Microgenics Corporation
Part of Thermo Fisher Scientific

DRI™ FENTANYL APPLICATION ORTHO CLINICAL DIAGNOSTICS VITROS® XT 7600 INTEGRATED SYSTEM, VITROS® 5600 INTEGRATED SYSTEM, AND VITROS® 4600 CHEMISTRY SYSTEM

Reference No. 10016437

This Application is Intended for the Qualitative Determination of Fentanyl in Human Urine.

IVD For In Vitro Diagnostic Use Only
Rx Only

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen preparation, specimen storage, quality control, and additional performance data. For package inserts, visit www.orthoclinicaldiagnostics.com > Ortho Care > Technical Documents > MicroTip Partnership Assays (MPA).

Ordering Information

Please place your order with Ortho Clinical Diagnostics. Ordering information available on www.orthoclinicaldiagnostics.com.

Technical Support Information

Contact Ortho Clinical Diagnostics for technical support. Contact information available on www.orthoclinicaldiagnostics.com.

Microgenics Corporation, part of Thermo Fisher Scientific
46500 Kato Road, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5000
U.S. Toll free fax: (888) 527-8001 / Fax: (510) 979-5420

EC REP B·R·A·H·M·S GmbH, Neuendorfstrasse 25, 16761 Hennigsdorf, Germany

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Reagent Pack Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagents stored in UDxx reagent packs onboard the analyzer are stable for 31 days.

Reagents are supplied liquid ready-to-use.

The UDxx reagent pack may be filled up to 15 mL of Reagent A in UDxx/A bottle and 15 mL of Reagent B in UDxx/B bottle, which provides 144 tests.

R1 (mL) in UDxx/A	R2 (mL) in UDxx/B	Tests/pack
15 mL	15 mL	144

If Splitting: The 3 x 18 mL configuration will provide 3.6 UDxx reagent packs with 518 tests.

***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.*

Special Reagent Packs for User Defined Assays
(Please order from Ortho Clinical Diagnostics; not available from Microgenics)

Part Number	Description	Quantity
680 2246	UD01 Packs (Empty)	1 BOX/6PKS
680 2247	UD02 Packs (Empty)	1 BOX/6PKS
680 2248	UD03 Packs (Empty)	1 BOX/6PKS
680 2249	UD04 Packs (Empty)	1 BOX/6PKS
680 2250	UD05 Packs (Empty)	1 BOX/6PKS
680 2251	UD06 Packs (Empty)	1 BOX/6PKS
680 2252	UD07 Packs (Empty)	1 BOX/6PKS
680 2253	UD08 Packs (Empty)	1 BOX/6PKS
680 2254	UD09 Packs (Empty)	1 BOX/6PKS
680 2255	UD10 Packs (Empty)	1 BOX/6PKS
684 4449	UD11 Packs (Empty)	1 BOX/6PKS
684 4448	UD12 Packs (Empty)	1 BOX/6PKS
684 4445	UD13 Packs (Empty)	1 BOX/6PKS
684 4442	UD14 Packs (Empty)	1 BOX/6PKS
684 4447	UD15 Packs (Empty)	1 BOX/6PKS
684 4444	UD16 Packs (Empty)	1 BOX/6PKS
684 4441	UD17 Packs (Empty)	1 BOX/6PKS
684 4446	UD18 Packs (Empty)	1 BOX/6PKS
684 4443	UD19 Packs (Empty)	1 BOX/6PKS
684 4440	UD20 Packs (Empty)	1 BOX/6PKS
680 2256	UDDL1 Packs (Empty)	1 BOX/6PKS
680 2257	UDDL2 Packs (Empty)	1 BOX/6PKS

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Results and Data Interpretation

For the Qualitative assay, the VITROS® XT 7600 System, VITROS® 5600 System and VITROS® 4600 System can report both a unit-less Index number and a NEG / POS classification. The assay is calibrated at the cutoff concentration so Index numbers less than the cutoff value are negative and those greater than the cutoff value are positive.

NOTE: *Qualitative results must only be reported as Negative or Positive. Unit-less Index numbers cannot be used in reportable results.*

Out of Range Error Codes

A very high analyte sample can produce an absorbance outside the VITROS® System photometer range and will result in a CB error code. Sample results above the high calibrator should be diluted with negative urine and retested.

Calibration Frequency

It is recommended that recalibration occur after a reagent pack change, a calibrator lot change, and as required following quality control procedures.

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DRI Fentanyl Assay-Qualitative
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, and VITROS® 4600 System

Full Assay Name: FENTANYL Version Date: 3/14/2019

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: 31 Days

Reagent Lot Num: *Kit Lot*

Shelf Exp. Date: *Kit Exp Date*

Edit Dilution Parameters

Diluent: DATDIL Standard Dilution Factor: 1.0

Reflex Dilution: OFF Dilution Factor: 20.0

Reduction Factor: 1.0

Edit Result Parameters

Units: %

Significant Digits: 4 Precision Digits: 0

User Adjusted Parameters

Slope: 1.0 Intercept: 0.0

CuveTip Exp Time: 35 Temp Sens : No

Number of Qualitative Ranges: 2

1. NEGATIVE

2. POSITIVE 100

Report Qualitative Result Outside of Range: Yes

Measuring (Reportable) 0 to 10000

(More Assay Parms) – Edit 2 Pt Rate Additional Parameters

Initial Abs. Limits: -0.20 to 3.50

Second Abs. Limits: -0.20 to 3.50

Antigen Excess Factor: 9.0

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Edit Protocol Parameters

	Step	Volume	Pack ID	Seconds	Wavelength
1.	Reagent	80 µL	UDxx /A		
2.	Incubation			0.0	
3.	Sample	17.2 µL			
4.	Incubation			304.0	
5.	Reagent	80 µL	UDxx /B		
6.	Incubation			38.0	
7.	Read				340 nm
8.	Incubation			76.0	
9.	Read				340 nm

Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: *Cal Kit lot*
1	1.0	0.20	Cal value: *0*
2	1.0	0.20	Cal Value: 100

(More Cal Parms) – Edit Linear or Logit/Log Additional Parameters

Monotonicity: Increase

Max Resp High: 3.00 Min. Resp. High: 3.00 Cal Fit Goodness Limit: 0.950

Max Resp. Low: -3.00 Min Resp. Low: -3.00

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	0	[Let it fill in]
Critical Conc.:	2	8.0 %
Reportable Max.:	10000	8.0 %

Comments: N/A

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