



# ARK™ Fentanyl II Assay Application QuidelOrtho Vitros® XT 7600 Integrated System, Vitros 5600 Integrated System, and Vitros 4600 Chemistry System

Reference No. 5069000100

**Intended for the Qualitative Determination of Fentanyl in Human Urine.**

For *In Vitro* Diagnostic Use Only

<b>Intended Use</b>	<p>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 <i>in vitro</i> diagnostic device is for prescription use only.</p> <p>The ARK Fentanyl II Assay provides only a preliminary analytical result. A more specific alternative chemical method must be used 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 preliminary test result is positive.</p>
<b>Additional Information Required</b>	<p>The information provided in this application sheet is intended as a supplement to the package insert. Refer to applicable ARK reagent, calibrator, and control package inserts for intended use, reagent storage, specimen handling, calibration, quality control and other required information.</p> <p>For package inserts, visit <a href="http://www.quidelortho.com">www.quidelortho.com</a> &gt; Laboratory Professionals &gt; Vitros Systems &gt; MicroTip Partnership Assays (MPA).</p>

**Ordering Information** Please place your order with QuidelOrtho. Ordering information available on [www.quidelortho.com](http://www.quidelortho.com).

Item	Reference Number	Configuration
ARK Fentanyl II Assay	QO5069000100	R1: 1 x 28 mL R2: 1 x 28 mL
ARK Fentanyl II Assay	QO5069000101	R1: 1 x 115 mL R2: 1 x 115 mL
ARK Fentanyl Calibrator A (Negative)	QO5031000201	2 x 10 mL
ARK Fentanyl Calibrator B (Cutoff)	QO5031000202	2 x 10 mL
ARK Fentanyl Control LOW Neg, HIGH Pos	QO5031000300	2 x 10 mL each

<p><b>Technical Support Information</b></p>	<p>Contact QuidelOrtho for technical support. Contact information available on <a href="http://www.guidelortho.com">www.guidelortho.com</a>.</p>												
<p><b>Manufacturer Information</b></p>	<p>ARK Fentanyl reagents, calibrators, and controls are manufactured by ARK Diagnostics, Inc.</p> <p>ARK Diagnostics, Inc. 48089 Fremont Boulevard Fremont, CA 94538 <a href="http://www.ark-tdm.com">www.ark-tdm.com</a></p>												
<p><b>Reagent Pack Storage</b></p>	<p>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.</p> <p>Reagents stored in UDxx reagent packs onboard the analyzer are stable for 60 days and have a calibration interval of 14 days.</p> <p>Calibration Interval: It is recommended that recalibration occur after reagent and calibrator lot change, after performance of monthly instrument maintenance and as required following quality control procedure.</p> <p>The following assay components are ready-to-use liquids as supplied.</p> <p><b>Reagent R1:</b> Antibody/Substrate (28 mL) and <b>Reagent R2:</b> Enzyme (28 mL).</p> <p><b>Precaution:</b> Avoid cross-contamination of R1 and R2.</p> <table border="1" data-bbox="344 1115 1198 1205"> <thead> <tr> <th>R1 (mL) in UDxx/A</th> <th>R2 (mL) in UDxx/B</th> <th>Tests/pack</th> </tr> </thead> <tbody> <tr> <td>14.0</td> <td>14.0</td> <td>120</td> </tr> </tbody> </table> <p>1 UDxx reagent packs would be able to perform approximately 120 tests.</p> <p>Alternatively, the reagents can be split into 4 UDxx reagent packs containing a sufficient volume for a 60-day period of testing, based on anticipated utilization. The recommended fill volumes for each of the 4 UDxx reagent packs are as follows: R1 (7 mL) and R2 (7 mL) with 51 tests per UDxx pack.</p>	R1 (mL) in UDxx/A	R2 (mL) in UDxx/B	Tests/pack	14.0	14.0	120						
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<p><b>Calibrators and Controls</b></p>	<p>Supplied separately.</p> <table border="1" data-bbox="344 1606 760 1772"> <thead> <tr> <th colspan="2">ARK™ Fentanyl Calibrator Concentrations</th> </tr> </thead> <tbody> <tr> <td>A (Negative)</td> <td>0 ng/mL</td> </tr> <tr> <td>B(Cutoff)</td> <td>1.0 ng/mL</td> </tr> </tbody> </table> <table border="1" data-bbox="959 1606 1388 1772"> <thead> <tr> <th colspan="2">ARK™ Fentanyl Control Concentrations</th> </tr> </thead> <tbody> <tr> <td colspan="2">0.5 ng/mL (LOW/Negative)</td> </tr> <tr> <td colspan="2">1.5 ng/mL (HIGH/Positive)</td> </tr> </tbody> </table>	ARK™ Fentanyl Calibrator Concentrations		A (Negative)	0 ng/mL	B(Cutoff)	1.0 ng/mL	ARK™ Fentanyl Control Concentrations		0.5 ng/mL (LOW/Negative)		1.5 ng/mL (HIGH/Positive)	
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**Special  
Reagent Packs  
for User  
Defined Assays**

*\*Please order  
from  
QuidelOrtho\**

**Note:** Once the individual UDxx pack number is selected for use during the protocol programming, it is the only UDxx pack number to use for this protocol.

Reference No.	Description	Quantity
6802246	UD01 Packs (Empty)	1 BOX/6PKS
6802247	UD02 Packs (Empty)	1 BOX/6PKS
6802248	UD03 Packs (Empty)	1 BOX/6PKS
6802249	UD04 Packs (Empty)	1 BOX/6PKS
6802250	UD05 Packs (Empty)	1 BOX/6PKS
6802251	UD06 Packs (Empty)	1 BOX/6PKS
6802252	UD07 Packs (Empty)	1 BOX/6PKS
6802253	UD08 Packs (Empty)	1 BOX/6PKS
6802254	UD09 Packs (Empty)	1 BOX/6PKS
6802255	UD10 Packs (Empty)	1 BOX/6PKS
6844449	UD11 Packs (Empty)	1 BOX/6PKS
6844448	UD12 Packs (Empty)	1 BOX/6PKS
6844445	UD13 Packs (Empty)	1 BOX/6PKS
6844442	UD14 Packs (Empty)	1 BOX/6PKS
6844447	UD15 Packs (Empty)	1 BOX/6PKS
6844444	UD16 Packs (Empty)	1 BOX/6PKS
6844441	UD17 Packs (Empty)	1 BOX/6PKS
6844446	UD18 Packs (Empty)	1 BOX/6PKS
6844443	UD19 Packs (Empty)	1 BOX/6PKS
6844440	UD20 Packs (Empty)	1 BOX/6PKS

## ARK™ Fentanyl II Assay – Qualitative QuidelOrtho Vitros® XT 7600 System, Vitros 5600 System and Vitros 4600 System Parameters

### Configure Assay

Full Assay Name: Fentanyl II Version Date: 12/15/2023  
 Short Assay Name: FENT Fluid Type: Urine  
 Assay Model Type: 2 Point Rate Template: \*2PT R1-S-R2  
 Cal Model Type: Linear Calibrator Bottles: 2 Reagent Reps per Cal: 2

### Reagent Lot Information

On-Board Stability: 60 Days  
 Reagent Lot Number: Kit Lot  
 Shelf Exp. Date: Kit Exp Date

### Edit Dilution Parameters

Diluent: None Standard Dilution Factor: 1.0  
 Reflex Dilution: Off Dilution Factor: 1.0  
 Reduction Factor: 1.0

### Edit Result Parameters

Units: % Number of Qualitative Ranges: 2  
 Significant Digits: 6 Precision Digits: 1  
 1. NEGATIVE <100  
 2. POSITIVE 100.0 or greater  
 Report Qualitative Result Outside of Range: Yes  
 Reportable Range: -40.0 to 400.0

### User Adjusted Parameters:

Slope: 1.00 Intercept: 0.00  
 Cuve Tip Exp Time: 35 Temp Sens: No

### Edit Additional Parameters:

Initial Abs. Limits: -0.200 to 3.500  
 Second Abs. Limits: -0.200 to 3.500  
 Antigen Excess Factor: 9.000

### Edit Protocol Parameters

Step	Volume	Pack ID	Seconds	Wavelength
1. Reagent (R1)	90.0 uL	UDxx /A		
2. Incubation			0.00	
3. Sample	11.5 uL			
4. Incubation			304	
5. Reagent (R2)	90.0 uL	UD xx/B		
6. Incubation			38	
7. Read				340 nm
8. Incubation			114	
9. Read				340 nm

## ARK™ Fentanyl II Assay – Qualitative

### QuidelOrtho Vitros® XT 7600 System, Vitros 5600 System and Vitros 4600 System Parameters

#### Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: <u>Cal Kit lot</u>
1	<u>1.0</u>	<u>0.20000</u>	Cal value: <u>0.00</u>
2	<u>1.0</u>	<u>0.20000</u>	Cal value: <u>100.0</u>

#### Edit Additional Calibration Parameters

Monotonicity: <u>Increase</u>			
Max Resp High: <u>5.000</u>	Min. Resp. High: <u>5.000</u>	Cal Fit Goodness Limit: <u>0.990</u>	
Max Resp. Low: <u>-5.000</u>	Min Resp. Low: <u>-5.000</u>	Calibration Interval: <u>14 Days</u>	

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#### Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit	
Reportable Min.:	<u>-40.0</u>	<u>0.1</u>	
Critical Conc.:	<u>180.0</u>	<u>8.00</u>	%
Reportable Max.:	<u>400.0</u>	<u>8.00</u>	%

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