

DRI™ OXYCODONE APPLICATION CE
**ORTHO CLINICAL DIAGNOSTICS VITROS® XT 7600
INTEGRATED SYSTEM, VITROS® 5600 INTEGRATED
SYSTEM, VITROS® 4600 CHEMISTRY SYSTEM, AND VITROS®
5,1 FS CHEMISTRY SYSTEM**

Reference No. 100248 (70 mL), 100249 (500 mL)

This Application is Intended for the Qualitative and Semiquantitative Determination of Oxycodone and Oxymorphone in Human Urine



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.



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U.S. Toll free fax: (888) 527-8001 / Fax: (510) 979-5420



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

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 28 days.

Reagents are supplied liquid ready-to-use. As supplied, the Antibody/Substrate Reagent A (70 mL) and the Enzyme Conjugate Reagent E (70 mL) can fill multiple VITROS reagent packs. 13 mL of Reagent A in a UDxx/A bottle and 13 mL of Reagent E in a UDxx/B bottles provides 100 tests. Filling 17 mL of each reagent (maximum fill for R2 bottle) provides 135 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

Calibration Frequency

It is recommended that recalibration occur after reagent pack change, after calibrator lot change, after performance of monthly instrument maintenance and as required following quality control procedure.

**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 VITROS[®] 5,1 FS System will only provide a unit-less Index number. 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.*

For the Semiquantitative assay, the VITROS[®] XT 7600 System, VITROS[®] 5600 System, and VITROS[®] 4600 System can report both semiquantitative numbers in ng/mL and a NEG / POS classification. The POS classification will also be given on samples above the Semiquantitative reporting range. The VITROS[®] 5,1 FS System will only provide semiquantitative ng/mL results. Sample results above the high calibrator should be diluted with negative urine and retested.

**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.

With the Semiquantitative assay on the VITROS[®] XT 7600 System, VITROS[®] 5600 System, VITROS[®] 4600 System or VITROS[®] 5,1 FS System, a sample above the logit/log4 spline prediction range, but within the analyzer photometer range, will produce an ER error. Sample results above the high calibrator should be diluted with negative urine and retested.

**DRI Oxycodone Assay-Qualitative 100 ng/mL or 300 ng/mL Cutoff
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System,
VITROS® 4600 System, and VITROS® 5,1 FS System Parameters**

Full Assay Name: Oxycodone Qual Version Date: 4/29/2011
Short Assay Name: OX100 or OX300 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: 28 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: 1.0
Reduction Factor: 1.0

Edit Result Parameters

NOTE: For XT 7600 / 5600 / 4600 only enter qualitative ranges and the Measuring (Reportable) range

For 5,1 FS, just enter Measuring (Reportable) range

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 or greater **(or enter 300)**
Report Qualitative Result Outside of Range: Yes
Measuring (Reportable) 0 to 9999

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

Initial Abs. Limits: -0.20 to 2.70
Second Abs. Limits: -0.20 to 2.70
Antigen Excess Factor: 9.0

**DRI Oxycodone Assay-Qualitative 100 ng/mL or 300 ng/mL Cutoff
Ortho Clinical Diagnostics VITROS[®] XT 7600 System, VITROS[®] 5600 System,
VITROS[®] 4600 System, and VITROS[®] 5,1 FS System Parameters, *continued***

Edit Protocol Parameters

Step	Volume	Pack ID	Seconds	Wavelength
1. Reagent	100 µL	UDxx /A		
2. Incubation			0.0	
3. Sample	6.0 µL			
4. Incubation			304.0	
5. Reagent	100 µL	UDxx /B		
6. Incubation			38	
7. Read				340 nm
8. Incubation			114	
9. Read				340 nm

Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: <u>Cal Kit lot</u>
1	<u>1.0</u>	<u>0.20</u>	Cal value: <u>0</u>
2	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>100 (or enter 300)</u>

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

Monotonicity: Increase

Max Resp High: 3.00

Min. Resp. High: 3.00

Cal Fit Goodness Limit: 0.990

Max Resp. Low: -3.00

Min Resp. Low: -3.00

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	<u>0</u>	<u>200</u>
Critical Conc.:	<u>100 (or enter 300)</u>	<u>8.0</u> %
Reportable Max.:	<u>9999</u>	<u>8.0</u> %

Comments: N/A

**DRI Oxycodone Assay-Semiquantitative 100/300 ng/mL Cutoff
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System,
VITROS® 4600 System, and VITROS® 5,1 FS System Parameters**

Full Assay Name: Oxycodone Semi-Quant

Version Date: 4/29/2011

Short Assay Name: _OXYC_

Fluid Type: _Urine_

Assay Model Type: 2 Point Rate

Template: *2Pt R1-S-R2

Cal Model Type: _Logit/Log4_

Calibrator Bottles: _5_ Reagent Reps per Cal: _2_

Reagent Lot Information

Edit Dilution Parameters

On-Board Stability: _28_ Days

Diluent: _DATDIL_ Standard Dilution Factor: _1.0_

Reagent Lot Num: _Kit Lot_

Reflex Dilution: _OFF_ Dilution Factor: _20.0_

Shelf Exp. Date: _Kit Exp Date_

Reduction Factor: _1.0_

Edit Result Parameters

NOTE: For XT 7600 / 5600 / 4600 only enter qualitative ranges and the Measuring (Reportable) range

For 5,1 FS, just enter Measuring (Reportable) range

Units: _ng/mL_

Number of Qualitative Ranges: _2_

Significant Digits: _5_ Precision Digits: _1_

1. _NEGATIVE_

User Adjusted Parameters

2. _POSITIVE_ _100_ or greater (**or enter 300**)

Slope: _1.0_ Intercept: _0.0_

Report Qualitative Result Outside of Range: _Yes_

CuveTip Exp Time: _35_ Temp Sens : _No_

Measuring (Reportable) _25_ to _1000_

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

Initial Abs. Limits: _ -0.20_ to _ 2.70_

Second Abs. Limits: _ -0.20_ to _ 2.70_

Antigen Excess Factor: _ 9.0_

**DRI Oxycodone Assay-Semiquantitative 100/300 ng/mL Cutoff
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System,
VITROS® 4600 System, and VITROS® 5,1 FS System Parameters, *continued***

Edit Protocol Parameters

Step	Volume	Pack ID	Seconds	Wavelength
1. Reagent	100 µL	UDxx /A		
2. Incubation			0.0	
3. Sample	6.0 µL			
4. Incubation			304.0	
5. Reagent	100 µL	UDxx /B		
6. Incubation			38	
7. Read				340 nm
8. Incubation			114	
9. Read				340 nm

Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: <u>Cal Kit lot</u>
1	<u>1.0</u>	<u>0.20</u>	Cal value: <u>0</u>
2	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>100</u>
3	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>300</u>
4	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>500</u>
5	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>1000</u>

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

Monotonicity: Increase

Max Resp High: 3.00

Min. Resp. High: 3.00

Cal Fit Goodness Limit: 0.990

Max Resp. Low: -3.00

Min Resp. Low: -3.00

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	<u>25</u>	<u>200</u>
Critical Conc.:	<u>100 (or enter 300)</u>	<u>8.0</u> %
Reportable Max.:	<u>1000</u>	<u>8.0</u> %

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