|  | Batch code |  YYYY-MM-DD | Use by/Expiration date |
|  | Catalog Number |  | Manufacturer |
|  | Consult Instructions for Use |  | Quality Control |
|  | Temperature limitation | | |

1 NAME

ARK™ Ethyl Glucuronide Control

2 INTENDED USE

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

The ARK Ethyl Glucuronide Control is intended for use in quality control of the ARK Ethyl Glucuronide Assay.

3 CONTENT

ARK Ethyl Glucuronide Control is composed of a non-sterile, processed human urine matrix with the following target concentrations of ethyl glucuronide.

For use with Cutoff Calibrator C (500 ng/mL)

| REF | Product Description | Quality Control |
|--------------|--|-----------------------------|
| 5036-0006-00 | ARK Ethyl Glucuronide Control (375 ng/mL and 625 ng/mL) (each 2 X 10 mL) Ethyl glucuronide, human urine, stabilizer and sodium azide | Expected Range (Mean ng/mL) |
| | LOW / Negative (375 ng/mL) | 300 – 450 |
| | HIGH / Positive (625 ng/mL) | 500 – 750 |

For use with Cutoff Calibrator D (1000 ng/mL)

| REF | Product Description | Quality Control |
|--------------|---|-----------------------------|
| 5036-0006-01 | ARK Ethyl Glucuronide Control (750 ng/mL and 1250 ng/mL) (each 2 X 10 mL) Ethyl glucuronide, human urine, stabilizer and sodium azide | Expected Range (Mean ng/mL) |
| | LOW / Negative (750 ng/mL) | 600 – 900 |
| | HIGH / Positive (1250 ng/mL) | 1000 – 1500 |

Traceability and Value Assignment: A certified solution of ethyl glucuronide is traceable to LC/MS. Testing is performed with the ARK Ethyl Glucuronide Assay calibrated with the ARK Ethyl Glucuronide Calibrator. Individual laboratory performance for semiquantitative determinations may vary. Mean values should fall within the expected ranges shown in the tables above.

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 applicable 500 ng/mL and 1000 ng/mL Cutoff Calibrators.

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

4 WARNINGS AND PRECAUTIONS

- Not 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 Ethyl Glucuronide Assay, refer to the package insert for the ARK Ethyl Glucuronide 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

ARK™ is a trademark of ARK Diagnostics, Inc.

Other brand or product names are trademarks of their respective holders.