

# Siemens Dimension<sup>®</sup> EXL<sup>TM</sup> 200, Dimension<sup>®</sup> EXL<sup>TM</sup> with LM, Dimension<sup>®</sup> RxL Max<sup>®</sup>, Dimension<sup>®</sup> RxL, Dimension<sup>®</sup> Xpand<sup>®</sup> Plus, Dimension<sup>®</sup> Xpand<sup>®</sup> Clinical Chemistry Systems

For In Vitro Diagnostic Use

The ARK Fentanyl II Assay is an immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 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 Fentanyl II Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed 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 <u>www.ark-tdm.com</u>.

### **MANUFACTURER INFORMATION**

ARK Fentanyl II reagents, ARK Fentanyl calibrators, and ARK Fentanyl controls are manufactured by ARK Diagnostics, Inc. and sold/distributed by Siemens Healthcare Diagnostics for application on the Siemens Dimension Systems.

ARK Diagnostics, Inc. 48089 Fremont Boulevard Fremont, CA 94538 <u>www.ark-tdm.com</u>



## ARK<sup>TM</sup> Fentanyl II Assay Siemens Dimension<sup>®</sup> EXL<sup>TM</sup> 200, Dimension<sup>®</sup> EXL<sup>TM</sup> with LM, Dimension<sup>®</sup> RxL Max<sup>®</sup>, Dimension<sup>®</sup> RxL, Dimension<sup>®</sup> Xpand<sup>®</sup> Plus, Dimension<sup>®</sup> Xpand<sup>®</sup> Clinical Chemistry Systems

For In Vitro Diagnostic Use

### **ORDERING INFORMATION**

For orders and technical support, contact Siemens Healthcare Diagnostics.

Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591 Siemens.com/healthineers

#### 1-800-227-8994 in the USA 1-800-264-0083 in Canada In other countries, please contact your local representative.

Product Name	Quantity/Kit	ARK Product Number	Siemens Material Number (SMN)
ARK™ Fentanyl II Assay	R1 28mL, R2 28mL	5069-0001-00	11554027
ARK™ Fentanyl II Assay	R1 115mL, R2 115mL	5069-0001-01	11554028
ARK™ Fentanyl II Assay	R1 500mL, R2 500mL	5069-0001-02	11554029
ARK <sup>™</sup> Fentanyl Calibrator	2 x 10mL; Negative	5031-0002-01	11354475
ARK <sup>™</sup> Fentanyl Calibrator	2 x 10mL; Cutoff	5031-0002-02	11354476
ARK <sup>™</sup> Fentanyl Control	2 x 10mL; Low 2 x 10mL; High	5031-0003-00	11354477
Siemens EMPTY Flex <sup>®</sup> Reagent Cartridge	N/A	N/A	10445039

#### **IMPORTANT INFORMATION**

ARK Diagnostics, Inc. manufactures the ARK Fentanyl II Assay, ARK Fentanyl Calibrators and ARK Fentanyl Controls and is solely responsible for the quality of the data obtained which is caused by performance of the reagents, any variation between lots of ARK reagents, ARK calibrators or ARK controls. ARK Diagnostics, Inc. is not responsible for user-defined changes. It is the responsibility of the user to validate any modifications to the parameters defined in this application sheet and their impact on all assay results.

### **SPECIMEN COLLECTION AND PREPARATION**

Refer to the ARK Fentanyl II Assay package insert for information on specimen collection and preparation.

### 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.

Page 2 of 7



# ARK<sup>TM</sup> Fentanyl II Assay Siemens Dimension<sup>®</sup> EXL<sup>TM</sup> 200, Dimension<sup>®</sup> EXL<sup>TM</sup> with LM, Dimension<sup>®</sup> RxL Max<sup>®</sup>, Dimension<sup>®</sup> RxL, Dimension<sup>®</sup> Xpand<sup>®</sup> Plus, Dimension<sup>®</sup> Xpand<sup>®</sup> Clinical Chemistry Systems

For In Vitro Diagnostic Use

**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.

### **Preparation of the Flex**<sup>®</sup> Reagent Cartridge:

#### Venting the Flex<sup>®</sup>

The Flex<sup>®</sup> well must be vented before filling with a reagent. To vent a Flex<sup>®</sup> well, puncture the film at a corner of the well (1) and then fill the well from the opposite corner (2). Care must be taken to minimize the size of the vent and fill holes without tearing the film.



#### Filling the Flex<sup>®</sup>

Transfer reagent into an empty, vented Flex<sup>®</sup> according to the table below.

Well fill volumes shown below have demonstrated 48 hours on-board stability. Use of lower volumes may result in shorter on-board stability.



Reagent	Wells	Volume per Well	Tests per Well	# of Tests Per Flex
Reagent B (R2)	1 and 2	1.85 mL	10	$10 \ge 2 = 20$
Reagent A (R1)	5 and 6	1.85 mL	10	$10 \ge 2 = 20$

### **Flex Cartridge Configuration**

Well	1	2	3	4	5	6
Component	В	В			Α	Α
Number of tests	10	10	0	0	10	10
Well Life (hours)	48	48	48	48	48	48
On Board Life	48 hrs		Calibrat	ion Time	336	hrs



## **ARK<sup>TM</sup>** Fentanyl II Assay Siemens Dimension<sup>®</sup> EXL<sup>TM</sup> 200, Dimension<sup>®</sup> EXL<sup>TM</sup> with LM, Dimension<sup>®</sup> RxL Max<sup>®</sup>, Dimension<sup>®</sup> RxL, Dimension<sup>®</sup> Xpand<sup>®</sup> Plus, Dimension<sup>®</sup> Xpand<sup>®</sup> Clinical **Chemistry Systems**

For In Vitro Diagnostic Use

A pre-filled Flex<sup>®</sup> must be stored at 2–8°C with the vent and fill holes covered. When taped, the pre-filled cartridge is stable at 2-8°C for 7 days. Remove this covering before loading the Flex<sup>®</sup> on the analyzer.

The following are parameters for use when performing the ARK Fentanyl II Assay on the Siemens Dimension Systems. Instrument operating instructions are contained in the Siemens Dimension System Operator's Guide.

For customers whose software is at 10.5.1 or greater, we recommend turning on the continuous cuvette option.

#### **INSTRUMENT SETTINGS (QUALITATIVE)**

From the Main Menu press: [F7] Diagnostics [F8] Open Channels

Channel:	Choose a channel from 1 to 15
METHOD:	X*** (User Defined)
MODE MEASURE:	ABSORBANCE
TYPE:	LINEAR

ര

**1ST REAGENT** 

Time: - 57.6 sec for	RxL <sup>®</sup> /EXL <sup>™</sup>
– 76.4 sec for	Xpand <sup>®</sup>
Component 1: (A)	155 μL
Component 2: ( )	0 μL
Component 3: ()	0 μL
Chase: 0 µL	
Mix: NONE	

#### SAMPLE

Time: 0.0 sec Volume: 20.0 µL Chase: 10µL Mix: GENTLE

#### 2nd REAGENT

Time: 2	220.0 sec	
Compon	ent 1: (B)	155 μL
Compon	ent 2: ( )	0 µL
Compon	ent 3: ( )	0 µL
Chase: 2	20 µL	
Mix:	MODERATE	



Siemens Dimension<sup>®</sup> EXL<sup>TM</sup> 200, Dimension<sup>®</sup> EXL<sup>TM</sup> with LM, Dimension<sup>®</sup> RxL Max<sup>®</sup>, Dimension<sup>®</sup> RxL, Dimension<sup>®</sup> Xpand<sup>®</sup> Plus, Dimension<sup>®</sup> Xpand<sup>®</sup> Clinical Chemistry Systems

For In Vitro Diagnostic Use

	3rd REAGENT Time: Compo Compo Compo Chase: Mix:	*** onent 1: ( onent 2: ( onent 3: ( 0 μL NONE	) 0 μL ) 0 μL ) 0 μL				
	PHOTOMETR Time P Time P Time P Time P	Y 21: 22: 23: 24:	270.0 sec 360.0 sec *** ***				
	Press [F7] Calc	ulate:					
	[F5] Template						
I	Enter the follow	ving info	rmation:	240	D1 1' D'1	(00	1
	Mode F	Kate	Measuring Fill	ter 340	Blanking Filter	600 DELOW	
	PT Time 2 D2 Time 2	2/0	Dilution 0.000		IOD 30 EOD 1800	ADOVE	
	P2 Time 3	500	Dilution 0.000	0	FOD 1800	ABUVE	
	Press: [F4] Acc [Exit] multipoin Press: [F2] Set- See Continuous [Exit] [F4] Store [F8] Print Return to the M	eept nt mau ca up s cuvette Iain Men	alculations scree option: Press d	en rop down	ON		
	Press: [F6] Sy [F1] M [Assign Verify	vstem Co ethods P ned Assa	nfig arameters y Key]	a shown	halow		
ſ	Test Name: Use	er Define	ed	as shown			
	Decimals: 0	Unit	s: Qual C	Calculation	n: LINEAR		
	Std vol:	Au	to Dilute Vols:	serum/p	plasma: urine:		
	REFERENCE ASSAY	Ser	um/Plasma ** _ ** ** _ **	CSF/Blo ** - * ** - *	ood Urine ** 1000-1000 ** 0-2000		
	PANIC		Ketlex if $< 0.0$	v  or  > 0.0	KUN		



## Siemens Dimension<sup>®</sup> EXL<sup>TM</sup> 200, Dimension<sup>®</sup> EXL<sup>TM</sup> with LM, Dimension<sup>®</sup> RxL Max<sup>®</sup>, Dimension<sup>®</sup> RxL, Dimension<sup>®</sup> Xpand<sup>®</sup> Plus, Dimension<sup>®</sup> Xpand<sup>®</sup> Clinical Chemistry Systems

For In Vitro Diagnostic Use

LOT	C0	C1
(Lot nb)	0.00	1.00
	0.00	1.00

### Press [F4] Store Param

1. Calibrate each new reagent kit and when quality controls are out of their expected ranges.

Press: [F5] Process CTRL

[F1] Calibration

[Enter]

[F2] Set up and Run

[Assigned Assay key]

[F1] Select reagent lot (if necessary)

### To calibrate:

Fill 3 sample cups with appropriate calibrators.

Enter the normalized values as shown in table below.

Cup	Level	Normalized Value
1	Cal A (0.0 ng/mL)	0
2	Cal B (1.0 ng/mL)	1000
3	Cal B (1.0 ng/mL)	1000

2. After calibration, review the data.

### Validation

Return to Main Menu Press: [F5] Process CTRL [F1] Calibration [Enter] [F3] Review Data [Assigned Assay key] [F1] Select reagent lot (if necessary) [F7] Calculate [F2] Accept data

#### Results

A factor is calculated to adjust the calibrator to 1000. Negative samples are  $\leq 1000$  and positive samples are  $\geq 1000$ .

Distributed by: Siemens Healthcare Diagnostics, Inc. 511 Benedict Avenue, Tarrytown, NY 10591.



Siemens Dimension<sup>®</sup> EXL<sup>TM</sup> 200, Dimension<sup>®</sup> EXL<sup>TM</sup> with LM, Dimension<sup>®</sup> RxL Max<sup>®</sup>, Dimension<sup>®</sup> RxL, Dimension<sup>®</sup> Xpand<sup>®</sup> Plus, Dimension<sup>®</sup> Xpand<sup>®</sup> Clinical Chemistry Systems

For In Vitro Diagnostic Use

Siemens.com/healthineers