



ARK Diagnostics, Inc.

For Export Only – Not For Sale in USA

ARK™ UR-144/JWH-018 Calibrator

This ARK Diagnostics, Inc. package insert for the ARK UR-144/JWH-018 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.

Report any serious incident that has occurred in relation to the device to the manufacturer and the appropriate competent authority as applicable.

Customer Service



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2797

EC REP

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Key to Symbols Used

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer
	Authorized Representative	 2797	CE Mark with notified body number
	Consult Instructions for Use		Calibrator
	Temperature limitation		In Vitro Diagnostic Medical Device
	For Prescription Use Only		

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Negative Kit 5054-0002-01

Cutoff Kit 5054-0002-02

1 Name

ARK™ UR-144/JWH-018 Calibrator

2 Intended Use

The ARK UR-144/JWH-018 Calibrator is intended for use in calibration of the ARK UR-144/JWH-018 Assay.

3 Content

The ARK UR-144/JWH-018 Negative Calibrator is composed of a non-sterile, processed human urine matrix. The ARK UR-144/JWH-018 Cutoff Calibrator is composed of non-sterile, processed human urine containing 10 ng/mL of UR-144 Pentanoic Acid.

REF	Product Description	Quantity/Volume
5054-0002-01	ARK UR-144/JWH-018 Negative Calibrator Human urine, stabilizer and sodium azide	Dropper Vials
	Negative	0 ng/mL

REF	Product Description	Quantity/Volume
5054-0002-02	ARK UR-144/JWH-018 Cutoff Calibrator UR-144 Pentanoic Acid, human urine, stabilizer and sodium azide	Dropper Vials
	Cutoff	10 ng/mL

4 Standardization

There is no internationally recognized standard for UR-144 Pentanoic Acid. A certified solution of UR-144 Pentanoic Acid is traceable to HPLC. ARK UR-144/JWH-018 Calibrators are prepared by volumetric dilution of high purity UR-144 Pentanoic Acid into non-sterile, processed human urine.

Calibrators are made with non-sterile, processed human urine. 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. For prescription use only.
- Harmful if swallowed.
- Contains human urine. Handle as potentially infectious.

- Product contains $\leq 0.09\%$ 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 UR-144/JWH-018 Assay, refer to the package insert for the ARK UR-144/JWH-018 Assay.
- Calibrators are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume ($\sim 40\mu\text{L}/\text{drop}$) into individual sample cups for each level. Consult instrument-specific sample volume requirements. Return caps to their original containers and keep tight.
- Store vials at 2-8°C. Once opened, use within 12 months and prior to the expiration date.

7 Procedure

Qualitative Results

Use the 10 ng/mL Cutoff Calibrator to distinguish negative and positive samples. Run the Low and High 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.

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 25 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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