ARK Diagnostics, Inc.

CE

ARK™ UR-144/JWH-018 Assay
Viva-ProE™, Viva-E®, V-Twin®, and Viva-Jr® Systems

For In Vitro Diagnostic Use

The ARK UR-144/JWH-018 Assay is an immunoassay intended for the qualitative determination of UR-144, JWH-018 and their metabolites in human urine at a cutoff concentration of 10 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers. This in vitro diagnostic device is for prescription use only.

The ARK UR-144/JWH-018 Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

Please review **IMPORTANT INFORMATION** below. Refer to applicable package inserts for information regarding intended use, reagent storage, specimen handling, calibration, quality control and other required information. ARK package inserts for reagent, calibrator, and control are available online at www.ark-tdm.com.

MANUFACTURER INFORMATION

ARK UR-144/JWH-018 reagents, calibrators, and controls are manufactured by ARK Diagnostics, Inc. and sold/distributed by Siemens Healthcare Diagnostics for application on the Viva Systems.

ARK Diagnostics, Inc.
48089 Fremont Boulevard
Fremont, CA 94538
www.ark-tdm.com

ORDERING INFORMATION

For orders and technical support, contact Siemens Healthcare Diagnostics.

For technical assistance, call
Siemens Healthcare Diagnostics:
1-800-227-8994 in the USA
1-800-264-0083 in Canada

In other countries, please contact your local representative.

(SMN) APS 19-032CE Rev 02 VIVA Drug Testing Systems
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For Export Only – Not for Sale in USA: Product Name	ARK Product Number	Siemens Material Number (SMN)
ARK UR-144/JWH-018 Assay	5054-0001-00 5054-0001-01	11355233 11355234
ARK UR-144/JWH-018 Calibrator	5054-0002-01 5054-0002-02	11355235 11355236
ARK UR-144/JWH-018 Control	5054-0003-00	11355237

PREPARATION OF ASSAY COMPONENTS

The following assay components are ready-to-use liquids as supplied. When not in use, store upright at 2-8°C. Components are stable until the expiration date printed on the label if stored as directed.

Reagent R1: Antibody/Substrate and **Reagent R2:** Enzyme. Transfer the respective reagent into the appropriate size reagent bottle. Mark the label on the bottle with the reagent name and expiration date.

Precaution: Avoid cross-contamination of R1 and R2.

Calibrators and Controls: Supplied separately. Perform assay-specific calibration and quality control as recommended in the package insert.

SPECIMEN COLLECTION AND PREPARATION

Refer to the ARK UR-144/JWH-018 Assay package insert for information on specimen collection and preparation.

IMPORTANT INFORMATION

Each laboratory is responsible for validating assay performance on their system. The parameters provided should be verified with additional testing as applicable before reporting diagnostic results.

ARK Diagnostics, Inc. manufactures the ARK UR-144/JWH-018 Assay, Calibrators and Controls and is solely responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of ARK reagent, ARK calibrator or ARK control. ARK is not responsible for user-defined changes.

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The following are parameters for use when performing the ARK UR-144/JWH-018 Assay on the VIVA Drug Testing Systems. Instrument operating instructions are contained in the VIVA Drug Testing Systems Operations Manual.

Parameters for Viva-E, V-Twin, and Viva-Jr

Qualitative Mode

TEST PARAMETERS 1:	
NAME	UR-JWH+
ABBR. NAME	URJ+
MODE	KINETIC
WAVELENGTH	340 nm
UNITS	dAbs/m
Test repeats	1 or User Defined
Calibrator Name	**URJ Cal C**
CALIBRATION SETTING	
Number of standards	1
Calibration accepted	No
Number of points	1
Repeats	2
Interval	User defined days
Auto predilution	No
Cut-off	Yes
Cut-off value	**0.0000* dAbs/m**
Direction	Increase
Deviation	0.0000 dAbs/m
Prozone check	No
Control 1	User defined
Control 2	User defined
Control 3	None or User defined

TEST PARAMETERS 2	
SAMPLE BLANK	No
R1 BOTTLE	No buffer
NORMAL VOLUME	**150** µL
RERUN VOLUME	**150** µL
SAMPLE	
NORMAL VOLUME	**9** µL
RERUN VOLUME	**9** µL
R2 BOTTLE	
NORMAL VOLUME	0 µL
RERUN VOLUME	0 µL
R3 BOTTLE	
NORMAL VOLUME	**75** µL
RERUN VOLUME	**75** µL
PREDILUTION	No
SLOPE BLANK	No
DELAY, MIN. TIME	**50, 106 secs**
A LINEARITY LIMIT	10.0%
LOW ABSORBANCE	-0.100 Abs
HIGH ABSORBANCE	3.000 Abs
RAbs. L. LIMIT	-0.100 Abs
RAbs. H. LIMIT	3.000 Abs
Reagent Blank	No
Substrate Depletion	0.000 Abs

					Absorbance		
Used		Predilution	Conc. (dAbs/m)	Absorbance (dAbs/m)	Low (dAbs/m)	High (dAbs/m)	Dup-Diff (dAbs/m)
0	√	No	0.0	0.0000	0.0000	0.0000	0.0150

***Analyzer updates after each calibration.**

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Parameters for Viva-ProE

Qualitative Mode

Configure> Tests> Calibrators

Calibrator	User Defined
Calibrator Code	User Defined
Revision	User Defined
Name	URJ Cal C
Levels	1
Level Names	User Defined

Configure> Tests> Tests

General

Test Code	User Defined	Serum	☐
Revision	User Defined	Urine	☒
Name	UR-JWH+	Whole Blood	☐
Abbreviation	URJ+	CSF	☐
Mode	Kinetic	Plasma	☐
Reagent Onboard Stability	User Defined Days		
Reagent Low Warning	User Defined		
Service Test	☐		
Suppress Test Result	☐		

Processing

Sample Blank	No	Diluent	☒None
Sample Volume	9 µL		☐Test Diluent
Reagent Volume -2.25 min (R1)	150 µL		☐Saline
			☐DI Water
Reagent Volume 2.90 min (R2)	0 µL		
Reagent Volume 4.70 min (R3)	75 µL		

Measurement

Wavelength	340 nm	
	Delay	50 s
Kinetic	Min Time	106 s

Abs Check

Absorbance Check	
Absorbance Limit	-0.1 – 3 Abs
Reagent Abs Limit	-0.1 – 3 Abs
Reaction Direction	Increasing
Substrate Depletion	☐
Slope Blank	☐
Alinearity Limit	10 %

Result Calculation

Result Type	Qualitative
Qualitative Mode	Increasing
Qualitative Uncertainty Deviation	0

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Calibration

Calibration Type	Calibrator	Reagent Blank	☐
Calibrator Name	URJ Cal C		
Replicates	2		
Expiration Time	User Defined days		
		Number of Points	1
		Algorithm	Linear Regression

Calibration Points

Label	Calibrator Level
User Defined	User Defined

Configure> Tests> Calibrator Lot

Calibrator	User Defined Name

Lot	User Defined	Expiration	User Defined	
Test	Level	Concentration	Auto-Acceptance Range	Dup-diff
UR-JWH+	User Defined	10		0.015

Auto Acceptance Limits ☐ Duplicate Difference ☒

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500 GBC Drive
Newark, DE 19714 U.S.A.
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